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37 CFR Part 1

**Changes To Practice for Continued
Examination Filings, Patent Applications
Containing Patentably Indistinct Claims,
and Examination of Claims in Patent
Applications; Final Rule**

DEPARTMENT OF COMMERCE**Patent and Trademark Office****37 CFR Part 1**

[Docket Nos.: PTO-P-2005-0022; PTO-P-2005-0023]

RINs 0651-AB93; 0651-AB94

Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The United States Patent and Trademark Office (Office) is revising the rules of practice in patent cases relating to continuing applications and requests for continued examination practices, and for the examination of claims in patent applications. The Office is revising the rules of practice to require that any third or subsequent continuing application that is a continuation application or a continuation-in-part application, and any second or subsequent request for continued examination in an application family, be filed to obtain consideration of an amendment, argument, or evidence, and be supported by a showing as to why the amendment, argument, or evidence sought to be entered could not have been previously submitted. The Office is also revising the rules of practice to provide that an applicant must provide an examination support document that covers all of the claims in an application if the application contains more than five independent claims or more than twenty-five total claims. The Office is also revising the rules of practice with respect to multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and common ownership. These changes will allow the Office to conduct a better and more thorough and reliable examination of patent applications.

DATES: *Effective Date:* November 1, 2007. For applicability and compliance dates see **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: The Office of Patent Legal Administration, by telephone at (571) 272-7704, by mail addressed to: Mail Stop Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or by facsimile to (571) 273-0100, marked to the attention of the Office of Patent Legal Administration.

SUPPLEMENTARY INFORMATION: The Office is revising the rules of practice in patent cases relating to continued examination filings (continuing applications and requests for continued examination), multiple applications containing patentably indistinct claims, and the examination of claims in applications.

The Office is revising the rules of practice for continuation applications, continuation-in-part applications and requests for continued examination. Under these revisions, an applicant may file two continuation applications (or continuation-in-part applications), plus a request for continued examination in the application family, without any justification. An application family includes the initial application and its continuation or continuation-in-part applications. Applicant may file any additional continuation application, continuation-in-part application, or request for continued examination with a justification. Specifically, the Office is revising the rules of practice to require a justification for any third or subsequent continuing application that is a continuation application or a continuation-in-part application, and any second or subsequent request for continued examination in an application family. The third or subsequent continuing application or request for continued examination must be filed with a petition showing why the amendment, argument, or evidence sought to be entered could not have been previously submitted.

The Office is also revising the rules of practice for divisional applications. Under these revisions, an applicant is permitted to file a divisional application of an application for the claims to a non-elected invention that has not been examined if the application was subject to a requirement for restriction. The divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. Thus, applicant may file the divisional application during the pendency of the application that was subject to a requirement for restriction or the pendency of any continuing application of such an application. Applicant may also file two continuation applications of the divisional application plus a request for continued examination in the divisional application family, without any justification. A divisional application family includes the divisional application and its continuation applications. In addition, applicant may file any additional continuation application or request for continued examination in the divisional

application family with a petition and adequate justification.

The Office is also revising the rules of practice for the examination of claims in an application to provide that if the number of independent claims is greater than five or the number of total claims is greater than twenty-five, the Office will require the applicant to help focus examination by providing additional information to the Office in an examination support document covering all of the claims (whether in independent or dependent form) in the application.

The Office is also revising the rules of practice with respect to multiple applications that have patentably indistinct claims and a common assignee by either requiring that all patentably indistinct claims in such applications be submitted in a single application or effectively treating the multiple applications as a single application.

These changes will mean more effective and efficient examination for the typical applicant without any additional work on the part of most applicants. However, in the applications that place an extensive burden on the Office, the applicant will be required to help focus examination by providing additional information to the Office.

Applicability Dates: The changes to 37 CFR 1.75, 1.142(c), and 1.265 are applicable to any nonprovisional application filed under 35 U.S.C. 111(a) on or after November 1, 2007, and to any nonprovisional application entering the national stage after compliance with 35 U.S.C. 371 on or after November 1, 2007. The changes to 37 CFR 1.75, 1.142(c), and 1.265 are also applicable to any nonprovisional application filed before November 1, 2007, in which a first Office action on the merits was not mailed before November 1, 2007.

The changes to 37 CFR 1.117 are applicable to any nonprovisional application filed before, on, or after November 1, 2007, with respect to any fee under 37 CFR 1.16(h), (i), or (j) or 1.492(d), (e), or (f) paid on or after December 8, 2004.

The changes to 37 CFR 1.78(a), 1.78(d)(1), 1.495 and 1.704(c)(11) are applicable only to any application, including any continuing application, filed under 35 U.S.C. 111(a) on or after November 1, 2007, or any application entering the national stage after compliance with 35 U.S.C. 371 on or after November 1, 2007. Except as otherwise indicated in this final rule, any application filed under 35 U.S.C. 111(a) on or after November 1, 2007, or any application entering the national stage after compliance with 35 U.S.C.

371 on or after November 1, 2007, seeking to claim the benefit under 35 U.S.C. 120, 121, or 365(c) and 37 CFR 1.78 of a prior-filed nonprovisional application or international application must either: (1) Meet the requirements specified in one of 37 CFR 1.78(d)(1)(i) through (d)(1)(v); or (2) include a grantable petition under 37 CFR 1.78(d)(1)(vi).

With respect to applications that claim the benefit under 35 U.S.C. 120, 121, or 365(c) only of nonprovisional applications or international applications filed before August 21, 2007: an application is not required to meet the requirements set forth in 37 CFR 1.78(d)(1) if: (1) The application claims the benefit under 35 U.S.C. 120, 121, or 365(c) only of nonprovisional applications filed before August 21, 2007 or applications entering the national stage after compliance with 35 U.S.C. 371 before August 21, 2007; and (2) there is no other application filed on or after August 21, 2007 that also claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such prior-filed nonprovisional applications or international applications.

The changes to 37 CFR 1.114 are applicable to any application in which a request for continued examination is filed on or after November 1, 2007. Specifically, a petition under 37 CFR 1.114(g) must accompany any request for continued examination filed on or after November 1, 2007, in an application in which a request for continued examination has previously been filed, or in a continuation application or continuation-in-part application of an application in which a request for continued examination has previously been filed, or in an application whose benefit is claimed in a continuation application or continuation-in-part application in which a request for continued examination has previously been filed.

The changes to 37 CFR 1.17, 1.26, 1.52, 1.53, 1.76, 1.78 (except 1.78(a) and 1.78(d)(1)), 1.104, 1.105, 1.110, 1.136, 1.142(a), and 1.145 are applicable to any nonprovisional application pending on or after November 1, 2007.

Compliance Date: For applications filed before November 1, 2007, applicants must comply with the requirements in 37 CFR 1.78(f)(1) within the time periods specified in 37 CFR 1.78(f)(1)(ii), or by February 1, 2008, whichever is later, and applicants must comply with the requirements in 37 CFR 1.78(f)(2) within the time periods specified in 37 CFR 1.78(f)(2)(iii), or by February 1, 2008, whichever is later.

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I. Background

In view of the need for a better focused and effective examination process to reduce the large and growing backlog of unexamined applications

while maintaining or improving the quality of issued patents, the Office published two notices in January of 2006 proposing changes to the practice for continuing applications, requests for continued examination, multiple applications containing patentably indistinct claims, and the examination of claims in applications. See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR 48 (Jan. 3, 2006), 1302 *Off. Gaz. Pat. Office* 1318 (Jan. 24, 2006) (proposed rule) (hereinafter "Continuing Applications Proposed Rule") and *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR 61 (Jan. 3, 2006), 1302 *Off. Gaz. Pat. Office* 1329 (Jan. 24, 2006) (proposed rule) (hereinafter "Claims Proposed Rule").

Both the Continuing Applications Proposed Rule and the Claims Proposed Rule requested public comments and provided a comment period of four months to give the public an opportunity to submit written comments. The Office provided this extended comment period to ensure that the public would have sufficient time to submit written comments on the proposed changes to the rules of practice and to ensure that the Office would receive comments from all interested persons and organizations. In addition to the notices and requests for written comments, the Office conducted public meetings including town hall meetings and presentations at various locations in the United States to discuss the proposed changes and obtain feedback from the public. The Office received over five hundred written comments from government agencies, universities, intellectual property organizations, industry, law firms, individual patent practitioners, and the general public. The Office has spent nearly one year carefully analyzing and considering all of the written comments that were received. The comments and the Office's responses to the comments are provided in Section III, Response to Comments. In response to the comments, the Office has made appropriate modifications to the proposed changes to balance the interests of the public, patent owners, applicants, practitioners, and other interested parties with the need to reduce the large and growing backlog of unexamined patent applications, improve the quality of issued patents, and make the patent examination process more effective.

Under the proposed changes, applicants would have been permitted to file one of the following without any

justification: A continuation application, a continuation-in-part application, or a request for continued examination. By contrast, this final rule permits applicants to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Applicant may file any additional continuing application or request for continued examination with a justification. Under the proposed changes, about eleven percent of the applications and requests for continued examination filed in fiscal year 2006 would have required a justification, where under the changes being adopted in this final rule less than three percent of the applications and requests for continued examination filed in fiscal year 2006 would have required a justification.

The proposed changes would have permitted applicants to file a divisional application of an application for the claims to a non-elected invention if the application is subject to a requirement for restriction and the divisional application is filed during the pendency of that application. However, this final rule permits applicant to file a divisional application of an application if the application is subject to a requirement for restriction and the divisional application meets the copendency requirement of 35 U.S.C. 120. Thus, this final rule allows applicants to file divisional applications in series whereas the proposed rule would have required applicants to file divisional applications in parallel. This final rule also permits applicant to file two continuation applications of a divisional application, plus a request for continued examination in the divisional application family, without any justification. Under the proposed changes, about thirteen percent of divisional applications filed in fiscal year 2006 would need to have been filed earlier, where the changes being adopted in this final rule would not have required any of the divisional applications filed in fiscal year 2006 to have been filed earlier.

The proposed changes would have required applicant to provide an examination support document before the first Office action on the merits if applicant designated more than ten representative claims including all of the independent claims in the application for initial examination. The Office received a substantial number of comments from the public opposing this "representative claims" examination approach and suggesting that the Office should simply adopt a threshold to

invoking the examination support document requirement based upon whether an application contains more than a given number of independent and total claims. The Office took those comments into consideration and adopted a similar approach. This final rule requires an applicant to submit an examination support document before the issuance of a first Office action on the merits of an application to assist in the patentability determination when the applicant presents more than five independent claims or more than twenty-five total claims in an application. This final rule also encourages applicant to submit all of the claims that are patentably indistinct in one single application and requires applicant to identify multiple applications that contain patentably indistinct claims (same as the proposed rule). Therefore, for each invention, an applicant is permitted to present up to fifteen independent claims and seventy-five total claims via an initial application and two continuation or continuation-in-part applications without providing either an examination support document or justification, as long as those applications are either prosecuted serially or contain patentably distinct claims. An examination support document must include a preexamination search statement, a listing of references deemed most closely related to the subject matter of each of the claims, an identification of all of the claim limitations that are disclosed in the references, a detailed explanation particularly pointing out how each of the independent claims is patentable over the cited references, and a showing of where each claim limitation finds support under 35 U.S.C. 112, ¶ 1, in the application and any prior-filed application. The examination support document will assist the Office in the examination process and the determination of patentability of the invention by providing the most relevant prior art and other useful information.

Under the proposed changes, about one percent of the applications filed in fiscal year 2006 would have required either the cancellation of one or more independent claims or an examination support document. Furthermore, about eighty percent of the applications filed in fiscal year 2006 would have required either a designation of dependent claims for initial examination or an examination support document. Under the changes being adopted in this final rule, less than eight percent of the applications filed in fiscal year 2006

would have required either the cancellation of one or more independent claims or an examination support document. In addition, less than twenty-five percent of the applications filed in fiscal year 2006 would have required either the cancellation of one or more dependent claims or an examination support document. However, by prosecuting an initial application and two continuation applications serially, about ninety-five percent of the applications filed in fiscal year 2006 would not have required either the cancellation of any claims or an examination support document.

A. Changes to Practice for Continued Examination Filings

The volume of continued examination filings (including both continuing applications and requests for continued examination) and duplicative applications that contain "conflicting" or patentably indistinct claims, is having a crippling effect on the Office's ability to examine "new" (*i.e.*, non-continuing) applications. Continued examination filings, other than divisional applications, as a percentage of overall filings, has increased from about 11.4 percent in fiscal year 1980, to about 18.9 percent in fiscal year 1990, to 21.9 percent in fiscal year 2000, to 29.4 percent in fiscal year 2006. The cumulative effect of these continued examination filings is too often to divert patent examining resources from the examination of new applications disclosing new technology and innovations, to the examination of applications that are a repetition of prior applications that have already been examined and have either issued as patents or become abandoned. In addition, when the continued examination process fails to reach a final resolution, and when multiple applications containing claims to patentably indistinct inventions are filed, the public is left with an uncertainty as to what the set of patents resulting from the initial application will cover. Thus, these practices impose a burden on innovation both by retarding the Office's ability to examine new applications and by undermining the function of claims to notify the public as to what technology is or is not available for use.

Commentators have noted that an applicant's use of the unrestricted continuing application and request for continued examination practices may preclude the Office from ever finally rejecting an application or even from ever finally allowing an application. See Mark A. Lemley and Kimberly A. Moore, *Ending Abuse of Patent*

Continuations, 84 B.U. L. Rev. 63, 64 (2004). The burden imposed by the repetitive filing of applications (as continuing applications) on the Office (as well as on the public) is not a recent predicament. See *To Promote the Progress of Useful Arts, Report of the President's Commission on the Patent System*, at 17–18 (1966) (recommending changes to prevent the repetitive filing of dependent (*i.e.*, continuing) applications). Unrestricted continued examination filings and multiple applications containing patentably indistinct claims, however, are now having such an impact on the Office's ability to examine new applications that it is appropriate for the Office to clarify the applicant's duty to advance applications to final action by placing some conditions on the filing of multiple continuing applications, requests for continued examination, and other multiple applications to the same invention. See 35 U.S.C. 2(b) (authorizes the Office to establish regulations, not inconsistent with law, which shall govern the conduct of proceedings in the Office, and shall facilitate and expedite the processing of patent applications). The changes in this final rule will permit the Office to apply the patent examining resources otherwise consumed by these applications to the examination of new applications and thereby reduce the backlog of unexamined applications.

The Office also notes that not every application as filed particularly points out and distinctly claims what the applicant regards as his or her invention. For example, this may occur where the applicant's attorney or agent has not adequately reviewed or revised the application documents received from the applicant. Applicants frequently file literal translations of foreign documents as applications, resulting in problems with compliance with U.S. patent law, such as the written description requirement, as well as problems with formatting and presentation of the claims. In these situations, examination of what applicants actually regard as their invention may not begin until after one or more continued examination filings. Applicants should not rely on an unlimited number of continued examination filings to correct deficiencies in the claims and disclosure that applicant or applicant's representative could have corrected earlier. In addition, while only a small minority of applications are a third or subsequent continuing application, it appears that some applicants and practitioners have used multiple

continued examination filings as a strategy to delay the conclusion of examination. The Office, however, considers such a strategy to be a misuse of continued examination practice. Specifically, the Office considers such a strategy to be inconsistent with an applicant's and practitioner's duty under 37 CFR 10.18(b)(2)(i) not to submit an application or other filing to cause unnecessary delay or needless increase in the cost of prosecution before the Office. This misuse of continued examination practice also prejudices the public by keeping applications in pending status while awaiting developments in similar or parallel technology and then later amending their applications to cover these developments. The courts have permitted the addition of claims, when supported under 35 U.S.C. 112, ¶ 1, to encompass products or processes later discovered in the marketplace. See *PIN/NIP, Inc. v. Platt Chemical Co.*, 304 F.3d 1235, 1247, 64 U.S.P.Q.2d 1344, 1352 (Fed. Cir. 2002). However, the practice of maintaining continuing applications to delay the conclusion of examination for the purpose of adding claims after such discoveries is inconsistent with the duty under 37 CFR 10.18(b)(2)(i) not to submit filings to cause unnecessary delay or needless increase in the cost of prosecution before the Office.

The Office, in light of its backlog and anticipated continued increase in application filings, is making every effort to become more efficient. Achieving greater efficiency requires the cooperation of those who provide the input into the examination process, the applicants and their representatives.

In the Continuing Applications Proposed Rule, the Office proposed to change the rules of practice to require that: (1) Any second or subsequent continued examination filing (continuation or continuation-in-part application or request for continued examination) include a showing that the amendment, argument, or evidence could not have been submitted prior to the close of prosecution after a single continuation or continuation-in-part application or request for continued examination; and (2) multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and a common assignee include either an explanation of how the claims are patentably distinct, or a terminal disclaimer and explanation of why patentably indistinct claims have been filed in multiple applications.

In response to the comments on the proposed changes to the practices for continued examination filings, the

Office has modified these provisions relative to proposed changes. Under this final rule, an applicant may instead file two continuation applications (or two continuation-in-part applications, or one continuation application and one continuation-in-part application), plus a request for continued examination in any one of the initial application or two continuation or continuation-in-part applications, without any justification. Any additional continuation application, continuation-in-part application, or request for continued examination, however, must be filed to obtain consideration of an amendment, argument, or evidence, and be supported by a showing as to why the amendment, argument, or evidence sought to be entered could not have been previously submitted. This final rule would also ease the burden of examining multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and common assignee by requiring that all patentably indistinct claims in such applications be submitted in a single application absent good and sufficient reason.

As discussed previously, the unrestricted continued examination practice and the filing of multiple applications containing patentably indistinct claims are impairing the Office's ability to examine new applications without real certainty that these practices effectively advance prosecution, improve patent quality, or serve the typical applicant or the public. These changes to the rules in title 37 of the CFR are intended to ensure that continued examination filings are used efficiently to move applications forward. The Office expects that the changes to the rules of practice in this final rule will: (1) Lead to more focused and efficient examination, improve the quality of issued patents, result in patents that issue faster, and give the public earlier notice of what the patent claims cover; and (2) address the growing practice of filing (by a common applicant or assignee) multiple applications containing patentably indistinct claims.

35 U.S.C. 111(a) and 120, respectively, permit an applicant to file a nonprovisional application and to claim the benefit of a prior-filed nonprovisional application. Similarly, 35 U.S.C. 363 and 365(c), respectively, permit an applicant to file an international application under Patent Cooperation Treaty (PCT) Article 11 and 35 U.S.C. 363 and, if the international application designates the United States of America, to claim the benefit of a prior-filed international application

designating the United States of America or a prior-filed nonprovisional application. Similarly again, 35 U.S.C. 111(a) and 365(c) permit an applicant to file a nonprovisional application (filed under 35 U.S.C. 111(a)) and to claim the benefit of a prior-filed international application designating the United States of America (under 35 U.S.C. 365(c)).

35 U.S.C. 120 is generally considered the statutory basis for continuing application practice. See *Symbol Techs., Inc. v. Lemelson Med.*, 277 F.3d 1361, 1365, 161 U.S.P.Q.2d 1515, 1518 (Fed. Cir. 2002) (35 U.S.C. 120 and 121 form the backbone of modern continuation and divisional application practice) (*Symbol I*). Nothing in 35 U.S.C. 120 or its legislative history suggests that the Office must or even should permit an applicant to file an unlimited number of continuing applications without any justification.

The practice of filing "continuation applications" arose early in Office practice mainly as a procedural device to effectively permit the applicant to amend an application after a rejection and receive an examination of the "amended" (or new) application. See *In re Bogese*, 22 U.S.P.Q.2d 1821, 1824 (Comm'r Pats. 1991) (*Bogese I*). The concept of a continuation application per se was first recognized in *Godfrey v. Eames*, 68 U.S. (1 Wall.) 317, 325-26 (1864). See *Bogese I*, 22 U.S.P.Q.2d at 1824. 35 U.S.C. 120 is a codification of the continuation application practice recognized in *Godfrey v. Eames*. See *id.* (citing *In re Hogan*, 559 F.2d 595, 603, 194 U.S.P.Q. 527, 535 (C.C.P.A. 1977)).

An applicant should understand, however, that he or she does not have an unfettered right to file multiple continuing applications without making a good faith attempt to claim the applicant's invention. 35 U.S.C. 2(b) gives the Director the inherent authority to promulgate regulations to ensure that applicants prosecute applications in good faith. Moreover, by assuming that an unlimited number of continuations are available, applicants have slipped into unfocused practices in prosecution that impede the Office's ability to conduct effective examination. Such practices likewise cause delays in prosecution and increase the cost of examination, both of which are contrary to an applicant's duties under the rules of conduct before the Office set forth in 37 CFR Part 10.

The changes in this final rule do not set a *per se* limit on the number of continuing applications. Nor are the changes intended to address extreme cases of prosecution laches or to codify *In re Bogese*, 303 F.3d 1362, 1369, 64

U.S.P.Q.2d 1448, 1453 (Fed. Cir. 2002) (*Bogese II*). Rather, the rules require that applicants who file multiple continuing applications from the same initial application show that the third and following applications, and any second or subsequent request for continued examination in an application family, be filed to obtain consideration of an amendment, argument, or evidence that could not have been previously submitted.

Likewise, the Office is putting conditions on request for continued examination practice. 35 U.S.C. 132(b) provides for the request for continued examination practice set forth in § 1.114. Unlike continuation application practice, the request for continued examination practice was recently added to title 35, United States Code, in section 4403 of the American Inventors Protection Act of 1999 (AIPA). See Public Law 106-113, 113 Stat. 1501, 1501A-560 (1999). 35 U.S.C. 132(b) provides, *inter alia*, that the Office "shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." Nothing in 35 U.S.C. 132(b) or its legislative history suggests that the Office must or even should permit an applicant to file an unlimited number of requests for continued examination in an application. Therefore, this final rule allows applicants to file their first request for continued examination in an application family without any justification, but requires applicants to justify the need for any further requests for continued examination in light of the past prosecution.

The Office appreciates that appropriate continued examination practice permits an applicant to obtain further examination and advance an application to final action. The unrestricted continued examination practice, however, does not provide adequate incentives to assure that the exchanges between an applicant and the examiner during the examination process are efficient. The marginal value *vis-à-vis* the patent examination process as a whole of exchanges between an applicant and the examiner during the examination process tends to decrease after each additional continued examination filing. The Office resources absorbed by the examination of additional continued examination filings are diverted away from the examination of new applications, thus increasing the backlog of unexamined applications.

The Office also appreciates that applicants sometimes use continued examination practice to obtain further

examination rather than file an appeal to avoid the delays that historically have been associated with the appeal process. The Office, however, has taken major steps to eliminate such delays. First, the Board of Patent Appeals and Interferences (BPAI) has radically reduced the inventory of pending appeals and appeal pendency during the last five fiscal years. Second, the Office has adopted an appeal conference program to review the rejections in applications in which an appeal brief has been filed. See *Manual of Patent Examining Procedure* (MPEP) § 1207.01 (8th ed. 2001) (Rev. 5, August 2006). Third, the Office has also adopted a pre-appeal brief conference program to permit an applicant to request that a panel of examiners review the rejections in his or her application prior to the filing of an appeal brief. See *New Pre-Appeal Brief Conference Program*, 1296 *Off. Gaz. Pat. Office* 67 (July 12, 2005), and *Extension of the Pilot Pre-Appeal Brief Conference Program*, 1303 *Off. Gaz. Pat. Office* 21 (Feb. 7, 2006). These changes provide for a relatively expeditious review of rejections in an application under appeal. Thus, for an applicant faced with a rejection that he or she feels is improper, the appeal process offers a more effective resolution than seeking continued examination before the examiner.

This final rule also provides that an applicant may file a divisional application directed to each non-elected invention that has not been examined if the prior-filed application is subject to a requirement for restriction. The divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. This final rule also permits applicant to file two continuation applications of a divisional application plus a request for continued examination in the divisional application family, without any justification. This final rule, however, does not permit a "divisional" application to be filed if it is not the result of a requirement for restriction in the prior-filed application (a so-called "voluntary" divisional application). Such a "voluntary" divisional application would be a continuation application, and subject to the requirements for continuation applications, under the changes in this final rule.

B. Changes to Practice for Examination of Claims in Patent Applications

A number of patent applications contain a large number of claims, which makes efficient and effective

examination of such applications problematic. The Office previously requested comments in 1998 on a proposal to limit the number of independent and total claims that would be examined in an application. See *Changes to Implement the Patent Business Goals*, 63 FR 53497, 53506–08 (Oct. 5, 1998), 1215 *Off. Gaz. Pat. Office* 87, 95–97 (Oct. 27, 1998). Specifically, in 1998, the Office requested comments on a proposal to change the rules of practice to: (1) Limit the number of total claims that will be examined (at one time) in an application to forty; and (2) limit the number of independent claims that will be examined (at one time) in an application to six. See *Changes to Implement the Patent Business Goals*, 63 FR at 53506, 1215 *Off. Gaz. Pat. Office* at 95. Under the 1998 proposal, if the applicant presented more than forty total claims or six independent claims for examination at one time, the Office would withdraw the excess claims from consideration, and require the applicant to cancel those claims. See *id.* The Office, however, ultimately decided not to proceed with a proposed change to § 1.75 to place an absolute limit on the number of total and independent claims that would be examined in an application. See *Changes to Implement the Patent Business Goals*, 64 FR 53771, 53774–75 (Oct. 4, 1999), 1228 *Off. Gaz. Pat. Office* 15, 17–18 (Nov. 2, 1999).

Applications which contain a large number of claims, however, continue to absorb an inordinate amount of patent examining resources, as they are extremely difficult to properly process and examine. As a result, contrary to the proposal under consideration in 1998, the Claims Proposed Rule sought a change to the practice for examination of claims that would not place a limit on the number of total or independent claims that may be presented for examination in an application. The Office proposed in the Claims Proposed Rule to revise the practice for the examination of claims in an application as follows: (1) The Office would give an initial examination only to the representative claims, namely, all of the independent claims and only the dependent claims that are expressly designated for initial examination; and (2) if the number of representative claims is greater than ten, the Office would require the applicant to help focus examination by submitting an examination support document covering all of the representative claims. See *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR

at 61–69, 1302 *Off. Gaz. Pat. Office* at 1329–35.

The Office received a substantial number of comments from the public opposing the proposed “representative claims” examination approach and suggesting that the Office should simply adopt a strategy based upon whether an application contains more than a given number of independent and total claims. As a result of the public comments on the Claims Proposed Rule, the Office is not adopting the “representative claims” examination approach.

Instead, this final rule provides that if the number of independent claims is greater than five or the number of total claims is greater than twenty-five, the applicant must help focus examination by providing an examination support document covering all of the claims in the application (whether in independent or dependent form) before the issuance of a first Office action on the merits of an application. An applicant may present up to five independent claims and twenty-five total claims in an initial application and each continuation or continuation-in-part application without providing either an examination support document or justification, as long as those applications are either prosecuted serially or contain patentably distinct claims. Thus, an applicant may present up to fifteen independent claims and seventy-five total claims to a single patentably distinct invention via an initial application and two continuation or continuation-in-part applications that are filed and prosecuted serially without providing either an examination support document or a justification. Furthermore, an applicant may present up to fifteen independent claims and seventy-five total claims via a divisional application and its two continuation applications without providing either an examination support document or a justification, if the Office issues a restriction requirement in the prior-filed application. Thus, the change to the practice for examination of claims adopted in this final rule avoids placing a limit on the number of total or independent claims that may be presented for examination in an application, but does require an applicant who presents more than five independent claims or more than twenty-five total claims in an application to help focus examination by providing additional information to the Office in an examination support document.

If an applicant thinks fifteen independent claims or seventy-five total claims to an invention is not sufficient,

or if applicant wishes to present more than five independent claims or twenty-five total claims in any one application, then applicant has the option of presenting as many independent and total claims as desired by providing an examination support document. The examination support document will assist the examiner in examining the application and determining the patentability of a claimed invention by providing the most relevant prior art and other useful information. Specifically, the examination support document will assist the examiner in understanding the invention and interpreting the claims before conducting a prior art search. The examination support document will also assist the examiner in evaluating the prior art cited by the applicant and in determining whether a claim limitation has support in the original disclosure and in any prior-filed application. An examination support document must be filed before the issuance of a first Office action on the merits of an application. This is so that the information concerning the invention will be available when the Office begins the examination process, and thus avoids the piecemeal examination that would result if the examination support document were not provided until after the first Office action on the merits in the application.

C. Changes to Practice for Patent Applications Containing Patentably Indistinct Claims

The changes in this final rule also require that applicants provide additional information to the Office when they file multiple applications containing “conflicting” or patentably indistinct claims. The rules of practice provided that “[w]here two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.” See 37 CFR 1.78(b) (2006).

This final rule provides that an applicant must identify other pending applications or patents that are commonly owned, have a common inventor, and have a claimed filing or priority date within two months of the claimed filing or priority date of the application. This requirement does not supplant an applicant’s duty to bring other applications that are “material to patentability” of an application (e.g., applications containing patentably indistinct claims) to the attention of the examiner. See *Dayco Prod., Inc. v. Total*

Containment, Inc., 329 F.3d 1358, 1365–69, 66 U.S.P.Q.2d 1801, 1806–08 (Fed. Cir. 2003); *see also* MPEP § 2001.06(b). Thus, applicants are cautioned against intentionally filing related applications outside of this two-month window in an attempt to avoid the requirement to identify other applications that are material to the patentability of the application at issue. *See Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1367–68, 81 U.S.P.Q.2d 1705, 1711 (Fed. Cir. 2007) (there is no such thing as a good faith intent to deceive).

This final rule provides that if there are other pending applications or patents that are commonly owned and have a common inventor, substantial overlapping disclosures, and the same claimed filing or priority date, the Office will presume that the applications contain patentably indistinct claims. In such a situation, the applicant must either rebut this presumption by explaining how the applications contain patentably distinct claims, or submit the appropriate terminal disclaimers and explain why two or more pending applications containing “conflicting” or patentably indistinct claims should be maintained.

The Office proposed a provision that if an application contains at least one claim that is patentably indistinct from at least one claim in one or more other applications or patents, the Office would (if certain conditions were met) treat the independent claims and the dependent claims designated for initial examination in the first application and in each of such other applications or patents as present in each of the applications for purposes of determining whether the applicant would be required to submit an examination support document. *See Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR at 64, 68, 1302 *Off. Gaz. Pat. Office* at 1331, 1334. This final rule provides that if multiple applications, including applications having a continuity relationship, contain patentably indistinct claims, the Office will treat the multiple applications as a single application for purposes of determining whether each of the multiple applications exceeds the five independent claim and twenty-five total claim threshold. This provision is to preclude an applicant from submitting multiple applications with claims that are patentably indistinct, each with five or fewer independent claims or twenty-five or fewer total claims, for the purposes of avoiding the requirement to submit an examination support document in compliance with § 1.265. The Office, however, will not count the

claims in issued patents that contain patentably indistinct claims in determining whether a pending application exceeds the five independent claim and twenty-five total claim threshold. Nevertheless, those patentably indistinct claims would still be subject to a double patenting rejection.

D. Retention of First Action Final Practice and Changes in Second Action Final Practice

The Office has a first action final rejection practice under which the first Office action in a continuing application, or in the prosecution of a request for continued examination, may be made final under certain circumstances. *See* MPEP § 706.07(b) and 706.07(h), paragraph VIII. The Office proposed to eliminate this practice in continuing applications under 35 U.S.C. 120, 121, or 365(c) and in requests for continued examination under 35 U.S.C. 132(b) as unnecessary in view of the proposed changes to continuing applications and requests for continued examination practice that would permit an applicant to file only one continuing application or request for continued examination without any justification. *See Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 51, 1302 *Off. Gaz. Pat. Office* at 1321. This final rule, however, provides that an applicant may file a request for continued examination in either the initial application or either of the two continuing applications without any justification. Therefore, the Office is retaining its first action final rejection practice. Applicants, however, are reminded that it would not be proper for the Office to make a first Office action final in a continuing application or after a request for continued examination if the application contains material which was presented after final rejection or the close of prosecution but was denied entry because: (1) new issues were raised that required further consideration and/or search; or (2) the issue of new matter was raised. *See* MPEP § 706.07(b) and 706.07(h). Thus, applicants may guard against first action final rejection in a continuing application or after a request for continued examination by first seeking entry of the amendment, argument, or new evidence under § 1.116.

The Office is also not changing the final action practice for the Office action following a submission under § 1.129(a). *See Changes to the Transitional Procedures for Limited Examination*

After Final Rejection in Certain Applications Filed Before June 8, 1995, 70 FR 24005 (May 6, 2005), 1295 *Off. Gaz. Pat. Office* 22 (Jun. 7, 2005) (notice).

The Office is revising second action final practice as it pertains to second or subsequent Office actions that include a new double patenting rejection (either statutory or obviousness-type double patenting). Double patenting can arise when a party (or parties to a joint research agreement under the Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act), Public Law 108–453, 118 Stat. 3596 (2004)) has filed multiple patent applications containing patentably indistinct claims. The applicant (or the owner of the application) is in a far better position than the Office to determine whether there are one or more other applications or patents containing patentably indistinct claims. For this reason, when an applicant files multiple applications that are substantially the same, the applicant is responsible for assisting the Office in resolving potential double patenting situations, rather than taking no action until faced with a double patenting rejection. Thus, if an Office action must include a double patenting rejection, it is because the applicant has not met his or her responsibility to resolve the double patenting situation. Therefore, the inclusion of a new double patenting rejection in a second or subsequent Office action will not preclude the Office action from being made final.

The Office is also revising second action final practice as it pertains to second or subsequent Office actions that include a new ground of rejection necessitated by a showing that a claim element that does not use the phrase “means for” or “step for” is nevertheless a means- (or step-) plus-function claim element under 35 U.S.C. 112, ¶ 6. The Office revised the examination guidelines for means- (or step-) plus-function claim elements under 35 U.S.C. 112, ¶ 6, in June of 2000. *See Supplemental Examination Guidelines for Determining the Applicability of 35 U.S.C. 112, ¶ 6*, 65 FR 38510 (June 21, 2000), 1236 *Off. Gaz. Pat. Office* 98 (July 25, 2000) (2000 Examination Guidelines); *see also Interim Supplemental Examination Guidelines for Determining the Applicability of 35 U.S.C. 112, ¶ 6*, 64 FR 41392 (July 30, 1999). The 2000 Examination Guidelines for means- (or step-) plus-function claim elements under 35 U.S.C. 112, ¶ 6, have been incorporated into the MPEP. *See* MPEP sections 2181–2184 (8th ed. 2001) (Rev. 5, August 2006). The 2000 Examination

Guidelines set forth a three-prong procedure for determining whether a claim element is a means- (or step-) plus-function claim element under 35 U.S.C. 112, ¶ 6. *See Supplemental Examination Guidelines for Determining the Applicability of 35 U.S.C. 112, ¶ 6*, 65 FR at 38514, 1236 *Off. Gaz. Pat. Office* at 101. The 2000 Examination Guidelines provide that if a claim element does not include the phrase “means for” or “step for” as provided in the first prong of the three-prong procedure and the applicant wishes to have the claim element treated under 35 U.S.C. 112, ¶ 6, in a proceeding before the Office, the applicant has two options: (1) Amend the claim to include the phrase “means for” or “step for”; or (2) show that even though the phrase “means for” or “step for” is not used, the claim element is written as a function to be performed and does not recite sufficient structure, material, or acts which would preclude application of 35 U.S.C. 112, ¶ 6. *See Supplemental Examination Guidelines for Determining the Applicability of 35 U.S.C. 112, ¶ 6*, 65 FR at 38514, 1236 *Off. Gaz. Pat. Office* at 101. To avoid any unnecessary delay in the prosecution of the application, an applicant who wishes to have a claim element treated under 35 U.S.C. 112, ¶ 6, should either use the phrase “means for” or “step for” in the claim element or provide the necessary showing before the examination of the application begins so that the examiner can properly interpret the claims in the application and make a patentability determination. Furthermore, because submitting a showing is tantamount to an amendment of the claim to include the phrase “means for” or “step for,” a showing will be treated as an amendment of the claim for second action final purposes. Thus, the inclusion of a new rejection in a second or subsequent Office action necessitated by a showing submitted by applicant will not preclude the Office from making the second or subsequent Office action final.

This final rule requires applicant to identify any claims in a continuation-in-part application for which the subject matter is disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application. *See* § 1.78(d)(3) and the discussion of § 1.78(d)(3). Any claim in the continuation-in-part application for which the subject matter is not identified as being disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application will be treated as entitled only to the actual filing date of the continuation-in-part application, and will be subject to prior

art based on the actual filing date of the continuation-in-part application. To avoid any unnecessary delay in the prosecution of the application, applicant should provide the identification before the examiner begins to conduct a prior art search. If the failure to identify the claims for which the subject matter is disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application causes the examiner to include a new prior art rejection in a second or subsequent Office action, the inclusion of the new prior art rejection will not preclude the Office action from being made final.

Therefore, the Office is revising second action final practice to provide that a second or any subsequent Office action on the merits may be made final, except when the Office action contains a new ground of rejection that is not: (1) Necessitated by applicant's amendment of the claims, including amendment of a claim to eliminate unpatentable alternatives; (2) necessitated by applicant's providing a showing that a claim element that does not use the phrase “means for” or “step for” is written as a function to be performed and does not otherwise preclude application of 35 U.S.C. 112, ¶ 6; (3) based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p); (4) based upon double patenting (statutory or obviousness-type double patenting); or (5) necessitated by applicant's identification of the claim or claims in a continuation-in-part application for which the subject matter is disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application. The provision in MPEP § 904.02 that a search should cover the claimed subject matter and should also cover the disclosed features which might reasonably be expected to be claimed does not preclude an examiner from making the second or any subsequent Office action on the merits final if the Office action contains a new ground of rejection that was necessitated solely by applicant's amendment of the claims to eliminate an unpatentable alternative. An examiner cannot be expected to foresee whether or how an applicant will amend a claim to overcome a rejection except in very limited circumstances (*e.g.*, where the examiner suggests how applicant can overcome a rejection under 35 U.S.C. 112, ¶ 2).

II. Discussion of Specific Rules

Title 37 of the Code of Federal Regulations, part 1, is amended as follows:

Section 1.17 (patent application and reexamination processing fees): Section 1.17(f) is amended to include a reference to: (1) Petitions under § 1.78(d)(1)(vi) for a continuing application not provided for in §§ 1.78(d)(1)(i) through (d)(1)(v); and (2) petitions under § 1.114(g) for a request for continued examination not provided for in § 1.114(f). *See* discussion of §§ 1.78 and 1.114.

Section 1.26 (refunds): Section 1.26(a) is amended to add the phrase “[e]xcept as provided in § 1.117 or § 1.138(d)” to the sentence “[a] change of purpose after the payment of a fee, such as when a party desires to withdraw a patent filing for which the fee was paid, including an application, an appeal, or a request for an oral hearing, will not entitle a party to a refund of such fee.” The “change of purpose” provision of § 1.26(a) is directed to the provision in 35 U.S.C. 42(d) authorizing a refund of “any fee paid by mistake or any amount paid in excess of that required.” 35 U.S.C. 42(d). Sections 1.117 and 1.138(d), however, are directed to the provisions in 35 U.S.C. 41(a)(2) and (d)(1)(D) as amended by the Consolidated Appropriations Act, 2005 (Consolidated Appropriations Act) that permit the Office to develop procedures to refund search fees or excess claims fees under certain limited conditions. *See* Public Law 108–447, 118 Stat. 2809 (2004). Section 1.26(b) is amended to change “except as otherwise provided in this paragraph or in § 1.28(a)” to “except as otherwise provided in this paragraph, or in § 1.28(a), § 1.117(b), or § 1.138(d)”. This change is for consistency with § 1.117(b) and § 1.138(d), which also specify time periods within which certain refunds must be requested.

Section 1.52 (language, paper, writing, margins, compact disc specifications): Section 1.52(d)(2) is amended to refer to § 1.78(b) concerning the requirements for claiming the benefit of a provisional application in a nonprovisional application. Section 1.52(d)(2) is also amended to provide that if a provisional application is filed in a language other than English and the benefit of such provisional application is claimed in a nonprovisional application, an English language translation of the non-English language provisional application will be required in the provisional application. This change conforms § 1.52(d)(2) to the September 2005 revision to the provisions in § 1.78 for claiming the benefit of a provisional application. *See Provisions for Claiming the Benefit of a Provisional Application With a Non-English Specification and Other Miscellaneous Matters*, 70 FR 56119,

56121, 56128 (Sept. 26, 2005), 1299 *Off. Gaz. Pat. Office* 142, 143–44, 150 (Oct. 25, 2005) (final rule). With respect to claiming the benefit of a provisional application that was filed in a language other than English, § 1.78(b)(5) now provides that: (1) If the prior-filed provisional application was filed in a language other than English and both an English-language translation of the prior-filed provisional application and a statement that the translation is accurate were not previously filed in the prior-filed provisional application, applicant will be notified and given a period of time within which to file the translation and the statement in the prior-filed provisional application; (2) if the notice is mailed in a pending nonprovisional application, a timely reply to such a notice must include the filing in the nonprovisional application of either a confirmation that the translation and statement were filed in the provisional application, or an amendment or supplemental application data sheet withdrawing the benefit claim, or the nonprovisional application will be abandoned; and (3) the translation and statement may be filed in the provisional application, even if the provisional application has become abandoned.

Section 1.53 (application number, filing date, and completion of application): Section 1.53(b) and (c)(4) are amended to refer to § 1.78, rather than specific paragraphs of § 1.78. Section 1.53(b)(1) is also amended to provide that continuation or divisional applications naming an inventor not named in the prior application must be filed under § 1.53(b) (this provision was formerly in § 1.53(b)(2)), and to reference § 1.78(a)(2) for the definition of a divisional application and § 1.78(a)(3) for the definition of a continuation application. Section 1.53(b)(2) is amended to reference § 1.78(a)(4) for the definition of a continuation-in-part application.

Section 1.75 (claims): Section 1.75(b) is amended to provide for the revised practice for the examination of claims in an application. Section 1.75(b) (introductory text) provides for the requirements of a dependent claim. Section 1.75(b)(1) provides for the five independent claim and twenty-five total claim threshold for invoking the examination support document requirement. Section 1.75(b)(2) provides for claims in dependent form that are effectively independent claims. Section 1.75(b)(3) provides for situations in which an examination support document has not been provided in an application that exceeds the five independent claim and twenty-five total

claim threshold. Section 1.75(b)(4) provides that the total number of claims present in all of the copending commonly owned applications that contain patentably indistinct claims may not exceed the five independent claim and twenty-five total claim threshold. Section 1.75(b)(5) provides that claims withdrawn from consideration will not, unless they are reinstated or rejoined, be taken into account in determining whether an application exceeds the five independent claim and twenty-five total claim threshold. Section 1.75(c) is amended to provide that multiple dependent claims and claims depending from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in the multiple dependent claim for claims counting purposes.

Section 1.75(b) (introductory text) is amended to set forth the existing provisions concerning dependent claims in § 1.75(c), namely, that “[o]ne or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application.” Section 1.75(b) (introductory text) is also amended to clarify that a dependent claim is required to incorporate by reference all the limitations of the previous claim to which it refers and to specify a further limitation of the subject matter of the previous claim. *See Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 437 F.3d 1284, 1292, 79 U.S.P.Q.2d 1583, 1589–90 (Fed. Cir. 2006) (a dependent claim is required to include all the limitations of the claim from which it depends and the failure to incorporate by reference all the limitations is a violation of 35 U.S.C. 112, ¶ 4, and renders the dependent claim invalid).

Section 1.75(b)(1) provides that an applicant must file an examination support document in compliance with § 1.265 that covers each claim (whether in independent or dependent form) before the issuance of a first Office action on the merits of the application if the application contains or is amended to contain more than five independent claims or more than twenty-five total claims. Section 1.75(b)(1) also provides that the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims if an examination support document in compliance with § 1.265 has not been filed before the issuance of a first Office action on the merits of an application. The examination support document in compliance with § 1.265 is required to be filed before the issuance of the first

Office action on the merits of the application because the information provided by the applicant in the examination support document will assist the examiner in understanding the invention of the application, determining the effective filing date of each claim, interpreting the claims before a prior art search, understanding the state of the art and the most closely related prior art cited by the applicant, and determining the patentability of the claims. Applicant is permitted to present more than five independent claims or more than twenty-five total claims in a continuing application, if the applicant files an examination support document in compliance with § 1.265 before the first Office action on the merits of the continuing application, regardless of whether an examination support document has been filed in the prior-filed application.

Claims withdrawn from consideration under §§ 1.141 through 1.146 or § 1.499 as drawn to a non-elected invention or inventions are not taken into account in determining whether an application exceeds this five independent claim and twenty-five total claim threshold. *See* § 1.75(b)(5) and discussion of § 1.75(b)(5).

Section 1.75(b)(2) concerns claims in dependent form that are effectively independent claims. Section 1.75(b)(2) provides that a claim that refers to another claim but does not incorporate by reference all the limitations of the claim to which such claim refers will be treated as an independent claim for fee calculation purposes under § 1.16 (or § 1.492) and for purposes of § 1.75(b). The Office must treat such claims as independent claims because 35 U.S.C. 112, ¶ 4, provides (*inter alia*) that a dependent claim “shall be construed to incorporate by reference all the limitations of the claim to which it refers.” *See* 35 U.S.C. 112, ¶ 4. For examples of such claims, see: *In re Thorpe*, 777 F.2d 695, 696, 227 U.S.P.Q. 964, 965 (Fed. Cir. 1985) (“product by process” claim 44); *In re Kuehl*, 475 F.2d 658, 659, 177 U.S.P.Q. 250, 251 (C.C.P.A. 1973) (claim 6); and *Ex parte Rao*, 1995 WL 1747720, *1 (BPAI 1998) (claim 8). Section 1.75(b)(2) also provides that a claim that refers to a claim of a different statutory class of invention will be treated as an independent claim for fee calculation purposes under § 1.16 (or § 1.492) and for purposes of § 1.75(b). For examples of such claims, see: *Thorpe*, 777 F.2d at 696, 227 U.S.P.Q. at 965 (“product by process” claim 44); *Ex parte Porter*, 25 U.S.P.Q.2d 1144, 1145 (BPAI 1992) (claim 6); and *Ex parte Blattner*, 2

U.S.P.Q.2d 2047, 2047-48 (BPAI 1987) (claim 14).

Section 1.75(b)(3) provides that the applicant will be notified if the application contains or is amended to contain more than five independent claims or more than twenty-five total claims but the applicant has not complied with the requirements set forth in § 1.75(b)(1) or 1.75(b)(4) (e.g., an examination support document in compliance with § 1.265 has been omitted). Section 1.75(b)(3) also provides that if the non-compliance appears to have been inadvertent, the notice will set a two-month time period that is not extendable under § 1.136(a) within which, to avoid abandonment of the application, the applicant must comply with the requirements set forth in § 1.75(b). Again, claims withdrawn from consideration under §§ 1.141 through 1.146 or § 1.499 as drawn to a non-elected invention or inventions are not taken into account in determining whether an application exceeds this five independent claim and twenty-five total claim threshold. See § 1.75(b)(5) and discussion of § 1.75(b)(5).

If a notice under § 1.75(b)(3) is mailed before the first Office action on the merits of an application and it appears that the omission of an examination support document was inadvertent, the notice will set a two-month time period within which the applicant must: (1) File an examination support document in compliance with § 1.265 that covers each claim (whether in independent or dependent form); or (2) amend the application such that it contains no more than five independent claims and no more than twenty-five total claims. Section 1.75(b)(3) provides that this two-month time period is not extendable under § 1.136(a) and that the failure to reply to such a notice will result in abandonment of the application. Due to the increase in patent pendency that would result from the routine granting of extensions in the situation in which an application contains or is amended to contain more than five independent claims or more than twenty-five total claims but the applicant has not complied with the requirements set forth in § 1.75(b)(1) or 1.75(b)(4) (e.g., an examination support document in compliance with § 1.265 has been omitted), the Office is limiting extensions of this two-month time period in § 1.75(b)(3) to those for which there is sufficient cause (§ 1.136(b)).

Once the Office issues a notice under § 1.75(b)(3), the applicant may not simply submit a suggested alternative requirement for restriction under § 1.142(c), but instead must: (1) File an examination support document in

compliance with § 1.265 that covers each claim (whether in independent or dependent form); or (2) amend the application such that it contains no more than five independent claims and no more than twenty-five total claims.

If an examination support document in compliance with § 1.265 as required under § 1.75(b) was not filed before the issuance of a first Office action on the merits of an application, an amendment that results in the application containing more than five independent claims or more than twenty-five total claims will be treated as non-responsive. Specifically, if the non-compliance with § 1.75(b) appears to have been inadvertent, the Office would give the applicant a two-month time period that is not extendable under § 1.136(a) within which to provide an amendment that does not result in the application containing more than five independent claims or more than twenty-five total claims. See § 1.135(c) (“[w]hen reply by the applicant is a *bona fide* attempt to advance the application to final action, and is substantially a complete reply to the non-final Office action, but consideration of some matter or compliance with some requirement has been inadvertently omitted, applicant may be given a new time period for reply under § 1.134 to supply the omission.”).

Section 1.75(b)(4) provides for the situation in which: (1) A nonprovisional application contains at least one claim that is patentably indistinct from at least one claim in one or more other pending nonprovisional applications; and (2) the nonprovisional application and the one or more other pending nonprovisional applications either are owned by the same person or are subject to an obligation of assignment to the same person. In this situation, § 1.75(b)(4) provides that the Office will treat the claims in the first nonprovisional application and in each of such other pending nonprovisional applications as being present in each of the pending nonprovisional applications for purposes of § 1.75(b). That is, if the conditions specified in § 1.75(b)(4) are present, the Office will treat each such nonprovisional application as having the total number of claims present in all of such applications (and not just the claim that is patentably indistinct) for purposes of determining whether an examination support document is required by § 1.75(b). For example: If application “A” contains only one claim that is patentably indistinct from the claims in application “B”, application “A” and application “B” are owned by the same company, and each

application contains three independent claims and twenty total claims, the Office will treat each application as having six independent claims and forty total claims in determining whether each application exceeds the five independent claim and twenty-five total claim threshold set forth in § 1.75(b). In this example, an examination support document would be required in each application before the issuance of a first Office action on the merits of the application. To avoid the provisions of § 1.75(b)(4), applicant may present all of the patentably indistinct claims in application “B” by canceling the patentably indistinct claim from application “A”. As discussed previously, § 1.75(b)(4) is to preclude an applicant from submitting multiple applications to the same subject matter (with claims that are patentably indistinct), each with five or fewer independent claims or twenty-five or fewer total claims, for the purpose of avoiding the requirement to submit an examination support document in compliance with § 1.265.

Under § 1.75(b)(4), the Office will count the claims in the copending nonprovisional applications containing patentably indistinct claims (including applications having a continuity relationship) but not in issued patents containing patentably indistinct claims, in determining whether each such application exceeds the five independent claim or twenty-five total claim threshold for invoking the examination support document requirement. An applicant may present up to five independent claims and twenty-five total claims in an initial application and each continuing application, provided that continuing applications that contain patentably indistinct claims are not prosecuted in parallel with the initial application or each other. Thus, an applicant may present up to fifteen independent claims and seventy-five total claims to a single invention via an initial application and two continuing applications that are filed and prosecuted serially without providing either an examination support document or a justification. In addition, an applicant may prosecute a divisional application (an application containing claims that are patentably distinct from the claims to the invention prosecuted in the initial application) in parallel with the initial application or its continuation or continuation-in-part applications without the claims in the divisional application being taken into account in determining whether the initial application or its continuation or continuation-in-part applications

exceed the five independent claim or twenty-five total claim threshold for invoking the examination support document requirement.

Section 1.75(b)(4) also provides that the total number of claims present in all of such copending nonprovisional applications containing patentably indistinct claims may not exceed five independent claims or twenty-five total claims unless an examination support document in compliance with § 1.265 is filed before the issuance of a first Office action on the merits of the application containing patentably indistinct claims.

The provisions of § 1.75(b)(4) do not depend upon the relative filing dates of the nonprovisional application and the one or more other nonprovisional applications. The provisions of § 1.75(b)(4) apply regardless of whether the filing dates of the applications are the same, are within two months of each other (*cf.* § 1.78(f)(1) and (f)(2)), or are not within two months of each other. In other words, the provision of § 1.75(b)(4) does not depend on the filing dates of the respective applications. In addition, the provisions of § 1.75(b)(4) are applicable regardless of any continuity relationship between the applications (*e.g.*, the provision applies if a parent application is still pending at the time the child application is under examination). For applications having a continuity relationship, the prior application must be pending at the time the continuing application is filed. *See* 35 U.S.C. 120 (requires that a continuing application be filed before the patenting or abandonment of or termination of proceedings on the prior application). The Office, however, will treat the application as no longer pending for purposes of § 1.75(b)(4) if: (1) A notice of allowance is issued, unless the application is withdrawn from issue (§ 1.313); (2) the Office recognizes the application is abandoned; (3) a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. 141 is filed, unless the appeal is terminated; or (4) a civil action under 35 U.S.C. 145 or 146 is commenced, unless the civil action is terminated.

Section 1.75(b)(4) as adopted in this final rule differs from proposed § 1.75(b)(4) in that it does not provide that the Office may require elimination of the patentably indistinct claims from all but one of the applications. Such a provision would be a substantial duplicate of § 1.78(f)(3) as adopted in this final rule, which provides that if the conditions set forth in § 1.75(b)(4) exist, the Office may require elimination of the patentably indistinct claims from all but one of the applications in the

absence of good and sufficient reason for there being two or more such nonprovisional applications containing patentably indistinct claims.

Section 1.75(b)(5) provides that claims withdrawn from consideration under §§ 1.141 through 1.146 or § 1.499 as drawn to a non-elected invention or inventions will not, unless they are reinstated or rejoined, be taken into account in determining whether an application exceeds the five independent claim and twenty-five total claim threshold set forth in §§ 1.75(b)(1), (b)(3), and (b)(4). Thus, claims withdrawn from consideration as the result of an Office-initiated requirement under § 1.142, 1.146, or 1.499 (regardless of whether the election is with or without traverse), or as the result of the acceptance of a suggested restriction requirement under § 1.142(c), are not taken into account in determining whether an application exceeds the five independent claim and twenty-five total claim threshold. In addition, claims withdrawn from consideration in an application (*e.g.*, the initial application) as the result of either an Office-initiated requirement under § 1.142, 1.146, or 1.499, or the acceptance of a suggested restriction requirement under § 1.142(c), are not taken into account in determining whether a copending application (*e.g.*, a continuation application of the initial application) contains a claim that is patentably indistinct from a claim in such application for purposes of § 1.75(b)(4).

Section 1.142(c) as adopted in this final rule provides that the applicant may submit a suggested requirement for restriction if two or more independent and distinct inventions are claimed in the application. Section 1.142(c) further provides that any suggested requirement for restriction must be filed before the earlier of the first Office action on the merits or any Office action that contains a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction (including an election of species) under 35 U.S.C. 121 in the application. Section 1.142(c) provides that any suggested requirement for restriction must also be accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims, and identify the claims to the elected invention. If the applicant submits a suggested restriction requirement, the suggested restriction requirement is accepted, and there are five or fewer independent claims and twenty-five or fewer total claims to the elected

invention (as required by § 1.142(c)), the Office will simply treat the non-elected claims as withdrawn from consideration and proceed to act on the application (assuming the application is otherwise in condition for action). The Office action will set out the requirement for restriction under § 1.141(a), *e.g.*, in the manner that an Office action on the merits would contain a written record of a requirement for restriction previously made by telephone. *See* MPEP section 810. Applicants are reminded, however, that the Office may refund excess claims fees only for claims that are canceled prior to the issuance of a first Office action on the merits of the application. *See* 35 U.S.C. 41(a)(2) (“[t]he Director may, by regulation, provide for a refund of any part of the fee specified in [35 U.S.C. 41(a)(2)] for any claim that is canceled before an examination on the merits, as prescribed by the Director, has been made of the application under [35 U.S.C.] 131”).

If the applicant files a suggested requirement for restriction in an application containing more than five independent claims or more than twenty-five total claims, the applicant will also be notified if the suggested restriction requirement is not accepted. The refusal to accept a suggested requirement for restriction may result in the examiner making a different restriction requirement or making no restriction requirement.

If the examiner makes a restriction requirement (which includes an election of species requirement) different from the suggested restriction requirement, the applicant will be notified of the restriction requirement. The applicant will be given a two-month time period that is not extendable under § 1.136(a) within which the applicant must make an election consistent with the Office-issued restriction requirement in order to avoid abandonment of the application. Once the Office issues a requirement for restriction, the applicant may not simply submit a suggested alternative requirement for restriction under § 1.142(c). Instead, the applicant must make an election (with or without traverse) responsive to the Office-issued requirement for restriction. If an application subject to an Office-issued requirement for restriction contains more than five independent claims or more than twenty-five total claims, the reply must also either: (1) Amend the application to contain no more than five independent claims and no more than twenty-five total claims to the elected invention and/or species; or (2) include an examination support document in compliance with § 1.265 that covers

each claim (whether in independent or dependent form) pending in the application.

If the examiner does not make a restriction requirement, the applicant will simply be given a notice under § 1.75(b)(3). That notice will set a two-month time period that is not extendable under § 1.136(a) within which, to avoid abandonment of the application, the applicant must: (1) Amend the application to contain no more than five independent claims and no more than twenty-five total claims; or (2) file an examination support document in compliance with § 1.265 that covers each claim (whether in independent or dependent form) pending in the application. *See* § 1.75(b)(3).

Section 1.75(b)(5) also provides that claims reinstated (*e.g.*, as a result of a request for reconsideration of the requirement) or rejoined (*e.g.*, upon allowance of a generic claim) in the application are taken into account in determining whether an application exceeds the five independent claim and twenty-five total claim threshold. As discussed previously, unless an examination support document in compliance with § 1.265 was filed before the issuance of a first Office action on the merits of an application, the application must remain at or under the five independent claim and twenty-five total claim threshold. Therefore, if an examination support document was not filed before the issuance of a first Office action on the merits of the application, and the reinstatement or rejoinder of non-elected claims results in the application containing more than five independent claims or more than twenty-five total claims, the Office will give the applicant a two-month time period within which to amend the application to contain five or fewer independent claims and twenty-five or fewer total claims. *See* § 1.75(b)(3). This two-month time period is not extendable under § 1.136(a). The failure to file such an amendment will result in abandonment of the application.

Since claims reinstated or rejoined in the application are taken into account in determining whether an application exceeds the five independent claim and twenty-five total claim threshold, applicants cannot rely upon a requirement for restriction to avoid submitting an examination support document before the issuance of a first Office action on the merits of an application. This is especially true where: (1) The applicant traverses the requirement for restriction; (2) the requirement for restriction may be conditional, such as a requirement for

election of species in an application that contains a claim that is generic to all of the claimed species (hereafter “generic claim”) (*see* MPEP section 809), or a requirement for restriction in an application that contains a linking claim (*e.g.*, a subcombination claim linking plural combinations); or (3) the applicant plans to request rejoinder of the claims to the non-elected invention (*see* MPEP § 821.04 *et seq.*). Thus, applicants are advised to file an examination support document in the application before the first Office action on the merits if they anticipate the occurrence of any of the aforementioned three situations. Furthermore, applicants cannot rely upon the requirement for restriction to file a divisional application because the Office will withdraw the requirement for restriction, including an election of species, if the non-elected claims are reinstated or rejoined.

Applicant is not permitted to file a divisional application of a prior-filed application that is no longer subject to a restriction requirement. Under § 1.78(a)(2) and 1.78(d)(1)(ii), the prior-filed application to which a divisional application claims the benefit must be subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. Sections 1.78(a)(2) and 1.78(d)(1)(ii) also require a divisional application to contain only claims directed to a non-elected invention that has not been examined.

For an application that contains a generic claim in which a requirement for an election of species has been made, applicants should conclude prosecution (in the initial application and its continuation or continuation-in-part applications), including exhaustion of any available appeals, as to the generic claim before ever filing a divisional application to a non-elected species. If applicant no longer wants to pursue the generic claim, applicant may file a divisional application directed to a non-elected species. If an applicant files a divisional application directed to a non-elected species, applicant should: (1) Cancel the claims to the non-elected species and the generic claim in the prior-filed application before rejoinder or reinstatement occurs; (2) not present the non-elected claims and the generic claim in any continuation or continuation-in-part application of the initial application; and (3) not present the generic claim in the divisional application or any other continuation application of the divisional application (because the generic claim has been examined in the initial application and

it is patentably indistinct from the claims of the non-elected species).

When an application contains a generic claim and the examiner makes a provisional restriction requirement, requiring an election of species for initial search and examination purposes, the applicant must elect a single species. (The requirement is provisional because the restriction will be withdrawn upon allowance of the generic claim.) The examiner will determine the patentability of the elected species and generic claim. Upon the allowance of the generic claim, the provisional restriction requirement will be withdrawn, as explained above. The claims of the non-elected species then will be rejoined. The Office will count the rejoined claims together with the other pending claims to determine whether the application exceeds the five independent claim and twenty-five total claim threshold set forth § 1.75(b)(1). *See* § 1.75(b)(5). If the application contains more than five independent claims and twenty-five total claims (counting the rejoined claims) and the applicant did not file an examination support document in compliance with § 1.265 before the issuance of a first Office action on the merits in the application, then the applicant must amend the application to contain no more than five independent claims and no more than twenty-five total claims. *See* § 1.75(b)(1). Therefore, applicants cannot rely upon a provisional requirement for restriction to avoid submitting an examination support document before the issuance of the first Office action on the merits in the application.

Furthermore, upon the allowance of a claim that is generic to all of the claimed species (either in the initial application or any continuing application), the application is no longer subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. In such a situation, if applicant had filed a “divisional” application to the non-elected species following the provisional restriction in the prior-filed application, that “divisional” application would no longer be proper under §§ 1.78(a)(2) and 1.78(d)(1)(ii). This is because the “divisional” application would not meet the conditions set forth in §§ 1.78(a)(2) and 1.78(d)(1)(ii). If applicant wishes to maintain the application, then applicant must delete or correct the benefit claim to indicate that the application is a continuation application, provided the requirements set forth in § 1.78(d)(1)(i) can be

satisfied. In such case, the Office will treat the application as one of the two continuation applications of the prior-filed application permitted under § 1.78(d)(1)(i). But, if the prior-filed application already has its benefit claimed in two other nonprovisional applications, applicant must delete the benefit claim in the application. See § 1.78(d)(1)(i). Therefore, applicant is cautioned not file a divisional application drawn to a non-elected species if a generic claim is pending in the initial application or any continuing application of the initial application and could be found allowable.

When an application subject to an election of species is allowed with no claim that is generic to all of the claimed species being found to have been allowable, the applicant will be notified that the Office considers the requirement that the application be restricted to a single species to be final. At that point, the applicant may cancel the claims to the non-elected species and the generic claim in the prior-filed application and file a divisional application in accordance with § 1.78(d)(1)(ii) to the non-elected species. However, if the applicant later files a continuing application of the initial application or the divisional application presenting one or more generic claims in such later application, the Office will consider the requirement that the initial application be restricted to a single species to no longer be final. Should that occur, the “divisional” application directed to the non-elected species would not be proper under §§ 1.78(a)(2) and 1.78(d)(1)(ii) for the reasons explained above. Thus, applicants should conclude prosecution, including exhaustion of any available appeals, as to the generic claim before ever filing a divisional application to a non-elected species. In other words, applicants cannot rely upon a requirement that an application containing a generic claim will be restricted to a single species to permit filing one or more divisional applications until the applicant has concluded prosecution with respect to any generic claims.

Under the Office’s rejoinder practice, an applicant may request rejoinder of claims to a non-elected invention that depend from or otherwise require all the limitations of an allowable claim. See MPEP § 821.04 *et seq.* This “rejoinder” practice was developed in light of the Federal Circuit’s decisions in *In re Ochiai*, 71 F.3d 1565, 37 U.S.P.Q.2d 1127 (Fed. Cir. 1995), and *In re Brouwer*, 77 F.3d 422, 37 U.S.P.Q.2d 1663 (Fed. Cir. 1996), and the enactment of 35 U.S.C. 103(b) in The Biotechnology

Process Act of 1995 (Pub. L. 104–41, 109 Stat. 351 (1995)). See *Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer, and 35 U.S.C. 103(b)*, 1184 *Off. Gaz. Pat. Office* 86 (Mar. 26, 1996). Applicants may retain claims to a non-elected invention in an application for possible rejoinder in the event of the allowance of a claim to the elected invention. However, as discussed previously, the Office will count rejoined claims towards the five independent claim and twenty-five total claim threshold in § 1.75(b)(1). See § 1.75(b)(5). If applicant cancels all of the claims directed to a non-elected invention before rejoinder occurs and files a divisional application, the restriction requirement will not be withdrawn and the non-elected process claims that are now canceled will not be rejoined. This will preserve applicant’s rights under 35 U.S.C. 121 and § 1.78(d)(1)(ii). See MPEP § 821.04(b).

Section 1.75(c) is amended to provide for multiple dependent claims only. Dependent claims are now provided for in § 1.75(b). Section 1.75(c) further provides that multiple dependent claims and claims that depend from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in the multiple dependent claim for purposes of § 1.75(b) (as well as § 1.16 or 1.492).

The changes to § 1.75 are applicable to any application (including any reissue application) filed under 35 U.S.C. 111(a) on or after November 1, 2007, and to any nonprovisional application entering the national stage after compliance with 35 U.S.C. 371 on or after November 1, 2007, as well as to any application (including any reissue application) in which a first Office action on the merits (§ 1.104) was not mailed before November 1, 2007. The Office will provide an applicant who filed a nonprovisional application under 35 U.S.C. 111(a) before November 1, 2007, or a nonprovisional application that entered the national stage after compliance with 35 U.S.C. 371 before November 1, 2007, and who would be affected by the changes in the final rule, with an opportunity to submit: (1) An examination support document under § 1.265; (2) a new set of claims such that the application contains five or fewer independent claims and twenty-five or fewer total claims; or (3) a suggested restriction requirement under § 1.142(c). Specifically, the Office will issue a notice setting a two-month time period that is extendable under § 1.136(a) or (b) within which the applicant must exercise one of these options in order to avoid abandonment of the application.

The Office, however, may combine such a notice with a requirement for restriction, in which case the applicant must make an election responsive to the restriction requirement and, if there are more than five independent claims or more than twenty-five total claims drawn to the elected invention, the applicant must also: (1) File an examination support document in compliance with § 1.265; or (2) amend the application such that it contains five or fewer independent claims and twenty-five or fewer total claims drawn to the elected invention. Thus, if such a notice is combined with a requirement for restriction, the applicant does not have the option of replying to such notice with a suggested restriction requirement under § 1.142(c).

With respect to the application of the changes to § 1.75 in this final rule to a reissue application, an examination support document under § 1.265 will not be required pursuant to § 1.75(b) in a reissue application if the reissue application does not seek to change the claims in the patent being reissued. A change in the claims in the patent being reissued is sought either by an amendment to or addition of a claim or claims, or by an amendment to the specification which changes a claim or claims.

Section 1.76 (application data sheet): Section 1.76(b)(5) is amended to refer to §§ 1.78(b)(3) and (d)(3) for consistency with the changes to § 1.78. Section 1.76(b)(5) is also amended to clarify that the relationship of the applications is not required for a benefit claim under 35 U.S.C. 119(e) and to delete “the status (including patent number if available)”. Such information is not necessary for claiming the benefit of a prior-filed application under 35 U.S.C. 119(e), 120, 121, or 365(c).

Section 1.78 (claiming benefit of earlier filing date and cross-references to other applications): Section 1.78 is reorganized as follows: (1) § 1.78(a) defines “continuing application”, “continuation application”, “divisional application”, and “continuation-in-part application”; (2) § 1.78(b) contains provisions relating to claims under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application; (3) § 1.78(c) contains provisions relating to delayed claims under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application; (4) § 1.78(d) contains provisions relating to claims under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filed nonprovisional or international application; (5) § 1.78(e) contains provisions relating to delayed claims under 35 U.S.C. 120, 121, or 365(c) for

the benefit of a prior-filed nonprovisional or international application; (6) § 1.78(f) contains provisions relating to applications naming at least one inventor in common and containing patentably indistinct claims; (7) § 1.78(g) contains provisions relating to applications or patents under reexamination naming different inventors and containing patentably indistinct claims; (8) § 1.78(h) contains provisions pertaining to the treatment of parties to a joint research agreement under the CREATE Act; and § 1.78(i) provides that the time periods set forth in § 1.78 are not extendable.

Section 1.78(a)(1) defines a “continuing application” as a nonprovisional application or international application designating the United States of America that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed nonprovisional application or international application designating the United States of America. Section 1.78(a)(1) provides that an application that does not claim the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed application, is not a continuing application even if the application claims the benefit under 35 U.S.C. 119(e) of a provisional application, claims priority under 35 U.S.C. 119(a)–(d) or 365(b) to a foreign application, or claims priority under 35 U.S.C. 365(a) or (b) to an international application designating at least one country other than the United States of America. A continuing application must be a continuation application, a divisional application, or a continuation-in-part application. *See* MPEP § 201.11 (“To specify the relationship between the applications, applicant must specify whether the application is a continuation, divisional, or continuation-in-part of the prior application. Note that the terms are exclusive. An application cannot be, for example, both a continuation and a divisional or a continuation and a continuation-in-part of the same application.”).

Section 1.78(a)(2) defines a “divisional application” as a continuing application that discloses and claims only an invention or inventions that were disclosed and claimed in a prior-filed application, but were subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the prior-filed application, and were not elected for examination and were not examined in any prior-filed application. This definition is more precise than the definition of “divisional application” currently found in MPEP § 201.06.

MPEP § 201.06 defines a divisional application as an application for an independent and distinct invention, which discloses and claims only subject matter that was disclosed in the prior-filed nonprovisional application. Section 1.78(a)(2), however, limits the definition of “divisional application” to an application that claims only an invention or inventions that were subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the prior-filed application and not elected for examination and not examined in any prior-filed application. *See* 35 U.S.C. 121 (“[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions [and i]f the other invention is made the subject of a divisional application which complies with the requirements of [35 U.S.C.] 120 * * *”). The Office will revise the definition of divisional application in MPEP § 201.06 in the next revision of the MPEP. An application that claims the benefit of a prior-filed divisional application as defined in § 1.78(a)(2), and claims the same patentable invention as the prior-filed divisional application, would not be a divisional application as defined by § 1.78(a)(2). Instead, such an application would be a continuation application.

Section 1.78(a)(3) defines a “continuation application” as a continuing application as defined in § 1.78(a)(1) that discloses and claims only an invention or inventions that were disclosed in the prior-filed application. *See* MPEP § 201.07 (defines a continuation application as an application that discloses (or discloses and claims) only subject matter that was disclosed in the prior-filed nonprovisional application).

Section 1.78(a)(4) defines a “continuation-in-part application” as a continuing application as defined in § 1.78(a)(1) that discloses subject matter that was not disclosed in the prior-filed application. *See* MPEP § 201.08 (a continuation-in-part repeats some substantial portion or all of the earlier nonprovisional application and adds matter not disclosed in the prior-filed nonprovisional application).

Section 1.78(b) addresses claims under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application. Under 35 U.S.C. 119(e)(1), a provisional application must disclose the invention claimed in at least one claim of the later-filed application in the manner provided by 35 U.S.C. 112, ¶ 1, for the later-filed application to receive the

benefit of the filing date of the provisional application. *See New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294, 63 U.S.P.Q.2d 1843, 1846 (Fed. Cir. 2002) (for a nonprovisional application to actually receive the benefit of the filing date of the provisional application, “the specification of the provisional [application] must ‘contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms,’ 35 U.S.C. 112 ¶ 1, to enable an ordinarily skilled artisan to practice the invention claimed in the nonprovisional application”). Section 1.78(b), however, does not also state (as did former § 1.78(a)(4)) that the provisional application must disclose the invention claimed in at least one claim of the later-filed application in the manner provided by 35 U.S.C. 112, ¶ 1, because it is not necessary for the rules of practice to restate provisions of a statute.

Section 1.78(b)(1) provides that the nonprovisional application or international application designating the United States of America must be filed not later than twelve months after the date on which the provisional application was filed, and that this twelve-month period is subject to 35 U.S.C. 21(b) and § 1.7(a). 35 U.S.C. 21(b) and § 1.7(a) provide that when the day, or the last day, for taking any action (e.g., filing a nonprovisional application within twelve months of the date on which the provisional application was filed) or paying any fee in the Office falls on Saturday, Sunday, or a Federal holiday within the District of Columbia, the action may be taken, or fee paid, on the next succeeding secular or business day. Section 1.78(b) otherwise contains the provisions of former § 1.78(a)(4) and (a)(5).

Sections 1.78(b)(2) through (b)(5) contain the provisions of former 1.78(a)(4) and (a)(5). Section 1.78(c) contains provisions relating to delayed claims under 35 U.S.C. 119(e) for benefit of prior-filed provisional applications. Section 1.78(c) contains the provisions of former § 1.78(a)(6).

Section 1.78(d) contains provisions relating to claims under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filed nonprovisional or international application.

Section 1.78(d)(1) provides conditions under which an application may claim the benefit under 35 U.S.C. 120, 121, or 365(c) and § 1.78 of a prior-filed nonprovisional application or international application designating the United States of America. Section 1.78(d)(1) also provides that the Office

will refuse to enter, or will delete if present, any specific reference to a prior-filed application that is not permitted by § 1.78(d)(1). If the claim for the benefit of a prior-filed nonprovisional application or international application designating the United States of America is not permitted by § 1.78(d)(1), the Office will refuse benefit. Section 1.78(d) also provides that the entry of or failure to delete a specific reference to a prior-filed application that is not permitted by § 1.78(d)(1) does not constitute a waiver of the provisions of § 1.78(d)(1). The grant of a petition under § 1.78(d)(1)(vi) or waiver of a requirement of § 1.78(d)(1) would be only by an explicit decision by an official who has been delegated the authority to decide such a petition or waiver. It would not occur by implication due to the entry of or failure to delete a specific reference to a prior-filed application that is not permitted by § 1.78(d)(1).

These provisions of § 1.78(d)(1) were included in the proposed changes to § 1.78(d)(3). See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 54, 60, 1302 *Off. Gaz. Pat. Office* at 1323, 1328.

Section 1.78(d)(1)(i) provides for continuation applications or continuation-in-part applications that do not claim the benefit of a divisional application (either directly or indirectly). Section 1.78(d)(1)(i) permits such a continuation application or continuation-in-part application of a prior-filed nonprovisional application or international application designating the United States of America if: (1) The application is a continuation application as defined in § 1.78(a)(3) or a continuation-in-part application as defined in § 1.78(a)(4) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than two prior-filed applications; and (2) any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than one other nonprovisional application. This does not include any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

Section 1.78(d)(1)(i) permits an applicant to continue prosecution of an application via two continuation applications (in parallel or serially), a continuation application and a continuation-in-part application (in parallel or serially), or two continuation-in-part applications (in parallel or serially). Applicants

choosing to file applications (whether continuing or non-continuing) in parallel are reminded that § 1.75(b)(4) provides that, if certain conditions are met, the Office will treat each such application as having the total number of claims present in all of such applications for purposes of determining whether an examination support document is required by § 1.75(b). See also § 1.78(f) concerning additional provisions that are applicable if there are multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and common assignee.

If an application is identified as a continuation-in-part application, however, § 1.78(d)(3) provides that the applicant must identify the claim or claims in the continuation-in-part application for which the subject matter is disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application. See discussion of § 1.78(d)(3). Any claims in the continuation-in-part application that are not identified under § 1.78(d)(3) as supported by the prior-filed application will be subject to prior art based on the actual filing date of the continuation-in-part application.

For a continuation-in-part application that contains one or more claims for which the subject matter is not disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application, § 1.78(d)(1)(i) will permit an applicant to continue prosecution of the claims that are directed solely to subject matter added in such continuation-in-part application via two continuation applications (or a continuation application and a continuation-in-part application, or two continuation-in-part applications). However, the “additional” continuation or continuation-in-part applications cannot claim the benefit of the prior-filed application relative to the first continuation-in-part application. The subject matter of at least one claim of a later-filed application must be disclosed in the prior-filed application in the manner provided by 35 U.S.C. 112, ¶ 1, for the later-filed application to actually receive the benefit of the filing date of the prior-filed application under 35 U.S.C. 120. See *Studiengesellschaft Kohle m.b.H. v. Shell Oil Co.*, 112 F.3d 1561, 1564–65, 42 U.S.P.Q.2d 1674, 1677–78 (Fed. Cir. 1997). In addition, the term of any resulting patent will be measured under 35 U.S.C. 154(a)(2) from the filing date of the prior-filed application, even if the later-filed application never receives any benefit from the prior-filed application. See

Abbott Labs. v. Novopharm Ltd., 104 F.3d 1305, 1309, 41 U.S.P.Q.2d 1535, 1537 (Fed. Cir. 1997) (rejecting patentee’s argument that it should not be bound by the filing date of the prior-filed application because the later-filed application never received any actual benefit from the prior-filed application). Thus, the Office will not require that such “additional” continuation or continuation-in-part applications contain a showing that all of the claims are directed solely to subject matter added in the first continuation-in-part application. Rather, § 1.78(d)(1)(i) permits the “additional” continuation or continuation-in-part application to claim the benefit of the first continuation-in-part application, but does not permit the “additional” continuation or continuation-in-part application to also claim the benefit of the prior-filed initial application (the prior-filed application relative to the first continuation-in-part application). For example, consider an applicant who files: (1) An initial application “A”; (2) a first continuation-in-part application “B” that claims the benefit of application “A”; (3) a second continuation (or continuation-in-part) application “C” that claims the benefit of applications “B” and “A”; and (4) an additional continuation (or continuation-in-part) application “D” that claims the benefit of applications “C” and “B”. Under § 1.78(d)(1)(i), application “D” may claim the benefit of application “C” and continuation-in-part application “B”, but may not claim any benefit of application “A” (except as permitted under § 1.78(d)(1)(vi)).

Applicants are permitted to file two continuation or continuation-in-part applications (§ 1.78(d)(1)) and one request for continued examination (§ 1.114) without any justification. The provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. Therefore, the filing of a request for continued examination does not preclude an applicant from filing two continuation or continuation-in-part applications. In addition, an applicant may not agree to forgo a continuation application (or continuation-in-part application) to obtain a second or third request for continued examination, nor can an applicant agree to forgo a request for continued examination in exchange for a third continuation or continuation-in-part application. For example, an applicant cannot file a second request for continued examination without any justification instead of filing one of the two permitted continuation applications; and an applicant cannot file three continuation applications

instead of filing a request for continued examination. Of course, applicant may seek by petition a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination.

The Office, however, is implementing an optional streamlined continuation application procedure under which an applicant may request to have a continuation application filed on or after November 1, 2007, placed on an examiner's amended (Regular Amended) docket. The examiner will normally pick up for action a continuation application that has been placed on the examiner's amended (Regular Amended) docket faster (*e.g.*, within a few months from the date the application is docketed) than an application placed on the examiner's new continuing application (New Special) docket. The following conditions must be met for the continuation application to be placed on an examiner's amended (Regular Amended) docket rather than on the new continuing application (New Special) docket: (1) The application must disclose and claim only an invention or inventions that were disclosed and claimed in the prior-filed application; (2) the applicant must agree that any election in response to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121, including an election of species requirement, in the prior-filed application carries over to the continuation application; (3) the prior-filed application must be under a final Office action (§ 1.113) or under appeal at the time of filing the continuation application; (4) the prior-filed application must be expressly abandoned upon filing of the continuation application, with a letter of express abandonment under § 1.138 being concurrently filed in the prior-filed application; and (5) applicant must request that the continuation application be placed on an examiner's amended (Regular Amended) docket. This procedure is not applicable to design applications because the continued prosecution application procedures of § 1.53(d) currently provide design applicants with an optional streamlined continuation application procedure.

The optional streamlined continuation application procedure, however, does require that the applicant provide a continuation application filed under 35 U.S.C. 111(a) and § 1.53(b) (and not a request for continued examination under 35 U.S.C. 132(b) and

§ 1.114 or a continued prosecution application under § 1.53(d)). Thus, the applicant must file a continuation application that meets the conditions set forth in 35 U.S.C. 111(a) and § 1.53(b) to be accorded a filing date. The continuation application must also be complete under § 1.51(b) or completed under § 1.53(f). The Office will not docket an application for examination until the application is complete (§§ 1.51(b) and 1.53(f)) and in condition for publication (§ 1.211). *See* § 1.53(h). Thus, any delay in submitting the filing fee and oath or declaration (or copy of the oath or declaration from the prior-filed application under § 1.63(d)) will delay the docketing of a continuation application even if the applicant has requested that the continuation application be given streamlined docketing.

This optional streamlined continuation application procedure concerns only the placement of the continuation application on an examiner's amended (Regular Amended) docket. The continuation application is otherwise treated as a new application for patent. For example, (1) the application filing fees including the basic filing fee, search and examination fees, and any required excess claims fees (and not the request for continued examination fee set forth in § 1.17(e)) are required; (2) the continuation application will be assigned a new application number; and (3) the continuation application is subject to the patent term provisions of 35 U.S.C. 154(b) and § 1.702 *et seq.* as a new continuation application (and not a request for continued examination in the prior-filed application).

Section 1.78(d)(1)(ii) provides for divisional applications of an application for the claims to a non-elected invention that has not been examined if the application was subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. The divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. This final rule also permits applicant to file two continuation applications of a divisional application plus a request for continued examination in the divisional application family, without any justification. *See* §§ 1.78(d)(1)(iii) and 1.114(f).

Specifically, § 1.78(d)(1)(ii) permits a divisional application of a prior-filed nonprovisional application or international application designating

the United States of America under the following conditions. First, the divisional application must be a divisional application as defined in § 1.78(a)(2) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed application that was subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. Second, the divisional application must contain only claims directed to an invention or inventions that were identified in the requirement to comply with the requirement of unity of invention or requirement for restriction but were not elected for examination and were not examined in the prior-filed application or in any other nonprovisional application. The "not elected for examination and were not examined in any other nonprovisional application" requirement does not apply to any continuation application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of the divisional application and satisfies the conditions set forth in § 1.78(d)(1)(iii) or (d)(1)(vi).

Section 1.78(d)(1)(ii)(A) permits an applicant to obtain examination of claims that were withdrawn from consideration in the prior-filed application due to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. Thus, § 1.78(d)(1)(ii)(A) permits a divisional application filed as a result of a requirement to comply with the requirement of unity of invention under PCT Rule 13 or requirement for restriction under 35 U.S.C. 121 in the prior-filed application. Section 1.78(d)(1)(ii)(A), however, does not permit a divisional application not filed as a result of such a requirement in the prior-filed application. Thus, § 1.78(d)(1)(ii)(A) permits so-called "involuntary" divisional applications but does not permit so-called "voluntary" divisional applications.

Section 1.78(d)(1)(ii)(B) does not permit the filing of a set of parallel divisional applications containing claims to the same invention. Applicant, however, may serially prosecute up to two continuation applications that contain claims to the same invention as is claimed in a prior-filed divisional application if the continuation application satisfies the conditions of § 1.78(d)(1)(iii).

As discussed previously, applicants cannot rely upon a requirement for restriction including an election of species to file a divisional application in situations where: (1) The applicant traverses the requirement for restriction;

(2) the requirement for restriction may be conditional, such as a requirement for election of species in an application that contains a claim that is generic to all of the claimed species (*see* MPEP section 809); and (3) the claims to the non-elected invention may be rejoined at the request of the applicant (*see* MPEP § 821.04 *et seq.*). *See* the discussion of § 1.75(b)(5). This is because when the requirement for restriction is withdrawn in the prior-filed application, any divisional application that has been filed as the result of the restriction requirement of the prior-filed application will not be proper under §§ 1.78(a)(2) and 1.78(d)(1)(ii). Applicant is not permitted to file a divisional application of a prior-filed application that is no longer subject to a restriction requirement. Under §§ 1.78(a)(2) and 1.78(d)(1)(ii), the prior-filed application to which a divisional application claims the benefit must be subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. Sections 1.78(a)(2) and 1.78(d)(1)(ii) also require a divisional application to contain only claims directed to a non-elected invention that has not been examined.

For an application that contains a generic claim in which a requirement for an election of species has been made, applicants should conclude prosecution of the generic claim in the initial application and its continuation or continuation-in-part applications, including exhaustion of any available appeals, before even filing a divisional application to a non-elected species. If applicant no longer wants to pursue the generic claim, applicant may file a divisional application directed to a non-elected species. If applicant files a divisional application directed to a non-elected species, applicant must: (1) Cancel the claims to the non-elected species and the generic claim in the prior-filed application before a rejoinder or reinstatement occurs; (2) not present the non-elected claims and the generic claim in any continuation or continuation-in-part application of the initial application; and (3) not present the generic claim in the divisional application or any continuation application of the divisional application.

Under the Office's rejoinder practice, an applicant may request rejoinder of claims to a non-elected invention that depend from or otherwise require all the limitations of an allowable claim. *See* MPEP § 821.04 *et seq.* Applicants may retain claims to a non-elected invention in an application for possible rejoinder

in the event of the allowance of a claim to the elected invention. If applicant cancels all of the claims directed to a non-elected invention before rejoinder occurs and files a divisional application, the restriction requirement will not be withdrawn and the non-elected claims that are now canceled will not be rejoined. This will preserve applicant's rights under 35 U.S.C. 121 and § 1.78(d)(1)(ii). *See* MPEP § 821.04(b).

Section 1.78(d)(1)(iii) provides for continuation applications that claim the benefit of a divisional application (either directly or indirectly). Section 1.78(d)(1)(iii) permits such a continuation application of a prior-filed nonprovisional application or international application designating the United States of America if: (1) The application is a continuation application as defined in § 1.78(a)(3) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a divisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii); (2) the application discloses and claims only an invention or inventions that were disclosed and claimed in the divisional application; (3) the application claims the benefit of only the divisional application, any application to which such divisional application claims benefit under 35 U.S.C. 120, 121, or 365(c) in compliance with the conditions set forth in § 1.78(d)(1)(ii), and no more than one intervening prior-filed nonprovisional application (*i.e.*, only one continuation application of the divisional application filed between the divisional application and the second continuation application of the divisional application); and (4) no more than one other nonprovisional application claims the benefit of the divisional application. This does not include any other divisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii) or any nonprovisional application that claims the benefit of such divisional application and satisfies the conditions set forth in § 1.78(d)(1)(iii) or (d)(1)(vi). Section 1.78(d)(1)(iii) permits an applicant to continue prosecution of a divisional application via two continuation applications (in parallel or serially). The Office, however, will treat each application prosecuted in parallel as having the total number of claims present in all of such applications for purposes of determining whether an examination support document is required by § 1.75(b) provided that the continuation application contains at least one claim that is patentably indistinct from at least one claim in the divisional application.

Section 1.78(d)(1)(iii) does not permit a continuation-in-part of a divisional application. Section 1.78(d)(1)(iii) is designed to permit an applicant to complete prosecution with respect to an invention or inventions that were disclosed and claimed in a divisional application, and not to permit an applicant to seek patent protection for a new invention that merely bears some relationship to an invention or inventions that were disclosed and claimed in a divisional application. Section 1.78(d)(1)(i) provides a mechanism for applicants to seek patent protection for a new invention that is an improvement of an invention or inventions that were disclosed and claimed in an initial or continuing (including a divisional) application.

The provisions of §§ 1.78(d)(1)(i) through (d)(1)(iii) are illustrated with the following example: (1) There is an initial application "A" that is subject to a restriction requirement under 35 U.S.C. 121 and § 1.141 *et seq.*; (2) a continuation application "B" of application "A"; (3) a further continuation application "C" which claims the benefit of continuation application "B" and initial application "A"; (4) a divisional application "D" (based upon the restriction requirement under 35 U.S.C. 121 and § 1.141 *et seq.* in application "A"), which claims the benefit of continuation application "C", continuation application "B", and initial application "A"; (5) a continuation application "E" of divisional application "D", which claims the benefit of divisional application "D", continuation application "C", continuation application "B", and initial application "A"; and (6) a further continuation application "F" of continuation application "E", which claims the benefit of continuation application "E", divisional application "D", continuation application "C", continuation application "B", and initial application "A".

Under § 1.78(d)(1)(i), application "C" is either a continuation application under § 1.78(a)(3) or a continuation-in-part application under § 1.78(a)(4) that claims the benefit of no more than two prior-filed applications "B" and "A". In addition, applications "B" and "A" whose benefit is claimed in application "C" have their benefit claimed in no more than one other application (not including divisional application "D" or continuation applications "E" and "F" of the divisional application "D"). That is, the benefit of application "A" is claimed in only one other application "B" (not including divisional application "D" or continuation

applications "E" and "F" of the divisional application "D"), and the benefit of application "B" is claimed in only one other application "C" (not including divisional application "D" or continuation applications "E" and "F" of the divisional application "D").

Under § 1.78(d)(1)(ii), nonprovisional application "D" is a divisional application under § 1.78(a)(2) since it claims the benefit of prior-filed application "A" that was subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121. Divisional application "D" may contain only claims directed to an invention identified in the requirement to comply with the requirement of unity of invention or requirement for restriction but were not elected for examination in prior-filed application "A" or in any other nonprovisional application (applications "B and "C"), except for a nonprovisional application (applications "E" and "F") that claims the benefit of divisional application "D" and satisfies the conditions of § 1.78(d)(1)(iii). That is, divisional application "D" may contain only claims directed to an invention or inventions that were identified in such requirement to comply with the requirement of unity of invention or requirement for restriction but were not elected for examination in any other application except for its continuation applications "E" and "F". Finally, the divisional application "D" claims the benefit of the prior-filed applications (applications "A", "B", and "C").

Under § 1.78(d)(1)(iii), nonprovisional application "F" is a continuation application under § 1.78(a)(3) that claims the benefit of divisional application "D". Application "D" is a divisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii). The nonprovisional application "F" may disclose and claim only an invention that was disclosed and claimed in divisional application "D". The nonprovisional application "F" claims the benefit of only divisional application "D", the applications to which divisional application "D" claims benefit in compliance with the conditions of § 1.78(d)(1)(ii) (applications "A", "B", and "C"), and no more than one intervening prior-filed nonprovisional application (application "E"). Divisional application "D" whose benefit is claimed in nonprovisional application "E" and in nonprovisional application "F" has its benefit claimed in no more than one other nonprovisional application. That is, with respect to application "F",

divisional application "D" has its benefit claimed in no more than one other nonprovisional application (application "E"), and with respect to application "E", divisional application "D" has its benefit claimed in no more than one other nonprovisional application (application "F").

Section 1.78(d)(1)(iv) pertains to the situation in which an applicant files a bypass continuation (or continuation-in-part) application rather than paying the basic national fee (entering the national stage) in an international application in which a Demand for international preliminary examination (PCT Article 31) has not been filed, and the international application does not claim the benefit of any other nonprovisional application or international application designating the United States of America. Section 1.78(d)(1)(iv) provides that in this situation the applicant may file "one more" continuation application (or continuation-in-part application) without there being a requirement for a petition and showing under § 1.78(d)(1)(vi). A "bypass" continuation (or continuation-in-part) application is an application for patent filed under 35 U.S.C. 111(a) that claims the benefit of the filing date of an earlier international application designating the United States of America that did not enter the national stage under 35 U.S.C. 371. See H.R. Rep. No. 107-685, at 222 (2002).

Specifically, § 1.78(d)(1)(iv) provides that a continuation application or continuation-in-part application is permitted if the following conditions are met: (1) The application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed international application designating the United States of America, and a Demand has not been filed and the basic national fee (§ 1.492(a)) has not been paid in the prior-filed international application and the prior-filed international application does not claim the benefit of any other nonprovisional application or international application designating the United States of America; (2) the application is a continuation application as defined in § 1.78(a)(3) or a continuation-in-part application as defined in § 1.78(a)(4) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three prior-filed applications; and (3) any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two other nonprovisional applications. This does not include any nonprovisional application that satisfies the conditions

set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

Section 1.78(d)(1)(v) pertains to the situation in which an applicant files a continuation (or continuation-in-part) application to correct informalities rather than completing an application for examination under § 1.53 (*i.e.*, the prior-filed application became abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f)). The prior-filed nonprovisional application, however, must be entitled to a filing date and have paid therein the basic filing fee within the pendency of the application. See § 1.78(d)(2). Section 1.78(d)(1)(v) provides that in this situation the applicant may file "one more" continuation application (or continuation-in-part application) without there being a requirement for a petition and showing under § 1.78(d)(1)(vi). Specifically, § 1.78(d)(1)(v) provides that a continuation application or continuation-in-part application is permitted if the following conditions are met: (1) The application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed nonprovisional application filed under 35 U.S.C. 111(a), and the prior-filed nonprovisional application became abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f) and does not claim the benefit of any other nonprovisional application or international application designating the United States of America; (2) the application is a continuation application as defined in § 1.78(a)(3) or a continuation-in-part application as defined in § 1.78(a)(4) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three prior-filed applications; and (3) any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two other nonprovisional applications. This does not include any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

Section 1.78(d)(1)(vi) provides that a continuing nonprovisional application that is filed to obtain consideration of an amendment, argument, or evidence that could not have been submitted during the prosecution of the prior-filed application, and does not satisfy the conditions set forth in § 1.78(d)(1)(i), (ii), (iii), (iv) or (v), may claim the benefit under 35 U.S.C. 120, 121, or 365(c) of such prior-filed application. Under § 1.78(d)(1)(vi), a petition must be filed in such nonprovisional application that is accompanied by the fee set forth in § 1.17(f) and a showing

that the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application. This will permit an applicant to continue prosecution of an application via a continuing application to obtain consideration of an amendment, argument, or evidence that could not have been submitted during the prosecution of the prior-filed application. Section 1.78(d)(1)(vi) sets forth the time period within which such a petition must be provided: (1) If the later-filed continuing application is an application filed under 35 U.S.C. 111(a), within four months from the actual filing date of the later-filed application; and (2) if the continuing application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, within four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the international application.

With respect to the application of the changes to § 1.78 in this final rule to a reissue application, benefit claims under 35 U.S.C. 120, 121, or 365(c) in the application for patent that is being reissued will not be taken into account in determining whether a continuing reissue application claiming the benefit under 35 U.S.C. 120, 121, or 365(c) of the reissue application satisfies one or more of the conditions set forth in §§ 1.78(d)(1)(i) through 1.78(d)(1)(vi). However, an applicant may not use the reissue process to add to the original patent benefit claims under 35 U.S.C. 120, 121, or 365(c) that do not satisfy one or more of the conditions set forth in §§ 1.78(d)(1)(i) through 1.78(d)(1)(vi), if the application for the original patent was filed on or after November 1, 2007.

Section 1.78(d)(2) provides that each prior-filed application must name as an inventor at least one inventor named in the later-filed application. In addition, each prior-filed application must either be: (1) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or (2) a nonprovisional application under 35 U.S.C. 111(a) that is entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) for which the basic filing fee set forth in § 1.16 has been paid within the pendency of the application (provisions from former § 1.78(a)(1)).

Section 1.78(d)(3) is amended to include the parenthetical “(i.e., whether the later-filed application is a continuation, divisional, or continuation-in-part of the prior-filed nonprovisional application or

international application)” to clarify in the rules of practice what is meant by the requirement that an applicant identify the relationship of the applications. See MPEP § 201.11.

Section 1.78(d)(3) also provides that if an application is identified as a continuation-in-part application, the applicant must identify the claim or claims in the continuation-in-part application for which the subject matter is disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application. Any claim in the continuation-in-part application for which the subject matter is not identified as being disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application will be treated as entitled only to the actual filing date of the continuation-in-part application, and will be subject to prior art based on the actual filing date of the continuation-in-part application. As discussed previously, to avoid any unnecessary delay in the prosecution of the application, applicant should provide the identification before the examiner begins to conduct a prior art search. If the failure to identify the claims for which the subject matter is disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application causes the examiner to include a new prior art rejection in a second or subsequent Office action, the inclusion of the new prior art rejection will not preclude the Office action from being made final.

This final rule eliminates from § 1.78(d) the provision that the prior-filed application disclose the invention claimed in at least one claim of the later-filed application in the manner provided by 35 U.S.C. 112, ¶ 1. For a later-filed application to receive the benefit of the filing date of a prior-filed application, 35 U.S.C. 120 requires that the prior-filed application must disclose the invention claimed in at least one claim of the later-filed application in the manner provided by 35 U.S.C. 112, ¶ 1. The Office, however, does not make a determination as to whether a prior-filed application discloses the invention claimed in a claim of the later-filed application in the manner provided by 35 U.S.C. 112, ¶ 1, unless that determination is necessary to determine the patentability of such claim. See MPEP § 201.08 (“Unless the filing date of the earlier nonprovisional application is actually needed * * *, there is no need for the Office to make a determination as to whether the requirement of 35 U.S.C. 120, that the earlier nonprovisional application discloses the invention of the second application in the manner provided by

35 U.S.C. 112, ¶ 1, is met and whether a substantial portion of all of the earlier nonprovisional application is repeated in the second application in a continuation-in-part situation. Accordingly, an alleged continuation-in-part application should be permitted to claim the benefit of the filing date of an earlier nonprovisional application if the alleged continuation-in-part application complies with the * * * formal requirements of 35 U.S.C. 120.”).

Section 1.78(d)(4) and (d)(5) contain the provisions of former § 1.78(a)(2).

Section 1.78(d)(6) provides that cross-references to applications for which a benefit is not claimed must be located in a paragraph separate from the paragraph containing the references to applications for which a benefit is claimed. Including cross-references to applications for which a benefit is not claimed in the same paragraph as the paragraph containing the references to applications for which a benefit is claimed may lead to the Office inadvertently scheduling the application for publication under 35 U.S.C. 122(b) and § 1.211 *et seq.* on the basis of the cross-referenced applications having the earliest filing date.

Section 1.78(e) contains provisions relating to delayed claims under 35 U.S.C. 120, 121, or 365(c) for benefit of prior-filed nonprovisional or international applications. Section 1.78(e) contains the provisions of former § 1.78(a)(3).

Section 1.78(f) contains provisions relating to applications and patents naming at least one inventor in common.

Section 1.78(f)(1)(i) provides that the applicant in a nonprovisional application that has not been allowed (§ 1.311) must identify by application number (*i.e.*, series code and serial number) and patent number (if applicable) each other pending or patented nonprovisional application, in a separate paper, for which the following conditions are met: (1) The application has a filing date that is the same as or within two months of the filing date of the other pending or patented application, taking into account any filing date for which a benefit is sought under title 35, United States Code; (2) the application names at least one inventor in common with the other pending or patented application; and (3) the application is owned by the same person, or subject to an obligation of assignment to the same person, as the other pending or patented application. This identification requirement would also apply to each identified application because the identifying application has

a filing date that is the same as or within two months of the filing date of the identified application and vice versa.

The phrase "taking into account any filing date for which a benefit is sought under title 35, United States Code" in § 1.78(f)(1)(i)(A) means any filing date for which a benefit (or priority) is sought or claimed under 35 U.S.C. 111, 119, 120, 121, 363, or 365. *Cf.* 35 U.S.C. 122(b)(1)(A) (requires publication of patent applications "promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought under this title" (emphasis added), meaning eighteen months from the earliest filing date for which a benefit or priority is sought or claimed under 35 U.S.C. 111, 119, 120, 121, 363, or 365). Thus, if an application claims the benefit of or priority to other applications, "the filing date of [the application], taking into account any filing date for which a benefit is sought under title 35, United States Code," is the actual filing date of the application as well as the filing date of each application to which the application claims a benefit or priority. For example, if an application has a filing date of December 1, 2006, and claims the benefit of a nonprovisional application that was filed on June 1, 2004, and claims the priority of a foreign application that was filed on June 1, 2003, for purposes of §§ 1.78(f)(1) and (f)(2) the filing date of the application "taking into account any filing date for which a benefit is sought under title 35, United States Code," is December 1, 2006, June 1, 2004, and June 1, 2003.

The phrase "owned by the same person, or subject to an obligation of assignment to the same person" in § 1.78(f)(1)(i)(C) (and in § 1.78(f)(2)(i)(C) and 1.78(f)(3)) has the same meaning as it does in 35 U.S.C. 103(c). *See* MPEP § 706.02(l)(2) for a discussion of the definition of this phrase as it is used in 35 U.S.C. 103(c).

The phrase "has not been allowed" in § 1.78(f)(1)(i) (and in § 1.78(f)(2)(ii) and (iii)) means a notice of allowance under § 1.311 has not been mailed in the application, or a notice of allowance under § 1.311 has been mailed in the application but the application has been withdrawn from issue. Thus, the identification of such one or more other pending or patented nonprovisional applications under § 1.78(f)(1)(i) is not required in an application in which a notice of allowance has been mailed, unless the application is withdrawn from issue.

Section 1.78(f)(1)(ii) also provides that one or more other nonprovisional applications under § 1.78(f)(1)(i) must

be identified within the later of: (1) Four months from the actual filing date of a nonprovisional application filed under 35 U.S.C. 111(a); (2) four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in a nonprovisional application entering the national stage from an international application under 35 U.S.C. 371; or (3) two months from the mailing date of the initial filing receipt in the other nonprovisional application that is required to be identified under § 1.78(f)(1)(i).

Section 1.78(f)(2)(i) provides that a rebuttable presumption shall exist that a nonprovisional application contains at least one claim that is not patentably distinct from at least one of the claims in the one or more other pending or patented nonprovisional applications if: (1) The application has a filing date that is the same as the filing date of another pending application or patent, taking into account any filing date for which a benefit is sought; (2) the application names at least one inventor in common with the other pending application or patent; (3) the application is owned by the same person, or subject to an obligation of assignment to the same person, as the other pending application or patent; and (4) the application contains substantially overlapping disclosure as the other pending application or patent. Section 1.78(f)(2)(i) further provides that substantial overlapping disclosure exists if the other pending or patented nonprovisional application has written description support under 35 U.S.C. 112, ¶ 1, for at least one claim in the nonprovisional application.

If these conditions exist, the applicant must under § 1.78(f)(2)(ii) in the nonprovisional application, unless the nonprovisional application has been allowed (§ 1.311), within the time period specified in § 1.78(f)(2)(iii) either: (1) Rebut this presumption by explaining how the application contains only claims that are patentably distinct from the claims in each of such other pending applications or patents; or (2) submit a terminal disclaimer in accordance with § 1.321(c). In addition, § 1.78(f)(2)(ii)(B) provides that where one or more other pending nonprovisional applications containing patentably indistinct claims have been identified, the applicant must explain why there are two or more pending nonprovisional applications naming at least one inventor in common and owned by the same person, or subject to an obligation of assignment to the same person, which contain patentably indistinct claims. Unless applicant presents good and sufficient reasons for

such multiple applications, the Office may require elimination of the patentably indistinct claims from all but one of the applications. *See* § 1.78(f)(3).

As discussed previously, for applications having a continuity relationship, the prior application must be pending at the time the continuing application is filed. *See* 35 U.S.C. 120 (requires that a continuing application be filed before the patenting or abandonment of or termination of proceedings on the prior application). An applicant is not required to provide an explanation under § 1.78(f)(2)(ii)(B) for a continuation application or continuation-in-part application of a prior-filed application that has been allowed, provided that the prior-filed application is not withdrawn from issue. Furthermore, where the other nonprovisional application containing patentably indistinct claims is allowed, the Office will not count the claims of the allowed application in determining whether the total number of claims present in all of the copending nonprovisional applications containing patentably indistinct claims exceeds the five independent claim and twenty-five total claim threshold under § 1.75(b)(4). *See* the discussion of § 1.75(b)(4). A terminal disclaimer in accordance with § 1.321(c) will, however, be required in each nonprovisional application containing patentably indistinct claims to overcome any obviousness-type double patenting rejection.

Under § 1.78(f)(2)(iii), the actions specified in § 1.78(f)(2)(ii) (if required) must be taken within the later of: (1) Four months from the actual filing date of a nonprovisional application filed under 35 U.S.C. 111(a); (2) four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in a nonprovisional application entering the national stage from an international application under 35 U.S.C. 371; (3) the date on which a claim that is not patentably distinct from a claim in one or more other pending or patented applications is presented; or (4) two months from the mailing date of the initial filing receipt in the one or more other pending or patented applications.

The requirement under § 1.78(f)(2)(ii) for taking one of the actions specified in § 1.78(f)(2)(ii) does not apply to the applicant in the application in which a notice of allowance has been mailed, unless the application is withdrawn from issue (§ 1.313). For example, if an applicant filed a continuation application after a notice of allowance has been mailed in the prior-filed application, the applicant must either rebut the presumption under

§ 1.78(f)(2)(i) or submit a terminal disclaimer in accordance with § 1.321(c) within the time period set forth in § 1.78(f)(2)(iii) in the continuation application. Under § 1.78(f)(2)(ii), the applicant, however, is not required to rebut the presumption or submit a terminal disclaimer in the allowed prior-filed application. Nevertheless, a terminal disclaimer in accordance with § 1.321(c) will be required in each nonprovisional application containing patentably indistinct claims to overcome any obviousness-type double patenting rejection.

As discussed previously, when an applicant files multiple applications that are substantially the same, the applicant is responsible for assisting the Office in resolving potential double patenting situations, rather than taking no action until faced with a double patenting rejection. Thus, if an Office action must include a double patenting rejection (either statutory or obviousness-type double patenting), it is because the applicant has not met his or her responsibility to resolve the double patenting situation. Therefore, the inclusion of a new double patenting rejection in a second or subsequent Office action will not preclude the Office action from being made final.

Section 1.78(f)(3) applies when there are two or more commonly owned (owned by the same person, or are subject to an obligation of assignment to the same person) nonprovisional applications containing patentably indistinct claims. Under § 1.78(f)(3), unless applicant presents good and sufficient reasons for such multiple applications, the Office may require elimination of the patentably indistinct claims from all but one of the applications. Section 1.78(f)(3) contains provisions similar to former § 1.78(b). The Office expects to apply this provision primarily in situations covered by § 1.78(f)(2)(ii), under which applicants must explain why it is necessary that there are two or more pending nonprovisional applications naming at least one inventor in common and owned by the same person, or subject to an obligation of assignment to the same person, which contain patentably indistinct claims. The Office, however, may require that an applicant provide good and sufficient reason whenever there are two or more pending nonprovisional applications with such common ownership or assignment obligation and patentably indistinct claims, regardless of the relative filing dates of the applications. Section 1.78(f)(3) does not apply to the claims in a patent.

The following are two examples where an applicant may have a good and sufficient reason under § 1.78(f)(3) for there being two or more pending nonprovisional applications that contain patentably indistinct claims: (1) An applicant filed a continuation application after the mailing of a notice of allowance in the prior-filed application, but the allowance of the prior-filed application was subsequently withdrawn by the Office; or (2) an interference was declared in an application that contains both claims corresponding to the count and claims not corresponding to the count, the BPAI suggests that the claims not corresponding to the count be canceled from the application in interference and pursued in a separate application, and the applicant filed a continuation application to present the claims not corresponding to the count. These examples are merely illustrative and not exhaustive.

Section 1.78(g) addresses applications or patents under reexamination that name different inventors and contain patentably indistinct claims. Section 1.78(g) contains the provisions of former § 1.78(c), except that “conflicting claims” is changed to “patentably indistinct claims” for clarity and for consistency with the language of § 1.78(f).

Section 1.78(h) covers the situation in which parties to a joint research agreement are treated (in essence) as a common owner for purposes of 35 U.S.C. 103 by virtue of the CREATE Act. Section 1.78(h) provides that if an application discloses or is amended to disclose the names of parties to a joint research agreement under 35 U.S.C. 103(c)(2)(C), the parties to the joint research agreement are considered to be the same person for purposes of § 1.78. The CREATE Act amended 35 U.S.C. 103(c) to provide that subject matter developed under a joint research agreement shall be treated as owned by the same person or subject to an obligation of assignment to the same person for purposes of determining obviousness if three conditions are met: (1) The claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; (2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and (3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. *See Changes to Implement the Cooperative Research and Technology Enhancement Act of 2004,*

70 FR 1818, 1818 (Jan. 11, 2005), 1291 *Off. Gaz. Pat. Office* 58, 58–59 (Feb. 8, 2005) (final rule). Section 1.78(h) also provides that if the application is amended to disclose the names of parties to a joint research agreement, the applicant must identify the one or more other nonprovisional applications as required by § 1.78(f)(1) with the amendment unless the applications have been identified within the four-month period specified in § 1.78(f)(1).

Section 1.78(i) provides that the time periods set forth in § 1.78 are not extendable.

The changes to § 1.78 (except §§ 1.78(a) and 1.78(d)(1)) are applicable to any nonprovisional application pending on or after November 1, 2007. The changes to §§ 1.78(a) and 1.78(d)(1) are applicable to any application filed on or after November 1, 2007, or any application entering the national stage after compliance with 35 U.S.C. 371 on or after November 1, 2007. Except as otherwise indicated in this final rule, any application filed under 35 U.S.C. 111(a) on or after November 1, 2007, or any application entering the national stage after compliance with 35 U.S.C. 371 on or after November 1, 2007, seeking to claim the benefit under 35 U.S.C. 120, 121, or 365(c) and § 1.78 of a prior-filed nonprovisional application or international application must either: (1) Meet the requirements specified in one of §§ 1.78(d)(1)(i) through (d)(1)(v); or (2) include a grantable petition under § 1.78(d)(1)(vi).

With respect to applications that claim the benefit under 35 U.S.C. 120, 121, or 365(c) only of nonprovisional applications or international applications filed before August 21, 2007: An application is not required to meet the requirements set forth in § 1.78(d)(1) if: (1) The application claims the benefit under 35 U.S.C. 120, 121, or 365(c) only of prior-filed nonprovisional applications filed before August 21, 2007 or prior-filed applications entering the national stage after compliance with 35 U.S.C. 371 before August 21, 2007; and (2) there is no other application filed on or after the publication date of this final rule in the **Federal Register** that also claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such prior-filed nonprovisional applications or international applications. This provision will provide applicants with “one more” continuation application or continuation-in-part application of a second or subsequent continuing application (continuation application or continuation-in-part application) that was filed prior to the publication date of this final rule in the **Federal Register**

without a petition under § 1.78(d)(1)(vi). Thus, an applicant may file a single continuation application or continuation-in-part application on or after November 1, 2007, without meeting the requirements specified in § 1.78(d)(1)(i) through (d)(1)(v), or including a petition under § 1.78(d)(1)(vi), even if the prior-filed application was a second or subsequent continuation or continuation-in-part application. It should be noted that the purpose of this provision is to ensure that an applicant may file “one more” continuation application or continuation-in-part application of an application that was filed prior to the publication date of this final rule in the **Federal Register** without a petition and showing, and not to provide an “extra” continuation application or continuation-in-part application for applications filed prior to the publication date of this final rule in the **Federal Register**. If an application filed before the publication date of this final rule in the **Federal Register** is not a continuing application or is only the first continuing application, this provision will not entitle an applicant to file a third or subsequent continuation or continuation-in-part application without a petition under § 1.78(d)(1)(vi) showing that the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application.

Section 1.104 (nature of examination): The Office proposed a number of changes to § 1.104 to implement the “representative claims” examination approach. See *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR at 64, 68, 1302 *Off. Gaz. Pat. Office* at 1131, 1332. The Office is not proceeding with the changes to § 1.104 to implement the “representative claims” examination approach, but is revising § 1.104 for consistency with current examination practices.

Section 1.104(a)(1) is amended to add the phrase “and other requirements” to the phrase “the examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes and rules” to address situations in which the requirement is based upon Office practice as set forth in the MPEP or in the case law. For example, the phrase “other requirements” would address the situation in which a claim did not comply with the requirement in MPEP § 608.01(m) that each claim be the object of a single sentence starting with “I (or we) claim,” “The invention claimed is,”

or the equivalent. See *Fressola v. Manbeck*, 36 U.S.P.Q.2d 1211, 1212 (D.D.C. 1995). In addition, in the event that there is a requirement for restriction including election of species, or both, the provision in § 1.104(a)(1) for a “thorough study [and] investigation of the available prior art relating to the subject matter of the claimed invention” will continue to apply only with respect to the invention and species elected for examination on the merits. This provision of § 1.104 does not apply with respect to an invention or species that has been withdrawn from consideration as a result of a requirement for restriction, including an election of species.

Section 1.104(b) is also amended to delete the sentence “[h]owever, matters of form need not be raised by the examiner until a claim is found allowable.” The Office would prefer that all matters of form be resolved at the earliest time during the patent examination process. Nevertheless, an Office action would not be considered improper simply because the Office action did not raise every applicable issue of form present in the application.

Section 1.105 (requirements for information): Section 1.105(a)(1) is amended to provide that an applicant may be required to set forth where (by page and line or paragraph number) in the specification of the application, or any application the benefit of whose filing date is sought under title 35, United States Code, there is written description support for the invention as defined in the claims (whether in independent or dependent form), and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention, under 35 U.S.C. 112, ¶ 1. Therefore, in situations in which it is not readily apparent where the specification of the application, or an application for which a benefit is claimed, provides written description support and enablement under 35 U.S.C. 112, ¶ 1, for a claim or a limitation of a claim, the examiner may require the applicant to provide such information. The Office considers this authority to be inherent under the patent statute and existing rules (including § 1.105), but is revising § 1.105 to make the authority explicit.

Section 1.110 (inventorship and date of invention of the subject matter of individual claims): Section 1.110 is amended to refer to § 1.78, rather than a specific paragraph (paragraph (c)) of § 1.78. The first sentence of § 1.110 is also amended to relocate the phrase

“when necessary for purposes of an Office proceeding” to the end of the sentence for clarity.

Section 1.114 (request for continued examination): Under § 1.114, an applicant is permitted to file a single request for continued examination without a petition and showing in a single application family. See § 1.114(f)(1). An application family includes the initial application and its continuation or continuation-in-part applications. An applicant is also permitted to file a single request for continued examination without a petition and showing in a divisional application family. See §§ 1.114(f)(2) and (f)(3). A divisional application family includes the divisional application and its continuation applications. An applicant may file a second or subsequent request for continued examination if the applicant files a petition and a showing that the amendment, argument, or evidence sought to be entered could not have been submitted earlier. See § 1.114(g).

Section 1.114(a) is amended to make clear that an applicant may not file an unrestricted number of requests for continued examination, that a request for continued examination must include a petition under § 1.114(g) unless the conditions set forth in § 1.114(f)(1), (f)(2), or (f)(3) are satisfied, and that a request for continued examination must be identified as a request for continued examination. Section 1.114(a) otherwise contains the provisions of former § 1.114(a).

Section 1.114(d) is revised to eliminate the sentence “[i]f an applicant timely files a submission and fee set forth in § 1.17(e), the Office will withdraw the finality of any Office action and the submission will be entered and considered.” This change is to avoid misleading applicants into believing that the Office will *pro forma* withdraw the finality of any Office action and the submission will be *pro forma* entered and considered upon timely filing of a submission and fee set forth in § 1.17(e). Under revised § 1.114, a second or subsequent request for continued examination must also include a petition accompanied by the fee set forth in § 1.17(f) except under the conditions set forth in § 1.114(f).

Section 1.114(f) provides the conditions under which an applicant may file a request for continued examination under § 1.114 without a petition under § 1.114(g).

Section 1.114(f)(1) permits an applicant to file a single request for continued examination in any one (but only one) of an initial application or its continuation applications or

continuation-in-part applications. Section 1.114(f)(1) provides that an applicant may file a request for continued examination under § 1.114 without a petition under § 1.114(g) if a request for continued examination has not been previously been filed in any of: (1) The application; (2) any application whose benefit is claimed in the application under 35 U.S.C. 120, 121, or 365(c); and (3) any application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of the application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), 1.78(d)(1)(iii) or 1.78(d)(1)(vi). For example, if applicant filed one request for continued examination in an initial application, applicant is precluded from filing a second request for continued examination in the initial application and in any continuation applications or continuation-in-part applications that claim the benefit of the initial application (not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), 1.78(d)(1)(iii) or 1.78(d)(1)(vi)), without a petition under § 1.114(g).

Section 1.114(f)(2) permits an applicant to file a single request for continued examination under § 1.114 in a divisional application meeting the conditions set forth in § 1.78(d)(1)(ii) provided that no request for continued examination has been filed in any continuation application of the divisional application. Section 1.114(f)(2) provides that an applicant may file a request for continued examination under § 1.114 in a divisional application without a petition under § 1.114(g) if a request for continued examination has not previously been filed in any of: (1) The divisional application; and (2) any application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of that divisional application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

Section 1.114(f)(3) permits an applicant to file a single request for continued examination in a continuation application of a divisional application meeting the conditions set forth in § 1.78(d)(1)(ii) provided that no request for continued examination has been filed in the divisional application or any other continuation application of the divisional application. Section 1.114(f)(3) provides that an applicant may file a request for continued examination under § 1.114 in a continuation application of a divisional

application without a petition under § 1.114(g) if a request for continued examination has not previously been filed in any of: (1) The continuation application; (2) the divisional application; and (3) any other application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of that divisional application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

The provisions of § 1.114(f) are illustrated with the following example (the example used to illustrate the provisions of §§ 1.78(d)(1)(i) through (d)(1)(iii)): (1) There is an initial application "A" that is subject to a restriction requirement under 35 U.S.C. 121 and § 1.141 *et seq.*; (2) a continuation application "B" of application "A"; (3) a further continuation application "C" which claims the benefit of continuation application "B" and initial application "A"; (4) a divisional application "D" (based upon the restriction requirement under 35 U.S.C. 121 and § 1.141 *et seq.* in application "A"), which claims the benefit of continuation application "C", continuation application "B", and initial application "A"; (5) a continuation application "E" of divisional application "D", which claims the benefit of divisional application "D", continuation application "C", continuation application "B", and initial application "A"; and (6) a further continuation application "F" of continuation application "E", which claims the benefit of continuation application "E", divisional application "D", continuation application "C", continuation application "B", and initial application "A".

Section 1.114(f)(1) permits the filing of a single request for continued examination without a petition under § 1.114(g) in any one of applications "A", "B", or "C". Specifically, a request for continued examination may be filed in application "A", if a request for continued examination has not previously been filed in any of: (1) application "A"; (2) any application (none) whose benefit is claimed in application "A"; and (3) any application (applications "B" and "C") that claims the benefit of application "A", not including divisional application "D" and its continuation applications "E" and "F". In addition, a request for continued examination may be filed in application "B", if a request for continued examination has not previously been filed in any of: (1) Application "B"; (2) any application

(application "A") whose benefit is claimed in application "B"; and (3) any application (application "C") that claims the benefit of application "B", not including divisional application "D" and its continuation applications "E" and "F". Finally, a request for continued examination may be filed in application "C", if a request for continued examination has not previously been filed in any of: (1) Application "C"; (2) any application (applications "A" and "B") whose benefit is claimed in application "C"; and (3) any application (none) that claims the benefit of application "C", not including divisional application "D" and its continuation applications "E" and "F".

Section 1.114(f)(2) permits the filing of a single request for continued examination without a petition under § 1.114(g) in application "D", if a request for continued examination has not previously been filed in application "E" or application "F". Specifically, a request for continued examination may be filed in application "D", if a request for continued examination has not previously been filed in any of: (1) Divisional application "D"; and (2) any application (applications "E" and "F") that claims the benefit of divisional application "D".

Section 1.114(f)(3) permits the filing of a single request for continued examination without a petition under § 1.114(g) in any one of applications "E" or "F", if a request for continued examination has not previously been filed in application "D". Specifically, a request for continued examination may be filed in continuation application "E", if a request for continued examination has not previously been filed in any of: (1) Continuation application "E"; (2) divisional application "D"; and (3) any other application (application "F") that claims the benefit of divisional application "D". In addition, a request for continued examination may be filed in continuation application "F", if a request for continued examination has not previously been filed in any of: (1) continuation application "F"; (2) divisional application "D"; and (3) any other application (application "E") that claims the benefit of divisional application "D".

Section 1.114(g) provides that a request for continued examination must include a petition accompanied by the fee set forth in § 1.17(f) and a showing that the amendment, argument, or evidence sought to be entered could not have been submitted before the close of prosecution in the application. A petition under § 1.114(g) and the fee set forth in § 1.17(f) are not required if the

conditions set forth in § 1.114(f) are satisfied. Since a petition under § 1.114(g) requires a showing that there is an amendment, argument, or evidence that could not have been submitted prior to the close of prosecution in the application, a petition under § 1.114(g) for a request for continued examination including only an information disclosure statement as the submission required by § 1.114(c) (*i.e.*, not including an amendment, argument, or evidence) would not be granted.

Thus, an applicant may file a single request for continued examination without a petition under § 1.114(g) in any one (but only one) of an initial application or its continuation applications or continuation-in-part applications. An applicant may also file a single request for continued examination without a petition under § 1.114(g) in any one (but only one) of a divisional application (meeting the conditions set forth in § 1.78(d)(1)(ii)) or its continuation applications. Any second or subsequent request for continued examination in an application or application family must include a petition, accompanied by the fee set forth in § 1.17(f), and a showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution in the application.

Section 1.114(h) provides that the filing of an improper request for continued examination, including a request for continued examination with a petition under § 1.114(g) that is not grantable, will not stay any period for reply or other proceedings. This is consistent with the current practice for requests for continued examination. *See* MPEP § 706.07(h), subsection V (the mere request for continued examination and fee will not operate to toll the running of any time period set in the previous Office action for reply to avoid abandonment of the application).

The Office proposed § 1.114(f) to include: “[a]ny other proffer of a request for continued examination in an application not on appeal will be treated as a submission under § 1.116. Any other proffer of a request for continued examination in an application on appeal will be treated only as a request to withdraw the appeal.” *See Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 61, 1302 *Off. Gaz. Pat. Office* 1329. This final rule does not adopt that proposed change because it is unnecessary. Section 1.116 applies only to amendments, affidavits, and other evidence filed after the mailing of a final

Office action but prior to an appeal. However, applicants are permitted to file a request for continued examination under § 1.114 after the mailing of a notice of allowance or an action that otherwise closes prosecution in the application (*e.g.*, an Office action under *Ex parte Quayle*, 1935 Dec. Comm’r Pat. 11 (1935)). *See* § 1.114(b). Furthermore, § 1.114(d) already provides for the situation in which a request for continued examination is filed in an application on appeal.

As discussed previously, applicants are permitted to file two continuation or continuation-in-part applications and a single request for continued examination without any justification. The provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. Thus, filing a request for continued examination does not preclude an applicant from filing a first or second continuation application (or continuation-in-part application). In addition, an applicant may not agree to forgo a first or second continuation application (or continuation-in-part application) to obtain a second or third request for continued examination, nor can applicant forgo a request for continued examination to obtain a third continuation or continuation-in-part application. For example, an applicant cannot file two requests for continued examination without a petition and showing in an application instead of filing one of the two permitted continuation applications.

The Office is implementing an optional streamlined continuation application procedure under which an applicant may have a continuation application placed on an examiner’s amended (Regular Amended) docket (see discussion of § 1.78(d)(1)(i)). Thus, an applicant may effectively obtain the docketing benefit (*i.e.*, being placed on an examiner’s amended (Regular Amended) docket) of a second and third request for continued examination without a petition under § 1.114(g) by requesting that the two continuation applications permitted under § 1.78(d)(1)(i) be treated under the optional streamlined continuation application procedure.

The changes to § 1.114 apply to any application in which a request for continued examination is filed on or after November 1, 2007. Thus, a request for continued examination filed on or after November 1, 2007, in an application in which a request for continued examination has previously been filed, in a continuation or continuation-in-part application of an application in which a request for continued examination has previously

been filed, or in an application whose benefit is claimed in any other nonprovisional application in which a request for continued examination has previously been filed, must include a petition under § 1.114(g). That is, an applicant may file a request for continued examination (and not “one more” request for continued examination) on or after November 1, 2007, without a petition under § 1.114(g) only if the conditions set forth in § 1.114(f)(1), (f)(2), or (f)(3) are met.

Section 1.117 (refund due to cancellation of claim): The Consolidated Appropriations Act provides that 35 U.S.C. 41(a), (b), and (d) shall be administered in a manner that revises patent application fees (35 U.S.C. 41(a)) and patent maintenance fees (35 U.S.C. 41(b)), and provides for a separate filing fee (35 U.S.C. 41(a)), search fee (35 U.S.C. 41(d)(1)), and examination fee (35 U.S.C. 41(a)(3)) during fiscal years 2005 and 2006. *See* Public Law 108–447, 118 Stat. 2809 (2004). The Consolidated Appropriations Act also provides that the Office may, by regulation, provide for a refund of any part of the excess claim fee specified in 35 U.S.C. 41(a)(2) for any claim that is canceled before an examination on the merits has been made of the application under 35 U.S.C. 131. *See* 35 U.S.C. 41(a)(2) (as administered during fiscal years 2005 and 2006 pursuant to the Consolidated Appropriations Act). The Revised Continuing Appropriations Resolution, 2007 (Pub. L. 110–5, 121 Stat. 8 (2007)), keeps the patent fee and fee structure provisions of the Consolidated Appropriations Act, 2005, in effect during fiscal year 2007 (until September 30, 2007).

Section 1.117 is added to implement this provision of the Consolidated Appropriations Act. Section 1.117(a) provides that if an amendment canceling a claim is filed before an examination on the merits has been made of the application, the applicant may request a refund of any fee under § 1.16(h), (i), or (j) or under § 1.492(d), (e), or (f) paid on or after December 8, 2004, for such claim. Thus, if an applicant decides to cancel the claims in excess of five independent claims and in excess of twenty-five total claims rather than provide an examination support document in compliance with § 1.265, the applicant may request a refund of any fee for such claim that is paid on or after December 8, 2004. Section 1.117(a) as adopted, however, does not require that the amendment have been filed in reply to a notice under § 1.75(b)(3). Section 1.117(a) requires only that the amendment have been filed before an examination on the

merits has been made of the application. The Consolidated Appropriations Act authorizes a refund only for a claim that has been canceled before an examination on the merits has been made of the application under 35 U.S.C. 131. The Office thus lacks authority to grant a refund either on the basis of: (1) The withdrawal from consideration of a claim directed to a non-elected invention or species; or (2) the cancellation of a claim after an examination on the merits has been made of the application under 35 U.S.C. 131. Section 1.117(a) also provides that if an amendment adding one or more claims is also filed before the application has been taken up for examination on the merits, the Office may apply any refund under § 1.117 to any excess claims fees due as a result of such an amendment. The date indicated on any certificate of mailing or transmission under § 1.8 will not be taken into account in determining whether an amendment canceling a claim was filed before an examination on the merits has been made of the application.

• “[A]n examination on the merits has been made of the application” for purposes of § 1.117(a) once a first Office action on the merits, notice of allowability or allowance, or action under *Ex parte Quayle* is shown in the Patent Application Locating and Monitoring (PALM) system as having been counted. For purposes of § 1.117(a), “before” means at least one day before. If an amendment canceling a claim is filed and an Office action is counted on the same day, the amendment canceling a claim was not filed before an examination on the merits has been made of the application. The Patent Application Information Retrieval (PAIR) system is a system that provides public access to PALM for patents and applications that have been published. The PAIR system does not provide public access to information concerning applications that are maintained in confidence under 35 U.S.C. 122(a). Applicants, however, may use the private side of PAIR to access confidential information about their pending application. To access the private side of PAIR, a customer number must be associated with the correspondence address for the application, and the user of the system must have a digital certificate. For further information, contact the Customer Support Center of the Electronic Business Center at (571) 272-4100 or toll free at (866) 217-9197.

Section 1.117(b) (§ 1.117(c) as proposed) provides that if a request for refund under this section is not filed

within two months from the date on which the claim was canceled, the Office may retain the excess claims fee paid in the application. This two-month period is not extendable. If an amendment canceling a claim is not filed before an examination on the merits, the Office will not refund any part of the excess claims fee paid in the application except as provided in § 1.26.

The provisions of § 1.117(b) as proposed are duplicative of the provisions of § 1.138(d) and have not been adopted as unnecessary.

The patent fee provisions of the Consolidated Appropriations Act expire (in the absence of additional legislation) on September 30, 2007 (at the end of fiscal year 2007). Therefore, in the absence of subsequent legislation, the refund provision in § 1.117 will likewise expire on September 30, 2007 (at the end of fiscal year 2007), regardless of the date on which the excess claims fee was paid.

Section 1.136 (extensions of time): Section 1.136(a)(1) is amended to add “[t]he reply is to a notice requiring compliance with § 1.75(b) or § 1.265” to the enumerated list of replies to which the extension of time provision of § 1.136(a) is not applicable. A notice under § 1.75(b)(3) is a “notice requiring compliance with § 1.75(b).” A “notice requiring compliance with § 1.75(b)” would include a notice mailed before the issuance of a first Office action on the merits setting a two-month time period within which the applicant must: (1) File an examination support document in compliance with § 1.265; or (2) amend the application such that it contains no more than five independent claims and no more than twenty-five total claims. A “notice requiring compliance with § 1.75(b)” would also include a notice issued after a first Office action on the merits in an application in which the applicant is given a time period within which the applicant must amend the application such that it contains no more than five independent claims and no more than twenty-five total claims. For example, if a reply to a non-final Office action on the merits seeks to amend an application such that it contains more than five independent claims and more than twenty-five total claims, the reply would be held non-responsive and (if the non-compliance with § 1.75(b) appears to have been inadvertent) the Office would give the applicant a two-month time period that was not extendable under § 1.136(a) within which to provide an amendment that does not result in the application containing more than five independent

claims or more than twenty-five total claims. See § 1.135(c).

Section 1.142 (requirement for restriction): Section 1.142(a) is amended to state that an examiner “may” (rather than “will”) require restriction if two or more independent and distinct inventions are claimed in a single application. The change is for consistency with current Office practice under which a requirement that an application containing claims to two or more independent and distinct inventions be restricted to a single invention is discretionary (see 35 U.S.C. 121 and MPEP § 803.01). An application containing claims to two or more independent and distinct inventions typically is not restricted to a single invention if the search and examination of all of the claims in the application can be made without serious burden (see MPEP section 803).

Section 1.142(c) is added to permit applicants to suggest requirements for restriction. Specifically, § 1.142(c) provides that if two or more independent and distinct inventions are claimed in a single application, the applicant may file a suggested requirement for restriction under § 1.142(c). Any suggested requirement for restriction must be filed before the earlier of the first Office action on the merits or an Office action that contains a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the application. It must also be accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims, and must identify the claims to the elected invention. Claims to the non-elected invention, if not canceled, will be withdrawn from further consideration by the examiner. If the examiner accepts the suggested restriction, then the claims to the non-elected invention, if not canceled by the applicant, will be withdrawn from further consideration by the examiner. See the discussion of §§ 1.75(b)(5) and 1.78(d)(1)(ii).

Section 1.75(b)(3)(iii) as proposed would have permitted applicants to reply to a notice from the Office that an application contains more than ten representative claims (under certain conditions) by submitting a suggested requirement for restriction accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims. See *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR

at 64, 67–68, 1302 *Off. Gaz. Pat. Office* 1331, 1334. However, because the “representative claims” examination approach is not adopted in this final rule, this proposed provision of § 1.75(b)(3)(iii) is unnecessary. In this final rule, applicants may file a suggested requirement for restriction accompanied by an election without traverse (§ 1.142(c)) of an invention to which there are no more than five independent claims and no more than twenty-five total claims without first awaiting a notice from the Office under § 1.75(b)(3).

Section 1.142(c) further provides that if the applicant’s suggested requirement for restriction is accepted, the restriction requirement will be set forth in a subsequent Office action. Any claim to the non-elected invention or inventions, if not canceled, is by the election withdrawn from further consideration.

If the suggested requirement for restriction is refused, the applicant will be notified in an Office action. That Office action may include, a notice under § 1.75(b)(3) requiring applicant to file an examination support document or amend the application to contain no more than five independent claims or no more than twenty-five total claims. If an applicant’s suggested restriction requirement is refused, the examiner may make a different restriction requirement or make no restriction requirement. 35 U.S.C. 121 authorizes, but does not compel, the Director to require that an application containing two or more independent and distinct inventions be restricted to one of the inventions. A decision not to restrict an application to a single invention is not an action or requirement within the meaning of § 1.181(a). Thus, any review of an examiner’s requirement for restriction that differs from a suggested restriction requirement will only concern the appropriateness of the examiner’s restriction requirement and will not address the appropriateness of the applicant’s suggested restriction requirement or compare the examiner’s restriction requirement and the suggested restriction requirement.

Section 1.145 (subsequent presentation of claims for different invention): Section 1.145 is amended to state that an applicant “may” (rather than “will”) be required to restrict the claims to the invention previously claimed if, after an Office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed (*see* discussion of § 1.142(a)). Section 1.145 is amended to add “on the merits” to clarify that

§ 1.145 applies only after a first Office action on the merits.

Section 1.265 (examination support document): Section 1.265 is added to set forth what an “examination support document” entails. An examination support document is required under § 1.75(b)(1) when an applicant presents more than five independent claims or more than twenty-five total claims in an application. *See* § 1.75(b)(1) and the discussion of § 1.75(b)(1). Section 1.265(a) sets forth the requirements for an examination support document. Section 1.265(b) provides for the requirements of the preexamination search required under § 1.265(a)(1). Section 1.265(c) provides for the requirements of the listing of references required under § 1.265(a)(2). Section 1.265(d) provides for certain situations in which a supplemental examination support document is required when applicant files an information disclosure statement citing additional references. Section 1.265(e) provides for situations in which the examination support document is insufficient. Section 1.265(f) provides an exemption to applications filed by a small entity as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The exemption is for the requirement in § 1.265(a)(3) that an examination support document must include an identification of all of the claim limitations (whether in independent or dependent form) that are disclosed by the cited references.

Section 1.265 contains fewer requirements than an accelerated examination support document under the revised procedures for certain petitions to make special (*see Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination*, 71 FR 36232 (June 26, 2006), 1308 *Off. Gaz. Pat. Office* 106 (July 18, 2006) (notice)). For example, § 1.265 does not require that the examination support document identify any cited references that may be disqualified as prior art under 35 U.S.C. 103(c) as amended by the Cooperative Research and Technology Act (although applicants are encouraged to identify any cited references that may be so disqualified). Thus, the Office’s guidelines concerning the accelerated examination support document may be helpful to applicants who are preparing an examination support document under § 1.265. The guidelines under the revised accelerated examination procedure, search templates, and samples of a preexamination search document and an examination support document can be found on the Office’s Internet Web site at [http://](http://www.uspto.gov/web/patents/accelerated/)

www.uspto.gov/web/patents/accelerated/. The Office will provide similar guidelines for examination support document under § 1.265 and will post such guidelines on the Office’s Internet Web site.

Section 1.265(a)(1) provides that an examination support document must include a statement that a preexamination search in compliance with § 1.265(b) was conducted. The examination support document must identify (in the manner set forth in MPEP § 719.05) the field of search by class and subclass and the date of the search, where applicable. For database searches, the examination support document must identify the search logic or chemical structure or sequence used as a query, the name of the file or files searched and the database service, and the date of the search.

Section 1.265(a)(2) provides that an examination support document must include a listing in compliance with § 1.265(c) of the reference or references deemed most closely related to the subject matter of each of the claims (whether in independent or dependent form). The references that would be most closely related to the subject matter of each of the claims include: (1) A reference that discloses the most number of limitations in an independent claim; (2) a reference that discloses a limitation of an independent claim that is not shown in any other reference in the listing of references required under § 1.265(a)(2); and (3) a reference that discloses a limitation of a dependent claim that is not shown in any other reference in the listing of references required under § 1.265(a)(2). References that are only relevant to the general subject matter of the claims would not be most closely related to the subject matter of each of the claims if there are other references that are deemed to be more closely related to the subject matter of the claims.

It is envisioned that the reference or references presented as being most closely related to the subject matter of the claims will generally be references that result from the preexamination search provided for in § 1.265(a)(1). The preexamination search provided for in § 1.265(a)(1) should result in the reference or references that are most closely related to the subject matter of the claims. However, an applicant may not exclude a reference from an examination support document simply because the reference was not the result of the preexamination search provided for in § 1.265(a)(1). The reference, for instance, may have been brought to applicant’s attention via a foreign or PCT search report. References that have

been brought to the applicant's attention regardless of the source of those references must be considered in identifying the reference or references most closely related to the subject matter of each of the claims.

Section 1.265(a)(3) provides that an examination support document must, for each reference in the listing of references required under § 1.265(a)(2), identify all of the limitations of each of the claims (whether in independent or dependent form) that are disclosed by the reference. Applicant may satisfy this requirement either by mapping the limitations of each of the claims to the references or by mapping the references to the limitations of the claims. Applicants may map the limitations of each of the claims to the references by, for each claim, identifying where the cited references disclose features, showings, or teachings that are relevant to each limitation of such claim. Applicants may map the references to the limitations of the claims by, for each cited reference, identifying where the reference discloses features, showings, or teachings that are relevant to the limitations of each of the claims.

Section 1.265(a)(3) requires the applicant to identify at least one appearance in the reference (a representative portion) of a specific feature, showing, or teaching for which the reference is being cited. If the feature, showing, or teaching appears in more than one portion of the reference, applicant would not need to specifically point out more than one occurrence. Applicant, however, should do so where the additional appearance may not be apparent to the examiner and may have some additional significance over its first identified appearance. If an applicant recognizes that a document is relevant for more than one feature, showing, or teaching, the applicant would need to specifically identify each additional feature, showing, or teaching and the portion where the feature, showing, or teaching appears in the document. A mere statement indicating that the entire reference, or substantially the entire reference, is relevant would not comply with § 1.265(a)(3).

Section 1.265(a)(4) provides that an examination support document must include a detailed explanation particularly pointing out how each of the independent claims is patentable over the references cited in the listing of references required under § 1.265(a)(2). The explanation required by § 1.265(a)(4) may be set forth together with the identification required by § 1.265(a)(3) or may be provided separately. For example, the identification required by § 1.265(a)(3)

and the explanation required by § 1.265(a)(4) may be set out in a single spreadsheet with two columns, or may be set out in two spreadsheets. A general statement that all of the claim limitations are not described in a single reference does not satisfy the requirements of § 1.265(a)(4). Section 1.265(a)(4) requires that the examination support document set out with particularity, by reference to one or more specific claim limitations, why the claimed subject matter is not described in the references, taken as a whole. The applicant must explain why a person of ordinary skill in the art would not have combined the features disclosed in one reference with features disclosed in another reference to arrive at the claimed subject matter. The applicant must also explain why the claim limitations referenced render the claimed subject matter novel and non-obvious over the cited prior art.

Section 1.265(a)(5) provides that an examination support document must include a showing of where each limitation of the claims (whether in independent or dependent form) finds support under 35 U.S.C. 112, ¶ 1, in the written description of the specification. If the application claims the benefit of one or more applications under title 35, United States Code, the showing must also include where each limitation of the claims finds support under 35 U.S.C. 112, ¶ 1, in each such application in which such support exists. For means- (or step-) plus-function claim elements under 35 U.S.C. 112, ¶ 6, this requires: (1) That the claim limitation be identified as means- (or step-) plus-function claim element under 35 U.S.C. 112, ¶ 6; and (2) that the structure, material, or acts in the specification that correspond to each means- (or step-) plus-function claim element under 35 U.S.C. 112, ¶ 6, be identified. See *Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination*, 71 FR at 36325, 1308 *Off. Gaz. Pat. Office* at 107.

If the examiner, after considering the application and any examination support document, still has questions concerning the invention or how the claims define over the prior art or are patentable, the examiner may request an interview before the first Office action. If the applicant declines such a request for an interview or if the interview does not result in the examiner obtaining the necessary information, the examiner may issue a requirement for information under § 1.105 to obtain such information. Section 1.133(a)(2) was amended in November of 2005 to permit an interview before the first Office

action if the examiner determines that such an interview would advance prosecution. See *Provisions for Claiming the Benefit of a Provisional Application With a Non-English Specification and Other Miscellaneous Matters*, 70 FR at 56121, 56128, 1299 *Off. Gaz. Pat. Office* at 144, 150. Applicant may request an interview before the first Office action. Such a request is ordinarily granted in a continuing application or if the examiner determines that the interview would advance prosecution. See § 1.133(a)(2) and MPEP § 713.02.

Section 1.265(b) provides that the preexamination search must involve U.S. patents and patent application publications, foreign patent documents, and non-patent literature, unless the applicant can justify with reasonable certainty that no references more pertinent than those already identified are likely to be found in the eliminated source. That justification must be included in the statement required by § 1.265(a)(1). Section 1.265(b) also provides that the preexamination search must encompass all of the limitations of the independent claims. It must also encompass all of the limitations of the dependent claims separately from the claim or claims from which they depend. The claims must be given the broadest reasonable interpretation. A search report from a foreign patent office will not automatically satisfy the requirement in § 1.265(a)(1) for a preexamination search unless it includes the information required by § 1.265.

Section 1.265(c) provides for the content requirements of the listing of references required under § 1.265(a)(2) as part of an examination support document. Section 1.265(c) provides the same content requirements as those that are currently provided in §§ 1.98(a) and (b). Specifically, § 1.265(c) provides that the listing of references required under § 1.265(a)(2) as part of an examination support document must include a list identifying each of the cited references (§§ 1.265(c)(1) and (c)(2)), a copy of each reference except for references that are U.S. patents or U.S. patent application publications (§ 1.265(c)(3)), and each English language translation if required by § 1.265(c)(4). Applicant may use the USPTO form, "Examination Support Document Listing of References," to submit the listing of references. The form will be available on the Office's Internet Web site at <http://www.uspto.gov/web/forms/index.html#patent>.

Section 1.265(c)(1) provides that the list of cited references must group U.S. patents and U.S. patent application publications (including international

applications designating the United States) in a section separate from other references. Section 1.265(c)(1) also provides that each page of the list of the cited references must include: (1) The application number, if known, of the application in which the examination support document is being filed; (2) a column that provides a space next to each cited reference for the examiner's initials; and (3) a heading that clearly indicates that the list is part of an examination support document listing of references.

Section 1.265(c)(2) provides that the list of cited references must identify each cited reference as follows: (1) Each U.S. patent must be identified by first named patentee, patent number, and issue date; (2) each U.S. patent application publication must be identified by applicant, patent application publication number, and publication date; (3) each U.S. application must be identified by the applicant, application number, and filing date; (4) each foreign patent or published foreign patent application must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application; and (5) each publication must be identified by publisher (e.g., name of journal), author (if any), title, relevant pages of the publication, publication date, and place of publication.

Section 1.265(c)(4) provides that if a non-English language document is being cited, any existing English language translation of the non-English language document must be submitted if the translation is within the possession, custody, or control of, or is readily available to any individual identified in § 1.56(c).

Section 1.265(d) provides for a supplemental examination support document. If an information disclosure statement is filed in an application in which an examination support document is required and has been filed, the applicant must also file a supplemental examination support document addressing the references cited in the information disclosure statement in the manner required under §§ 1.265(a)(3) and (a)(4), unless the information disclosure statement cites only references that are less closely related to the subject matter of one or more claims than the references cited in the examination support document listing of references required under § 1.265(a)(2).

Section 1.265(e) provides that the applicant will be notified if: (1) The

examination support document or preexamination search is deemed to be insufficient; or (2) the claims have been amended such that the examination support document no longer covers each claim. The notice will give the applicant a two-month time period within which the applicant must either file a corrected or supplemental examination support document or amend the application such that it contains no more than five independent claims and no more than twenty-five total claims in order to avoid abandonment. Section 1.265(e) further provides that this two-month period is not extendable under § 1.136(a).

Section 1.265(f) provides an exemption from the requirement in § 1.265(a)(3) that an examination support document must, for each reference cited in the listing of references required under § 1.265(a)(2), include an identification of all of the limitations of each of the claims (whether in independent or dependent form) that are disclosed by the reference that applies to applications by a small entity as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The Regulatory Flexibility Act defines a "small entity" as a "small business" as defined in 5 U.S.C. 601(3), a "small organization" as defined in 5 U.S.C. 601(4), and a "small governmental jurisdiction" as defined in 5 U.S.C. 601(5). See 5 U.S.C. 601(6). Section 1.265(f) specifically provides that an examination support document, or a corrected or supplemental examination support document, is not required to comply with the requirements set forth in § 1.265(a)(3) if the examination support document is accompanied by a certification that any rights in the application have not been assigned, granted, conveyed, or licensed, and there is no obligation under contract or law to assign, grant, convey, or license any rights in the application, other than a security interest that has not been defaulted upon, to any entity other than a business or other concern as defined in § 1.265(f)(1), a not-for-profit enterprise as defined in § 1.265(f)(2), or a government as defined in § 1.265(f)(3). A business or other concern which meets the definition set forth in § 1.265(f)(1), a not-for-profit enterprise that meets the definition set forth in § 1.265(f)(2), or a government that meets the definition set forth in § 1.265(f)(3) may make the certification provided for in § 1.265(f) regardless of whether the business or other concern, not-for-profit enterprise, or government is located in or operates primarily in the United States.

With respect to the business or other concerns defined in § 1.265(f)(1), the Regulatory Flexibility Act provides that "the term 'small business' has the same meaning as the term 'small business concern' under section 3 of the Small Business Act, unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**." See 5 U.S.C. 601(3). The Office has established the standard set forth in 13 CFR 121.802 for paying reduced patent fees as the definition of "small business" for Regulatory Flexibility Act purposes with respect to patent-related regulations. Therefore, a "small business" for Regulatory Flexibility Act purposes with respect to patent-related regulations is a business or other concern: (1) Whose number of employees, including affiliates, does not exceed 500 persons; and (2) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition.

With respect to the not-for-profit enterprises defined in § 1.265(f)(2), the Regulatory Flexibility Act provides that "the term 'small organization' means any not-for-profit enterprise which is independently owned and operated and is not dominant in its field, unless an agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**." See 5 U.S.C. 601(4). The Office has not established any definition of "small organization" for Regulatory Flexibility Act purposes with respect to patent-related regulations. Therefore, a "small organization" for Regulatory Flexibility Act purposes with respect to patent-related regulations is a not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

With respect to the governments defined in § 1.265(f)(3), the Regulatory Flexibility Act provides that "the term 'small governmental jurisdiction' means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand, unless an

agency establishes, after opportunity for public comment, one or more definitions of such term which are appropriate to the activities of the agency and which are based on such factors as location in rural or sparsely populated areas or limited revenues due to the population of such jurisdiction, and publishes such definition(s) in the **Federal Register**.” See 5 U.S.C. 601(5). The Office has not established any definition of “small governmental jurisdiction” for Regulatory Flexibility Act purposes with respect to patent-related regulations. Therefore, a “small governmental jurisdiction” for Regulatory Flexibility Act purposes with respect to patent-related regulations is a government of a city, county, town, township, village, school district, or special district, with a population of less than fifty thousand.

An entity that meets the definition of a small entity set forth in § 1.27 for paying reduced patent fees may or may not meet one of the definitions under §§ 1.265(f)(1) through (f)(3) to make a certification under § 1.265(f). The Office will not give advisory opinions as to whether or not a specific individual or entity meets the definitions under §§ 1.265(f)(1) through (f)(3) to make a certification under § 1.265(f). Questions related to standards for small business concerns, not-for-profit enterprises, or governments may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW., Washington, DC 20416.

Section 1.495 (entering the national stage in the United States of America): Section 1.495(g) provides that if the documents and fees contain conflicting indications as to whether the submission is an application under 35 U.S.C. 111 or a submission to enter the national stage under 35 U.S.C. 371, the documents and fees will be treated as a submission to enter the national stage under 35 U.S.C. 371. It is Office experience that, in most cases, documents and fees that contain such conflicting indications were intended as submissions under 35 U.S.C. 371.

Section 1.704 (reduction of period of adjustment of patent term): Section 1.704(c) is amended to provide the patent term adjustment consequences of a failure to comply with § 1.75(b) (e.g., a failure to file an examination support document in compliance with § 1.265 when necessary under § 1.75(b)). Such a failure will be considered a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application under 35 U.S.C. 154(b)(2)(C). The failure to comply with § 1.75(b) will delay

processing or examination of an application because the Office must issue a notice and await the applicant’s reply before examination of the application may begin. Therefore, § 1.704(c) provides for a reduction of any patent term adjustment when there is a failure to comply with § 1.75(b). Specifically, any patent term adjustment will be reduced by the number of days in the period between the following beginning and ending dates. The beginning date of the period is the day after the date that is the later of: (1) The filing date of the amendment resulting in the noncompliance with § 1.75(b); (2) four months from the filing date of the application in an application under 35 U.S.C. 111(a); or (3) four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in an application which entered the national stage from an international application after compliance with 35 U.S.C. 371. The ending date of the period is the filing date of: (1) An examination support document in compliance with § 1.265; (2) an election responsive to an Office-issued requirement for restriction including an election of species that places the application in compliance with § 1.75(b) (e.g., the election of an invention that is drawn to five or fewer independent claims and twenty-five or fewer total claims that would obviate the need for an examination support document under § 1.265); (3) an amendment resulting in compliance with § 1.75(b) (e.g., amending the application to contain five or fewer independent claims and twenty-five or fewer total claims); (4) a suggested requirement for restriction under § 1.142(c) accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims.

The examiner’s acceptance of a suggested requirement for restriction accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims would be sufficient to obviate the need for an examination support document under § 1.265. If the suggested requirement for restriction is not accepted, the applicant will be notified and given a time period within which the applicant must either file an examination support document or amend the application such that it contains no more than five independent claims and no more than twenty-five total claims. Failure to timely reply to such a notice would result in the

abandonment of the application. The abandonment of an application results in the period of adjustment set forth in § 1.703 (if any) being reduced under § 1.704(c)(3).

III. Response to Comments

As discussed previously, the Office published notices in January of 2006 proposing: (1) Changes to practice for continuing applications, requests for continued examination, and applications containing patentably indistinct claims; and (2) changes to the practice for the examination of claims in patent applications. See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 48–61, 1302 *Off. Gaz. Pat. Office* 1318–29, and *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR 61–69, 1302 *Off. Gaz. Pat. Office* 1329–35. The Office received over five hundred written comments (from government agencies, universities, intellectual property organizations, industry, law firms, individual patent practitioners, and the general public) in response to this notice. The comments and the Office’s responses to the comments follow:

A. Changes to Continuing Application Practice

Comment 1: A number of comments stated that the changes in the definitions of continuation, divisional, and continuation-in-part applications set forth in § 1.78(a) are likely to confuse the public and examiners and that the Office has not identified any value that would result from these changes. Several comments suggested that further guidance was needed to resolve ambiguities as to whether an application is a divisional or continuation application. One comment argued that the requirement to identify the relationship of the applications could create hardship when it is unclear whether the changes to the specification or claims make the application a continuation, divisional, or continuation-in-part application.

Response: The definitional changes are necessary in order to clearly define the conditions for claiming benefit of prior-filed applications under § 1.78(d)(1). This final rule further clarifies the definition of a divisional application set forth in § 1.78(a)(2). Under this final rule, an applicant may file a divisional application directed to a non-elected invention if the prior-filed application is subject to a requirement for restriction. The divisional application need not be filed during the

pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. Thus, applicant may file a divisional application claiming the benefit of the initial application that was subject to the requirement for restriction and any intermediate continuing applications.

Furthermore, the definitions of continuation, divisional, and continuation-in-part application set forth in § 1.78(a) are substantially the same as the previous definitions set forth in the MPEP, except that a divisional application is now defined more narrowly. See the discussion of § 1.78(a). The former practice permitted an applicant to file a continuing application and identify the application as a "divisional" application even when the prior-filed application was not subject to a requirement for restriction. Such a continuing application was called a "voluntary" divisional application. Under this final rule, a "voluntary" divisional application would instead fall under the definition of a continuation application. Therefore, a continuing application would be a continuation application and not a divisional ("voluntary" divisional) application if the prior-filed application was not subject to a requirement for restriction. If the prior-filed application was subject to a requirement for restriction, a continuing application claiming only a non-elected invention or inventions would be a divisional application. It is noted that although the definition of continuation application set forth in § 1.78(a)(2) uses the phrase "invention or inventions" rather than "subject matter" (as used in the definition of continuation application set forth in MPEP § 201.07), no substantive difference between these terms is intended. The requirement to identify the relationship (*i.e.*, continuation, divisional, or continuation-in-part) between the prior-filed application and the continuing application is not a new requirement under this final rule. This requirement has been provided in the former § 1.78(a)(2)(i). Accordingly, the definitions of continuation, divisional, and continuation-in-part application set forth in § 1.78(a) are not likely to confuse the public or examiners for any extended period.

Comment 2: A number of comments observed the proposed requirement that a divisional application may claim the benefit of only a single application would require that all divisional applications filed as a result of a restriction requirement in a prior-filed application be filed before the patenting

or abandonment of that application. A number of comments suggested that the rule changes limiting divisional applications to claim benefit to only a single prior-filed application would result in an overall increase in application filings and pendency, contrary to their intended purpose. The comments contended the changes being adopted in this final rule effectively force applicants to claim all patentably distinct inventions in the prior-filed application or file related applications in parallel in order to preserve potential patent rights in those inventions. The comments suggested that since a divisional application must be filed during the pendency of the prior-filed application, many more divisional applications would be filed than would be filed under the current system, as applicants will not have sufficient time and information to determine whether the invention is worth pursuing. The comments stated that, consequently, the Office will be forced to examine more inventions than it would under current practice, wasting both applicants' and the Office's resources. A number of comments also suggested that the inability to prosecute divisional applications sequentially, thus allowing applicants to spread filing and prosecution costs over time and to file only those divisional applications that are commercially valuable in view of subsequent market development, will have a particularly negative impact on the biotechnology and pharmaceutical industries and on small entities. The comments suggested that patent rights will be lost due to a lack of funding and that the increased costs will be particularly onerous in certain technologies, *e.g.*, biotechnology and chemical arts, where the Office routinely issues complex restriction requirements, sometimes alleging hundreds or thousands of independent and distinct inventions. Several comments also suggested that the rules should be modified to account for the economic impossibility, in many cases, of pursuing numerous divisional applications simultaneously. One comment also suggested that the need to file multiple stand alone applications or divisional applications at an early stage in prosecution to cover all embodiments of the invention will cause small companies to cut back funding on research in favor of patent prosecution, thus hindering innovation. One comment also suggested that the rules be revised, consistent with European Patent Office divisional practice, to permit the serial filing of divisional applications with the limitation that

claims pursued in a continuation of any serial divisional application must be of the same scope as, or of a narrower scope than, the claims presented in that serial divisional application. One comment also suggested that prior to implementing the rule changes, the Office should conduct a study to assess the scope of potential divisional filing problems by studying the divisional filing habits of large and small entity applicants.

Response: The Office notes the concerns expressed in the public comment regarding the proposed requirement in § 1.78(d)(1)(ii) that a divisional application be filed during the pendency of the initial application. In response to those concerns and suggestions, § 1.78(d)(ii) as adopted in this final rule does not require that a divisional application be filed during the pendency of the initial application. This final rule permits applicants to file a divisional application for the claims to a non-elected invention if the initial application is subject to a requirement for restriction, the claims to the non-elected invention are cancelled in the initial application, and the divisional application meets the copendency requirement of 35 U.S.C. 120. That is, an applicant may file a divisional application during the pendency of the application that was subject to a restriction requirement or the pendency of any continuing application of such application. This final rule also permits applicant to file two continuation applications of a divisional application, plus a request for continued examination in the divisional application family, without any justification.

Comment 3: A number of comments suggested that the rule changes would encourage applicants to file more petitions challenging restriction requirements, thus further burdening the Office.

Response: The criteria for making a restriction requirement remain the same. Applicant may still seek review of any restriction requirements, if appropriate. The Office, however, does not anticipate any substantial increase in the number of petitions seeking review of restriction requirements. As discussed previously, § 1.78(d)(1)(ii) as adopted in this final rule does not require that a divisional application be filed during the pendency of a single prior-filed application. This final rule permits applicant to file a divisional application of an application if the application is subject to a requirement for restriction, claims to the non-elected invention are cancelled in the prior-filed application, and the divisional

application meets the copendency requirement of 35 U.S.C. 120. That is, applicant may file a divisional application during the pendency of the application that was subject to a requirement for restriction or the pendency of any continuing application of such application. Applicant will have sufficient time to determine whether to file a divisional application directed to a non-elected invention.

Comment 4: Several comments stated that the rule changes do not adequately address the situation where a restriction requirement is made by the examiner in a continuing application. The comments expressed concern that the rule changes appear to require applicant to forego all but one invention. One comment stated that the applicant's prior application, if published, may constitute prior art if benefit to the prior application is not permitted. Another comment suggested that concerns over prolonging patent term, abuse or bad faith are not raised where a divisional application is filed as a result of a restriction requirement made in the continuing application, and that such filings may actually improve quality, as the searches performed in the initial and first continuing application often provide significant information and guidance to the examiner in the second continuing application.

Response: As discussed previously, the Office has modified the proposed § 1.78(d)(1)(ii) in this final rule such that it does not require a divisional application to be filed during the pendency of a single prior-filed application. Instead, this final rule permits an applicant to file a divisional application for the claims to a non-elected invention that was not examined if the application was subject to a requirement for restriction, the claims to the non-elected invention are cancelled in the prior-filed application, and the divisional application meets the copending requirement of 35 U.S.C. 120. Therefore, applicant may file a divisional application of a continuing application for the claims to a non-elected invention that has not been examined if the continuing application was subject to a requirement for restriction. Such a divisional application may claim the benefit of the continuing application that was subject to a requirement for restriction and the initial application whose benefit is claimed in the continuing application.

Comment 5: One comment requested clarification as to whether a divisional application can be filed if a request for continued examination was filed in the initial application.

Response: The filing of a request for continued examination in the initial

application does not preclude an applicant from filing a divisional application under the proposed rule as well as under this final rule. The condition that "no request for continued examination under § 1.114 has been filed in the prior-filed application" as proposed applied only to the filing of continuation and continuation-in-part applications under proposed § 1.78(d)(1)(i). Compare proposed §§ 1.78(d)(1)(i) and 1.78(d)(1)(ii). Furthermore, § 1.78(d)(1) as adopted in this final rule contains no conditions with respect to continuation applications, divisional applications, or continuation-in-part applications concerning whether a request for continued examination was filed in the initial application or a prior-filed continuing application. Therefore, the filing of a request for continued examination does not preclude an applicant from filing two continuation or continuation-in-part applications, and any divisional application directed to a non-elected invention that has not been examined if the prior-filed application was subject to a requirement for restriction.

Comment 6: A number of comments requested that the Office not limit "voluntary" divisional applications. In addition, several comments noted the importance of "voluntary" divisional applications in protecting important inventions the significance of which could not reasonably be anticipated when the application was filed. Another comment indicated the importance of "voluntary" divisional applications for obtaining quick patents to protect applicants' products from competitors while preserving the opportunity to obtain patent protection on other aspects of the invention. Several comments stated that the standard under § 1.78(d)(1) makes little sense when the objective of filing the continuing application is to obtain patents on distinct inventions. One of the comments expressed concern that each patent is, both by law and regulation, to be directed to a single invention and that patent applications directed to multiple inventions are subject to restriction under 35 U.S.C. 121.

Response: This final rule permits applicants to file a so-called "voluntary" divisional application as a continuation application in compliance with § 1.78(d)(1)(i) when the prior-filed application was not subject to a requirement for restriction. Under § 1.78(d)(1)(i), applicant may file two such continuation applications without a petition and showing of why the amendment, argument, or evidence

sought to be entered could not have been previously submitted. Applicant likewise may file a third or subsequent continuation application with a petition and showing pursuant to § 1.78(d)(1)(vi).

Furthermore, applicant may suggest a requirement for restriction under § 1.142(c) if the applicant believes that two or more independent and distinct inventions are claimed in the application. See § 1.142(c) and the discussion of § 1.142(c). In such case, § 1.78(d)(1)(ii) provides that an applicant may file a divisional application directed to a non-elected invention that has not been examined if the prior-filed application is subject to a requirement for restriction. The divisional application is not required to be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. Section § 1.78(d)(1)(iii) also permits an applicant to file, without a petition and showing, two continuation applications of a divisional application plus a request for continued examination in the divisional application family. Therefore, applicants have sufficient opportunity to obtain patent protection on other aspects of the invention.

35 U.S.C. 121 provides that "[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions." (Emphasis added.) Thus, 35 U.S.C. 121 authorizes, but does not compel, the Director to require that an application containing two or more independent and distinct inventions be restricted to one of the inventions. The Office typically decides whether to issue a restriction requirement when an application contains two or more independent and distinct inventions based upon, *inter alia*, the burden on the Office to search and examine more than one invention. See *MPEP § 803*.

Comment 7: Several comments suggested that the restriction on a so-called "voluntary" divisional application would be a major divergence from other countries and would not be favorable from the viewpoint of promoting global harmonization of patent practices. One comment noted that the Japan Patent Office (JPO) and the European Patent Office (EPO) have liberal "voluntary" divisional application rules and have not reported any evidence of abuse.

Response: Under this final rule, applicant still has the opportunity to file a so-called "voluntary" divisional application except that such an application is defined in this final rule

as a continuation application. That is, as discussed previously, applicant may file a "voluntary" divisional application as a continuation application in compliance with § 1.78(d)(1)(i) when the prior-filed application was not subject to a requirement for restriction. Specifically, under § 1.78(d)(1)(i), applicant may file two continuing applications of an initial application without a petition and showing and then may file a third or subsequent continuation with a petition and showing under § 1.78(d)(1)(vi). Accordingly, this final rule is not a major divergence from the "voluntary" divisional practice available in other countries.

Moreover, under the PCT and the Paris Convention, the determination of the conditions and effect of internal (domestic) priority claims is a matter for the authority concerned. *See, e.g.*, PCT Article 8(2)(b) and Article 4(G)(2) of the Paris Convention. Efforts in recent years to harmonize substantive patent law have not focused on achieving harmonization on domestic priority. (*See* <http://www.wipo.int/patent/law/en/harmonization.htm> for further information).

Comment 8: Several comments suggested that eliminating "voluntary" divisional applications violates Article 4G(2) of the Paris Convention.

Response: Section 1.78(d) as adopted in this final rule does not eliminate what has traditionally been referred to as a "voluntary" divisional application. The second sentence of Article 4G(2) of the Paris Convention provides that each country "shall have the right to determine the conditions under which such division shall be authorized." As discussed previously, a "voluntary" divisional application would not meet the definition of divisional application set forth in § 1.78(a)(2), but would instead be a continuation application as defined in § 1.78(a)(3). If the prior-filed application is not subject to a requirement for restriction, the applicant may file a "voluntary" divisional application as a continuation application under the conditions set forth in § 1.78(d)(1)(i). Such a definition is consistent with 35 U.S.C. 121.

Furthermore, if the prior-filed application is subject to a requirement for restriction, § 1.78(d)(1)(ii) provides that an applicant may file an "involuntary" divisional application directed to a non-elected invention that has not been examined. Therefore, § 1.78(d) is consistent with Article 4G(2) of the Paris Convention.

Comment 9: One comment suggested amending proposed § 1.78(d)(1)(ii) to define a divisional application as an

application that only includes claims that were non-elected in the prior-filed application to prevent new claims from being filed in the divisional application, thus further increasing the numbers of claims that examiners have to examine.

Response: Such a requirement is unnecessary because applicant may amend the non-elected claims that have been filed in the divisional application during the course of prosecution of the divisional applications as the prior art is developed and/or to correct formal matters. Section § 1.78(d)(1)(ii) as adopted in this final rule permits an applicant to file a divisional application directed to a non-elected invention that has not been examined that was subject to a requirement for restriction in the prior-filed application. Therefore, applicant may present claims in the divisional application that are different than the claims in the prior-filed application if the claims in the divisional application are directed to the subject matter of the non-elected invention.

Comment 10: One comment expressed concern that the Office may pressure examiners to limit the issuance of restrictions in order to reduce the number of applications to be examined, thus artificially making it look like the pendency rate has gone down. The comment requested that the Office implement a policy mandating examiners to issue restrictions when requested by the applicant, except in cases where it is clear that such restrictions are not proper.

Response: Restriction practice is set forth in Chapter 800 of the MPEP. As discussed previously, the applicant may suggest a requirement for restriction under § 1.142(c) if the applicant believes that two or more independent and distinct inventions are claimed in the application. The examiner may accept or refuse the suggested restriction requirement. Alternatively, the examiner may issue a different restriction. *See* the discussion of § 1.142(c). Either way, it remains important from the standpoint of the public interest that no requirements for restriction are made that might result in the issuance of two patents for the same invention. *See* MPEP § 803.01.

Comment 11: One comment questioned the status of a divisional application if the restriction requirement is withdrawn after filing of the divisional application.

Response: If a restriction requirement is made and the applicant cancels the non-elected claims (and any generic claims or other types of linking claims if present) in the prior-filed application and files a divisional application, the

restriction requirement will not be withdrawn. Also, as discussed previously, applicants cannot rely upon a requirement for restriction to avoid the requirement for an examination support document where: (1) The applicant traverses the requirement for restriction; (2) the requirement for restriction may be conditional, such as a requirement for election of species in an application that contains a claim that is generic to all of the claimed species (*see* MPEP § 809), or a requirement for restriction in an application that contains a linking claim (*e.g.*, a subcombination claim linking plural combinations); or (3) the applicant plans to request rejoinder of the claims to the non-elected invention (*see* MPEP § 821.04 *et seq.*). Under §§ 1.78(a)(2) and 1.78(d)(1)(ii), the prior-filed application to which a divisional application claims the benefit must be subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 and the invention claimed in the divisional application must not have been elected for examination and must not have been examined in any prior-filed application. Thus, a divisional application will be improper when the claims to the non-elected invention have not been cancelled and the requirement for restriction is withdrawn in the prior-filed application (or when the invention claimed in the divisional application has been examined in the prior-filed application). Furthermore, since the claims of the prior-filed application and the divisional application would be drawn to the same invention, both applications may be subject to a double patenting rejection (*see* MPEP § 821.04) and the provisions of 1.75(b)(4) (determining number of claims for purposes of examination support document threshold when multiple applications contain patentably indistinct claims).

For example, where claims directed to a product and to a process of making and/or using the product are presented in the same application and subject to a requirement for restriction, the applicant may request rejoinder of the non-elected process claims that depend from or otherwise require all the limitations of an allowable product claim. *See* MPEP § 821.04(b). Upon rejoinder of claims to a non-elected process invention, the requirement for restriction between the elected product and non-elected process invention is withdrawn. Thus, the rejoinder of non-elected process claims after allowance of the elected product claims may result in a prior or subsequently filed

“divisional” application not being a proper divisional application under § 1.78(a)(2) and 1.78(d)(1)(ii) because the prior-filed application is no longer subject to a requirement for restriction. Applicant may avoid this problem by canceling the non-elected process claims and claiming them in a divisional application before rejoinder occurs. In such a situation, because the non-elected claims have been cancelled, the restriction requirement cannot be withdrawn. This will preserve applicant’s rights under 35 U.S.C. 121 and § 1.78(d)(1)(ii).

If the applicant chooses to retain the non-elected claims and files a divisional application claiming the non-elected invention and then the restriction requirement is withdrawn in the prior-filed application, the benefit claim under § 1.78(d)(1)(ii) in the later-filed divisional application would no longer be proper. Thus, the later-filed application would not be entitled to the benefit of the prior-filed application. If applicant still desires to maintain the later-filed application, applicant must delete or correct the benefit claim to indicate that the application is a continuation application if the requirements set forth in § 1.78(d)(1)(i) can be met. If applicant no longer wants to maintain the later-filed application, applicant may abandon the application before the examination has been made of the application and may request a refund of any previously paid search and excess claims fees.

Comment 12: A number of comments suggested that limiting continuation-in-part applications was unnecessary. The comments explained that concerns associated with continually reopening prosecution do not apply to continuation-in-part applications, which are usually filed as a result of the inventor having developed a significant improvement in the invention. One comment stated that limiting continuation-in-part applications will not reduce application filings, but rather will simply cause applicants to file the application as a new application without a benefit claim because the claims of the continuation-in-part application are usually directed to the new subject matter and thus not entitled to benefit of the parent filing date. Several comments suggested that continuation-in-part applications are necessary for adequate protection of improvements to the invention and that these improvements often become the key feature of an invention that leads to its success. One comment, however, suggested that continuation-in-part practice be terminated, because with the twenty-year patent term, there is no

benefit to applicant or to the Office associated with continuing this practice.

Response: Inconsistent rules for continuation applications and continuation-in-part applications would likely lead to confusion and create the potential for abuse. First, there is no reason to treat continuation applications different from continuation-in-part applications where both fall under § 1.78 and are contemplated by 35 U.S.C. 120. Second, there is no reason why the Office should maintain the ability to file an unlimited string of continuation-in-part applications without justification while proceeding with a change to § 1.78 to require a justification for any third or subsequent continuation application. Third, if applicants could file continuation-in-part applications without restriction, then they could be used as a tool to circumvent this final rule. Thus, the Office considers it appropriate to require a justification for any third or subsequent continuing application that is a continuation application or a continuation-in-part application.

The changes in this final rule do not impact applicants’ ability to protect improvements to the invention disclosed in a prior-filed application. Section 1.78(d)(1)(i) allows an applicant to file two continuation-in-part applications of a prior-filed application without a petition and showing. Applicant may also file any third or subsequent continuation-in-part application with a petition and showing. Hence, applicants have ample opportunity to seek protection for improvements.

Furthermore, for the continuation-in-part application to actually receive the benefit of the filing date of the prior-filed application, 35 U.S.C. 120 requires that the subject matter of at least one claim of the continuation-in-part application must be disclosed in the prior-filed application in the manner provided by 35 U.S.C. 112, ¶ 1. See *Studiengesellschaft Kohle m.b.H.*, 112 F.3d at 1564–65, 42 U.S.P.Q.2d at 1677–78. The term of any patent resulting from the continuation-in-part application will be measured under 35 U.S.C. 154(a)(2) from the filing date of the prior-filed application, even if the continuation-in-part application never receives any benefit from the prior-filed application. See *Abbott Labs.*, 104 F.3d at 1309, 41 U.S.P.Q.2d at 1537. To maximize the term of any resulting patent, applicant should file the application containing only claims directed to the improvements without claiming the benefit of the prior-filed application rather than a continuation-in-part application.

Comment 13: Several comments suggested that, if the prior-filed application is abandoned in favor of a continuation-in-part application before examination of the prior-filed application, or is filed within a short time of the prior-filed application, the limits on continuing applications should not include such continuation-in-part applications. Several comments explained that in rapidly advancing sciences, continuation-in-part applications are often filed while abandoning the prior application in the chain before an examination of the merits. Thus, a continuation-in-part application is often the first in a series to be examined as an initial application. At a minimum, the rules should be modified to exclude from counting prior-filed applications that are abandoned before issuance of a first action on the merits.

Response: Section 1.78(d)(1)(v) as adopted in this final rule addresses the situation in which an applicant files a continuation (or continuation-in-part) application to correct informalities rather than completing an application for examination under § 1.53. Under § 1.78(d)(1)(v), if the prior-filed application is abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f), the applicant may file “one more” continuation application (or continuation-in-part application) without there being a requirement for a petition and showing under § 1.78(d)(1)(vi). Specifically, § 1.78(d)(1)(v) provides that a continuation application or continuation-in-part application is permitted if the following conditions are met: (1) The application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed nonprovisional application filed under 35 U.S.C. 111(a), and the prior-filed nonprovisional application became abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f) and does not claim the benefit of any other nonprovisional application or international application designating the United States of America; (2) the application is a continuation application as defined in § 1.78(a)(3) or a continuation-in-part application as defined in § 1.78(a)(4) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three prior-filed applications; and (3) any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two other nonprovisional applications. This does not include any divisional

application that satisfies the conditions set forth in § 1.78(d)(1)(ii) or continuation application that claims the benefit of such divisional application and satisfies the conditions set forth in § 1.78(d)(1)(iii).

For example, applicant may file a third continuation (or continuation-in-part) application claiming the benefit of an intervening (second) continuation (or continuation-in-part) application, a first continuation (or continuation-in-part) application, and a prior-filed application without a petition under § 1.78(d)(1)(vi), if the prior-filed application became abandoned due to the failure to timely reply to a Notice to File Missing Parts mailed by the Office of Initial Patent Examination and does not claim the benefit of any other application. The prior-filed application, however, must be entitled to a filing date and have paid therein the basic filing fee within the pendency of the application. See § 1.78(d)(2).

Comment 14: One comment suggested that the rule changes encourage applicants to file two applications, *i.e.*, a continuation-in-part application and a divisional application, rather than a single continuation-in-part application, where the non-elected invention is further developed. The comment stated that this is inefficient for both the Office and applicants.

Response: The Office appreciates that the changes being adopted in this final rule do provide some incentive for applicants who seek only to maximize the number of continuing applications and requests for continued examination permitted without any justification to file both a continuation-in-part application and a divisional application in this situation. However, applicants seeking to maximize the number of continued examination filings are not likely to file only a single continuation-in-part application in this situation under either the former practice or the change to continuing application practice being adopted in this final rule. Furthermore, this final rule permits applicant to file two continuation or continuation-in-part applications plus one request for continued examination in an application family, without any justification. And, this final rule permits applicant to file two continuation applications plus one request for continued examination in the divisional application family, without any justification.

Comment 15: One comment suggested that continuation-in-part applications are an important tool for correcting errors in the initial application (*e.g.*, correction of test data) and this should be encouraged, rather than discouraged.

Response: The Office is neither encouraging nor discouraging the filing of continuation-in-part applications. Rather, this final rule treats continuation-in-part applications roughly the same as continuation applications. That is, applicant is permitted to file two continuation or continuation-in-part applications of an initial application without a petition and showing. Applicant is also permitted to file a third or subsequent continuation or continuation-in-part application with a petition and showing. See § 1.78(d)(1)(i). The only notable difference between the two, apart from their definitions, is that an applicant may file only a continuation application of a divisional application and not a continuation-in-part application of a divisional application. See § 1.78(d)(1)(iii). Nevertheless, applicants may use continuation-in-part applications to correct initial applications under this final rule to the extent they were used for this purpose before this final rule. Furthermore, as previously discussed, § 1.78(d)(1)(v) as adopted in this final rule provides that if an applicant files a continuation (or continuation-in-part) application to correct informalities rather than completing an application for examination under § 1.53, the applicant may file “one more” continuation application (or continuation-in-part application) without there being a requirement for a petition and showing under § 1.78(d)(1)(vi). See § 1.78(d)(1)(v).

Comment 16: One comment suggested that the Office should require applicants to certify that no 35 U.S.C. 102(b) bar applies for continuation-in-part applications filed more than twelve months from the earliest claimed date.

Response: Under § 1.56, applicant has a duty to disclose to the Office all information known to applicant to be material to patentability including any prior art under 35 U.S.C. 102(b). This includes a reference with a publication date more than one year prior to the filing date of the continuation-in-part application if at least one claim in the continuation-in-part application is drawn to the subject matter not disclosed in the prior-filed application. Applicant is required to file a newly executed oath or declaration under § 1.63 upon the filing of a continuation-in-part application. See § 1.63(e). The oath or declaration under § 1.63 must include a statement that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in § 1.56. See § 1.63(b)(3).

Comment 17: One comment argued that requiring applicant to identify whether the claims are supported by the specification before the examination is unfair and unreasonable because it is a legal issue that should be determined during the prosecution. Another comment suggested that the Office should, at most, require applicant to identify the differences between the continuation-in-part application and the prior-filed application. Another comment suggested that when a continuation-in-part application is filed, the Office should require the applicant to discuss whether the new matter added to the specification is inventive or based on ordinary skill. One comment, however, supported the requirement for a continuation-in-part applicant to identify which claims are disclosed in the prior-filed application and thus are entitled to the earlier filing date.

Response: Applicants are in the best position to identify the effective filing date of their claims. Thus, § 1.78(d)(3) provides that if an application is identified as a continuation-in-part application, the applicant must identify the claim or claims for which the subject matter is disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application. Any claim that is not so identified will be treated as only being entitled to the actual filing date of the continuation-in-part application, and subjected to prior art based on the actual filing date of the continuation-in-part application.

Whether any “new matter” is inventive or based on ordinary skill is not determinative of whether the claims of the continuation-in-part application are entitled to the filing date of the prior-filed application. The test is whether the original disclosure of the prior-filed application provides adequate support and enablement for the claimed subject matter of the continuation-in-part application in compliance with the requirement of 35 U.S.C. 112, ¶ 1. See MPEP § 201.11, I, Disclosure Requirement.

Comment 18: A number of comments suggested that the rule changes effectively eliminate the use of “bypass” continuing applications (*i.e.*, an application filed under 35 U.S.C. 111(a) that claims benefit under 35 U.S.C. 120 or 365(c) of the filing date of an earlier international application that did not enter the national stage under 35 U.S.C. 371). The comments argued that a bypass continuing application would be counted as a continuing application whereas a national stage submission under 35 U.S.C. 371 would not. The comments indicated that there are

important reasons for filing bypass applications and suggested that it is unfair to treat bypass applications differently than national stage applications because in both applications the examiner will be examining the claims for compliance with U.S. national law for the first time. Consequently, a number of comments recommended that the international application should not be counted toward the threshold for filing continuing applications unless the international application enters the U.S. national stage, while other comments recommended that the bypass application should not be counted.

Response: The Office notes the concerns expressed in the public comment regarding the proposed changes to § 1.78(d)(1). The Office has modified proposed § 1.78(d)(1) in this final rule to provide for certain “bypass” continuing applications. Under § 1.78(d)(1)(iv), if a Demand has not been filed and the basic national fee has not been paid in the international application, and the international application does not claim the benefit of any other nonprovisional application or international application designating the United States of America, the applicant may file “one more” continuation application (or continuation-in-part application) of such international application without there being a requirement for a petition and showing under § 1.78(d)(1)(vi). Specifically, § 1.78(d)(1)(iv) provides that a continuation application or continuation-in-part application is permitted if the following conditions are met: (1) The application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed international application designating the United States of America, and a Demand has not been filed and the basic national fee (§ 1.492(a)) has not been paid in the prior-filed international application and the prior-filed international application does not claim the benefit of any other nonprovisional application or international application designating the United States of America; (2) the application is either a continuation application as defined in § 1.78(a)(3) or a continuation-in-part application as defined in § 1.78(a)(4) that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three (rather than two) prior-filed applications; and (3) any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two (rather than one) other nonprovisional applications. This does

not include any divisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii) or continuation application that claims the benefit of such divisional application and satisfies the conditions set forth in § 1.78(d)(1)(iii).

For example, applicant may file a third continuation application claiming the benefit of an intervening (second) continuation (or continuation-in-part) application, the first “bypass” continuation (or continuation-in-part) application, and the prior-filed international application without a petition under § 1.78(d)(1)(vi), if a Demand has not been filed and the basic national fee has not been paid in the international application, and the international application does not claim the benefit of any other nonprovisional application or international application designating the United States of America.

Comment 19: Several comments questioned whether an international application that designates the United States of America and claims benefit to a prior nonprovisional application would be treated as a second continuation application upon entry into the U.S. national stage if a request for continued examination is filed in the nonprovisional application prior to entering the national stage. Another comment questioned whether a request for continued examination could be filed in a nonprovisional application if a U.S. national stage application claims benefit under 35 U.S.C. 120 or 365(c) to the nonprovisional application. Several comments suggested that if an international application designating the United States of America claims benefit to a prior-filed nonprovisional application, and a request for continued examination is filed in the nonprovisional application, then a petition under § 1.78(d)(1)(vi) would be required, in violation of PCT Rule 51*bis*, in order to perfect entry of the international application into the U.S. national stage. The comments also suggested that any refusal to grant such a petition would violate the PCT because there is no basis in the treaty for refusing national stage perfection on such grounds.

Response: The Office notes the concerns expressed in the public comment regarding the proposed changes to §§ 1.78(d)(1) and 1.114 that would permit an applicant to file only one of the following: A continuation application, a continuation-in-part application, or a request for continued examination, without any justification. The Office has made modifications to these proposed changes such that this

final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Therefore, under this final rule, applicant is permitted to have the national stage of an international application designating the United States of America claim the benefit of a prior-filed nonprovisional application in which a request for continued examination has been filed without a petition and showing. The provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. The filing of a request for continued examination in a nonprovisional application does not preclude a U.S. national stage application from claiming the benefit of the nonprovisional application. Likewise, a U.S. national stage application claiming the benefit under 35 U.S.C. 120 or 365(c) of a nonprovisional application will not preclude an applicant from filing a request for continued examination in the nonprovisional application.

Applicant may also file any additional continuation or continuation-in-part application or request for continued examination with a petition and showing. If an international application that enters the U.S. national stage contains or is amended to contain a specific reference to a prior-filed application that is not permitted by at least one of §§ 1.78(d)(1)(i) through (d)(1)(vi), the Office will refuse to enter, or will delete if present, the specific reference to the prior-filed application. See § 1.78(d)(1). Furthermore, the national stage application will be treated as entitled only to the actual international filing date of the national stage application, and will be subject to prior art based on the actual international filing date.

Refusal to grant a petition under § 1.78(d)(1)(vi) (assuming such a petition is necessary) would not prevent an applicant from completing the requirements for entry into the national phase under 35 U.S.C. 371. The requirements for entry of an international application into the national phase under 35 U.S.C. 371 are set forth in 35 U.S.C. 371(c) and § 1.495. The effect of a refusal to grant any such petition would only be that the national stage application would not be entitled to the benefit of the filing date of the nonprovisional application under 35 U.S.C. 120 and 365(c). Furthermore, the necessity to file a petition under § 1.78(d)(1)(vi) in the national stage application to obtain benefit to the nonprovisional application would not

violate PCT Rule 51*bis*. PCT Rule 51*bis* does not govern the requirements that a designated Office may impose for recognition of domestic benefit claims. Rather, the ability of a designated Office to establish conditions for, and the effect of, domestic benefit claims is expressly provided for in PCT Article 8(2). PCT Article 8(2) states, in pertinent part, that “[w]here, in the international application, the priority of one or more national applications filed in or for a designated State is claimed, or where the priority of an international application having designated only one State is claimed, the conditions for, and the effect of, the priority claim in that State shall be governed by the national law of that State.”

Comment 20: Several comments suggested that the rules create an anomaly. The comments argued that if an application is first filed as a nonprovisional application followed by an international application claiming benefit to the nonprovisional application, and a request for continued examination is subsequently filed in the nonprovisional application, then a petition under § 1.78(d)(1)(vi) would be needed when the international application enters the U.S. national phase. The comments, however, further argued that if the application is first filed as a provisional application followed by, one year later, concurrently filed international and nonprovisional applications both claiming benefit to the provisional application, then a petition under § 1.78(d)(1)(vi) would not be needed when the international application enters the U.S. national phase even if a request for continued examination was filed in the nonprovisional application.

Response: The Office has made modifications to the proposed changes to §§ 1.78(d)(1) and 1.114 such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Therefore, under this final rule, applicant may enter the U.S. national stage in an international application designating the United States of America claiming the benefit of a prior-filed nonprovisional application in which a request for continued examination has been filed without a petition and showing. As discussed previously, the provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. The filing of a request for continued examination in a nonprovisional application does not preclude a U.S. national stage

application from claiming the benefit of the nonprovisional application.

Note that, in the first described application chain, the international application claims benefit to a nonprovisional application under 35 U.S.C. 120 or 365(c) and therefore is a “continuing application” as defined in § 1.78(a). In the second described application chain, the international application is not a continuing application as it only claims benefit to the provisional application. In any event, § 1.78(d)(1) as adopted in this final rule would not require a petition and showing for the national stage application to claim the benefit of a prior-filed application in which a request for continued examination has been filed.

Comment 21: One comment argued that applicants who first file a nonprovisional application followed by a continuation-in-part application would not be able to designate the United States in any subsequently filed international application without a showing as to why the international application could not have been filed earlier. The comment argued that this violates the PCT.

Response: The Office has made modifications to the proposed changes to § 1.78(d)(1) such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Therefore, under this final rule, applicant may file an international application designating the United States of America claiming the benefit of two prior-filed nonprovisional applications without a petition and showing. Applicant may also file any additional continuation or continuation-in-part application or request for continued examination with a petition and showing. The petition procedure under § 1.78(d)(1)(vi) applies only to international applications that have entered the U.S. national stage after compliance with 35 U.S.C. 371. Thus, the rule neither requires nor provides for the submission of such petitions in international applications during the international phase. It is also noted that under PCT Rule 4.9, the designation of all states, including the United States of America, in international applications is automatic upon filing of the PCT request.

Comment 22: Several comments questioned whether the limitation on the examination of claims in nonprovisional applications under § 1.75(b) could be circumvented by first filing an international application with

as many claims as desired and then entering the U.S. national phase after the claims have been searched in the international phase. The comments suggested that the Office should examine all claims in a national stage application that were the subject of a search and written opinion in the international phase, particularly if the United States Patent and Trademark Office was the international searching authority.

Response: The requirements of § 1.75(b) apply to national stage applications under 35 U.S.C. 371 as well as to applications filed under 35 U.S.C. 111(a). Thus, the rule cannot be circumvented by utilizing the PCT route. The fact that more than five independent claims or more than twenty-five total claims may have been searched and even subjected to international preliminary examination in the international phase will not entitle applicants to more than five independent claims or more than twenty-five total claims in the U.S. national phase application without the submission of an examination support document. This is analogous to existing practice under § 1.499, which permits restriction of claims in a national stage application for lack of unity notwithstanding that such claims may have been searched and subject to international preliminary examination in the international phase. Applying § 1.75(b) to national stage applications is appropriate because prior art uncovered during the international search often necessitates the need to make substantial amendments to the claims in the national phase. Additionally, the claims would need to be examined for compliance with all substantive requirements of U.S. national law.

Comment 23: One comment suggested that the rules limiting continuing applications would result in more applicants filing international applications and entering the U.S. national stage in order to avoid onerous restriction requirements. Another comment suggested that the rules limiting the examination of claims might trigger increased usage of the PCT and national stage entry into the U.S.

Response: Applicants are free to choose whichever route they believe is more advantageous for obtaining patent protection in the United States, whether through the PCT or through a direct national filing under 35 U.S.C. 111(a).

Comment 24: A number of comments requested that the Office should notify the applicant in an Office action when a continuing application is not available under any one of the first three conditions in § 1.78(d)(1). A number of

comments stated that the refusal to enter or to delete any references to prior-filed applications that are not permitted under § 1.78(d)(1) would place a heavy burden on the Office.

Response: The changes to §§ 1.78 and 1.114 in this final rule are clearly set forth in this final rule. Applicant and his or her representative have the duty to know the rules of practice when prosecuting an application for patent before the Office. Applicant should not file a continuing application without knowing whether it is proper. The refusal to enter or to delete any references to prior-filed applications that are not permitted under § 1.78(d)(1) would not place any additional burden on the Office.

Comment 25: A number of comments argued that the rule changes would protract the examination process and divert resources from examining functions to administrative tasks. In particular, the comments predicted that the rule changes would increase the number of petitions, including petitions for filing additional continuing applications and requests for continued examination and petitions for supervisory review of Office actions and restriction requirements. Several other comments argued that the delay in prosecution of an application would increase while decisions on petitions under §§ 1.78(d)(1)(vi) and 1.114(g) were debated and reviewed. Several comments questioned whether the Office would be adequately staffed with enough personnel to handle the onslaught of petitions, as well as further review of decisions dismissing the petitions. Several comments also argued that any reduction in backlog would be insignificant given that the Office would grant some of the petitions for additional continuing applications and requests for continued examination. Several comments suggested that the proposed changes to the continued examination practice will force applicants to petition every improper procedural requirement by examiners, including restriction requirements, finality and non-entry of after-final amendments, in order to preserve applicant's rights. One comment stated that applicants are likely to file petitions, such as petitions addressing the prematurity of a final rejection under § 1.181, to save their one "as-matter-of-right" continuation or continuation-in-part application or request for continued examination. Several comments stated that applicants would petition almost all restriction requirements, resulting in an increase in the number of petitions filed. Another comment stated petitions seeking

review of restriction requirements would be filed in order to determine early in the prosecution cycle the number of divisional applications that must be filed to preserve patent rights.

Response: One of the Office's goals is to focus its limited patent examining resources on the examination of new applications, and thereby increase the effectiveness of Office resources while also reducing the backlog of unexamined patent applications. The requirements for seeking third and subsequent continuing applications will not have an effect on the vast majority of patent applications. The changes being adopted in this final rule, however, will reduce the strain on the Office's patent examining resources, which will allow for a better, more timely examination of new applications.

The Office recognizes the amount and type of resources needed to implement the changes to §§ 1.78 and 1.114 being adopted in this final rule. The authority to decide petitions under §§ 1.78(d)(1)(vi) and 1.114(g) has been delegated to the Deputy Commissioner for Patent Examination Policy (who may further delegate this authority to officials under the Deputy Commissioner for Patent Examination Policy). The Office is planning to provide sufficient staff to handle the projected number of petitions.

The Office provides the procedure under § 1.181 for applicants to seek review of requirements and objections made by the examiner. If applicant finds that a requirement or an objection made in an Office action is procedurally wrong, applicant should request reconsideration or file a petition under § 1.181 to review the requirement or objection. As an example, when applicant challenges the finality of an Office action as being premature, the applicant should focus on whether the Office action met the appropriate standard for finality. The Office will make every effort to decide the petitions in a timely manner. Applicant, however, should not file a continuing application or a request for continued examination in an effort to address improper procedural requirements. Petitions for supervisory review of Office actions and restriction requirements will continue to be decided by supervisory patent examiners or other managers. Therefore, examiners will not be diverted from the examination process by these petitions. Finally, it should be noted that complaints about an Office action that relate to the merits of patentability of the claims must be addressed in an appeal to the BPAI, and not in a petition under § 1.181 for supervisory review, even if the issues may be phrased in

procedural terms. *See Boundy v. U.S. Pat. & Trademark Office*, 73 U.S.P.Q. 2d 1468, 1472 (E.D. Va. 2004).

Comment 26: Several comments stated that any resources saved via implementation of these final rules would be used for other filings necessitated by the changes. Thus the rule changes, according to the comments, would increase the backlog and pendency and add to the administrative cost and burdens of the Office. In particular, a number of comments predicted that the number of applications would increase because applicants would file more of the following: (1) Provisional applications; (2) continuation applications rather than requests for continued examination; (3) reissue applications to perfect or broaden claims; (4) reexamination proceedings to have prior art considered; (5) divisional applications (because applicants are required to file all divisional applications during the pendency of the first application); (6) multiple parallel applications that have similar or the same disclosures; and (7) continuing applications before the effective date.

Response: The Office notes the concerns expressed in the public comment and has attempted to avoid the possibility of increased filings necessitated by modifying the proposed changes. The Office has made modifications to the proposed changes to §§ 1.78(d)(1) and 1.114 such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Also, under this final rule, a divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. This final rule also permits applicant to file two continuation applications of a divisional application plus a request for continued examination in the divisional application family, without any justification. Therefore, the Office does not expect any significant increase in filings of applications. Specifically, the Office does not expect that the number of divisional applications would increase in response to the changes being adopted in this final rule because applicants should have sufficient time to determine whether to file a divisional application for a non-elected invention following a restriction requirement. Furthermore, an increase in filings of provisional applications will not place additional burden on the Office's patent

examining resources because no examination is provided in provisional applications. The Office does not expect its examining resources to be impacted when applicants file continuation applications rather than requests for continued examination, or when applicants file reissue applications and reexamination proceedings rather than continuing applications.

The changes being adopted in this final rule do not encourage applicants to file multiple applications with patentably indistinct claims. Pursuant to § 1.78(f)(3), the Office may require elimination of the patentably indistinct claims from all but one of the nonprovisional applications. If the patentably indistinct claims are not eliminated from all but one of the applications, the Office will treat each application as having the total of all of the claims (whether in independent or dependent form) for purposes of determining whether an examination support document is required by § 1.75(b). See § 1.75(b)(4). Moreover, when an applicant (or assignee) files multiple applications with the same claimed filing or priority date, a common inventor, and substantial overlapping disclosures, the Office will presume that the applications contain patentably indistinct claims. See § 1.78(f)(2). The applicant must either rebut this presumption or submit the appropriate terminal disclaimers and explain why two or more pending applications containing patentably indistinct claims should be maintained. Once applicant recognizes that having multiple applications that contain patentably indistinct claims is not needed, applicant would abandon the applications or stop filing multiple applications that have patentably indistinct claims.

Comment 27: One comment stated that a requirement for Director's approval to file a second or subsequent continuing application or request for continued examination would create a disincentive for examiners to provide a thorough examination, leaving the burden on the applicant to prosecute the application.

Response: The Office modified the proposed provision that would have limited applicant to one continuation or continuation-in-part application or to one request for continued examination, without any justification. This final rule allows applicant to file two continuation or continuation-in-part applications plus a request for continued examination in an application family, without any justification. What is more, the Office expects that limiting the number of

continuing applications and requests for continued examination that may be filed without justification will encourage both applicants and examiners to engage in a more thorough prosecution and examination earlier in the application process. Examiners are professionals who perform their duties in compliance with patent laws, rules of practice, and patent examining procedures set forth in the MPEP. They are responsible for the quality of their work product. There is no reason why examiners would provide lower quality examination in response to the changes in this final rule. In fact, this final rule is intended to improve the quality of examination by facilitating the examination of applications that contain more than five independent claims or twenty-five total claims via the examination support document.

Comment 28: A number of comments stated that the Office should treat continuing applications the same as new applications and should not limit the available protection because applicants who file continuing applications pay the same filing fees as those who file a new application. One comment argued that continuing applications should not be limited because they claim "new inventions" in that they pursue broader claims, a different invention, or an improvement, and the purpose of patents is to protect inventions, not to facilitate examination. One comment argued that continuation and continuation-in-part applications are legitimate because the statutes that create and authorize "continuation practice" do not distinguish such applications from "new" applications in terms of their importance, nor do they limit the resources that are committed to them.

Response: The former unrestricted continued examination practice was impairing the Office's ability to examine new applications. As a result, the Office is modifying continued examination practice in this final rule to address the backlog of unexamined new applications. Under this final rule, therefore, if the amendments, arguments, or evidence sought to be entered could have been previously submitted in the initial application, two continuing applications, and a request for continued examination, applicants are encouraged to make such submissions early rather than wait to do so in another continuing application or request for continued examination. That way, the examiner would have the information earlier to make the patentability determination. If applicant could not have submitted them earlier, applicant may file a third continuing

application with a petition and showing under § 1.78(d)(1)(vi) or a second request for continued examination with a petition and showing under § 1.114(g).

Comment 29: A number of comments stated that the rule changes would not permit applicants to file even a single continuation or continuation-in-part application, when the applicant filed a request for continued examination in the initial application.

Response: The Office has made modifications to the proposed changes to §§ 1.78(d)(1) and 1.114 such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Applicant may also file any additional continuation or continuation-in-part application or request for continued examination with a petition and showing as to why the amendment, argument, or evidence sought to be entered could not have been submitted earlier. The provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. The filing of a request for continued examination in the initial application does not preclude applicant from filing a continuing application of the initial application.

Comment 30: Several comments objected to the Office's proposal that a petition under § 1.78 to accept an unintentionally delayed claim under 35 U.S.C. 120, 121, or 365(c) will not be granted in an application in which a request for continued examination has been filed. One comment argued that applicant would lose substantial rights if the Office dismisses a petition to accept an unintentionally delayed claim filed after a request for continued examination has been filed in the prior-filed application.

Response: The Office has made modifications to the proposed changes to §§ 1.78 and 1.114 such that the provisions of § 1.78(d) as adopted in this final rule are independent of the provisions of § 1.114. Thus, § 1.78(e) as adopted in this final rule does not provide that a petition to accept an unintentionally delayed claim under 35 U.S.C. 120, 121, or 365(c) will not be granted in an application in which a request for continued examination has been filed.

Comment 31: A number of comments stated that the rule changes would not permit applicants to consolidate two applications into a single continuation-in-part application, which is contrary to the goal of reducing the number of applications.

Response: The Office has made modifications to the proposed changes such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Therefore, applicant is permitted to file a continuation-in-part application that claims the benefit of two prior-filed applications without a petition and showing under § 1.78(d)(1)(vi). If applicant thinks that a third or subsequent continuation-in-part application is necessary for consolidation purposes, then such applicant may file a petition and showing under § 1.78(d)(1)(vi) to obtain the additional filing.

Comment 32: Several comments argued that applicants need continuing applications and requests for continued examination because the reissue procedure does not give applicants the same flexibility.

Response: Continuing applications and requests for continued examination are not, by statute, available for the same purposes as reissue applications. Continuing applications and requests for continued examination are available to an applicant during the prosecution of an initial application to enable an applicant to secure protection on the full scope of an invention with the correct benefit claim. See 35 U.S.C. 120, 121, and 365(c). By contrast, the reissue procedure is available to an applicant after a patent has issued to permit an applicant to correct errors made during the prosecution of the original application without any deceptive intention and to enlarge the scope of the claims of the original patent if the reissue application is filed within two years from the grant of the original patent. See 35 U.S.C. 252. Furthermore, this final rule permits applicant to file two continuation or continuation-in-part applications plus one request for continued examination in an application family, without any justification. These available filings provide sufficient flexibility.

Comment 33: One comment suggested that the rule changes would be contrary to patent harmonization goals. One comment argued that the rule changes would hurt foreign applicants because they would be required to assess the degree of protection much earlier than they normally would, resulting in retaliatory challenges abroad for U.S. applicants.

Response: The Office did not receive any comments from any foreign patent office or authority. The Office does not expect any retaliation from other

countries or any adverse impact. Many countries do not have flexible practices for filing continuation applications, continuation-in-part applications, and requests for continued examination.

Comment 34: A number of comments argued that the rule changes would increase the cost to applicants for prosecuting each application, and for filing more multiple parallel applications, divisional applications, appeals, and petitions under §§ 1.78 and 1.114. Several comments argued that the rule changes would cause applicants to incur excessive expenses before determining whether the invention is commercially viable. One comment argued that the Office would cause applicants to perform patent searches in order to have a good working knowledge of the prior art to draft claims for full coverage. One comment argued that the rule changes would increase practitioner fees because applicants must submit more carefully drafted claims and replies (estimated five additional hours per case for drafting all possible claims, at an average of 150 dollars per hour, the additional cost would be 750 dollars per application or 200 million dollars for 317,000 applications). One comment estimated that the attorney cost in preparing an application would at least double if not increase by a factor of ten, which would place new applications out of reach of small businesses. Several comments argued that it would be practically impossible or at least much more difficult, expensive and time-consuming to obtain patent protection for the full scope of inventions, especially for large, complex inventions. One comment argued that the rule changes are extremely burdensome for patent applicants and practitioners to maintain and develop a cohesive patent strategy. One comment stated that the rule changes were very complex and fraught with ambiguity and would create difficulties and misunderstandings for applicants and practitioners in the implementation, possibly resulting in the loss of inventors' rights and an increase in practitioners' exposure to malpractice.

Response: The Office encourages applicants to diligently prosecute the initial application, two continuation or continuation-in-part applications, and one request for continued examination, without a petition and showing, so that applicants do not need to file a petition and showing to secure a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination and incur the costs associated with these filings. The

patent system best serves the interests of all parties, including the public, when applicants and their representatives are diligent in drafting the claims and replies. Applicant would get a quality patent with desirable claim coverage. The Office would not waste patent examining resources to examine applications that are not diligently prepared. Even prior to the changes being adopted in this final rule, applicants and their representatives had certain duties when prosecuting applications in front of the Office. Applicant is required to submit fully responsive replies to Office actions (see § 1.111) and to particularly point out and distinctly claim what the applicant regards as his or her invention (see 35 U.S.C. 112, ¶ 2). Furthermore, if applicant's lack of knowledge of the prior art (or lack of diligence) causes unnecessary delay or needless increase in the cost of prosecution before the Office, applicant would be violating § 10.18(b)(2)(i).

If applicants need more time to determine the aspect of the invention for which patent protection should be sought, applicant may file a request for deferred examination under § 1.103(d) upon filing the initial application. Applicant should have sufficient time to determine whether to file a divisional application for a non-elected invention because a divisional application is not required under this final rule to be filed during the pendency of the initial application, as long as the copendency requirement of 35 U.S.C. 120 is met. If applicant disagrees with the examiner's rejections, it would be more effective to appeal the rejections than to file a continuing application or a request for continued examination. It should not be burdensome for applicants and their representatives to prosecute diligently by drafting claims that particularly point out and distinctly claim the subject matter which the applicant regards as his or her invention, as well as replies that are fully responsive to the Office actions.

The requirements for seeking third and subsequent continuing applications in this final rule will not have an effect on the vast majority of patent applicants. Approximately 342,600 nonprovisional patent applications (excluding plant and design applications) were filed in the Office in fiscal year 2006. Of those applications, approximately 32,700 were identified as continuation applications, approximately 15,700 were identified as continuation-in-part applications, and approximately 20,600 were identified as divisional applications. In addition, approximately 74,700 requests for

continued examination were filed in the Office in fiscal year 2006. The requirements for seeking a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination would only have affected 2.7 percent of these filings (applications or requests for continued examination). As discussed previously, the changes being adopted in this final rule do not give any advantage to those applicants who file multiple parallel applications containing patentably indistinct claims. See §§ 1.75(b)(4) and 1.78(f).

Comment 35: One comment argued that the rule changes would encourage the courts to have a more liberal view on the doctrine of equivalents. Another comment argued that the rule changes limiting continuation practice takes away the right of the patentee to use continuing applications to secure patent protection for equivalents of the invention claimed in the prior-filed application, citing *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 68 U.S.P.Q.2d 1321 (Fed. Cir. 2003) (*Festo X*).

Response: The doctrine of equivalents is a patent law concept relating to infringement which protects patentees against efforts of copyists to evade liability for infringement by making only insubstantial changes to a patented invention. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 726–27, 62 U.S.P.Q.2d 1705, 1709 (2002) (*Festo VIII*). The case law on the doctrine of equivalents has been well established since *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 41 U.S.P.Q.2d 1865 (1997) and *Festo VIII*. A concurrence in *Festo X* noted that the demise of the flexible doctrine of equivalents “rule” may encourage applicants to (*inter alia*) use continuation strategies to avoid the lack of flexibility that now exists in the doctrine of equivalents. See *Festo X*, 344 F.3d at 1375, 68 U.S.P.Q.2d 1332. This concurrence in *Festo X*, however, was not espousing some “right” of the patentee to use continuing applications to maintain the doctrine of equivalents, but was simply noting that applicants now use continuing application practice as a substitute for a flexible doctrine of equivalents.

The Office is concerned that practitioners and applicants may indeed be increasingly using continuing applications not to advance prosecution but to compensate for changes in the law of the doctrine of equivalents. Such practices would appear to be likely to contravene § 10.18(b)(2)(i), under which a party presenting a paper to the Office

is certifying that the paper is not being presented to cause unnecessary delay or needless increase in the cost of prosecution before the Office. Under *Festo X*, a narrowing amendment gives rise to a presumption that equivalents not covered by the literal language of the claims have been foregone. Permitting two continuing applications plus a request for continued examination in any one of the initial application or two continuing applications as of right should in general assure that applicants have an adequate chance to advocate to the examiners that an amendment is unneeded. Beyond that, the Office is concerned that applications may be continued, rather than disputes on the need for amendment being appealed, for the purpose of delay. A requirement that an applicant at that stage be prepared to justify his or her need for an additional continuing application is reasonable in these circumstances.

Comment 36: A number of comments suggested that the rule changes are arbitrary and capricious, premature, imprudent and ill-advised. A number of comments argued that the Office has no rational basis for the rule change, and has not provided sufficient explanations, data or evidence to justify the rule changes and to show that the rule changes will actually improve the backlog of applications, the quality of examinations, overall examination efficiency, quality of patents, and pendency. In addition, the comments asserted patents would be harder to enforce and litigate because all relevant prior art may not have been considered.

One comment stated that the Office does not have a pendency problem because the average pendency is within zero to three years. One comment argued that the Office provides no studies to show that businesses are being harmed due to delayed prosecution. One comment argued that reducing the backlog is not an appropriate reason for limiting the number of continuing applications and requests for continued examination as a matter of right. Several comments argued that the Office has not identified continuation applications as a major source of the backlog, and therefore, the rule changes would have limited impact on the backlog. One comment pointed out that second and subsequent continued examination filings make up only a small percentage of the total number of continued examination filings. Several comments alleged that the Office’s statistics are misleading and the rule changes would only eliminate at most five to ten percent of the continuation applications because the

Office should not have included “involuntary” divisional applications and requests for continued examination. One comment argued that the Office provided no statistical data showing the percentage of applicants that “misuse” the continued examination practice as alleged. One comment also suggested that although the Continuing Applications Proposed Rule cites to data regarding the total number of continuations and the consequential burdens imposed on examiners, no analysis is provided as to the grounds for filing these applications and whether those grounds constituted “abuse.”

Several comments argued that there is no indication that the Office has conducted any serious analysis of how or why requests for continued examination and continuation applications are used by applicants. The comments suggested the following: A suitable analysis would involve review of prosecution histories of patents that were issued from a continuation application or a request for continued examination and determination of whether such patents could have issued if the rule changes were in place; and if such patents would not have issued, the Office should explain how such a loss of rights is consistent with the goals of the patent system. A number of comments asserted that the rule changes should be narrowly tailored to only those few applicants who intentionally delay the conclusion of examination rather than adversely impacting all applicants. A number of comments suggested that the Office should conduct a pilot program on the changes and report the results to the public prior to implementing the rule changes.

Several comments further argued that the Office has not identified any study showing that restricting applicants to a single continued examination opportunity would satisfactorily address its problems without causing substantial harm to the protection of innovation or the patent examining process. Several comments alleged that the Office has not sufficiently considered the effect of the rule changes on U.S. applicants and the U.S. economy and suggested that further study is needed because the ability to file multiple continuing applications helps U.S. applicants to protect their inventions against foreign competitors and the rule changes would cause further outsourcing of American manufacturing and loss of American jobs.

Several comments, however, supported the rule changes. The comments provided the following reasons why the rule changes would be appropriate: (1) They would improve

the Office's productivity, enhance patent quality, and eliminate growing abuses in the patent prosecution process, which would accelerate innovation, especially in the software and hardware technologies that have fast technology evolution and short product life cycle; (2) the rule changes would help the Office reduce backlog and pendency because they would reduce the ancillary loads on the examination process so that examiners can focus on important core issues, and the Office could focus its limited examining resources on faster examination of new applications; (3) the rule changes appropriately address those few applicants who disproportionately contribute to the backlog and provide applicants with the ability to file appropriate continued examination filings and multiple opportunities to present claims and arguments; (4) applicant may correct appropriate mistakes (including by broadening claims) through the reissue process; (5) by eliminating long chains of continued examination filings, the rule changes would provide earlier and greater legal certainty as to the scope of patent rights, reduce wasteful litigation, and encourage negotiations between patent holders and others; (6) the rule changes would likely promote confidence in U.S. patents, stimulate innovation, enhance competition, and increase consumer welfare; and (7) the rule changes would help to deter applicants from strategically using the continued examination practice to disadvantage competitors and their licensees, and would prevent applicants from keeping continuation applications pending for extended periods of time so that they can monitor the development of the market and modify their claims to cover their competitors' products.

Response: In fiscal year 2006, the average pendency to first Office action was 22.6 months for the entire Patent Examining Corps. The average was much higher in certain areas (e.g., in Technology Center 2100 (computer architecture, software and information security) the average pendency to first Office action was 30.8 months, and in Technology Centers 3620 and 3690 (electronic commerce) the average pendency to first Office action was 43.9 months). As several comments noted, long pendency of patent applications is problematic in some industries (e.g., computer software and hardware technologies) where product life cycles are short and new improvements can quickly make the technology obsolete. The Office has the authority and responsibility to establish regulations

that shall govern the conduct of proceedings in the Office and facilitate and expedite the processing of patent applications. See 35 U.S.C. 2(b)(2). The Office has the responsibility to take appropriate action to improve efficiency, patent quality and pendency. The Office does not expect that the changes being adopted in this final rule alone will be sufficient to address the growing backlog of unexamined patent applications. The Office is implementing many initiatives to improve efficiency in the examination process and quality of patents.

Continued examination filings divert the Office's limited examining resources from the examination of new applications. One of the Office's goals is to focus the limited examining resources on the examination of new applications. The rules do not place an absolute limit on the number of continued examination filings. The Office recognizes there are appropriate reasons for applicant to file a continuing application or request for continued examination. Under this final rule, applicant is permitted to file the initial application, two continuing applications, and a request for continued examination in an application family, without any justification. Thus, applicant has sufficient opportunities to present claims, amendments, arguments, evidence, and prior art during the prosecution of the initial application, two continuing applications, and a request for continued examination. An applicant who considers this to be insufficient may file a third or subsequent continuing application or second or subsequent request for continued examination with a petition and showing as to why the amendment, argument, or evidence sought to be entered could not have been previously submitted. If the amendment, argument, or evidence can be submitted earlier in the prosecution process, applicant is required to do so, rather than delay the prosecution and waste the Office's patent examining resources on a prosecution that is not focused. The examination process is more efficient when the applicant diligently prosecutes the application so that the examiner has all of the relevant information, including amendments, evidence, arguments, and prior art as early as possible. Most applicants who prosecute diligently will not need to file a third or subsequent continuing application. Reviewing the prosecution histories of patents, conducting pilot programs, publishing green papers, etc., would not show all of the reasons why

applicants would file multiple continued examination filings. Applicants could have different reasons for filing continuation applications, continuation-in-part applications and requests for continued examination. The rules appropriately provide applicant the opportunity to show why a third or subsequent continuing application or second or subsequent request for continued examination is needed. The comments do not provide any persuasive data or evidence that shows how the rule changes, or any restrictions on the continued examination filing practice, would have a negative impact on the quality of patents, the U.S. economy, or innovation.

As discussed previously, approximately 342,600 nonprovisional patent applications (excluding plant and design applications) and approximately 74,700 requests for continued examination were filed in the Office in fiscal year 2006. The requirements for seeking a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination would only have affected 2.7 percent of these filings (applications or requests for continued examination). The Office did not include divisional applications in this analysis. The Office included requests for continued examination because when an applicant files a request for continued examination, the examiner reopens the prosecution of the application and conducts another substantive examination similar to a continuation application.

Comment 37: Several comments argued that the amount of resources spent on additional continuing applications or requests for continued examination is not as high as asserted because continuation applications and requests for continued examination take less of the examiner's time than new applications since the examiner is already familiar with the prior art, issues, and subject matter of the application.

Response: The Office expects that limiting the number of continuing applications and requests for continued examination that may be filed without justification will encourage both applicants and examiners to focus on "getting it right the first time." In any event, examiners are given the same amount of time to examine a continuing application or request for continued examination as a new application. Certain continuing applications and requests for continued examination could have more complex issues than a new application, such as evaluating new evidence in a biotechnology application.

Any reduction in the number of continuing applications and requests for continued examination would increase the Office's ability to focus its patent examining resources on the examination of new applications.

Comment 38: Several comments asserted that the premise that expedited examination is more important than protection of inventor's rights is faulty.

Response: The Office did not state such a premise. Applicants may seek full protection of their inventions under this final rule, which does not place any absolute limits on the number of continuing applications and requests for continued examination. Limiting the number of continuing applications and requests for continued examination that may be submitted without justification is not counter to the protection of an inventor's rights.

Comment 39: Several comments predicted that the rule changes would decrease the Office's revenue due to the decrease in continuing applications and requests for continued examination.

Response: The Office's goal is to utilize its patent examining resources more efficiently to reduce backlog and improve pendency. In exchange for greater efficiency, the Office expects there would be some decrease in revenue as the number of continued examination filings declines, as the comment indicates. But, this final rule is not being implemented with a view toward revenue; instead, it is being implemented to improve the patent examination process.

Comment 40: A number of comments argued that there is no public notice problem. The comments argued that most applications (ninety percent) are published, the prosecution of the published applications is open to the public, and competitors are already able to analyze a file history to determine the broadest range of claim protection that may be granted in a patent of a continuing application. Several comments suggested that members of the public could prevent infringement by identifying the novel inventions in the disclosure and avoiding those inventions in their practices. Several comments, however, noted that publication of applications is not sufficient to provide public notice of what the patentee will ultimately claim because a patent may eventually issue with broader or significantly different claims than those published and any delays at the Office will perpetuate uncertainty as to the scope of the eventual patent.

Response: The Office agrees that the publication of an application is not sufficient notice of the scope of

protection afforded by an eventual patent because the claims have not been determined to be patentable at the time of publication. Asking the public to determine the broadest range of claim protection and to prevent infringement based on the publication of an application would defeat the purposes of patent examination and 35 U.S.C. 112, ¶ 2. The patent claims provide the public with notice of the patent protection, not the disclosure of an application.

Comment 41: A number of comments stated that the current patent law already contains its own solution to the problem of long chains of continuing applications. The comments argued that filing and maintenance fees and the twenty-year patent term provision discourage applicants from filing continuing applications. Several comments argued that the Office is acting prematurely because the recent changes (e.g., the Office electronic filing system, the increase in hiring and fees, court decisions on doctrine of equivalents, the twenty-year patent term provisions, and publication of applications) should be sufficient to reduce the backlog and improve public notice. A number of comments alleged that the doctrine of prosecution laches is sufficient to address abuses. One comment argued that the Office should not be concerned with enforcement issues and the problem with public notice should not be a reason for the rule changes. Several comments argued that the Office's concern over public notice is misplaced because the notice function of claims is limited to published or patented claims and it does not extend to any future claims that might arise. Several comments, however, noted that even with the twenty-year patent term provisions, unrestricted continued examination practice still gives applicants incentives to keep continuing applications pending after the issuance of a patent so that the applicants can monitor the industry development and capture other companies' products by changing the scope of the claims in the continuing applications.

Response: The percentage of continued examination filings did not decrease after the implementation of the twenty-year patent term provision of the Uruguay Round Agreement Act (Pub. L. 103-465, 108 Stat. 4809 (1994)). Thus, the twenty-year patent term provisions do not discourage applicants from filing continued examination filings. As discussed previously, this final rule is not intended to address extreme cases of prosecution laches or to codify *Bogese II*. Examiners already have the authority

(with a Technology Center Director's approval) to make a rejection on the grounds of prosecution history laches. See MPEP section 2190. Some of the reasons cited by the comments as to why an indefinite number of continuing applications is needed suggest that continuing applications may be used for purposes of delay more commonly than could be effectively addressed by the Office's application of its equitable prosecution history laches authority. Moreover, even where strategies of delay are not deliberately pursued, the lack of reasonable requirements on the use of continued examination practice may act as a disincentive to the examiner and applicant taking the most effective steps to reach conclusion.

The Office did not place a *per se* limit on the number of continuing applications and requests for continued examination. The rules require applicant to show why a third or subsequent continuing application or second or subsequent request for continued examination is necessary to advance prosecution. The Office recognizes both the adverse effects of unrestricted continued examination practice, and the appropriate uses of continued examination filings. The Office has sought to draw a reasonable balance in order not to discourage appropriate uses of continued examination filings while providing a regulatory setting in which unnecessary prolongation of proceedings can be avoided. The changes being adopted in this final rule are appropriately tailored to permit applicants to file the initial application, two continuation or continuation-in-part applications, and a request for continued examination in any one of these three applications without any justification. An applicant who considers this to be insufficient may file any additional continuation or continuation-in-part application or request for continued examination with a petition and showing as to why the amendment, argument, or evidence sought to be entered could not have been submitted earlier. The changes in this final rule will also permit the Office to focus its limited resources on examination of new applications in order to reduce the backlog of unexamined applications.

Comment 42: One comment argued that the Office's assertion that multiple patents tend to defeat the public notice function of patent claims does not justify the rule changes because the restriction practice tends to increase the number of patents. One comment argued that the Office is making unsupported assumptions that: (1) The possible issuance of multiple patents

arising from continuing applications tends to defeat the public notice function of patent claims; and (2) the public is left uncertain as to what a set of patents resulting from the initial application will cover when multiple applications with patentably indistinct claims are filed.

Response: Restriction practice encourages applicant to file a single application for each patentably distinct invention. The public notice function of patent claims is undermined, however, when multiple patents together claim only one patentable invention (*i.e.*, the patents contain patentably indistinct claims). In such case, applicant should file a single application claiming one patentable invention rather than multiple applications claiming the same patentable invention. The Office is not making unsupported assumptions that the possible issuance of multiple patents arising from continuing applications tends to defeat the public notice function of patent claims, and that the public is left uncertain as to what a set of patents resulting from the initial application will cover when multiple applications with patentably indistinct claims are filed. *See, e.g., To Promote Innovation: The Proper Balance of Competition and Intellectual Property Law and Policy*, Ch. 4 at 26–31 (Federal Trade Commission 2003); Lemley and Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. Rev. at 100 (eliminating continuing application practice would be consistent with the policy goal of giving adequate notice about what is and is not covered by a patent).

Comment 43: Several comments predicted that the rule changes would discourage public disclosure of technology, thereby hurting industrial growth and innovation. Several comments argued that by limiting an applicant's ability to claim everything that is disclosed in the application, the rule changes would cause the applicant to submit more narrow disclosures to avoid inadvertent dedication of the subject matter to the public (citing *Johnson & Johnston Associates, Inc. v. R.E. Service Co.*, 304 F.2d 1235, 62 U.S.P.Q.2d 1225 (Fed. Cir. 2002) (*en banc*)). Several comments noted that the rule changes would force applicants to delay filing until all foreseeable information has been obtained or forego continuation-in-part filings that contain additional information. Several comments stated that small entities that have limited resources would not disclose alternative embodiments or would file applications with narrow disclosures to avoid restriction requirements. Several comments

averred that inventors would delay the filing of applications until after clinical or market testing is concluded, a potentially commercially viable product is identified, or other refining of the invention is completed. The comments also predicted that some inventors would keep the invention secret from the public and/or limit the scope of the disclosure to avoid dedicating potentially commercial embodiments to the public. One comment argued that the Office is making an unsupported assumption that continuing applications and multiple applications containing patentably indistinct claims impose a burden on innovation. One comment argued that applicants would file multiple applications having divergent subject matter rather than a single application and applicants would omit certain concepts from the applications. One comment stated that the prior art complications caused by the inability to claim priority of an earlier filed application through intermediate applications would severely curb disclosure because applicants would avoid creating their own prior art under 35 U.S.C. 102(b) on a possible important commercial embodiment. One comment stated that the current continued examination practice encourages early disclosure of multiple embodiments of inventions developed through the iterative design process. One comment stated that large applications that disclose everything are good and advance the Office's mission. One comment argued that the proposed rule changes to the examination of claims will force applicants to file applications that incorporate secondary features into their own separately filed application. One comment argued that the new rules would result in omnibus filings on anything and everything.

Response: The Office has made modifications to the proposed rules concerning both continuing applications and examination of claims practices. First, this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Second, this final rule permits applicants to present more than five independent claims or more than twenty-five total claims in an application if applicant files an examination support document before the first Office action on the merits of the application. Taken together, the changes to continuing application and examination of claims practices adopted in this final rule permit applicant to file as many claims as desired in one

application and give applicant sufficient opportunity to seek appropriate protection for the disclosed invention. Accordingly, the changes being adopted in this final rule do not place a *per se* limit on the number of claims presented in an application, nor do they place a *per se* limit on the number of continuing applications and requests for continued examination available in an application family. The changes being adopted in this final rule likewise do not give any advantage to those applicants who file multiple applications that contain patentably indistinct claims because such applicants would be required to identify the multiple applications that contain patentably indistinct claims. *See* §§ 1.75(b) and 1.78(f).

The changes adopted in this final rule will not discourage applicants from filing patent applications because the substantive criteria for entitlement to a patent (exclusive rights) have not changed. Whether applicants file narrow or broad disclosures, the changes in this final rule will reduce uncertainty with respect to what the applicant is claiming as the invention. The Office also does not expect applicants to delay the filing of an application because any commercial activities and public disclosures that occurred more than one year prior to the filing of an application would still be considered prior art under 35 U.S.C. 102(b). The changes being adopted in this final rule simply require applicants to prosecute their applications diligently and submit amendments, argument, and evidence early in the prosecution of the initial application, two continuing applications and a request for continued examination. As previously discussed, applicant has sufficient time to determine whether to file a divisional application. If applicant needs more time to determine which aspect of the invention to seek protection for, applicant may file a request for deferral of examination under § 1.103(d).

Comment 44: Several comments alleged that the rule changes would have a significant adverse impact on applicants if the first-to-file system is adopted because applicants would need to file more continuing applications to protect their inventions because applicants would need to file as soon as possible with broadly conceptualized disclosures and subsequently file continuing applications (*e.g.*, continuation-in-part applications) on the improvement or detailed embodiments.

Response: The United States currently does not have a "first inventor-to-file"

standard. Other countries that have a "first inventor-to-file" standard have less flexible continued examination practice than the United States. For example, the Japan Patent Office does not permit continuation-in-part applications. Under the JPO practice, applicant may only submit an application on an improvement as a new application. The Office will continue to consider the issues related to the "first-to-invent" standard and the "first inventor-to-file" standard in determining the rights to a patent in the context of international harmonization efforts.

Comment 45: A number of comments argued that the rule changes would disproportionately impact small entities including universities, start-up companies, biotechnology companies, and public health industry because they are more likely to file continuing applications and requests for continued examination and have less resources. The comments provided the following reasons: (1) The proposed rule would require significant expenses early in the prosecution of the application that would cause small entities and independent inventors economic hardship; (2) the rule changes would encourage large companies that have more financial resources to "steal" inventions from the small entities because the increased cost of obtaining patent protection would prevent small entities from obtaining full protection of their inventions and cause many small entities not to seek patent protection; (3) small entities need the flexibility to respond to changing conditions by refining claims and they cannot afford up-front parallel filings as large companies can; (4) independent inventors and small entities need the ability to file multiple continued examination filings to spread the costs; (5) the rule changes could stifle the building of patent portfolios for small companies and cause a reduction of capital investment in these companies and in new technologies; (6) applicants should be permitted to get a patent on the allowed claims and then continue to prosecute the broader or rejected claims or to claim subject matter not previously claimed in a continuing application, in order to bring technologies to the market sooner, which would permit small entities to attract investors and obtain financing for further product development and patent prosecutions; (7) continued examination filings are more likely needed in complex fields like biotechnology because examiners are less likely to comprehend the invention fully in the limited time

allotted for the initial search and examination and more likely to make restriction requirements, and applicants need additional opportunities to address technical issues arising during prosecution and submit evidence and clinical testing data; (8) companies in the life sciences need continued examination filings to obtain multiple patents that protect innovations and improvements that arise over the long time period of research and development, clinical testing, and the Food and Drug Administration (FDA) approval process; (9) in biotechnology, applicants may not know at the time of filing which embodiments of the invention have commercial value or how a competitor may attempt to copy the invention or circumvent the patent. One comment that supports the rule changes noted that large entities also operate within limited filing budgets, and the effects of the rules will apply across the board because any applicant must decide what level of filing activity it can reasonably afford, and make filing decisions accordingly. The comment further stated that small entities already receive a fifty percent discount on fees and can take advantage of inexpensive provisional applications to delay paying filing fees. Several comments argued that the rule changes will disproportionately impact small entities and that the Office obscures this fact by including requests for continued examination into the analysis. The comments stated that: 32 percent of patents to the top nineteen universities are continuation or continuation-in-part applications; 35.2 percent of first continuations and continuation-in-part applications are filed by small entities; and 37.9 percent of second continuations and continuation-in-part applications are filed by small entities.

Response: The Office notes the concerns expressed in the public comment particularly by small entities regarding the proposed changes to §§ 1.78(d)(1) and 1.114 that would have permitted an applicant to file only one of the following: A continuation application, a continuation-in-part application, or a request for continued examination, without any justification. The Office has made modifications to these proposed changes such that this final rule will permit an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Under this final rule, an applicant may file a divisional application directed to a non-elected invention if the prior-filed

application is subject to a requirement for restriction. The divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. This final rule also permits applicant to file two continuation applications of a divisional application plus a request for continuation examination in the divisional application family, without any justification. Applicant may also file any third or subsequent continuation or continuation-in-part application, or any second or subsequent request for continued examination in an application family, with a petition and showing. Therefore, applicants should have sufficient time to determine whether to seek protection for a particular aspect of an invention and should have sufficient opportunities to present claims, amendments and evidence for that aspect. For example, applicant is permitted to obtain a patent on the allowed claims from the initial application, and then continue to prosecute the broader or rejected claims in two continuation or continuation-in-part applications, and one request for continued examination without justification. Beyond those filings, applicant may seek a third or subsequent continuation or continuation-in-part application and a second or subsequent request for continued examination with a petition and showing. As previously discussed, the changes being adopted in this final rule do not give any advantage to those applicants who file multiple parallel applications containing patentably indistinct claims. See §§ 1.75(b)(4) and 1.78(f).

Applicant should also have sufficient opportunities to spread the cost of prosecution. Applicant has a one-year grace period under 35 U.S.C. 102(b) before filing a patent application to test the market or obtain capital resources. Before the end of the one-year grace period, applicant may file a provisional application to obtain a U.S. filing date and wait up to twelve additional months to file an initial nonprovisional application. During this two-year time period, applicants may determine the commercial value of each aspect of the invention before filing the initial nonprovisional application. Applicant may also request a deferral of examination under § 1.103(d) and defer the examination up to three years from the earliest filing date claimed (e.g., the filing date of the provisional application). See § 1.103(d). By

requesting a deferral of examination, applicant would have even more time to determine the commercial value of the invention or obtain capital resources and would avoid the cost of filing and prosecuting multiple continued examination filings. Furthermore, divisional applications need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met.

The changes being adopted in this final rule do not disproportionately impact small entities. The Office estimates that the change would have required such a petition and showing in only 2.9 percent of the 112,210 small entity applications and requests for continued examination filed in fiscal year 2006. The Office included the number of requests for continued examination into the analysis because requests for continued examination divert the Office's patent examining resources from the examination of new applications and contribute to the increasing backlog of unexamined applications, just like continuation and continuation-in-part applications.

The Office notes that, during fiscal year 2006, it appears that the percentage of small entity continued examination filings that would have required a petition is slightly higher than the percentage of total continued examination filings that would have required a petition (2.9 percent small entity as opposed to 2.7 percent for all applicants). The Office also notes that, during fiscal year 2006, it appears that the percentage of small entity applications that exceeded the five independent claims and twenty-five total claim threshold is also slightly higher than the percentage of total applications that exceeded the five independent claim and twenty-five total claim threshold (24.4 as opposed to 23.7). These percentages are based upon data that is available in the Office's PALM system for applications filed during the most recent fiscal year. The Office does not think these slight differences establish that the changes in this final rule will have a disproportionate economic impact on small entities since these differences are within the margin of error. In addition, the comments provide no reason, and there is no apparent one for why small entity applicants would inherently require more continued examination filings to prosecute the applications to completion or more claims to adequately cover their inventions. Thus, even higher differences in these percentages could easily be explained by the fact that small entity applicants

pay only one-half of the fees that other applicants pay for continuing applications, requests for continued examination, and excess claims.

Comment 46: A number of comments predicted the rule changes would limit applicants' opportunities to present claims, which would reduce the scope of the patent claims because applicants would be pressured to pursue and accept narrower claims. The comments argued that inventors would not be able to adequately protect their inventions and would in turn lose patent protection to certain aspects of their inventions, which would have an adverse impact on the value of patents, patent quality, innovations, research and development, the competitiveness of U.S. companies, and the U.S. economy and would eliminate U.S. jobs. The comments provided the following reasons: (1) The Office has not appropriately addressed applicants' interests in maximizing patent protection and receiving a fair consideration of all claims submitted; (2) the rule changes would require applicants to claim all aspects of the disclosed invention initially, even though applicants often file applications without knowing the value of their inventions in order to determine which embodiment will have value and be worthy of the investment in patent protection; (3) applicants would not be able to identify and address all claim permutations in the initial application and one continuation application, and complex inventions often need more claims and more than one continuation application to protect the invention; (4) the Office should provide applicants the flexibility to prosecute different embodiments at a later time; (5) the applicant should be permitted to present claims (or change the scope of the claims) in continuing applications to cover an embodiment of the invention disclosed in the initial application when the applicant later determines the commercial value of the embodiment, develops the actual product, or discovers a potential infringer's product; (6) competitors could easily circumvent the patent claims because applicant would not have the ability to change the scope of the claims to cover the competitor's product in a continuing application; (7) in view of the courts' restrictive claim interpretation, the required showing under §§ 1.78(d)(1) and 1.114 would eliminate a vast number of legitimate continuing applications and requests for continued examination needed to provide coverage of alternate aspects of an invention.

Response: This final rule does not place any *per se* limits on the number of continued examination filings that

may be filed or on the number of claims an applicant may present in an application. Applicant is permitted to submit all of the claims that applicant desires during the prosecution of the initial application, two continuation or continuation-in-part applications, and a request for continued examination. An applicant who considers this to be insufficient may file a third or subsequent continuing application or second or subsequent request for continued examination with a petition showing why the amendment, argument, or evidence sought to be entered could not have been submitted earlier. For most applicants who prosecute their applications diligently, additional continued examination filings would not be needed. Applicant may also file a reissue application under 35 U.S.C. 251, if appropriate, to submit claims with different scope. Further, the use of continuation practice to circumvent statutory requirements for reissue and reexamination proceedings is not appropriate. In addition, the rules require an applicant to advance prosecution and not waste the Office's resources examining an application when the applicant is not ready to particularly point out and distinctly claim the subject matter which the applicant regards as his or her invention. *See also* § 10.18(b)(2)(i) and *Hyatt v. Dudas*, 2007 U.S. App. LEXIS 15350 (Fed. Cir. Jun. 28, 2007). Applicant should not use continued examination practice to delay the prosecution of the application because this adversely impacts the Office's ability to examine new applications and reduce the backlog of unexamined applications.

Comment 47: One comment predicted that the rule changes would discourage first action allowances because some applicants would intentionally file applications with at least one defect in order to receive a rejection to drag out pendency so that they can have more time to determine whether to file continuing applications.

Response: There is no reason why the new changes being adopted in this final rule will encourage an applicant to intentionally file an application with at least one defect to delay prosecution. Additionally, such an action by an applicant would violate § 10.18(b)(2)(i). By presenting to the Office any paper (including an application), the applicant is certifying that to the best of the applicant's knowledge, information and belief, formed after an inquiry reasonable under the circumstances, that the paper is not being presented to cause unnecessary delay or needless

increase in the cost of prosecution before the Office.

Comment 48: One comment sought clarification as to whether an applicant is permitted to amend the claims and/or file a continuation application to claim allowable subject matter presented in dependent claims.

Response: Applicant may amend the claims of an initial application to claim allowable subject matter presented in dependent claims if the amendment complies with the rules of practice (e.g., § 1.116). For example, applicant may submit such an amendment in the initial application in response to a non-final Office action in the initial application. Such an amendment, however, will not be entered in the initial application as a matter of right after a final Office action. Under this final rule, applicant alternatively may file two continuation or continuation-in-part applications plus one request for continued examination in an application family, without any justification and pursue the amendment in one of those two applications or in the request for continued examination.

Comment 49: Several comments argued that the combined effect of the limit on the number of representative claims and the limit on the number of continuing applications and requests for continued examination as a matter of right would increase the number of multiple parallel applications and divisional applications because applicants would file more multiple parallel applications with small numbers of claims or present claim sets that would provoke restriction requirements. Either way, the comments contended that the backlog will increase. One comment further alleged that applicants would file more continued examination filings and appeals because by limiting the number of claims examined, two Office actions would be insufficient, thus resulting in an increase in pendency and cost. One comment argued that the rule changes would disproportionately impact inventions that require more claims, continuing applications, or examiner time. One comment stated that the limitations on continued examination filings and claims would cause more litigation because they would create more uncertainty in infringement and validity.

Response: As discussed previously, the Office is not adopting the "representative claims" examination approach or restricting the number of continued examination filings to one without any justification. Rather, this final rule permits applicant to present more than five independent claims or

more than twenty total claims in an application if applicant files an examination support document. Applicant is also permitted to file two continuation or continuation-in-part applications, plus a request for continued examination in an application family, without any justification. The changes being adopted in this final rule do not place *per se* limits on the number of claims which applicant may present in an application or on the number of continued examination filings. The changes being adopted in this final rule do not encourage applicant to file multiple parallel applications that contain patentably indistinct claims. See §§ 1.75(b)(4) and 1.78(f). Applicants would obtain little benefit from filing multiple applications that contain patentably indistinct claims because the Office would treat each application as having the total of all of the claims (whether in independent or dependent form) in all such applications for purposes of determining whether an examination support document is required by § 1.75(b)(1) (but not for purposes of calculating the excess claims fee due in each application). Likewise, this final rule will not cause the number of divisional applications to increase because this final rule permits divisional applications to be filed serially. Therefore, applicant should have sufficient time to determine whether to file a divisional application to claim a non-elected invention.

Comment 50: A few comments suggested that the limits set in §§ 1.75(b)(4) and 1.78(d)(1) are inconsistent with interference practice under 35 U.S.C. 135 of copying claims for purposes of preserving the right to provoke an interference. One comment suggested that the changes to § 1.78 eliminates an applicant's right to add claims to an application to cover a similar or parallel technology, provided that the added claims find support in the specification, citing *PIN/NIP, Inc., v. Platt Chemical Co.*, 304 F.3d 1235, 1247, 64 U.S.P.Q.2d 1344, 1352 (Fed. Cir. 2002). One comment stated that subjecting patentably indistinct claims in multiple commonly owned applications to elimination under § 1.78(f)(3) violates case law, for example *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874, 9 U.S.P.Q.2d 1384, 1390 (Fed. Cir. 1988).

Response: The Office has modified proposed § 1.75(b)(4) and § 1.78(d)(1). This final rule permits an applicant to file two continuation or continuation-in-part applications plus one request for continued examination in an

application family, without any justification. Applicant may also file a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination with a petition and showing. This final rule permits applicant to present up to five independent claims or twenty-five total claims in each application, without an explanation. Applicant may also present more than five independent claims and more than twenty-five total claims if applicant files an examination support document before the first Office action on the merits of the application. Applicant may file as many claims as necessary to claim the full scope of his or her invention. This final rule provides sufficient opportunities for applicant to present claims to provoke an interference during the prosecution of these applications. Therefore, the changes to §§ 1.75(b)(4) and 1.78(d)(1) being adopted in this final rule are not inconsistent with 35 U.S.C. 135. Furthermore, applicant may also file a reissue application under 35 U.S.C. 251, if appropriate, to submit claims for provoking an interference. In other situations, however, applicant is not permitted to maintain an application in pending status, without advancing prosecution, for the sole purpose of awaiting developments in similar or parallel technology. As previously discussed, such practice does not advance prosecution before the Office and impairs the ability of the Office to examine new and existing applications.

In other situations, however, applicant is not permitted to maintain an application in pending status, without advancing prosecution, for the sole purpose of awaiting developments in similar or parallel technology. As previously discussed, such practice does not advance prosecution before the Office and impairs the ability of the Office to examine new and existing applications.

The Federal Circuit noted in *PIN/NIP* that one may amend an application for the purpose of encompassing devices or processes of others, subject to compliance with the requirements of the patent statute and regulations (the claim at issue was determined to be invalid under 35 U.S.C. 112, ¶ 1, for lack of written description support). See *PIN/NIP*, 304 F.3d at 1247, 64 U.S.P.Q.2d at 1352. As such, *PIN/NIP* cannot be relied upon to support a "wait and see" concept under which an applicant files an initial application followed by a stream of continuation applications just to wait for any competitor to develop and market an invention not claimed in the initial application. *PIN/NIP*, 304

F.3d at 1247, 64 U.S.P.Q.2d at 1352. Further, in *Kingsdown*, the Federal Circuit opined: "Nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application. Any such amendment or insertion must comply with all statutes and regulations, of course, but, if it does, its genesis in the marketplace is simply irrelevant." *Kingsdown*, 863 F.2d at 874, 9 U.S.P.Q.2d at 130. This statement does not equate to a pronouncement that an applicant has a "right" under the patent statutes to file a continuous stream of continuing applications to ensure that there is always a pending application in which to present claims encompassing devices or processes of others.

Further continuation practice is not intended to supplant or permit circumvention of reissue practice. The patent statute at 35 U.S.C. chapter 25 provides for the correction of patents, and specifically provides for the reissue of a patent in those situations in which a "patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of * * * the patentee claiming more or less than he had a right to claim in the patent." See 35 U.S.C. 251. See also *Toro Co. v. White Consol. Indus.*, 383 F.3d 1326, 1333, 72 U.S.P.Q.2d 1449, 1454 (Fed. Cir. 2004) (citing *Johnson & Johnston*, 304 F.2d at 1055, 62 U.S.P.Q.2d at 1231). Nothing, however, suggests that an applicant has a "right" under the patent statutes to file a continuing application to avoid the requirements of the reissue statute when seeking to correct or enlarge the scope of a patent. There is a difference between adding claims to an application that are otherwise pending, and deliberately prolonging prosecution in order to be able to do so. Deliberately prolonging a proceeding before the Office would not be consistent with the requirements of § 10.18.

Applicant may copy claims from another application or patent that is not commonly owned for the purposes of provoking an interference, without triggering § 1.78(f)(3). Section 1.78(f)(3) applies only to multiple commonly owned applications that contain patentably indistinct claims. Section 1.78(f)(3) is a restatement of former § 1.78(b), which previously gave the Office the same discretion to require elimination of patentably indistinct claims in all but one of the pending nonprovisional applications. The Office is not preventing applicants from providing such patentably indistinct claims in a single application, or in

multiple applications if applicant submits a terminal disclaimer in accordance with § 1.321(c) and explains why submitting patentably indistinct claims in separate applications is necessary.

Comment 51: Several comments suggested that if the Office implements the limits on continued examination filings, the limits on the number of claims would be unnecessary.

Response: The comment provides no explanation as to how or why implementation of the continued examination filing changes would make the claims provisions unnecessary. The Office determined that the implementation of the changes to the continued examination practice and practice for examination of claims in patent applications are necessary to achieve quality and efficiency in the patent examination process.

Comment 52: A number of comments argued that applicants should be permitted to file more than one continuation or continuation-in-part application or request for continued examination as a matter of right because there are many legitimate reasons for the filings. The comments provided the following examples: (1) The process of developing the best prior art and obtaining the broadest possible protection is a complex process and may extend the prosecution process; (2) applicants may use strategies that would avoid prosecution history estoppel and preserve doctrine of equivalents protection; (3) applicants may maintain a continuing application so that they could respond to any adverse court decisions and associated uncertainties; (4) the quality of the examination process may cause delays; (5) examiners would allow broader claims in a continuation application after becoming more familiar with the subject matter and have more time to improve the search and analysis; (6) applicants may maintain a continuing application pending to prevent competitors from copying the invention or circumventing the initial patent claims because the courts are less inclined to interpret the scope of invention beyond the literal meaning of the claims, precluding claim scope that once was captured under the doctrine of equivalents; (7) applicants may file continuation applications as an "insurance policy" so that applicants can correct any defects found in the first patent or adjust the claim coverage without surrendering the patent (as in the reissue and reexamination practices); (8) applicants may file continuing applications to build large patent portfolios and attract capital investments; (9) applicants want time to

conduct testing and to reevaluate the claim scope in light of new prior art, market experience, and technology development; (10) for complex technologies, it may take several prosecutions to determine the bounds of patentable subject matter; (11) applicants may want many patents on an invention to strengthen the protection; (12) applicants may file continuing applications to correct errors in the initial prosecution including those made by inexperienced representatives or applicants; and (13) applicants who are in a crowded or highly valuable field need to keep a continuing application pending for the purposes of provoking interference.

Response: The Office recognizes that there are some appropriate reasons for filing multiple continuing applications and requests for continued examination. There are, however, a number of reasons given for multiple continuing applications and requests for continued examination that are not considered appropriate. The changes being adopted in this final rule are tailored to permit applicants to file the initial application, two continuation or continuation-in-part applications, and a request for continued examination in an application family, without any justification. Any applicant who considers this to be insufficient may file an additional continuation or continuation-in-part application or a request for continued examination with a petition showing why the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior filings. Applicants are required to prosecute diligently and to particularly point out and distinctly claim the subject matter which the applicant regards as his or her invention, upon filing the application. If applicant's lack of knowledge of prior art, or lack of diligence during the prosecution of the application, causes unnecessary delay or needless increase in the cost of prosecution before the Office, applicant would be violating his or her duty under § 10.18. See § 10.18(b)(2)(i).

Comment 53: A number of comments argued that many continuing applications and requests for continued examination are caused by inadequate examinations, the final Office action practice, and the examiner production system. The comments provided the following examples: (1) It may take several exchanges between the examiner and applicant before the examiner appears to understand the invention; (2) examiners' lack of experience in the art and patent law; (3) some examiners have difficulty using the English

language in oral and written communications; (4) the Office has large turnover in examining personnel; (5) examiners make too many restriction requirements; (6) examiners want to obtain additional "counts"; (7) examiners make improper rejections; (8) examiners refuse to enter any after-final replies; (9) examiners are not given sufficient time to conduct a proper search and examination in the initial application; (10) examiners did not read the specification and claims; (11) examiners do not adequately consider arguments made by the applicants; (12) examiners make premature final rejections; (13) examiners conduct piecemeal examination; (14) examiners are being overturned by supervisors or quality control; (15) examiners do not indicate allowable claims; (16) examiners do not set forth the rejections clearly in the Office actions; (17) examiners do not apply legal standards consistently; and (18) examiners make new grounds of rejection or cite new art in final Office actions.

Response: The Office provides applicant with procedures to address inadequate examination issues. Applicant should not use the continued examination practice as a substitute for the petition or appeal process. The practice of permitting an unlimited number of continuing applications and requests for continued examination appears to have created lax practices. Applicants should raise any issue of inadequate examination before the examiner and/or the examiner's supervisor. For example, applicants should raise any question as to prematureness of a final rejection before the primary examiner. Applicant may seek review of the examiner's decision on the finality of the Office action by petition under § 1.181, if appropriate. See MPEP §§ 706.07(c) and 1002.02(c). Restriction requirements are also reviewable by petition under § 1.181. Applicants may request an interview with the examiner to ensure that the examiner understands the invention or claims correctly, or to seek clarification of the rejections or Office action. See § 1.133(a)(2). If applicant disagrees with the examiner's rejections, applicant may appeal the rejections to the BPAI and/or request a pre-appeal brief conference, if appropriate.

Comment 54: A number of comments argued that filing continuing applications and requests for continued examination is more efficient and cost-effective in dealing with deficiencies of the examination process (even before a "stubborn examiner") because the factual record is fixed on appeal and the appeal process takes a longer time and

is expensive, especially for independent inventors and small entities. The comments predicted that the rule changes would increase the number of pre-appeal brief conferences, examiner's answers and appeals, and force applicants to appeal applications that are not in condition for appeal (e.g., the record has not been fully developed and unamended claims may be appealed). Several comments pointed out that continuing applications and requests for continued examination help applicants to place the application in better condition for appeal because most examiners refuse to enter the after-final amendments. One comment stated that some applicants might file the appeal simply to preserve pendency. Some of the comments suggested that the Office should wait and see what effect a quicker appeal process would have on the backlog before implementing the rule changes. The comments stated that once applicants appreciate the appeal process changes, more applicants would file appeals rather than continuing applications and requests for continued examination. Furthermore, the comments noted that a study conducted by a firm shows that out of 121 appeal briefs (appeals from January 1, 2004 to March 23, 2006), examiners issued only nine answers, which represents an enormous waste of applicants' time and money. One comment predicted that the BPAI would be quickly overwhelmed and a broken appeal process would create more damage to the examination process than the current problems.

Response: If applicant disagrees with the examiner's rejections, applicants should file an appeal rather than filing a continuation application or a request for continued examination. The appeal process offers a more effective resolution than the filing of a continuation application or a request for continued examination. The pre-appeal brief conference program provides applicant a relatively expeditious and low cost review of rejections by a panel of examiners. If, after the conference, the prosecution is reopened, the applicant will have a further opportunity to prosecute in front of the examiner. Applicant would not need to file an appeal brief. If the Office decides that the application should remain under appeal, it would be more efficient to appeal the rejection to the BPAI by filing an appeal brief rather than delay the appeal by filing a continuation application or a request for continued examination. Furthermore, the pendency of an appeal is relatively short. The current (as of the end of the second quarter of fiscal year 2007)

pendency of a decided appeal was 5.6 months. The pendency of an appeal is the period between the assignment of an appeal number and the mailing date of the decision. In addition, the BPAI has reduced the inventory of pending appeals from 9,201 at the close of fiscal year 1997 to 1,357 at the close of fiscal year 2006. Nevertheless, continuing applications and requests for continued examination as a percentage of total filings have increased as BPAI appeal pendency and inventory of pending appeals has decreased. Applicants should have sufficient opportunity to place the application in condition for appeal during the prosecution of the initial application, two continuing applications, and one request for continued examination in an application family. An applicant who considers this to be insufficient may file any third or subsequent continuation or continuation-in-part applications or second or subsequent requests for continued examination with a petition showing why the amendment, argument, or evidence sought to be entered could not have been previously submitted.

Comment 55: Several comments alleged that the Office has provided no evidence for the assertion that the exchange between applicants and examiners becomes less beneficial and suffers from diminished returns after the initial application. A number of comments also argued that the Office did not provide any investigation or analysis of the frequency with which the value of exchanges between the examiner and applicant decrease after the first continuing application or request for continued examination. A number of comments suggested that continuing applications and requests for continued examination permit additional mutually beneficial interaction between the examiner and applicant because: (1) The examiner and applicant already are familiar with the issues in the prosecution; (2) they give the examiner more time to examine the same subject matter and gain better understanding of the prior art; and (3) they permit applicants multiple opportunities to refine the claims and present additional data or evidence which would result in better quality patents with valid claims and clearly defined subject matter. Several comments argued that the rule changes would not improve public notice and the exchanges between the examiner and applicant because applicants would file multiple parallel applications rather than one single application and the applications would be assigned to

different examiners. Several comments argued that the exchanges between the examiner and applicant would be less efficient and more contentious because applicants would present broader claims and argue rejections more aggressively resulting in higher pendency. Several comments also predicted that applicant would request more interviews which would be more work for both the examiner and applicant. Several comments argued that it is unclear how the exchange between examiners and applicants will be more efficient because there is nothing in the proposal to encourage examiners to be more reasonable and appeals are not more efficient. One comment also argued that the Office is making unexplained assumptions that: (1) The value of a continuing application or a request for continued examination is less than the value of a new application; (2) the changes to continuing applications practice being adopted in this final rule should improve the quality of issued patents, making them easier to evaluate, enforce, and litigate; (3) this small minority of applicants prejudices the public permitting applicants to keep applications in pending status while awaiting developments in similar or parallel technology and then later amending the pending application to cover the developments; and (4) the changes being adopted in this final rule will result in claims issuing faster.

Response: Under this final rule, applicant is permitted to file two continuation or continuation-in-part applications plus one request for continued examination in an application family. These filings will provide sufficient opportunities for applicants to submit amendments, arguments, and evidence. Furthermore, the exchange between applicant and the examiner will be more efficient because applicant can no longer delay the submissions of amendments, argument, and evidence and the examiner will have the information earlier to determine the patentability of the claims. In addition, even if one could argue that additional continuing applications and requests for continued examination are beneficial in the particular application, the marginal value of a third or subsequent continuing application or a second or subsequent request for continued examination vis-à-vis the patent examination process decreases due to the Office resources occupied by the additional continued examination filings for amendments, argument, and evidence that could have been

presented earlier. Nevertheless, an applicant can show on petition that an additional filing is necessary. Finally, the changes being adopted in this final rule require applicant to submit all of the claims that are patentably indistinct in one single application and to identify multiple applications that contain patentably indistinct claims. See §§ 1.75(b) and 1.78(f).

Comment 56: One comment argued that the Office should not impose a limit on the number of continuing applications an applicant may file when the Office can issue any number of rejections and improper final rejections.

Response: In this final rule, the Office has not placed an absolute limit on the number of continued examination filings. Rather, applicant is permitted to file the initial application, two continuing applications, and a request for continued examination in an application family, without any justification, and any third or subsequent continuing application or second or subsequent request for continued examination with a petition and a showing as why the amendment, argument, or evidence sought to be entered could not have been submitted earlier. Applicant may seek review of any improper finality of a rejection by filing a petition under § 1.181, or of any improper rejection by filing a notice of appeal, a request for pre-appeal brief conference, and an appeal brief.

Comment 57: Several comments argued that examiners will have to review larger submissions because applicants will be forced to front-load responses to every Office action with interviews, declarations and other evidence when the attorney's argument alone otherwise might have been sufficient. The comments argued that this would increase pendency. One comment predicted that the rule changes would decrease examiners' production because there would be "more hard cases" and "less easy counts." Several comments stated that the rule changes would require applicant to respond to a first Office action by preparing what would be a *de facto* appeal brief with all of the arguments and evidence because applicant would only file the one permissible continuation or continuation-in-part application or request for continued examination as a last resort after appeal.

Response: Section 1.78 as adopted in this final rule permits an applicant to file two continuing applications plus one request for continued examination in an application family, without any justification. Thus, the changes adopted in this final rule do not require

applicant to respond to a first Office action by preparing what would be a *de facto* appeal brief with all of the arguments and evidence. Nevertheless, the examination will be more efficient when applicant submits a fully responsive reply to each Office action so that the examiner will have the information, including amendments, arguments, and evidence, to determine the patentability sooner rather than later. Even prior to the changes being adopted in this final rule, applicants have been required to file a fully responsive reply to an Office action. See §§ 1.111(b) and (c). A change to the rules of practice that encourages applicants to submit complete, rather than piecemeal, replies will advance prosecution to final disposition with a minimum number of Office actions, continuing applications, and requests for continued examination. Such change streamlines the examination process, thereby benefiting both applicants and the Office.

Comment 58: A number of comments argued that continuation or continuation-in-part applications and requests for continued examination are needed so that applicants can submit prior art that is discovered after the prosecution is closed (e.g., through international search reports or foreign search reports), and amend the claims in view of late newly-discovered art. Several comments suggested that the Office should permit applicants to file a request for continued examination without a petition and showing to submit newly discovered prior art, and art cited by the U.S. International Searching Authority similar to art cited by a foreign patent office, because otherwise applicants would be penalized due to PCT administrative backlogs. One comment sought clarification in the situation where an applicant wishes to withdraw an application from issue to submit new art for consideration and a continuation application has been filed.

Response: Applicant is not required to file a continuation or continuation-in-part application or a request for continued examination in order to submit prior art discovered after the prosecution is closed or an amendment in view of the late discovered art. The Office recently proposed changes to information disclosure statement (IDS) requirements. See *Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 FR 38808 (July 10, 2006), 1309 *Off. Gaz. Pat. Office* 25 (Aug. 1, 2006) (proposed rule) (hereinafter "Information Disclosure Statement Proposed Rule"). The proposed changes

(if adopted) would permit applicant to submit an IDS after a first Office action on the merits, but before the mailing date of a notice of allowability or a notice of allowance under § 1.311, if applicant files the IDS with the certification under § 1.97(e)(1) and a copy of the foreign search report, or an explanation under proposed § 1.98(a)(3)(iv) and a non-cumulative description under proposed § 1.98(a)(3)(v). Applicant would also be permitted to submit an IDS after allowance, but before the payment of the issue fee, if applicant files the IDS with a patentability justification under proposed § 1.98(a)(3)(vi), including any appropriate amendments to the claims. Applicant would be permitted to submit an IDS after the payment of the issue fee if applicant files a petition to withdraw from issue pursuant to § 1.313(c)(1), the patentability justification under proposed § 1.98(a)(3)(vi)(B), and an amendment to the claims. Prior to the effective date of any final rule based upon the Information Disclosure Statement Proposed Rule, applicant may submit an IDS after the close of prosecution with a petition under § 1.183 if the IDS complies with the applicable requirements set forth in the Information Disclosure Statement Proposed Rule for such an IDS.

B. Treatment of Third and Subsequent Continuation or Continuation-In-Part Applications

Comment 59: Several comments supported the rule changes that permit one continued examination filing without any justification. A number of comments, however, suggested that the Office should permit more than one continued examination filing without requiring a petition and showing. The comments suggested the following without a petition and showing: (1) At least two continuation or continuation-in-part applications; (2) at least three continuation or continuation-in-part applications; (3) three to six continued examination filings; (4) three to five applications per application family; (5) only one patent to be issued from a chain of continuation applications; (6) unlimited number of continuation applications coupled with a requirement for a patentability report in the third or subsequent continuation application or a prior art search and compliance with the requirements under 35 U.S.C. 112; (7) two requests for continued examination, but only one continuation or continuation-in-part application; (8) at least one request for continued examination per application; (9) more than one request for continued examination per application; and (10)

two or three requests for continued examination per application. Several comments suggested that the Office should permit more than one continuation or continuation-in-part application if the applications are filed within a reasonable time period (*e.g.*, one to eight years from the earliest filing date claimed). One comment suggested that the Office should permit requests for continued examination filed within three years of the filing date if applicant has filed a petition to make special for accelerated examination. One comment suggested that the Office should permit applicant to file a request for continued examination, but allow the examiner to refuse the request for continued examination if the first action can be made final. One comment suggested that the Office should eliminate all continuing applications except for divisional applications. One comment proposed that the Office should eliminate all continuing applications, but permit requests for continued examination. One comment suggested that the limitation on the number of continued examination filings should not apply to divisional applications and requests for continued examination.

Response: The Office has modified the proposed provisions that permit applicant to file one continuation or continuation-in-part application or request for continued examination without any justification. Under this final rule, applicant may file two continuation or continuation-in-part applications plus one request for continued examination in an application family, without any justification. Applicant may also file any third or subsequent continuation or continuation-in-part application or second or subsequent request for continued examination with a petition and showing. The changes being adopted in this final rule will permit the Office to focus its patent examining resources on examining new applications, and thus reduce the backlog of unexamined applications and improve pendency for all applications. Permitting more than two continuation or continuation-in-part applications and more than one request for continued examination in an application family without any justification would significantly decrease the effectiveness of the changes being adopted in this final rule. These final rule requirements for seeking a third or subsequent continuation or continuation-in-part application will not impact the vast majority of the applications.

A time limit requirement for filing continuing applications and requests for continued examination would not be

desirable because it would encourage applicants to file an unlimited number of continued examination filings before the time period expires. Furthermore, a time limit would preclude an applicant from filing appropriate continued examination filings after the time period expires. Additionally, this suggested strategy would also disproportionately impact applications in certain technologies (*e.g.*, biotechnology) that have long prosecutions.

Requiring a patentability report or a prior art search in a continuation application would not increase efficiency in the examination of the initial application. If applicant submits the information earlier in the initial application, applicant most likely would not need to file a third or subsequent continuing application because the examiner would have all of the relevant information to make the patentability determination in the initial application.

The Office recognizes there are appropriate reasons for filing continued examination filings. As a result, the Office did not place an absolute limit on the number of continued examination filings. If the prior-filed application was subject to a requirement for restriction, applicant may file a divisional application directed to a non-elected invention that has not been examined. The divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. *See* § 1.78(d)(1)(ii). Therefore, the changes being adopted in this final rule appropriately balance the need to reduce the large and growing backlog of unexamined patent applications and make the patent examination process more effective.

Comment 60: Several comments expressed concerns that there would be an added economic burden on applicants, particularly small entities, to pursue additional continued examination filings due to the new petition process, and that the economic burden will effectively be a bar to many applicants. The comments stated that even when an additional continued examination filing is completely justified, applicants will suffer undue hardship and will likely be deterred from even attempting to request any additional continued examination filing because of the expense and time involved to review and prepare the petition. One comment suggested that the petition process under §§ 1.78(d)(1)(vi) and 1.114(g) will have a disparate effect on small entities. Several comments suggested that the

Office should provide an exception for filing additional continued examination filings to applicants who are small entities and those that qualify for financial hardship. One comment further suggested that the Office should provide the exception for five years.

Response: The Office notes the concerns expressed in the public comment regarding the proposed changes to §§ 1.78(d) and 1.114(g) that would permit an applicant to file one continuation application, continuation-in-part application, or request for continued examination, without any justification. The Office has made modifications to the proposed provisions such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Under this final rule, an applicant may also file a divisional application of a prior-filed application for the claims to a non-elected invention that was not examined if the application was subject to a requirement for restriction. The divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. This final rule also permits applicant to file two continuation applications of a divisional application plus a request for continued examination in the divisional application family, without any justification. Applicant may file any additional continuation application or request for continued examination with a petition and showing.

The changes to §§ 1.78(d) and 1.114(g) adopted in this final rule apply to all applicants, regardless of whether they are individuals, small businesses or large multinational corporations. These changes do not disproportionately affect individuals and small businesses. Applicants who seek to file a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination are required to file a petition under § 1.78(d)(1)(vi) or 1.114(g) regardless of their status. The requirements for seeking a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination would only have affected 2.9 percent of the applications or requests for continued examination filed by a small entity in fiscal year 2006. The Office notes that a vast majority of applicants do not file more than two continuation or continuation-

in-part applications and more than one request for continued examination in an application family. Therefore, the \$400 petition fee and the showing requirement will impact only a small minority of applicants.

C. Treatment of Second and Subsequent Requests for Continued Examination

Comment 61: Several comments supported the changes to § 1.114. A number of comments, however, objected to the changes and suggested that the Office should permit applicants to file requests for continued examination without a petition and showing. The comments provided the following reasons: (1) Requests for continued examination are different from continuing applications because requests for continued examination require applicant to advance prosecution and would not cause the Office to issue multiple patents to the same invention; (2) requests for continued examination are not continuation applications, but rather are the same application; (3) requests for continued examination help applicants to deal with deficiencies in the examination process and provide a more efficient, effective and cheaper procedure to advance prosecution and have art considered than the appeal, petition or reissue process; (4) limiting applicants to one request for continued examination without a petition would lead to more filings of continuation applications and petitions; (5) due to the changes in § 1.75, the Office would issue more final Office actions with new grounds of rejection, which would necessitate the filing of more requests for continued examination; and (6) applicants would file more appeals, and thus the pendency of applications would increase.

Response: The Office has modified the proposed provisions to provide that an applicant may file a request for continued examination in an application family, without a petition and showing. An application family includes the initial application and its continuation or continuation-in-part applications. Under this final rule, applicant may also file a request for continued examination in a divisional application family, without a petition and showing. A divisional application family includes the divisional application and its continuation applications. The provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. Therefore, the filing of a request for continued examination does not preclude an applicant from filing two continuation or continuation-in-part applications.

Similarly, the filing of a continuation or continuation-in-part application does not preclude an applicant from filing a request for continued examination.

When applicant files a request for continued examination, the prosecution of the application is reopened and the examiner conducts another substantive examination on the claims present in the application. Consequently, similar to continuation or continuation-in-part applications, requests for continued examination divert the Office's patent examining resources from the examination of new applications and contribute to the backlog of unexamined applications. The request for continued examination practice should not be used as a substitute for the appeal, petition or reissue process. If the applicant disagrees with the examiner's rejections, then the applicant should pursue the appeal process as a means to more efficiently resolve the disagreement.

In addition, under the Office's new optional streamlined continuation procedure, an applicant may request that a continuation application be placed on an examiner's amended (Regular Amended) docket (see discussions of §§ 1.78(d)(1)(i) and 1.114) which would be picked up for action faster than an application placed on the examiner's new continuing application (New Special) docket. By requesting that the two continuation applications permitted under § 1.78(d)(1)(i) be treated under the optional streamlined continuation application procedure, an applicant may obtain the benefits of faster processing similar to having a second and third request for continued examination without a petition under § 1.114(g).

Comment 62: One comment sought clarification on whether the changes to §§ 1.78 and 1.114 being adopted in this final rule apply to reissue applications.

Response: The changes to §§ 1.78 and 1.114 being adopted in this final rule apply to reissue applications. Under this final rule, applicant may file two reissue continuation applications plus a request for continued examination in the reissue application family, without any justification. Benefit claims under 35 U.S.C. 120, 121, or 365(c) in the application for patent that is being reissued will not be taken into account in determining whether a continuing reissue application claiming the benefit under 35 U.S.C. 120, 121, or 365(c) of the reissue application satisfies one or more of the conditions set forth in §§ 1.78(d)(1)(i) through 1.78(d)(1)(vi). For example, even if the application for the original patent was a second continuation application, applicant may still file two reissue continuation

applications. However, an applicant may not use the reissue process to add to the original patent benefit claims under 35 U.S.C. 120, 121, or 365(c) that do not satisfy one or more of the conditions set forth in §§ 1.78(d)(1)(i) through 1.78(d)(1)(vi) to the original patent, if the application for the original patent was filed on or after November 1, 2007.

Comment 63: One comment suggested that the examiner should not make any new rejections in a request for continued examination, unless the amendment to the claims raises new issues.

Response: When applicant files a request for continued examination in compliance with § 1.114, the prosecution of the application is reopened and the examiner will consider the amendment, argument, or evidence submitted by the applicant. The examiner will conduct another substantive examination, consistent with providing “for the continued examination of application” under 35 U.S.C. 132(b). Limiting the examiner’s ability to conduct a patentability determination after the filing of a request for continued examination would not result in efficiency in the examination process.

Comment 64: One comment argued that it would be inconsistent to permit the filing of a request for continued examination in a prior-filed application after a continuation application is filed, but to not permit the filing of a continuation application of an application that has a request for continued examination filed therein. Another comment suggested that the Office should permit an applicant to file a continuation application even though a request for continued examination had been filed in the prior-filed application.

Response: The Office has modified the proposed provisions to provide that an applicant may file a request for continued examination in an application family, without a petition and showing. The provisions of § 1.78(d)(1) are independent of the provisions of § 1.114. Therefore, the filing of a request for continued examination does not preclude an applicant from first filing two continuation or continuation-in-part applications. Likewise, the filing of a continuation or continuation-in-part application does not preclude an applicant from first filing a request for continued examination. Put differently, under this final rule, applicant may file a continuation application of an application in which a request for continued examination has already been filed. Applicant may also file a request

for continued examination in a prior-filed application after a continuation application has been filed.

D. Petitions Related to Additional Continuation Applications, Continuation-In-Part Applications, and Requests for Continued Examination

Comment 65: A number of comments were critical of the showing requirement set forth in §§ 1.78(d)(1) and 1.114. One comment argued that the required showing is a *per se* limit on the number of continuation or continuation-in-part applications and requests for continued examination. Several comments stated that the standard under §§ 1.78(d)(1) and 1.114 is a hindsight standard. The comments argued that except for rare instances when evidence was not in existence prior to filing the additional continuing examination filing, the Office could almost always conclude, in hindsight, that the amendment, argument, or evidence sought to be entered could have been previously submitted. One comment argued that the showing under §§ 1.78(d)(1) and 1.114(g) is too stringent and unrealistic given the practicalities of conventional and reasonable patent prosecution practice and the interests of patent applicants. Several other comments described the showing as exceptionally high, onerous, impossible to meet, restrictive, and ambiguous. Furthermore, several comments asserted that the rule changes required applicants to be aware of all possible prior art. Several other comments stated that the required showing set forth in §§ 1.78(d)(1) and 1.114 appears difficult to meet for any amendment submitted with an application that is not a continuation-in-part application, indicating that it is hard to imagine how one would prove that an amendment or argument “could not have been submitted” in the absence of new matter. One comment objected to the required showing under §§ 1.78(d)(1) and 1.114 because the purpose of filing an additional continuation or continuation-in-part application or a request for continued examination may be to do something other than present a new argument, evidence or amendment, such as protect a different aspect of the invention revealed by research and development subsequent to an initial application filing. One comment stated that given enough time and effort an applicant will almost always be able to come up with some reason why the amendment, argument, or evidence could not have been previously submitted as required by §§ 1.78(d)(1) and 1.114 and that this requirement merely adds a layer of

bureaucracy. One comment in support of the showing under §§ 1.78(d)(1) and 1.114 stated that it is a sensible compromise that does not ban additional continued examination filings, but requires applicants in essence to show good cause for additional continued examination filings. Several comments in support of the showing stated that the proposed rules accommodate the legitimate uses of continuations, limit abuses that can harm the competitive process, and promote the patent system’s ability to provide incentives to innovate by reducing pendency.

Response: The Office notes the concerns expressed in the public comment regarding the proposed provisions that would require a petition and showing if an applicant files more than one continued examination filing (a continuation application, a continuation-in-part application, or a request for continued examination). The Office has made modifications to these proposed changes such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification. Under this final rule, an applicant may also file a divisional application of an application for the claims to a non-elected invention that was not examined if the application was subject to a requirement for restriction. The divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. This final rule also permits applicant to file two continuation applications of a divisional application plus a request for continued examination in the divisional application family, without any justification. Applicant may file any additional continuation application or request for continued examination with a petition and showing. Therefore, given the multiple opportunities for applicant to submit amendments, arguments, or evidence, it is appropriate to require an applicant to justify why an amendment, argument, or evidence sought to be entered could not have been submitted earlier when filing any third or subsequent continuation application, continuation-in-part application, or second or subsequent request for continued examination. The Office considers the standard set forth in §§ 1.78(d)(1)(vi) and 1.114(g) to be an appropriate balance of the interests of applicants and the need for a better

focused and effective examination process to reduce the large and growing backlog of unexamined applications.

Applicants and practitioners have a duty to refrain from submitting an application or other filing to cause unnecessary delay or needless increase in the cost of prosecution before the Office. See § 10.18(b)(2). Applicants also have a duty throughout the prosecution of an application to make a *bona fide* attempt to advance the application to final agency action. See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 49, 1302 *Off. Gaz. Pat. Office* at 1319. Applicant should be prepared to particularly point out and distinctly claim what the applicant regards as his or her invention. Furthermore, the examination process is more efficient and the quality of the patentability determination will improve when applicant presents the desired claims, amendments, arguments and evidence as early as possible in the prosecution. The changes to §§ 1.78 and 1.114 in this final rule do not require an applicant to be aware of all possible prior art to meet the showing under §§ 1.78(d)(1)(vi) and 1.114(g), but applicant is required to conduct a prior art search for filing an examination support document under § 1.265. Nor do these changes add to applicant's existing duties under § 1.56(a) to disclose to the Office all information known to the applicant to be material to patentability, and under 37 CFR Part 10.

Comment 66: One comment asserted that the Office will not achieve its goal of reducing the number of filings of continuation applications because an applicant could easily show why the amendment, argument, or evidence could not have been previously submitted when the subject matter of the claims in the continuation application is different from the subject matter of the claims of the initial application.

Response: The submission of an amendment to the claims or new claims to different subject matter alone will not be sufficient to meet the showing requirement under § 1.78(d)(1)(vi). Applicant must provide a satisfactory showing that the amendment, argument, or evidence sought to be entered could not have been previously submitted during the prosecution of the initial application, two continuation applications, and the request for continued examination.

Comment 67: One comment stated that the required showing under §§ 1.78(d) and 1.114 might have far-

reaching implications that extend outside the patent process. Several comments expressed concerns that the showing may require applicants to disclose highly sensitive business information such as business strategies, and to alert their competitors as to how the applicants plan to gain a competitive edge. The comments further expressed concerns that the petition procedure may also invoke attorney-client privilege.

Response: Applicants or patent owners often present sensitive business information to the Office, such as a showing of unavoidable delay in a petition to revive under § 1.137(a) or a petition to accept late payment of a maintenance fee under § 1.378(b). The Office has procedures in place for applicants and patent owners to submit trade secrets, proprietary material, and protective order material and to prevent unnecessary public disclosure of the material. See MPEP §§ 724–724.06. If it is necessary for an applicant to disclose sensitive business information to the Office to meet the showing under § 1.78(d)(1)(vi) or 1.114(g), applicant may submit the information in compliance with the procedures set forth in MPEP §§ 724–724.06 (e.g., the information must be clearly labeled as such and be filed in a sealed, clearly labeled, envelope or container).

Comment 68: One comment stated that the petitions under §§ 1.78(d)(1) and 1.114 would be scrutinized in court, creating a substantial increase in time and resources devoted to litigating and enforcing otherwise valid patent rights. One comment expressed concern that the petitions under §§ 1.78(d)(1) and 1.114 are unlikely to be granted and are likely to be the subject of an attack in litigation. A number of comments asserted that applicants would be subject to a higher potential for allegations of inequitable conduct. Additionally, one comment argued that the proposed rule changes would increase the frequency of malpractice litigation.

Response: The rules adopted in this final rule require applicants to prosecute their applications with reasonable diligence and foresight. The submission of a showing as to why an amendment, argument or evidence sought to be entered could not have been submitted earlier does not expose an applicant to a greater risk of inequitable conduct or litigation. The failure to disclose material information, or an affirmative misrepresentation of a material fact or submission of false material information or statements, coupled with an intent to deceive or mislead the Office, constitutes

inequitable conduct. The simple submission of a showing as to why an amendment, argument or evidence sought to be entered could not have been submitted earlier does not by itself raise such intent. If an applicant acts with candor and good faith in dealing with the Office, there should be no increased risk that the applicant will be accused of inequitable conduct. Similarly, if patent practitioners abide by the standards of professional conduct expected of practitioners in their relationships with their clients, and comply with the requirements of the patent statutes and rules, there should be no reason for increased exposure to malpractice suits.

Comment 69: Several comments suggested that the Office should adopt an alternate standard for additional continued examination filings in place of the standard set forth in §§ 1.78(d)(1) and 1.114. Some of the comments suggested the following alternatives: (1) A reasonable diligence standard; (2) a certification by a practitioner that it is necessary for the inventor to be adequately protected; (3) the “unduly interferes” standard as set forth in the former § 1.111(b); (4) a requirement that the submission be a *bona fide* attempt to advance prosecution; (5) an explanation of the need for the continued examination filing; (6) a reasonable justification standard; (7) a reasonable under the circumstances standard; or (8) a good cause standard. One of the comments stated that a good cause standard would not place an undue burden on the Office or prejudice the public. Additionally, the comment requested that an application filed for good cause should not count toward the single continued examination filing as a matter of right.

Response: The Office considers the standard that the amendment, argument or evidence sought to be entered could not have been previously submitted set forth in §§ 1.78(d)(1)(vi) and 1.114(g) appropriate for an additional continued examination filing. The standard set forth in §§ 1.78(d)(1)(vi) and 1.114(g) as adopted in this final rule (“a showing that the amendment, argument, or evidence sought to be entered could not have been submitted [earlier]”) is more definite than the alternatives suggested in the comments (e.g., “good cause” and “reasonable under the circumstances”) and other standards set forth in the patent statutes (see e.g., *Smith v. Mossinghoff*, 671 F.2d 533, 538, 213 U.S.P.Q. 977, 982 (DC Cir. 1982) (noting the absence of guidance concerning the meaning of the term “unavoidable” in 35 U.S.C. 133)). The comments do not provide an explanation as to why any of

these alternatives would be a more effective standard or more definite. Furthermore, §§ 1.78(d)(1) and 1.114(g) as adopted in this final rule do not set an absolute limit on the number of continued examination filings.

Applicants are permitted to file two continuation or continuation-in-part applications and one request for continued examination without any justification. Applicants are also permitted to file any third or subsequent continuation or continuation-in-part application or second or subsequent request for continued examination with a petition and showing. If an amendment, argument, or evidence could have been submitted during the prosecution of the initial application, two continuing applications, or a request for continued examination, applicant must present such submission earlier rather than wait to submit it later in a third or subsequent continuation or continuation-in-part application or in a request for continued examination. Thus, the required showing is an appropriate standard.

Finally, as discussed further in this final rule, the Office may grant relief “in an extraordinary situation” in which “justice requires” even if the situation does not technically meet the standard that the amendment, argument or evidence sought to be entered could not have been previously submitted. *See* § 1.183. The Office, however, does not anticipate granting petitions under § 1.78(d)(1)(vi) on a basis other than a showing that the amendment, argument or evidence sought to be entered could not have been previously submitted.

Comment 70: Several comments suggested that the changes to § 1.78 should only be temporary so that the Office may assess the impact of the changes before adopting the rule. One comment also suggested that if the Office adopts the rule changes, the Office should eliminate the changes once the backlog decreases.

Response: Unrestricted continued examination filings and duplicative applications that contain patentably indistinct claims are significantly hindering the Office’s ability to examine new applications to such an extent that it is necessary for the Office to adopt and implement the changes to these practices. After the implementation of the changes being adopted in this final rule, the Office will re-evaluate the rules of practice to determine what, if any, additional changes are necessary.

Comment 71: Several comments suggested that §§ 1.78(d)(1) and 1.114 should be revised from “a showing as to why the amendment, argument, or evidence presented could not have been

previously submitted” to “a showing as to why the new claim, amendment, argument, or evidence presented could not have been previously submitted” to resolve any potential ambiguity in the rules.

Response: The Office notes the comments’ concern for ambiguity in the language of the rules. The phrase, “a showing * * * that **the amendment**, argument, or evidence sought to be entered could not have been submitted” (emphasis added) inherently encompasses a showing as to why a new claim could not have been previously submitted. A new claim presented in a continuing application is considered to be an amendment to the claims of the prior-filed application. Thus, by using the word “amendment” in the standard of §§ 1.78(d)(1)(vi) and 1.114(g), the Office intended to capture new claims sought to be introduced in a third or subsequent continuation or continuation-in-part application or second or subsequent request for continued examination.

Comment 72: One comment recommended that the Office should only require a petition and showing if the claims are presented more than two years after the earliest filing date claimed.

Response: Sections 1.78(d)(1) and 1.114 as adopted in this final rule provide applicant sufficient opportunities to present claims during the prosecution of the initial application, two continuing applications, and a request for continued examination in an application family without a petition under § 1.78(d)(1)(vi) or 1.114(g). The prosecution of these applications and the request for continued examination, most likely, would extend more than two years from the earliest claimed filing date. Therefore, the suggestion, if adopted, would likely increase the number of applicants who would be required to file a petition and showing.

Comment 73: Several comments proposed an exception to the rule changes to permit applicant to file a continuing application or a request for continued examination as a matter of right, without requiring a petition and showing, if the prior application is abandoned prior to examination.

Response: As suggested, the Office has made modifications to the proposed provisions to provide that an applicant may file a continuation or continuation-in-part application without any justification in certain situations in which the prior-filed application was abandoned prior to examination. Section 1.78(d)(1)(v) as adopted in this final rule provides that if an applicant

files a continuation or continuation-in-part application to correct informalities rather than completing an application for examination under § 1.53 (*i.e.*, the prior-filed application became abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f)), the applicant may file “one more” continuation or continuation-in-part application without a petition and showing under § 1.78(d)(1)(vi). Thus, applicant may file a continuation or continuation-in-part application to correct informalities rather than completing an application for examination under § 1.53. The prior-filed nonprovisional application, however, must be entitled to a filing date and have paid therein the basic filing fee within the pendency of the application. *See* § 1.78(d)(2).

Comment 74: Several comments suggested the Office should include exceptions to the petition requirement of §§ 1.78(d)(1) and 1.114 to permit applicant to file a continuing application or a request for continued examination as a matter of right, without requiring a petition and showing, in the following situations: (1) Some of the claims in the prior-filed application have been allowed and the continuation application contains only claims that were rejected in the prior-filed application; (2) the continuation application contains claims to an unclaimed invention disclosed in the prior-filed application; (3) the continuing application is claiming an independent and distinct invention; (4) the continuing application claims species or subgenus that falls within a generic claim that has been allowed or issued in one of the prior-filed applications; (5) the continued examination filing is filed for the purposes of submitting newly discovered prior art or amendments or evidence in view of the newly discovered prior art; (6) the continued examination filing is filed after an unsuccessful appeal; (7) a divisional application of an application that was subject to a restriction requirement is filed for the purposes of claiming the non-elected inventions; (8) the continuation application includes claims that were canceled in the prior-filed application; (9) the applicant certifies that the filing is done in good faith to advance prosecution and without deceptive intent; (10) the continued examination filing is filed for submitting evidence or an amendment to overcome a final rejection; (11) a continuation or continuation-in-part is filed to overcome a lack of utility rejection; (12) the continued

examination filing is filed to submit a declaration under § 1.131 or 1.132; (13) the continued examination filing is filed to submit data or other evidence not available for submission in the parent application to obviate a rejection under 35 U.S.C. 101 or 112, ¶ 1 (e.g., for lack of utility or enablement); (14) the continued examination filing is filed to respond to an examiner's request for additional information; (15) the continued examination filing is filed to respond to a new ground of rejection; (16) the prior-filed application was abandoned in favor of a continuing application that is filed using the Office electronic filing system; and (17) a request for continued examination is filed via the Office electronic filing system. One comment stated that if Congress does not eliminate 35 U.S.C. 135(b)(2), the need to copy claims from published applications should be exempt from the limit of continued examination filings in an application as a matter of right.

Response: The Office notes the concerns expressed in the public comment regarding the proposed changes to §§ 1.78(d)(1) and 1.114 that would have required applicant to file a petition and showing for a second or subsequent continuation or continuation-in-part application or request for continued examination. The Office has modified these proposed changes such that this final rule permits an applicant to file two continuation applications or continuation-in-part applications, plus a single request for continued examination in an application family, without any justification.

Other than the situations provided in §§ 1.78(d)(1)(iv) and (d)(1)(v), this final rule permits that a third or subsequent continuing application or any second or subsequent request for continued examination to be filed with a petition and a showing as to why the amendment, argument, or evidence sought to be entered could not have been previously submitted. Sections 1.78(d)(1)(iv) and (d)(1)(v) provide that applicant may file "one more" continuation or continuation-in-part application without a petition and showing in certain situations. Specifically, § 1.78(d)(1)(iv) pertains to the situation where an applicant files a bypass continuation or continuation-in-part application rather than paying the basic national fee (entering the national stage) in an international application in which a Demand for international preliminary examination (PCT Article 31) has not been filed, and the international application does not claim the benefit of any other nonprovisional

application or international application designating the United States of America. See the discussion of § 1.78(d)(1)(iv). Section 1.78(d)(1)(v) pertains to the situation where an applicant files a continuation or continuation-in-part application to correct informalities rather than completing an application for examination under § 1.53. See the discussion of § 1.78(d)(1)(v).

The Office will decide petitions under §§ 1.78(d)(1)(vi) and 1.114(g) based on their substantive argument and the facts in the record and apply the standard in a consistent manner. There are no situations that will result in a *per se* or *pro forma* grant of a petition under § 1.78(d)(1)(vi) or 1.114(g). Whether specific situations would be a sufficient showing under § 1.78(d)(1)(vi) or 1.114(g) is discussed in the responses to subsequent comments.

Comment 75: Several comments opposed the \$400 fee for filing a petition under §§ 1.78(d)(1) and 1.114. The comments indicated that the proposed petition fee of \$400 is unnecessarily high, especially in view of the filing fees. Furthermore, the comments argued that it is unfair to require the submission of a costly fee and a time-consuming petition regardless of the reason for filing the continuing application or request for continued examination. One other comment stated that the proposed petition fee does not cover the amount of work required to determine if applicant's showing is sufficient to meet the requirements in §§ 1.78(d)(1) and 1.114. Another comment questioned why an applicant must pay a petition fee of \$400 when filing an additional continuation-in-part application simply to add new matter.

Response: The Office considers \$400 to be an appropriate fee for filing a petition under § 1.78(d)(1)(vi) or 1.114(g). 35 U.S.C. 41(d) authorizes the Director to establish fees to recover the estimated average cost to the Office for handling, reviewing and deciding petitions. The Office has determined that the average cost to the Office for handling, reviewing and deciding the petitions under §§ 1.78(d)(1)(vi) and 1.114(g) will be at least \$400. As previously discussed, applicants most likely will be able to avoid the requirements for filing a petition and the required fee if applicants diligently prosecute applications (including the continuing applications and a request for continued examination permitted under §§ 1.78(d)(1) and 1.114(f) without any petition). If an applicant desires to file an application simply to claim new subject matter, the applicant may file a new application (rather than a

continuation-in-part application) without claiming the benefit of the prior-filed applications and avoid paying the \$400 petition fee. As discussed previously, claims to new subject matter will not be entitled to any benefit of the prior-filed application that does not provide support under 35 U.S.C. 112, ¶ 1, for the claimed subject matter and the patent term of any resulting patent of the continuation-in-part application would be measured from the filing date of the prior-filed application.

Comment 76: One comment requested that the Office waive the requirement for a petition fee if applicant submits new art from a foreign search report or related application or files an amendment in response to new arguments made by the examiner.

Response: A petition, the appropriate showing, and the fee set forth in § 1.17(f) are required under § 1.78(d)(1)(vi) or 1.114(g) when applicant files a third or subsequent continuing application or a second or subsequent request for continued examination regardless of the reason for such a filing. In addition, a request to submit new art from a foreign search report or related application is not likely to be a sufficient showing under § 1.78(d)(1)(vi) or 1.114(g) (see discussion relating to the filing of continuing applications and requests for continued examination to obtain consideration of an information disclosure statement). Likewise, the mere fact that the examiner made new arguments or a new ground of rejection in a final Office action would not be considered a sufficient showing. The Office will decide each petition on a case-by-case basis focusing on whether the new ground of rejection in the final Office action could have been anticipated by the applicant.

Comment 77: Several comments stated that there is no public notice of the criteria the Director will apply to meet the required showing under § 1.78(d)(1) or 1.114. A number of comments sought clarification on what type of showing under § 1.78(d)(1) or 1.114 would be necessary to permit the filing of an additional continuing application or request for continued examination. A number of comments specifically sought clarification of the phrase, "could not have been previously submitted," in §§ 1.78(d)(1) and 1.114 regarding the satisfactory showing needed to be permitted to file an additional continuing application or request for continued examination. A number of other comments suggested that prior to the implementation of the final rule, the Office should publish

more specific guidelines such as a non-exclusive set of examples that would constitute a sufficient showing under §§ 1.78(d)(1) and 1.114. In addition, several comments requested that the Office provide an opportunity for public comment on the suggested guidelines.

Response: As discussed previously, the standard set forth in §§ 1.78(d)(1)(vi) and 1.114(g) as adopted in this final rule (“a showing that the amendment, argument, or evidence sought to be entered could not have been submitted [earlier]”) is more definite than the alternatives suggested in the comments (e.g., “good cause” and “reasonable under the circumstances”) and other standards set forth in the patent statutes (see e.g., *Smith v. Mossinghoff*, 671 F.2d 533, 538, 213 U.S.P.Q. 977, 982 (D.C. Cir. 1982) (noting the absence of guidance concerning the meaning of the term “unavoidable” in 35 U.S.C. 133)). If an amendment, argument or evidence could be submitted during the prosecution of the initial application, two continuing applications, and a request for continued examination in an application family, applicant must present such an amendment, argument or evidence earlier rather than wait to submit it later in an additional continuing application or request for continued examination. Applicants should not rely upon the availability of additional continuing applications or requests for continued examination in prosecuting an application. The Office will determine on a case-by-case basis whether the applicant’s showing as to why the amendment, argument or evidence sought to be entered could not have been submitted earlier is satisfactory. In addition to the showing submitted by the applicant, the Office may review the prosecution history of the initial application and the prior continuing applications or require additional information from the applicant in deciding a petition. The following are some factors that the Office may consider when deciding whether to grant a petition under § 1.78(d)(1)(vi) or 1.114(g): (1) Whether applicant should file an appeal or a petition under § 1.181 (e.g., to withdraw the finality of an Office action) rather than a continuing application or request for continued examination; (2) the number of applications filed in parallel or serially with substantially identical disclosures; and (3) whether the evidence, amendments, or arguments are being submitted with reasonable diligence.

With respect to the first factor (whether applicant should be filing an appeal or a petition under § 1.181 rather than a continuing application or request

for continued examination), if the showing under § 1.78(d)(1)(vi) or 1.114(g) relates to an issue that should be petitioned or appealed, the Office will likely not grant the petition for an additional continuing application or request for continued examination. Applicant should address any issues pertaining to inadequate examination by seeking review via a petition under § 1.181 or an appeal, rather than by filing a continuing application or request for continued examination.

If the disagreement between the examiner and applicant is procedural in nature (e.g., an objection), then applicant should file a petition under § 1.181. For example, an applicant should file a petition under § 1.181 to request the withdrawal of the finality of an Office action when the finality was premature, or to review the examiner’s refusal to enter an after-final amendment. The Office will likely not grant a petition under § 1.78(d)(1)(vi) or 1.114(g) if applicant argues only that an amendment after final rejection should have been entered in the prior-filed application because the final was premature. Applicant should have addressed the non-entry in the prior-filed application and not later in a petition under § 1.78(d)(1)(vi) or 1.114(g) for a continuing application or request for continued examination. If the issue goes to the merits of a rejection, applicant should file an appeal to the BPAI under 35 U.S.C. 134 and § 41.31.

With respect to the second factor (the number of applications filed in parallel or serially with substantially identical disclosures), the higher the number of applications with identical or substantially identical disclosures or the higher the number of applications in the chain of prior-filed copending applications, the more opportunities applicant had to present the amendment, argument or evidence. Accordingly, a petition under § 1.78(d)(1)(vi) or 1.114(g) is less likely to be granted.

With respect to the third factor (whether the evidence, amendments, or arguments are being submitted with reasonable diligence), the Office will focus on whether the evidence or data submitted with the petition to meet the showing under § 1.78(d)(1)(vi) or 1.114(g) was presented in a reasonably diligent manner. This will take into account the condition of the application at the time of examination (e.g., whether the initial application was in proper form for examination by the time of the first Office action in the initial application or whether it was necessary to first issue Office actions containing

rejections under 35 U.S.C. 112 or objections to have the application placed in proper form for examination), the consistency of the Office’s position during prosecution (e.g., whether applicant received wholly new prior art rejections versus prior art rejections slightly modified to address the amendments), and the earnestness of the applicant’s efforts to overcome outstanding rejections (e.g., whether replies fully addressed all of the grounds of rejection or objection in the Office actions, or whether amendments or evidence were submitted only when arguments were failing to persuade the examiner).

Comment 78: One comment sought clarification as to whether a petition under § 1.78(d)(1) would be available for “involuntary” divisional applications. Another comment suggested an applicant should be permitted to file any divisional application in response to a restriction requirement.

Response: The Office notes the concerns expressed in the public comment regarding the proposed changes to § 1.78(d)(1)(ii). The Office has modified this provision relative to the proposed changes such that § 1.78(d)(1)(ii) as adopted in this final rule does not require a divisional application to be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. Under this final rule, applicant may file, without any justification, a divisional application containing only claims directed to a non-elected invention that has not been examined if the prior-filed application was subject to a requirement for restriction (an “involuntary” divisional application”). Applicant may also file two continuation applications and a request for continued examination in the divisional application family, without any justification. Furthermore, applicant may file a third or subsequent continuation application or a second or subsequent request for continued examination with a petition and showing.

Comment 79: Several comments sought clarification on whether the Office will grant a petition under § 1.78(d)(1) for filing a divisional application of an application that was subject to a restriction requirement for the purposes of claiming the non-elected inventions.

Response: As previously discussed, the Office has modified the provisions of § 1.78(d)(1)(ii) relative to the proposed changes. In this final rule, § 1.78(d)(1)(ii) does not require a divisional application to be filed during

the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. This final rule provides that an applicant may file a divisional application directed to each non-elected invention that has not been examined if the prior-filed application is subject to a requirement for restriction. Section § 1.78(d)(1)(iii) as adopted in this final rule also permits applicant to file two continuation applications of a divisional application, plus a request for continued examination in the divisional application family, without any justification. Furthermore, applicant may file an additional continuation application or request for continuation examination with a petition and showing. Under this final rule, applicant should have sufficient time to file a divisional application for claiming a non-elected invention. Therefore, the Office will most likely not grant a petition under § 1.78(d)(1)(vi) to permit an applicant to file a divisional application directed to a non-elected invention.

Comment 80: One comment suggested a petition under § 1.78(d)(1) should be granted when an applicant needs an additional continuing application to partition the claims in the prior-filed application, such that a terminal disclaimer applies only to some but not all claims in the prior-filed application. The comment alternatively suggested changing the regulations to allow the filing of a terminal disclaimer for selected claims.

Response: This final rule permits applicant to file two continuation or continuation-in-part applications plus a request for continued examination in an application family, without justification. Therefore, applicant may use one of the two permitted continuation or continuation-in-part applications to partition the claims such that a terminal disclaimer applies to the prior-filed application but does not apply to the continuation application. Notably, applicant may avoid this situation by presenting all of the patentably indistinct claims in a single application. As discussed previously, multiple applications with patentably indistinct claims divert the Office's patent examining resources from the examination of new applications. Applicant should submit all patentably indistinct claims in a single application. See §§ 1.75(b)(4) and 1.78(f). Under this final rule, applicant must identify such multiple applications with patentably indistinct claims to the Office and assist the Office in resolving double patenting issues early in the prosecution. In the

situation in which an application contains at least one claim that is patentably indistinct from at least one claim in another application, the Office will treat the claims in both applications as being present in each of the applications for the purposes of determining whether each application exceeds the five independent claim and twenty-five total claim threshold under § 1.75(b). See the discussion of § 1.75(b)(4). Accordingly, the Office is not likely to grant a petition for the sole purpose of partitioning claims to avoid a terminal disclaimer.

Additionally, a disclaimer of a terminal portion of the term of an individual claim, or individual claims, is not allowed by statute. 35 U.S.C. 253 provides that "any patentee or applicant may disclaim or dedicate to the public * * * any terminal part of the term, of the **patent** granted or to be granted." (Emphasis added.) Therefore, under 35 U.S.C. 253, a terminal disclaimer must be of a terminal portion of the term of the entire patent and cannot be applied to selected claims as advocated in the comment.

Comment 81: Several comments asserted that an applicant filing an additional continuation-in-part application would be able to argue successfully that the amendment or argument could not have been previously submitted because the subject matter was not present at the time of filing the initial application. Thus, the proposed rules would force these applicants to file a *pro forma* petition.

Response: The mere fact that the subject matter was not present at the time of filing the prior-filed application would not be a sufficient showing under § 1.78(d)(1)(vi). The Office will decide these petitions on a case-by-case basis based on the prosecution history of the prior-filed application as well as the records of the continuation-in-part application. The Office will consider the showing of why the new subject matter sought to be entered could not have been previously submitted in the prior-filed application. The Office will also consider the amendment including any new claims to determine whether the claims in the continuation-in-part application are directed to the new subject matter or mainly to the subject matter disclosed in the prior-filed application. For example, if the new subject matter is not being claimed in the continuation-in-part application, but merely being added to circumvent the rule, the Office will not grant the petition. Furthermore, 35 U.S.C. 120 requires that the prior-filed application disclose the subject matter of at least

one claim of the later-filed application in the manner provided by 35 U.S.C. 112, ¶ 1, for the later-filed application to actually receive the benefit of the filing date of the prior-filed application. Thus, any claim in the continuation-in-part application that is directed to the subject matter not disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application would be entitled only to the actual filing date of the continuation-in-part application (not the filing date of the prior-filed application), and subject to prior art based on the actual filing date of the continuation-in-part application. Applicant should not claim the benefit of the prior-filed application if all of the claims in the continuation-in-part application are directed to the new subject matter. The continuation-in-part application would not be entitled to the benefit of the filing date of the prior-filed application, and the term of any patent resulting from the continuation-in-part application will be measured under 35 U.S.C. 154(a)(2) from the filing date of the prior-filed application. That is, applicant would not receive any benefit of the earlier application but would have a patent term that is measured from the filing date of the earlier application. If there are any claims in the continuation-in-part application that are directed solely to subject matter disclosed in the prior-filed application, applicant must submit those claims in the prior-filed application rather than filing a continuation-in-part application unless applicant provides a showing as to why these claims could not have been previously submitted.

Comment 82: Several comments requested that the Office permit an applicant to file an additional continuing application or request for continued examination when the applicant indicates why the new invention could not otherwise be protected using another type of application, such as a reissue application or a reexamination proceeding. These comments also requested that the Office permit an additional continuing application or an additional request for continued examination that contains claims broader than in the previous application to which priority is claimed and contain claims not subject to a double patenting rejection.

Response: The Office will likely not grant such a petition. Applicant may file a reissue application under 35 U.S.C. 251 or a reexamination proceeding, if appropriate, to submit claims with different scope. A desire to avoid the requirements governing reissue

applications or reexamination proceedings would not be a sufficient showing under § 1.78(d)(1)(vi) or 1.114(g).

Comment 83: One comment sought clarification on whether the required showing under §§ 1.78(d)(1) and 1.114 will preclude explanations that are permitted when filing a reissue application. A further comment stated the required showing under §§ 1.78(d)(1) and 1.114 is greater than the showing required to file a reissue application.

Response: This final rule permits applicant to file two continuation or continuation-in-part applications plus one request for continued examination in an application family, without any justification. Applicant may also file a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination with a petition and showing that the amendment, argument, or evidence sought to be entered could not have been submitted previously. As previously discussed, if an amendment, argument, or evidence could have been submitted during the prosecution of the initial application, two continuation or continuation-in-part applications or a request for continued examination, applicant must submit the amendment, argument or evidence in one of these filings, rather than in a third or subsequent continuing application or second or subsequent request for continued examination to ensure that applicant advances the prosecution to final action and does not impair the ability of the Office to examine new applications.

Under 35 U.S.C. 251, applicant may file a reissue application to correct an error in the patent which was made without any deceptive intent, where, as a result of the error, the patent is deemed wholly or partly inoperative or invalid. See MPEP section 1402. The required showing under §§ 1.78(d)(1)(vi) and 1.114(g) is different than the explanation required for filing a reissue application. The showing under §§ 1.78(d)(1)(vi) and 1.114(g) does not require an error made without any deceptive intent and does not require as a result of the error, the patent to be deemed wholly or partly inoperative or invalid. If it is more appropriate for applicant to file a reissue application, applicant should file a reissue application under 35 U.S.C. 251 rather than filing a continuing application.

Comment 84: Several comments suggested that if the Office permits applicant to provide additional evidence of unexpected results with the filing of an additional continued

examination filing, then the experimentation leading to the evidence must have been conducted diligently and commenced within six months of the filing of the initial application. Another comment further suggested evidence that an applicant had not previously learned or known that others had developed similar or parallel technology should not be considered as evidence that an amendment, argument or evidence could not have been submitted previously under § 1.78(d)(1) or 1.114.

Response: The Office will decide petitions under § 1.78(d)(1)(vi) or 1.114(g) on a case-by-case basis. The Office will focus on whether the evidence or data submitted with the petition to meet the showing under § 1.78(d)(1)(vi) or 1.114(g) was presented in a timely manner and was diligently obtained. Any evidence or data that petitioner did not act diligently in obtaining in response to a rejection or requirement in an Office action will be considered unfavorably when deciding a petition under § 1.78(d)(1)(vi) or 1.114(g). For example, the Office will likely not grant a petition if the examiner made the rejection in the first Office action of the initial application and maintained it in the subsequent Office actions, but applicants responded only with arguments, instead of with evidence or an amendment, until after the final Office action. In contrast, the Office will likely grant a petition if, in a continuing application or request for continued examination, the data necessary to support a showing of unexpected results just became available to overcome a new rejection under 35 U.S.C. 103 made in the final Office action, and the data is the result of a lengthy experimentation that was diligently commenced and could not have been completed earlier. Applicant should exercise reasonable foresight to commence any appropriate experimentation early rather than wait until the examiner makes a rejection or finds applicant's arguments unpersuasive.

Comment 85: Several comments sought clarification on whether an additional continued examination filing would be permitted under § 1.78(d)(1) or 1.114 for submitting an information disclosure statement or an amendment in view of an information disclosure statement in the following situations: (1) To submit a newly discovered reference, including a reference cited in a foreign counterpart application; (2) to submit a new reference that was not publicly available at the time the previous amendment was filed; (3) to submit an amendment to the claims that is

necessitated by previously cited prior art or newly discovered prior art; and (4) to submit broadened claims after receipt of a foreign search or examination report citing new art. One comment argued that submissions of late discovered prior art should be permitted because the consideration of the prior art will improve patent quality and eliminate allegations of inequitable conduct in obtaining patent rights.

Response: The Office will likely not grant such a petition for submitting an information disclosure statement (IDS) or an amendment necessitated by (or in view of) newly discovered prior art. The effectiveness and quality of the examination process as well as patentability determinations would improve if the most pertinent information were presented early in the examination process. An additional continued examination filing is not necessary for the consideration of newly discovered prior art or an amendment to the claims that is necessitated by the newly discovered prior art. See *Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 FR at 38812–16, 38820–22, 1309 *Off. Gaz. Pat. Office* at 27–31, 34–36 (proposed changes to §§ 1.97 and 1.98 permit applicant to submit prior art for consideration by the examiner, when applicant complies with specific requirements at various time periods, including after final action, notice of allowance and payment of the issue fee).

The proposed IDS changes (if adopted) would permit applicant to submit an IDS after a first Office action on the merits, but before the mailing date of a notice of allowability or a notice of allowance under § 1.311, if applicant files the IDS with either: (1) The certification under § 1.97(e)(1) and a copy of the foreign search report, or (2) an explanation under proposed § 1.98(a)(3)(iv) as to why each reference is being cited, and a non-cumulative description under proposed § 1.98(a)(3)(v) as to how each reference is not cumulative of any other reference cited. Applicant would also be permitted to submit an IDS after allowance but before the payment of the issue fee, if applicant files the IDS with a patentability justification under proposed § 1.98(a)(3)(vi), including any appropriate amendments to the claims.

Applicant would also be permitted to submit an IDS after the payment of the issue fee if applicant files a petition to withdraw from issue pursuant to § 1.313(c)(1), the patentability justification under proposed § 1.98(a)(3)(vi)(B), and an amendment to the claims. Prior to the effective date of the final rule of the changes to IDS

requirements, applicant may submit an IDS after the close of prosecution with a petition under § 1.183 if the IDS submission complies with the proposed rule requirements in §§ 1.97 and 1.98.

Comment 86: Several comments sought clarification as to whether an additional continued examination filing would be permitted under §§ 1.78(d)(1) and 1.114 in the following situations: (1) When the examiner found the earlier arguments and amendments by applicants to be unpersuasive; (2) when the examiner's interpretation of the claims is unusual and only recently understood by the applicant; (3) when the examiner changes his or her interpretation of claim language; and (4) when the practitioner discovers that the examiner is under a misunderstanding.

Response: These circumstances alone more than likely would not be sufficient to establish a showing under § 1.78(d)(1)(vi) or 1.114(g). Applicant should request an interview with the examiner to resolve these types of issues during the prosecution of the initial application, two continuation or continuation-in-part applications and request for continued examination. In addition, applicant in each reply to an Office action must distinctly and specifically point out the supposed errors in the Office action and must reply to every ground of objection and rejection raised in the Office action. See § 1.111(b). The reply must also present detailed explanations of how each claim is patentable over any applied references. See §§ 1.111(b) and (c). If applicant disagrees with the examiner's decision to maintain a rejection on the basis that the applicant feels that the examiner is misinterpreting the claims, applicant should seek an appeal rather than file additional continuing applications or requests for continued examination.

Comment 87: Several comments sought clarification on whether an additional continued examination filing would be permitted under §§ 1.78(d)(1) and 1.114 when the examiner makes a new ground of rejection in a final Office action using a new prior art reference, a reference already of record but not previously applied, a new basis for the rejection (e.g., changing a rejection under 35 U.S.C. 102 to a rejection under 35 U.S.C. 103), or a different reasoning (e.g., the supporting arguments have changed or the rejection refers to a new portion of the applied art). Several comments stated that permitting a final rejection based on a new ground of rejection while not allowing further opportunity to amend through continued examination applications is

unfair and presents an opportunity for abuse.

Response: The Office will decide each petition for an additional continued examination filing on a case-by-case basis, focusing on whether the new ground of rejection in the final Office action could have been anticipated by the applicant. For example, the Office will likely grant a petition if the final rejection, after the two continuing applications and request for continued examination permitted under §§ 1.78(d)(1) and 1.114(g) without a petition, contains a new ground of rejection that could not have been anticipated by applicant. However, the Office will likely not grant a petition under § 1.78(d)(1)(vi) or 1.114(g) if the examiner only changed a rejection under 35 U.S.C. 102 to a rejection under 35 U.S.C. 103 (or maintained a rejection under 35 U.S.C. 103) with the addition of a new secondary reference in response to an amendment adding a new claim limitation because such a new rejection should have been anticipated by the applicant. Therefore, the mere fact that the examiner made a new ground of rejection in a final Office action probably would not constitute a sufficient showing.

Comment 88: Several comments sought clarification on whether an additional continued examination filing would be permitted under §§ 1.78(d)(1) and 1.114 in the following situations: (1) When the examiner indicates in an advisory action that an after-final amendment would require a new search; or (2) to submit evidence or an amendment to overcome a final rejection.

Response: The Office will likely not grant a petition based on the mere showing that the examiner indicates in an advisory action that the entry of an after-final amendment would require a new search, or that the evidence or amendment sought to be entered will overcome a final rejection. Applicants are permitted to submit any desired amendment, argument, or evidence during the prosecution of the initial application, two continuation or continuation-in-part applications and one request for continued examination. Since numerous opportunities are given to submit any desired amendment, argument, or evidence, the mere fact that an amendment, argument, or evidence is refused entry because prosecution in the prior-filed application is closed will not, by itself, be a sufficient reason to warrant the grant of a petition under § 1.78(d)(1)(vi) or 1.114(g). Rather, an applicant will be expected to demonstrate why the amendment, argument, or evidence

sought to be entered could not have been submitted prior to the close of prosecution in the prior-filed application.

Comment 89: Several comments sought clarification as to whether the Office will likely grant a petition for an additional continuing application if some of the claims in the prior application are rejected and other claims are allowed, and applicant wishes to appeal the rejected claims and obtain a patent on the allowed claims.

Response: The Office is not likely to grant a petition under § 1.78(d)(1)(vi) in this situation in the absence of special circumstances. Section 1.78(d)(1)(i) permits an applicant whose initial application contains rejected claims and allowed claims to obtain a patent on the allowed claims, and continue prosecution of the rejected or other claims in a continuation or continuation-in-part application. The applicant is expected to use the two continuation or continuation-in-part applications permitted without any petition or showing under § 1.78(d)(1)(i) for this purpose. The applicant needs to pursue an appeal (or cancel the rejected claims) if the application still contains rejected claims after a second continuing application and request for continued examination.

Comment 90: Several comments suggested that applicant should be permitted to file an additional continuing application under § 1.78(d)(1) or request for continued examination under § 1.114 for changing the scope of the claims in the following situations: (1) Pursue claims that have the same or narrower scope as the claims in an allowed application; (2) claim a species or subgenus that falls within a generic claim that has been allowed or issued in one of the prior-filed applications; (3) pursue the rejected or broader claims when other claims are allowable; (4) file broader claims, when applicant recently discovered a limitation in an allowed claim that was unduly limiting; (5) pursue broader claims, or claim aspects of the invention that are disclosed, but not claimed, in the prior-filed application (contains claims to an unclaimed invention disclosed in the prior-filed application); (6) pursue narrower claims; (7) claim inventions of a different scope when the scope of new claims finds specific support in the application as filed; (8) pursue new claims when the scope of new claims was unintentionally omitted from the initial application; or (9) protect a different aspect of the invention revealed by research and development

subsequent to an initial application filing.

Response: If a claim can be submitted during the prosecution of the initial application, two continuation or continuation-in-part applications and one request for continued examination, applicant must present such a claim early in these filings rather than wait to submit it later in an additional continuing application or request for continued examination. The situations described in the comments do not present any reason why claims directed to claims with the same, narrower, or broader scope could not have been submitted earlier. Applicants may file a reissue application under 35 U.S.C. 251, if appropriate, to submit claims with a different scope.

Comment 91: Several comments sought clarification on whether an additional continued examination filing would be permitted under §§ 1.78(d)(1) and 1.114 for the following situations: (1) When a product recently becomes commercially viable; (2) when a competing product is newly discovered; (3) when new information is discovered that could not have been provided in the prior application; (4) when applicant discovered new inherent properties that he or she now wishes to claim; (5) when applicant now has the financial resources to file previously unclaimed inventions; (6) when clinical trials indicate the previously unclaimed subject matter may be useful; or (7) when the court determined that the format of a patented claim is improper and applicant wishes to file a continuing application to seek the proper protection.

Response: The Office likely will not grant such a petition in these situations. Applicant is permitted to file two continuation or continuation-in-part applications and a request for continued examination without a petition and showing. Applicant should have sufficient time to submit any desired claims. Applicant should also know what the applicant regards as his or her invention and claim his or her invention during the prosecution of these applications, regardless of whether applicants have recently discovered a commercially viable product, financial resources, useful subject matter, a competing product, or similar or parallel technology on the market. Applicants may file a reissue application under 35 U.S.C. 251, if appropriate, to correct or amend any patented claims. The Office would not likely grant a petition to permit an applicant to end-run the two-year filing period requirement of 35 U.S.C. 251, ¶ 4.

Comment 92: Several comments suggested allowing an applicant to file an additional continuing application or request for continued examination to claim inventions related to drugs undergoing the FDA approval process. In particular, one comment suggested two ways of satisfying the required showing under §§ 1.78(d)(1) and 1.114: (1) An applicant provides an affidavit or other statement to the Office confirming that the applicant is presently engaged in obtaining information needed for submitting an Investigational New Drug (IND) application for that drug; or (2) an applicant provides evidence to the Office that the applicant has already submitted an IND or a Biologics License Application (BLA) (or an amended IND application or amended BLA) for the particular drug.

Response: Such evidence of ongoing FDA review for a drug allegedly claimed in an application would not by itself be considered a sufficient showing under § 1.78(d)(1)(vi) or 1.114(g). Applicant should know what the applicant regards as his or her invention upon filing an application and should claim the invention prior to, or regardless of, any FDA approval. There is no reason why an applicant must have FDA approval prior to deciding for which aspect(s) of the invention or which invention(s) to seek patent protection. See *In re Brana*, 51 F.3d 1560, 1568, 34 U.S.P.Q.2d 1436, 1442 (Fed. Cir. 1995) (“FDA approval * * * is not a prerequisite for finding a compound useful within the meaning of the patent laws.”). The changes adopted in this final rule permit an applicant to file two continuation or continuation-in-part applications and one request for continued examination in the application family, without any justification. In addition, applicant may file a divisional application directed to each non-elected invention that has not been examined if the prior-filed application was subject to a restriction requirement and the claims to the non-elected invention are cancelled upon filing of the divisional application. Applicant may also file two continuation applications of the divisional application and a request for continued examination in the divisional application family, without justification. And, applicant may file a third of subsequent continuation application or a second request for continued examination with a petition and showing. If applicant is not prepared to particularly point out and distinctly claim what the applicant regards as his or her invention during the prosecution of the initial application, its two continuing applications, and a request

for continued examination in each application family, applicant should consider using the deferral of examination process. See § 1.103(d).

The Office recognizes that, in certain unpredictable arts (including, for example, biotechnology and certain pharmaceuticals), there may be a need for research or testing to obtain additional evidence or data to obviate a rejection for lack of utility under 35 U.S.C. 101 (and consequently for lack of enablement under 35 U.S.C. 112, ¶ 1). The case law, however, does not shift the burden to the applicant to provide rebuttal evidence or data concerning the invention's utility until the examiner “provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility.” *Brana*, 51 F.3d at 1566, 34 U.S.P.Q.2d at 1441 (citing *In re Bundy*, 642 F.2d 430, 433, 209 U.S.P.Q. 48, 51 (CCPA 1981)). Even in situations in which a requirement for such additional evidence is appropriate, the evidence or data that would warrant an applicant's decision to initiate the FDA regulatory process should be sufficient to establish utility for purposes of compliance with 35 U.S.C. 101 and 112, ¶ 1. See MPEP § 2107.03 (as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility). With respect to situations in which it is questionable as to whether there is sufficient enablement for the invention as claimed, evidence submitted to the FDA to obtain approval for clinical trials may be submitted. However, considerations made by the FDA for approving clinical trials are different from those made by the Office in determining whether a claim is sufficiently enabled. See MPEP § 2164.05 (citing *Scott v. Finney*, 34 F.3d 1058, 1063, 32 U.S.P.Q.2d 1115, 1120 (Fed. Cir. 1994)). Thus, situations in which it is necessary for an applicant to submit data to the Office to demonstrate patentability using data obtained from research or testing carried out as part of the FDA regulatory process should be rare.

Nevertheless, in the situation in which there is a rejection such as lack of utility under 35 U.S.C. 101 (and/or consequently for lack of enablement under 35 U.S.C. 112, ¶ 1) in an application claiming subject matter in such an unpredictable art, the Office will likely grant a petition under § 1.78(d)(1)(vi) or 1.114(f) if, in a continuing application or request for

continued examination, the evidence or data to demonstrate utility or enablement just became available or could not have been otherwise earlier presented, and the evidence or data resulted from research or testing that was commenced with reasonable diligence. However, this presupposes that the applicant has taken reasonable steps to resolve the issue during the prosecution of the initial (or divisional) application, its two continuing applications, and a request for continued examination in each application family. In particular, the Office will consider, *inter alia*, whether the applicant: (1) Sought review of the rejection via an appeal that proceeded to at least the appeal conference stage and resulted in an examiner's answer (rather than simply filing continuing applications or a request for continued examination without the evidence or data to again argue patentability before the examiner); (2) initiated the research or testing promptly (rather than waiting for a decision to initiate the FDA regulatory review process); and (3) sought suspension of action (§ 1.103(a) or (c)) or deferral of examination if applicable (§ 1.103(d)) in the continuing applications or the request for continued examination and alerted the Office of the research or testing.

Comment 93: Several comments sought clarification whether the Office will grant a petition for an additional continuing application or request for continued examination to correct the inventorship of the application due to information discovered after prosecution of the application has closed.

Response: The Office will likely not grant such a petition. Applicant should make the correction early in the examination process. Furthermore, the Office has recently proposed changes to § 1.312 to provide that the Office may permit a correction of the inventorship filed in compliance with § 1.48 after the mailing of a notice of allowance if certain requirements are met, such as if the correction is filed before or with the payment of the issue fee or if the correction is filed with the processing fee set forth in § 1.17(i) and in sufficient time to permit the patent to be printed with the correction. See *Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 FR at 38817–8, 38823, 1309 *Off. Gaz. Pat. Office* at 32, 37. Finally, after the patent has issued, applicant may correct the inventorship by filing a reissue application under 35 U.S.C. 251 or pursuant to 35 U.S.C. 256.

Comment 94: One comment discussed that the limitations on continuing

applications may create due process issues because there may be different treatment of joint inventors of an application. The comment provided an example of an application filed naming joint inventors, *e.g.*, Inventors C and D, and ensuing problems caused by the proposed rules as follows: Inventor C files a continuation application to prosecute his or her invention. Inventor D may be deprived of filing a continuation application on his invention because the filing by Inventor D would be a second or subsequent continuing application that would require a petition under § 1.78(d)(1).

Response: This final rule permits applicants to file two continuation or continuation-in-part applications plus one request for continued examination without justification. Applicants may file a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination with a petition and showing. Under § 1.78(d)(1)(i), Inventor C is permitted to file a continuation application (the first continuation application) to prosecute his or her invention, and Inventor D is permitted to file a continuation application (the second continuation application) to prosecute his or her invention.

Comment 95: Several comments sought clarification whether the Office will grant a petition for an additional continuing application or request for continued examination for the purpose of provoking an interference.

Response: The Office will likely not grant a petition with a showing that the additional continuation or continuation-in-part application or request for continued examination is solely for the purpose of provoking an interference. In most situations, applicants should have sufficient opportunity to provoke an interference and copy claims in a timely manner in compliance with 35 U.S.C. 135(b)(2) in the initial application, two continuation or continuation-in-part applications, and one request for continued examination, all of which are available without any justification. In any event, the Office is likely to require that a request for a statutory invention registration under § 1.293 be submitted as a condition of granting any petition under § 1.78(d)(1)(vi) in the situation where a third or subsequent continuation or continuation-in-part application or second or subsequent request for continued examination is for the purpose of provoking an interference. The Office, however, would likely grant a petition under § 1.78(d)(1)(vi) (without requiring a request for a statutory invention

registration under § 1.293) in a limited situation where an interference is declared in a second continuation or continuation-in-part application that contains both claims corresponding to the count and claims not corresponding to the count, and the BPAI suggests that the claims not corresponding to the count be canceled from the application subject to the interference and pursued in a separate application.

Comment 96: Several comments sought clarification as to whether the Office will grant a petition for an additional continuing application or request for continued examination when the Office changes the examiner assigned to the application either on its own initiative or in response to the applicant's request.

Response: The Office will not grant such a petition. The mere fact that the Office changes the examiner assigned to the application would not be a sufficient showing under § 1.78(d)(1)(vi) or 1.114(g).

Comment 97: Several comments sought clarification as to whether the Office will grant a petition for an additional continuing application or request for continued examination when applicant changes the practitioner of record, when applicant states that the change of practitioner was made in good faith and certifies that the applicant was dissatisfied with the prior practitioner's claim drafting, or when the delay in filing claims was due to the practitioner's error or inaction and was not the fault of the applicant. One comment expressed concern that if changing the practitioner of record is an acceptable reason, it will promote attorney swapping.

Response: The Office will not grant such a petition for these circumstances. A change of practitioner, or errors or delays caused by the practitioner, would not be considered sufficient showings. An applicant is bound by the consequences of the acts or omissions of the applicant's duly authorized and voluntarily chosen legal representative. See *Link v. Wabash R. Co.*, 370 U.S. 626, 633–34 (1962).

Comment 98: One comment suggested that an applicant should be permitted to file an additional continuation or continuation-in-part application when the practitioner does not present the claims in the prior application because of excusable neglect.

Response: Rule 60(b) of the Federal Rules of Civil Procedure (Rule 60(b)) does provide "excusable neglect" as a basis (among others) for relieving a party of a judgment or order. See Fed. R. Civ. P. 60(b)(1). Rule 60(b), however, further provides that a motion based

upon “excusable neglect” must be “made within a reasonable time,” and “not more than one year after the judgment, order, or proceeding was entered or taken.” See Fed. R. Civ. P. 60(b). Sections 1.78(d)(1) and 1.114 as adopted in this final rule permit an applicant to file an initial application, two continuation or continuation-in-part applications, and a request for continued examination in any one of these three applications without justification. Given the numerous opportunities provided in §§ 1.78(d)(1) and 1.114 to prosecute an application for patent, the “mistake, inadvertence, surprise, or excusable neglect” standard set forth in Rule 60(b)(1) is not an appropriate basis for seeking yet another opportunity to prosecute the application. Therefore, the Office is not likely to grant a petition under § 1.78(d)(1)(vi) or 1.114(g) solely on the basis of “excusable neglect.”

Rule 60(b)(6), however, does provide for relief on the “catchall” basis of “any other reason justifying relief from the operation of the judgment.” See Fed. R. Civ. P. 60(b)(6). While this language appears to be open-ended, this provision is typically limited to exceptional or extraordinary circumstances suggesting that a party was faultless in the delay. See *Marquip, Inc. v. Fosber Am., Inc.*, 198 F.3d 1363, 1370, 53 U.S.P.Q.2d 1015, 1020 (Fed. Cir. 1999) (citing *Pioneer Inv. Serv. Co. v. Brunswick Assocs. Ltd. P’ship*, 507 U.S. 380, 393 (1993)). The patent rules of practice (§ 1.183) provide that “in an extraordinary situation” in which “justice requires,” the Office may waive or suspend any requirement of the regulations in 37 CFR part 1, which is not a requirement of statute. The Office does not anticipate granting petitions under § 1.78(d)(1)(vi) or 1.114(g) on a basis other than a showing that the amendment, argument or evidence sought to be entered could not have been previously submitted. However, in the rare exceptional or extraordinary situation in which an applicant was faultless in the delay, and the situation does not meet the standard that the amendment, argument or evidence sought to be entered could not have been previously submitted, the Office may grant relief pursuant to § 1.183.

Comment 99: Several comments sought clarification as to whether the Office will likely grant a petition for an additional continuing application or request for continued examination if the prior-filed application was abandoned in favor of a continuing application that was filed using the Office electronic filing system or if the request for

continued examination was filed using the Office electronic filing system.

Response: The Office will likely not grant such a petition. The mere fact that a continuing application or request for continued examination is electronically filed via the Office electronic filing system would not be a sufficient showing as to why the amendment, argument or evidence sought to be entered could not have been previously submitted.

Comment 100: A few comments sought clarification as to whether the Office will likely grant a petition for an additional continuing application or request for continued examination if the applicant becomes disabled for a lengthy time during pendency of application.

Response: The Office will likely not grant such a petition on the mere showing that the applicant becomes disabled for a lengthy time during pendency of application. The changes being adopted in this final rule permit applicants to file two continuation or continuation-in-part applications and a request for continued examination, without a petition and showing. Applicant may also file a third or subsequent continuation or continuation-in-part application or a second or subsequent request for continued examination with a petition and showing. Furthermore, applicant may file a petition for suspension of action under § 1.103(a) or a request for deferral of examination under § 1.103(d), when necessary.

Comment 101: Several comments suggested an applicant should be permitted to file an additional continuation or continuation-in-part application or a request for continued examination for patent term extension reasons.

Response: No patent term extension benefits under 35 U.S.C. 154 and 156 will accrue to applicant by filing a third or subsequent continuing application or a second or subsequent request for continued examination. Therefore, a desire to obtain a patent term extension would not be a sufficient reason to permit a third or subsequent continuing application or a second or subsequent request for continued examination. In fact, the filing of a continuing application or request for continued examination may result in the loss of a patent term adjustment under 35 U.S.C. 154(b).

Comment 102: A number of comments expressed concern regarding an example provided by the Office that would meet the showing under §§ 1.78(d)(1) and 1.114 to permit the filing of an additional continuing

application or request for continued examination. This example permits the applicant to file an additional continuing application or request for continued examination when the applicant can show that collection of the data necessary to demonstrate unexpected results was started after the applicant received the rejection for the first time, and was completed only shortly before filing the petition for an additional filing. A number of comments stated that granting a petition should only depend on when the information becomes available and not when the tests begin. One other comment stated that experiments are typically ongoing from the date of invention and that it would be inappropriate for the Office to require experimentation to overcome an obviousness rejection to commence only after the rejection has been made for the first time. One comment suggested removing the language, “could not have been anticipated by applicant,” from the example provided by the Office of an adequate showing under § 1.78(d)(1) or 1.114. The comment expressed concern that the Office’s example is vague and subjective, and that removal of the language, “could not have been anticipated by applicant,” would make the standard less arbitrary.

Response: The example is merely one illustration of when a petition under § 1.78(d)(1)(vi) or 1.114(g) will likely be granted. Other appropriate showings could result in a petition under § 1.78(d)(1)(vi) or 1.114(g) being granted. As discussed previously, the Office will focus on whether the evidence or data submitted was obtained and presented in a reasonably diligent manner.

Comment 103: One comment expressed concern regarding the requirement under § 1.78(d)(1) that an applicant must submit a petition within four months from the actual filing date of the later-filed continuing application, stating that applicant may need more time to complete the experimentation or to prepare the submission in response to a rejection or a requirement for information. This comment suggested that the Office should accept an interim statement from the applicant when more time is needed, such as a statement that the experimentation is progressing, but is not completed.

Response: Applicant should prepare a reply diligently upon receiving the final Office action in the prior application, which provides a six-month statutory period for reply. There is no reason why an applicant should delay preparing a petition under § 1.78(d)(1)(vi) until a third or subsequent continuing application has been filed. Applicants

should not rely solely upon the four-month time period under § 1.78(d)(1)(vi) to prepare and file a petition under § 1.78(d)(1)(vi) for a third or subsequent continuing application. Therefore, the four-month time period from the actual filing date of a third or subsequent continuing application is a reasonable deadline to file a petition under § 1.78(d)(1)(vi).

Comment 104: A number of comments requested clarification regarding who will decide the petitions under §§ 1.78(d)(1) and 1.114. Several comments argued that examiners should not decide the petitions under §§ 1.78(d)(1) and 1.114. Furthermore, a number of comments argued that there is a danger that the standard would be applied differently in different Technology Centers. Several comments suggested that the Office of Petitions should decide the petitions to encourage consistency, ensure uniform interpretation of the rules, and reduce the impact on examining resources. Yet another comment suggested that the BPAI should review the showing required under §§ 1.78(d)(1) and 1.114. The comments further argued that there is a potential for both disparate treatment and inconsistent application of §§ 1.78(d)(1) and 1.114 depending on who decides the petitions and that the potential of either would violate the concept of equal protection under the law.

Several comments requested clarification regarding the procedures for appealing the denial of a petition under § 1.78(d)(1)(vi) or 1.114(g). Specifically, the comments questioned whether a denial of a petition should be appealed to the BPAI or petitioned to the Director. The comment further requested that the Office publish the decisions to encourage consistency and understanding of the standard. One comment sought clarification on the remedies available to an applicant if the Office denies a petition for an additional continuing application or request for continued examination when the examiner introduced new prior art in a final Office action. One comment questioned whether petitions under §§ 1.78(d)(1) and 1.114 could be decided objectively due to the Office's desire to dramatically curtail continuing applications and requests for continued examination.

Response: The Office is making every effort to become more efficient, to apply the rules and statutes uniformly, and to allocate Office resources properly. The authority to decide petitions under §§ 1.78(d)(1)(vi) and 1.114(g) has been delegated to the Deputy Commissioner for Patent Examination Policy (who may

further delegate this authority to officials under the Deputy Commissioner for Patent Examination Policy). A decision on a petition under § 1.78(d)(1)(vi) or 1.114(g) is not appealable to the BPAI. The denial of a petition under § 1.78(d)(1)(vi) or 1.114(g) may be viewed as a final agency action for the purposes of judicial review under 5 U.S.C. 704. *See* MPEP § 1002.02. Final decisions of the Office of the Commissioner for Patents are accessible in the Freedom of Information Act (FOIA) section of the Office's Internet Web site at (<http://www.uspto.gov/web/offices/com/sol/foia/comm/comm.htm>).

The Deputy Commissioner for Patent Examination Policy and officials under the Deputy Commissioner for Patent Examination Policy will decide petitions under §§ 1.78(d)(1)(vi) and 1.114(g) on their merits and the facts in the record and apply the standard in a consistent manner. The officials who will decide petitions under §§ 1.78(d)(1)(vi) and 1.114(g) are professionals who perform their duties within the framework of the law, rules, and examination practice. The Office only desires to curtail continuing applications and requests for continued examination in situations in which the continued examination filing is for the purpose of presenting an amendment, argument or evidence that could have been, but was not, submitted earlier. The Office recognizes the need for continued examination filings for presenting an amendment, argument or evidence that truly could not have been submitted earlier.

Comment 105: A number of comments requested that the Office set a time limit for rendering decisions on petitions under §§ 1.78(d)(1) and 1.114. The comments suggested that the Office should set up an adequately staffed office to decide the petitions promptly, and in any event, before the close of prosecution of the parent application so that applicants are advised of their prosecution options. The comments further suggested that the Office should grant the petition if it is not decided prior to the close of prosecution.

Response: The Office is continuing to ensure prompt and consistent decisions on petitions. It is the general policy of the Office that petitions are decided in the order that they are filed in the Office. Moreover, the Office will likely deny any petition under § 1.78(d)(1)(vi) or 1.114(g) filed before the close of prosecution because applicant may still submit the amendment, argument, or evidence in the application if the prosecution is open. Further, in such situation, it is unlikely that applicants

will be able to show that the amendment, argument, or evidence sought to be entered could not have been previously submitted.

Comment 106: One comment sought clarification regarding the status of an application during consideration of the petition. Specifically, the comment questioned whether an applicant who had filed a petition under § 1.78(d)(1) or 1.114 would be permitted to file a notice of appeal under § 41.31(a) within the time period provided in § 1.134 to avoid abandonment of the application if the petition is dismissed. The comment also inquired whether the notice of appeal fee would be refunded if the petition were granted. Several other comments suggested that the filing of a petition under § 1.78(d)(1) or 1.114 should serve as a notice of appeal if the petition is dismissed. In the alternative, several comments suggested that the Office should allow applicants additional time to file a notice of appeal after the dismissal of a petition.

Response: The Office will make every effort to decide the petitions in a timely manner. The rules have not changed the time period for filing a notice of appeal or an appeal brief. Pursuant to § 41.31(a)(1), an applicant must file a notice of appeal accompanied by the fee set forth in § 41.20(b)(1) within the time period for reply set forth in the Office action. The notice of appeal fee is set by statute and is non-refundable. If the Office grants the petition prior to a decision on the merits by the BPAI, the fees paid for the notice of appeal and the appeal brief can be applied to a later appeal on the same application. *See* MPEP § 1207.04. Additionally, the filing of a petition will not serve as a notice of appeal, and the Office will not allow more time to file a notice of appeal. The filing of a petition, moreover, does not toll the period for reply to any outstanding Office action. An applicant should not use the continued examination practice as a substitute for an appeal. Rather, an applicant should appeal the decision if warranted.

Comment 107: One comment sought clarification of the status of the application if, after filing a notice of appeal under § 41.31(a), an applicant later files a petition under § 1.114 with a request for continued examination (with a submission and the appropriate fees), which is dismissed. The comment questioned whether the application would be abandoned given that the filing of a request for continued examination would be treated as a request to withdraw the appeal.

Response: In the situation described in the comment, the application would be abandoned if the application has no

allowed claims because the request for continued examination would be treated as a request to withdraw the appeal. *See* MPEP § 1215.01.

In the situation where applicant already filed a request for continued examination in the application family, a better alternative is for applicant to file the request for continued examination with a petition under § 1.114(g), and then if the petition is not decided prior to the expiration of the statutory period for reply to the final Office action, applicant may file a notice of appeal within the period for reply (and petition for any extension of this period under § 1.136(a) or (b), if necessary) to avoid abandonment of the application. If the Office subsequently dismisses the petition, the request for continued examination will be treated as an improper request for continued examination. However, the request for continued examination will not be treated as a request to withdraw the appeal because the request for continued examination was filed before the notice of appeal (*i.e.*, the application was not on appeal at the time of filing the request for continued examination).

E. Treatment of Multiple Applications

Comment 108: A number of comments suggested the four-month time period provided in § 1.78(f)(1) for identifying to the Office applications that meet the criteria set forth in § 1.78(f)(1) is unreasonably short and is impractical in view of the time often required by the Office to assign application numbers and communicate these numbers to the applicants. One comment suggested the time period provided in § 1.78(f)(1) for identifying to the Office applications that meet the criteria set forth in § 1.78(f)(1) does not permit an applicant to timely identify an international application designating the United States of America that entered the national stage thirty months after the filing date of a nonprovisional application filed under 35 U.S.C. 111(a) when these two applications meet the criteria set forth in § 1.78(f)(1).

Response: The Office notes the concerns expressed in the public comments concerning the proposed changes to § 1.78(f)(1). The Office has modified this provision relative to the proposed changes such that § 1.78(f)(1) as adopted in this final rule provides applicant four months from the actual filing date of a nonprovisional application filed under 35 U.S.C. 111(a), four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in a nonprovisional application which entered the national stage from an international application

after compliance with 35 U.S.C. 371, or two months from the mailing date of the initial filing receipt in the other nonprovisional application, to identify other nonprovisional applications in compliance with § 1.78(f)(1).

Comment 109: A number of comments requested identification of any consequences for failing to identify one or more applications that meet the criteria set forth in § 1.78(f)(1), or for failing to identify such applications within the time period set forth in § 1.78(f)(1).

Response: If applicant inadvertently fails to identify the other nonprovisional applications in compliance with § 1.78(f)(1)(i) within the time period provided in § 1.78(f)(1)(ii), applicant should submit the identification to the Office as soon as practical. If the submission necessitates a new rejection based upon double patenting (including an obviousness-type double patenting rejection) in a second or subsequent Office action on the merits, the examiner may make such an action final (assuming that the conditions for making a second or subsequent action final are otherwise met). The Office may also refer any registered practitioner who repeatedly fails to comply with the rule requirements to the Office of Enrollment and Discipline for appropriate action. Applicants and practitioners are strongly encouraged to revise their practices to ensure timely submissions of the required identification. Applicants and registered practitioners are reminded of their duties under § 10.18 and other professional responsibility rules, and the consequences of any violations (*e.g.*, §§ 10.18(c), 10.18(d) and 10.23).

Comment 110: A number of comments requested clarification of § 1.78(f)(1) and how it interacts with § 1.56, including the preexisting duty of an applicant to disclose similar information to the Office under § 1.56. Several comments stated that § 1.78(f)(1) imposes burdens on the applicants that provide a new basis for inequitable conduct allegations.

Response: Section 1.78(f)(1) provides that an applicant must identify other pending applications or patents that are commonly owned, have a common inventor, and have a claimed filing or priority date within two months of the claimed filing or priority date of the application. This requirement does not supplant an applicant's duty to bring other applications that are "material to patentability" of an application (*e.g.*, applications containing patentably indistinct claims) to the attention of the examiner. Section 1.78(f)(1) does not provide a new basis for allegations of

inequitable conduct when § 1.78(f)(1) is considered in light of the duties concurrently imposed on applicants and practitioners by § 1.56 and the ethics rules in 37 CFR Part 10, such as § 10.18. *See also Dayco*, 329 F.3d at 1365–69, 66 U.S.P.Q.2d at 1806–08 (individuals covered by § 1.56 cannot assume that the examiner of a particular application is necessarily aware of other applications which are "material to patentability" of the application under examination, but must instead bring such other applications to the attention of the examiner).

Comment 111: Several comments requested clarification regarding the applications that must be identified pursuant to § 1.78(f)(1) when common inventor(s) and common ownership exist.

Response: Applicant must identify those pending nonprovisional applications that are filed within two months of each other taking into account any filing date for which benefit is sought, that name at least one common inventor, and that are owned by the same person or subject to an obligation of assignment to the same person. For example, the applicant for application A is required to identify application B and the applicant for application B is required to identify application A in the following situation: The actual filing date of application A is August 8, 2006. Application A claims priority of a foreign application filed on August 10, 2005. The actual filing date of application B is April 11, 2006. Application B claims the benefit of a prior-filed nonprovisional application filed on October 4, 2005, and claims the benefit of a prior-filed provisional application filed on January 4, 2005. Application A and application B have at least one common inventor and common ownership. Each applicant must identify the other application because application A has a filing date (August 10, 2005, the foreign priority date) within two months of a filing date of application B (October 4, 2005, the filing date of the nonprovisional application whose benefit is claimed by application B). "Filing date" includes the actual filing date, foreign priority date, and the filing date of a provisional, nonprovisional, or international application whose benefit is sought under title 35, United States Code.

Comment 112: A number of comments objected that §§ 1.78(f)(1) and (2) require applicants to identify and resolve a possible double patenting issue prior to a rejection being issued by the examiner. One comment suggested that the rebuttable presumption in § 1.78(f)(2) was akin to saying that if an

applicant submits prior art, there is a presumption of obviousness. One comment suggested that § 1.78(f)(2) was unnecessary because § 1.78(f)(1) provides the Office with sufficient information to require a terminal disclaimer or require the cancellation of claims. One comment stated that many applicants will attempt to circumvent § 1.78(f)(2) by filing multiple applications that meet the criteria set forth in § 1.78(f)(2), but that include both patentably distinct claims and patentably indistinct claims.

Response: The rebuttable presumption set forth in § 1.78(f)(2) is a procedural tool requiring the applicant to help focus and consolidate the examination process and thus is not akin to a presumption of obviousness. The examination is more efficient when double patenting issues are identified and resolved early in the process. Where an applicant chooses to file multiple applications that are substantially the same, it will be the applicant's responsibility to assist the Office in resolving potential double patenting situations rather than taking no action until faced with a double patenting rejection. Although the ultimate determination of double patenting rests with the Office, applicants are in a far better position than the Office to identify applications that may raise double patenting concerns.

Section 1.78(f)(2) requires applicant to resolve the double patenting issues early in the prosecution by either: (1) Filing a terminal disclaimer and an explanation as to why the multiple applications containing patentably indistinct claims are necessary; or (2) explaining how the application contains only claims that are patentably distinct from the claims of other related applications. Therefore, with the benefit of § 1.78(f)(2), double patenting issues could be resolved more expeditiously before the first Office action on the merits, thus saving the examiner time by eliminating the need to search for related applications, analyze the potentially conflicting claims, and make the rejection. Merely identifying the other applications under § 1.78(f)(1) would not result in these benefits.

If the criteria set forth in § 1.78(f)(2) are met, the rebuttable presumption would apply regardless of whether a few of the claims are patentably distinct from the claims in the other related applications because § 1.78(f)(2) provides that "a rebuttable presumption shall exist that a nonprovisional application contains at least one claim that is not patentably distinct * * * ." To rebut this presumption, applicant must explain how the application

contains only claims that are patentably distinct. Merely explaining that some of the claims are patentably distinct would not be sufficient to rebut this presumption.

Comment 113: One comment objected that § 1.78(f)(2) would impose an undue burden on inventors because it creates a presumption that commonly owned patent applications which share a common disclosure and at least one inventor, are patentably indistinct. The comment further asserted that the presumption is not in the interest of American competitiveness as American companies often file numerous patent applications with claims directed to different features of the same new product. One comment suggested that § 1.78(f)(1) places an excessive burden on applicants to anticipate all the unique claims that could be filed at the time of filing the initial application.

Response: Section 1.78(f)(2)(i) requires that the related applications must have the same claimed filing or priority date in addition to being commonly owned with one inventor in common and with substantial overlapping disclosure. Multiple patent applications related to the same product are not precluded by § 1.78(f)(2). In the situation where § 1.78(f)(2)(i) actually applies and the multiple applications relate to patentably distinct features of the same new product, it should not be difficult to explain how the applications contain patentably distinct claims under § 1.78(f)(2)(ii)(A), and thereby rebut the presumption. Thus, the presumption of § 1.78(f)(2)(i) does not impose an undue burden on inventors.

None of the criteria under § 1.78(f)(1) for identifying certain related applications has anything to do with claims that could be filed in the initial application as suggested by the comment. Instead, § 1.78(f)(1) merely requires identification of applications that meet the identified criteria. Accordingly, there is no such burden placed on applicants.

Comment 114: Several comments requested clarification of the language "taking into account any filing date for which a benefit is sought under title 35, United States Code," in § 1.78(f)(1). Those comments also inquired whether this language includes provisional applications for which benefit is sought, merely the first nonprovisional application for which benefit is sought, or every nonprovisional application for which benefit is sought.

Response: Section 1.78(f)(1) requires applicant to consider all provisional, nonprovisional, international, and foreign applications for which benefit is sought. If the filing date of an

application whose benefit is claimed in a nonprovisional application is within two months of the filing date of another pending nonprovisional application, and the nonprovisional applications name at least one inventor in common and are owned by the same person or subject to an obligation of assignment to the same person, each applicant of the nonprovisional applications must identify the other nonprovisional application to the Office. For example, if two nonprovisional applications claim priority of the same foreign application (or two foreign applications filed within two months of each other), name at least one inventor in common, and are owned by the same person, then each applicant of the nonprovisional applications must identify the other nonprovisional application, no matter the difference in time between their U.S. filing dates.

Comment 115: A number of comments suggested that § 1.78(f)(1) could be eliminated if the Office assigned all related applications to the same examiner.

Response: The Office attempts to assign related applications to the same examiner where possible. However, applicant is in the best position to determine and identify when applications are related, not the Office. By meeting the provisions of § 1.78(f), applicants will reduce the burden on the Office to identify which applications are related and facilitate examination of the related application by the examiner.

Comment 116: Several comments suggested that § 1.78(f)(1) would be burdensome to applicants who file a large number of applications in related areas of research. These comments suggested that the examiners working in these areas of technology will also experience a significant burden. A number of comments suggested that the Office has not sufficiently justified how the benefits of § 1.78(f) outweigh the added costs for both applicants and the Office. These comments suggested that the existing rules relating to double patenting and the filing of terminal disclaimers are sufficient to solve the problems of patentably distinct claims, and that the Office's searchable database of applications makes the § 1.78(f) changes unnecessary. The comments argued that examiners can perform common inventor searches as easily as applicants. A number of comments doubted the Office's reasoning that duplicative applications containing "conflicting or patentably indistinct claims" are having a crippling effect on the Office's ability to examine non-continuing applications. A number of comments making such an objection

stated that in fiscal year 2005, less than three percent of the patents granted contained a terminal disclaimer, and accordingly there is no basis for the rebuttable presumption of patentably indistinct claims. One comment suggested that § 1.78(f)(2) would not reduce examiner workloads because examiners would still be required to make their own separate determinations regarding whether claims are patentably distinct in order to evaluate and address arguments made by applicants pursuant to § 1.78(f)(2).

Response: Multiple applications with patentably indistinct claims divert patent examining resources from the examination of new applications. This final rule encourages applicants to submit all of the claims that are patentably indistinct in one single application. See §§ 1.78(f) and 1.75(b)(4). By presenting all of the patentably indistinct claims in one application, applicants can alleviate the Office's burden of searching for multiple applications containing patentably indistinct claims, analyzing the applications for double patenting issues, and requiring cancellation of the claims or a terminal disclaimer. This will also ensure that one single examiner will examine the same invention to provide consistent and focused examination. Furthermore, it will preclude applicant from submitting multiple applications to the same subject matter (with claims that are patentably indistinct), each with five or fewer independent claims or twenty-five or fewer total claims, for the purpose of avoiding the requirement to submit an examination support document.

It is envisioned that many applicants will be proactive by filing fewer applications containing patentably indistinct claims, unless there is a good and sufficient reason to do so. By minimizing such filings, applicants will reduce the Office's burden of examining multiple applications containing patentably indistinct claims. Applicants are in a far better position than the Office to identify related applications pursuant to § 1.78(f)(1). The Office's searchable database is not a sufficient substitute for applicant's knowledge of related applications, particularly in view of the fact that ownership identification is not required when an application is filed, and the fact that applications are often filed without executed declarations that correctly name all of the inventors.

The terminal disclaimer statistic cited in the comment covers all granted patents. It does not specifically relate to the limited situation covered by § 1.78(f)(2). Furthermore, double

patenting issues must be considered in every application where the applicant filed another related application, not only those applications in which applicant filed a terminal disclaimer. For example, the statistic cited in the comment does not include applications in which the applicants canceled the patentably indistinct claims.

The burden on the examiner to evaluate arguments presented by applicant is less compared to the burden of independently identifying and reviewing each application that meets the criteria set forth in § 1.78(f)(2). Furthermore, the issues would be resolved earlier in the prosecution. Without the presumption of at least one patentably indistinct claim and applicant's assistance under § 1.78(f)(2), it is more difficult to resolve potential double patenting situations.

Comment 117: Several comments suggested that the two-month window between filing dates set forth in § 1.78(f)(1) is overly burdensome on both the Office and the applicant.

Response: The identification requirement under § 1.78(f)(1) is consistent with the duty to disclose information that is material to patentability under § 1.56. The two-month window set forth in § 1.78(f)(1) merely provides guidance to applicants for at least those applications that must be identified to the Office. Often, related applications filed outside the two-month window should also be identified to the Office under § 1.56.

Comment 118: One comment stated that compliance with § 1.78(f)(1) would be difficult for corporations that employ multiple law firms to handle their patent prosecution portfolios.

Response: Each corporation typically has a person or a group of people who oversees its outside counsel and manages its patent portfolio. It is not unreasonable for the Office to assume that the person(s) managing the patent portfolio is aware of the contents of the corporation's applications being prosecuted by different law firms. In any event, it is appropriate for the corporation to bear the burden of tracking applications for compliance with § 1.78(f)(1).

Comment 119: One comment suggested that some docketing systems currently used by practitioners do not permit searching by inventor names in a manner that would enable practitioners to identify applications with common inventors that were filed within two months of each other.

Response: The fact that some practitioners do not have a docketing system to identify applications with common inventors that were filed

within two months of each other is not a sufficient reason for the Office to not require the information under § 1.78(f)(1) that would assist the Office in identifying applications that potentially have double patenting issues. Practitioners should have the required information even though their docketing system may not keep track of applications with common inventors. Practitioners should have more reliable information regarding applications with common inventors than the Office's database because many applications are filed without an executed oath or declaration and the actual inventors are not often identified to the Office for a number of months after the filing date. Furthermore, ownership is not required to be identified when an application is filed.

Comment 120: One comment questioned whether extensions of time would be available for applicants attempting to comply with the requirements of § 1.78(f)(1).

Response: Section 1.78(i) as adopted in this final rule provides that "[t]he time periods set forth in [§ 1.78] are not extendable."

Comment 121: A number of comments questioned why applicants would need to identify to the Office applications with a common inventor under § 1.78(f)(1) that contain patentably distinct claims because those applications are not candidates for an obviousness-type double patenting rejection.

Response: Applicant is in the best position to identify to the Office applications with potentially conflicting claims. By taking responsibility for identifying such applications, applicant will be reducing the burden on the Office so that the Office can focus its limited examining resources on examining new applications. The ultimate determination of obviousness-type double patenting remains with the Office, which is why it is critical that applications that meet the criteria of § 1.78(f)(1) be identified to the Office.

Comment 122: A number of comments suggested that while an applicant is in a better position to know of related applications that have been filed, they are not in the position to determine whether the claims of these applications are patentably distinct. This is a function of the Office. One comment argued that the Office is making an unsupported assumption that the applicant is in a far better position than the Office to determine whether there are one or more other applications or patents containing patentably indistinct claims.

Response: The applications whose specifications possibly contain patentably indistinct claims were made by or on behalf of the inventor or applicant, and not the Office or the examiner. See 35 U.S.C. 111(a). Thus, the applicant is in a better position than the Office or examiner to know when such related applications have been filed. While the ultimate determinations of double patenting and patentability remain with the Office, the Office rejects the position that the applicant has no responsibility to facilitate those decisions. The information provided by applicant in compliance with § 1.78(f)(1) is reasonably necessary for the Office to determine double patenting issues. With the information provided before the first Office action on the merits, the Office could make the patentability determination more efficiently and thereby reduce pendency. For example, the examiner could identify and resolve any double patenting issues earlier in the prosecution.

Comment 123: One comment suggested that the requirements of § 1.78(f)(1) would raise inventorship and ownership issues when entities have entered into a confidential research agreement.

Response: The identification of such applications is reasonably necessary for an efficient and effective examination. This requirement is similar to that imposed upon applicants having knowledge of material prior art that became known to them via information covered by a confidentiality agreement. In such an instance, the existence of a confidentiality agreement does not relieve applicants from their duty to disclose this prior art information to the Office. In any event, § 1.78(f)(1) requires identification of only the commonly owned applications (if certain conditions are met), but not identification of the owner. 35 U.S.C. 115 requires that the inventors identify themselves.

Comment 124: One comment suggested that § 1.78(f) will have the greatest adverse impact on small entities.

Response: The rules apply equally to both non-small entities and small entities. The comment did not provide persuasive data or other evidence supporting the conclusion. The Office's experience is that small entities do not file a larger percentage of multiple applications than non-small entities. Thus, it is doubtful that any impact, if adverse, will affect small entities the most.

Comment 125: Several comments questioned whether the Office should

even concern itself with obviousness-type double patenting rejections. They suggested that essentially no harm at all to the public exists through the grant of plural applications having the same, or roughly the same, filing dates, while the technical traps for the unwary and the undue examination burdens established by double patenting rejections unduly complicate procurement and burden the Office.

Response: There are two reasons why the Office still needs to make obviousness-type double patenting rejections in applications filed on or after June 8, 1995, and that are subject to a twenty-year term under 35 U.S.C. 154(a)(2). First, 35 U.S.C. 154 does not ensure that any patent issuing on a utility or plant application will necessarily expire twenty years from the earliest filing date for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c) because 35 U.S.C. 154(b) includes provisions for patent term extension based upon prosecution delays during the application process. Second, § 1.321(c)(3) requires that a terminal disclaimer filed to obviate an obviousness-type double patenting rejection based on commonly owned patentably indistinct claims include a provision that any patent granted on that application be enforceable only for and during the period that the patent is commonly owned with the application or patent which formed the bases for the rejection. This requirement prevents the potential for harassment of an accused infringer by multiple parties with patents covering the same patentable invention. See MPEP § 804.02. If applicant files all of the patentably indistinct claims in one application, applicant could alleviate the Office's burden of searching for multiple applications containing patentably indistinct claims, analyzing the applications for double patenting issues, and requiring cancellation of the claims or a terminal disclaimer.

Comment 126: One comment suggested that § 1.78(f)(2) prevents an applicant from claiming different embodiments unless the embodiments are patentably distinct.

Response: Under this final rule, applicant may present claims during the prosecution of an initial application and two continuation or continuation-in-part applications plus one request for continued examination in the application family, without any justification. Applicant therefore should have sufficient opportunity to present claims to different embodiments of an invention in these filings. Furthermore, applicant is not required to provide an explanation under § 1.78(f)(2)(ii)(B) for a

continuation application or continuation-in-part application of a prior-filed application that has been allowed.

Comment 127: One comment suggested that examiners would not have any incentive to find claims patentably distinct.

Response: Examiners are professionals who perform their duties within the framework of the current patent laws, rules and examination practices. No persuasive explanation was given in support of the suggestion that examiners would be less likely to find claims patentably distinct.

Comment 128: One comment suggested that the rebuttable presumption set forth in § 1.78(f)(2) was inconsistent with the Office's restriction practice. The comment suggested that it was inconsistent to presume that claims are patentably indistinct when, if the claims were filed in one application, they would be found to be patentably distinct, and subject to a restriction requirement.

Response: The changes to § 1.78(f)(2) and restriction practice encourage applicant to file a single application for each patentably distinct invention. For example, if two or more independent and distinct inventions are claimed in a single application, the examiner may make a restriction requirement. See § 1.142. The filing of multiple applications that together claim only one patentable invention (*i.e.*, the applications contain patentably indistinct claims), however, is diverting the Office's limited examining resources from examining new applications. Applicant should file a single application claiming one patentable invention rather than multiple applications claiming the same patentable invention. Applicant may rebut the presumption that claims in multiple applications are not patentably distinct by explaining how the application contains only claims that are patentably distinct from the claims in each of the other applications. Similar to the restriction practice, applicant may maintain multiple applications if the applications contain patentably distinct claims (*i.e.*, each application is claiming one patentably distinct invention).

Comment 129: One comment objected that remarks by applicants under § 1.78(f)(2) to rebut the double patenting presumption would create prosecution history estoppel before the Office issued a rejection that could impact on the certainty and quality of the patent.

Response: First, applicant remarks under § 1.78(f)(2) would be akin to remarks set forth in response to a double

patenting rejection. The Office does not consider the possibility of prosecution history estoppel to be a sufficient reason to forego the presumption built into § 1.78(f)(2). Second, such remarks would not be required if all patentably indistinct claims are included in one application.

Comment 130: One comment suggested that the rebuttable presumption in § 1.78(f)(2) would require applicants who normally file multiple utility applications within two months of each other, each with more than the threshold number of claims and each claiming benefit of the same provisional application, to now file an examination support document for their applications. The comment suggested that this would be especially true for those applications forming a portfolio being developed for a new technology.

Response: The rebuttable presumption provision of § 1.78(f)(2) would apply only if the nonprovisional applications have the same filing date, taking into account any filing date for which a benefit is sought, name at least one inventor in common, are owned by the same person or are subject to an obligation of assignment to the same person, and contain substantial overlapping disclosure. The rebuttable presumption provision of § 1.78(f)(2) does not apply simply because commonly owned applications are filed within two months of each other. In addition, § 1.78(f)(2) provides for a rebuttable presumption that applications contain patentably indistinct claims. The applications thus will be treated as containing patentably indistinct claims for claim counting purposes under § 1.75(b)(4) if the applicant does not explain how the applications do not contain patentably indistinct claims or if the examiner does not agree with the explanation. If an applicant files multiple applications that contain patentably indistinct claims, there is no reason why the Office should treat an applicant who spreads patentably indistinct claims among multiple applications differently than an applicant who presents all of the patentably indistinct claims in a single application.

Comment 131: Several comments suggested that the filing of multiple applications having at least one common inventor and specifications with overlapping disclosures cannot be presumed to be bad faith prosecution because these applications typically claim distinct inventions that relate to the same product or service and such applications are not used to delay prosecution. One such comment stated that the rebuttable presumption under

§ 1.78(f)(2) represents an overreaction to tactics engaged in by a small minority of applicants. Another such comment took offense to § 1.78(f)(2) as appearing to be based on underlying presumptions that applicants are gaming the system and their representatives are acting in bad faith whenever applications are filed meeting the criteria of the rule.

Response: There is no presumption of bad faith on the part of applicant. The rebuttable presumption is simply a procedural tool requiring the applicant to help focus and consolidate the examination process. This will help examiners to resolve double patenting issues early in the examination process and contribute to examination efficiency by eliminating the need to search for related applications.

Comment 132: A number of comments stated that the § 1.78(f)(2) criteria do not automatically lead to the conclusion the claims are patentably indistinct and that applicants may easily maintain multiple applications by preparing claims that are uniquely supported only in the application in which they appear. One comment objected that the mere presence of specifications with overlapping disclosures does not create a *prima facie* case of patentably indistinct claims as evidenced by the fact that an obviousness-type double patenting rejection requires a comparison between the claims of the application being examined and those of the co-owned application or patent, not a comparison of their disclosures.

Response: The § 1.78(f)(2) criteria lead to a rebuttable presumption, which is rebuttable that patentably indistinct claims exist. The rebuttable presumption is not a merits determination of patentability, but is simply a procedural tool requiring the applicant to help focus and consolidate the examination process. Further, an overlapping disclosure is not the only condition for the presumption under § 1.78(f)(2). Section 1.78(f)(2) also specifies that the applications must have the same claimed filing or priority date, name at least one inventor in common, and have common ownership. Accordingly, the presumption is limited so that it only applies to applications that most likely contain patentably indistinct claims. The rebuttable presumption does not equate to a *prima facie* case of patentably indistinct claims. An applicant may rebut the presumption by explaining how the application contains claims that are patentably distinct from the claims in each of the other applications or patents. If the applicant cannot rebut the presumption, applicant must submit a

terminal disclaimer in accordance with § 1.321(c) and explain why there are two or more pending nonprovisional applications which contain patentably indistinct claims.

Comment 133: One comment suggested that the rebuttable presumption should be provisional as the scope of the claims in question may change during the course of prosecution.

Response: Section 1.78(f)(2) as adopted in this final rule requires the appropriate action within the later of: (1) Four months from the actual filing date of an application filed under 35 U.S.C. 111(a) or four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f); or (2) the date on which a claim that is not patentably distinct from at least one of the claims in the other applications is presented. For example, if the presumption under § 1.78(f)(2) applies, applicant must rebut this presumption within four months from the actual filing date of an application filed under 35 U.S.C. 111(a) for the original claims presented on the filing date of the application. If applicant subsequently files an amendment that adds a new claim after four months from the filing date of the application, applicant must rebut this presumption for such a claim when applicant files the amendment.

Comment 134: One comment suggested that since the Office has stated in MPEP § 804.02 that patent applications which give rise to obviousness-type double patenting rejections are in the public interest, it stands to reason that the rules that seek to preclude such applications are against public interest.

Response: The Office stated that the use of a terminal disclaimer in overcoming an obviousness-type double patenting rejection is in the public interest because it encourages the disclosure of additional developments, the earlier filing of applications, and the earlier expiration of patents whereby the inventions covered become freely available to the public. See MPEP § 804.02. The Office did not state that the public interest was served by all applications that contain patentably indistinct claims.

Comment 135: One comment questioned whether applications subject to the requirements of § 1.78(f)(2) would increase examination pendency or add to the Office's backlog since the rejections set forth in applications with patentably indistinct claims are typically overcome by a properly drafted terminal disclaimer.

Response: The changes to § 1.78(f)(2) in this final rule are aimed at reducing pendency and the Office's backlog. Specifically, § 1.78(f)(2) requires applicant to resolve the double patenting issues early in the prosecution (e.g., four months from the actual filing date of the application) by either: (1) Filing a terminal disclaimer and an explanation as to why the multiple applications containing patentably indistinct claims are necessary; or (2) explaining how the application contains only claims that are patentably distinct from the claims of other related applications. Therefore, double patenting issues could be resolved before the first Office action on the merits, thus saving the examiner time by eliminating the need to search for related applications, analyze the potentially conflicting claims, and make the rejection. As a result, examination can be more focused on prior art and other patentability issues.

Without the rebuttable presumption of § 1.78(f)(2), it would be harder for the examiner to identify and resolve the potential double patenting situation. In addition, if an Office action in an application to which the rebuttable presumption applies must include a double patenting rejection, it is because the applicant has not helped to resolve the double patenting situation pursuant to § 1.78(f)(2). Accordingly, a double patenting rejection made for the first time in a second or subsequent Office action will not preclude the Office action from being made final (assuming that the conditions for making a second or subsequent action final are otherwise met). Thus, applicants' responsibility to take the initiative under § 1.78(f)(2) to resolve double patenting situations will expedite examination, even if this responsibility does not result in the prompt resolution of the double patenting situation. Further, the Office envisions that many applicants will file fewer applications containing patentably indistinct claims in light of § 1.78(f)(2) unless there is a good and sufficient reason to do so. Therefore, the Office expects that the requirements of § 1.78(f)(2) will not increase examination pendency or add to the Office backlog.

Comment 136: One comment suggested that the strategy for circumventing the claim requirement set forth in § 1.75 by filing multiple applications in order to receive substantive examination on more than the threshold number of claims conflicts with § 1.78(f)(2).

Response: As suggested by the comment, some applicants might attempt to circumvent the requirements

in § 1.75(b)(1) by filing multiple applications. Such a strategy would be ineffective as a result of the provisions of § 1.75(b)(4) and § 1.78(f). For the purpose of determining whether each of the multiple applications exceeds the five independent claim and twenty-five total claim threshold, the Office will treat each application as having the total number of all of the claims (whether in independent or dependent form) from all of the multiple applications. See § 1.75(b)(4).

Comment 137: Several comments objected that applicants are being required to explain or justify why they are filing patent applications. Some of the comments stated that such a requirement is unnecessarily burdensome and forces applicants to make statements that could lead to prosecution history estoppel issues. One of the comments questioned why § 1.78(f)(2)(ii) requires applicants to explain why the filing of two applications is necessary if a terminal disclaimer has been filed.

Response: The filing of multiple applications containing patentably indistinct claims is impairing the Office's ability to examine new applications. Applicant has the opportunity to avoid drafting and filing applications that satisfy the criteria of § 1.78(f)(2) by filing a single application containing all of the patentably indistinct claims. Furthermore, § 1.78(f)(2)(i) gives applicant the option to rebut the presumption of patentably indistinct claims rather than filing a terminal disclaimer and an explanation. Also note that the § 1.78(f)(3) provision was similarly set forth in former § 1.78(b).

Comment 138: Several comments were critical of § 1.78(f)(2) and stated that the rule would merely result in applicants filing jumbo patent applications with multiple claim sets drawn to patentably distinct inventions in order to force the Office to issue restrictions instead of filing multiple applications on the same day that meet the criteria of § 1.78(f)(2).

Response: Section 1.78(f)(2) permits applicant to file multiple applications claiming patentably distinct inventions. Applicant may rebut the presumption by arguing that the applications claim patentably distinct inventions. Applicant also has the option of filing a single application to claim patentably distinct inventions or when applicant is unsure whether the inventions are patentably distinct. As noted in *Berg*, 140 F.3d at 1434, 46 U.S.P.Q.2d at 1231, applicants achieve no advantage by choosing to file patentably indistinct claims in separate applications because

the claims would be subject to a rejection under the one-way double patenting analysis. The *Berg* court stated that "[i]f a potential applicant is unsure whether it has more than one patentably distinct set of claims, the PTO advises that it file all of the claims as one application." See *id.* at 1435, 46 U.S.P.Q.2d at 1232. The option presented by the Office was considered by the court to be reasonable, notwithstanding the possibility that the examiner might not make a restriction requirement.

Comment 139: One comment suggested that applicants will be unfairly disadvantaged if they fail to convince the examiner that the claims are patentably distinct, as they will likely be simultaneously subject to a final rejection with the probability of just a single continuation application to gain allowance of the claims.

Response: This final rule permits applicant to file two continuation or continuation-in-part applications and one request for continued examination in an application family, without any justification. If a timely rebuttal under § 1.78(f)(2) is filed before the application is taken up for initial examination, the applicant will not be subject to a final rejection in the first Office action on the merits. Only if the rebuttal is not timely filed would the applicant be subject to a final rejection in the succeeding Office action in the event the examiner makes a determination of patentably indistinct claims.

Comment 140: One comment stated that the § 1.78(f)(2) rebuttable presumption of patentably indistinct claims is overreaching and its burden on the applicant cannot be justified since it is very common for an applicant to file multiple applications having a single specification and patentably distinct claims drawn to different inventions.

Response: The rebuttable presumption of § 1.78(f)(2) is not overreaching as it applies only to applications that have the same filing date, taking into account any filing date for which a benefit is sought, name at least one inventor in common, are owned by the same person or are subject to an obligation of assignment to the same person, and contain substantial overlapping disclosure. Thus, it applies only to applications that most likely contain patentably indistinct claims. Applicant who files multiple applications claiming patentably distinct inventions may simply rebut the presumption. Applicant also has the option of filing a single application to claim patentably distinct inventions or when applicant is unsure whether the inventions are patentably distinct. If an

application claims two or more independent and distinct inventions, the examiner may make a restriction requirement. See § 1.142.

Comment 141: Several comments requested clarification as to the standard for “patentably indistinct” as the term appears in § 1.78 and whether this applies to “same invention” double patenting under 35 U.S.C. 101, or “obviousness-type” double patenting, or something different. Several comments requested clarification concerning what would be an adequate explanation under § 1.78(f)(2)(i) to rebut the presumption of patentably indistinct claims.

Response: The standard for “patentably indistinct” as the term appears in § 1.78 is one-way distinctness in an obviousness-type double patenting analysis. See MPEP § 804(II)(B)(1)(a). The presumption under § 1.78(f)(2) may be rebutted by showing that the application claims are directed to a separate invention, or by pointing to a unique claim element(s) in the independent claim(s) that patentably distinguishes them from the claims in the application(s) that gave rise to the § 1.78(f)(2) presumption.

Comment 142: A number of comments questioned whether all patentably indistinct claims in multiple applications meeting the conditions of § 1.78(f)(2) are required to be submitted in a single application absent good and sufficient reason.

Response: If all patentably indistinct claims can be filed in a single application and there is no good and sufficient reason for the patentably indistinct claims to be filed in multiple applications, then applicant should file the patentably indistinct claims in a single application. Section 1.78(f)(3) provides that the Office may require elimination of the patentably indistinct claims meeting the conditions of § 1.78(f)(3) in all but one of the applications in the absence of a good and sufficient reason for there being two or more applications containing patentably indistinct claims.

Comment 143: Several comments suggested that § 1.78(f)(2) be changed to provide that the presumption of patentably indistinct claims be applied to all related applications only when a double patenting rejection is made in one of the related applications.

Response: The suggested change would delay triggering the presumption of patentably indistinct claims and not help reduce the burden on examiners with respect to reviewing and analyzing related applications with potentially conflicting claims.

Comment 144: One comment stated that by requiring more than a terminal disclaimer to overcome an obviousness-type double patenting rejection, the Office is outside its authority.

Response: No more than a terminal disclaimer is required to overcome obviousness-type double patenting if the reference is a patent. However, if the obviousness-type double patenting reference is a pending application, consideration of patentably indistinct claims can be expedited in a single application. Such a requirement is consistent with the Office’s statutory authority under 35 U.S.C. 2(b)(2). Nothing in the patent statutes requires the Office to accept patentably indistinct claims in multiple applications absent a good and sufficient reason.

Comment 145: Several comments suggested eliminating the presumption of double patenting in § 1.78(f)(2) and identification of similar applications in § 1.78(f)(1) as such requirements are already in the rules.

Response: The former rules of practice did not expressly require the identification of applications based on filing dates, inventorship and ownership conditions. Some of the applications identified pursuant to § 1.78(f)(1) may be applications with the potential to be material to patentability as prosecution progresses. Section 1.78(f)(2) as adopted in this final rule explicitly sets forth for the first time a presumption of patentably indistinct claims among related applications meeting certain conditions.

Comment 146: Several comments suggested permitting “voluntary” divisional applications instead of requiring an explanation adequate to rebut the § 1.78(f)(2) presumption of patentably indistinct claims.

Response: It is unclear how such a strategy would reduce pendency and promote quality. Anytime a terminal disclaimer is filed under the conditions of § 1.78(f)(2), the applicant would also have to file a satisfactory explanation of why there are two or more commonly owned pending nonprovisional applications naming at least one inventor in common which contain patentably indistinct claims. The alternative to filing a terminal disclaimer with the explanation is to rebut the § 1.78(f)(2) presumption with a showing that the application contains only patentably distinct claims.

Comment 147: Several comments requested clarification as to what constitutes “substantial overlapping disclosure” and whether it encompasses, for example, a single common sentence or disclosed element,

or an incorporation by reference to another application.

Response: As discussed previously, § 1.78(f)(2)(i) provides that substantial overlapping disclosure exists if the other pending or patented nonprovisional application has written description support under 35 U.S.C. 112, ¶ 1, for at least one claim in the nonprovisional application. This written description support may be either by express disclosure or by an incorporation by reference to another application. A single common sentence or disclosed element most likely would not, by itself, constitute “substantial overlapping disclosure.”

Comment 148: One comment was critical that § 1.78(f)(2)(i) will force applicants to prove a negative in order to show that there are no patentably indistinct claims among the pending nonprovisional applications.

Response: To rebut the presumption under 1.78(f)(2)(i), applicant could identify claim elements that patentably distinguish the applications from one another. It is not required that the applicant prove a negative.

Comment 149: Several comments objected that § 1.78(f)(3) could effectively promote a ban on continuation applications with patentably indistinct claims, and may unnecessarily limit claim broadening in continuation applications.

Response: Section 1.78(f)(3) is a restatement of former § 1.78(b), which previously gave the Office the same discretion to require elimination of patentably indistinct claims in all but one of the pending nonprovisional applications. The only difference is that the Office will now have the benefit of § 1.78(f)(2)(i) to evaluate when to properly exercise that discretion.

Comment 150: A number of comments noted that § 1.78(f)(3) essentially restates former § 1.78(b) and questioned whether § 1.78(f)(3) would achieve anything beyond what former § 1.78(b) achieved during its existence for over thirty-five years.

Response: This provision will be more effectively utilized with the other changes to § 1.78(f).

Comment 151: A number of comments requested clarification of the procedure for reviewing a determination of multiple applications with patentably indistinct claims. One comment requested clarification as to whether an adverse determination is redressed by way of appeal to the BPAI or to a district court.

Response: Applicants may petition the Director for review of administrative requirements by an examiner or other Office official, such as a requirement for

an examination support document under § 1.265 when claims in multiple applications are determined to be patentably indistinct thus causing the involved applications to exceed the five independent claim and twenty-five total claim threshold set forth in §§ 1.75(b)(1), (b)(3), and (b)(4), as well as a requirement that claims in multiple applications that are determined to be patentably indistinct be canceled from all but one application.

The BPAI's jurisdiction and appeal procedure in general has not been changed as a result of this final rule. As before, applicant may appeal the decision of the examiner to the BPAI under 35 U.S.C. 134 and § 41.31 if at least one claim has been twice rejected (*see* § 41.31(a)), including an obviousness-type double patenting rejection.

Comment 152: A number of comments were critical of the "may require elimination" in § 1.78(f)(3), suggesting that the discretion would be arbitrarily applied by individual examiners and inconsistently applied by the Patent Examining Corps. Some comments requested clarification of the procedure and questioned whether the Office will make a double patenting rejection and/or require elimination of patentably indistinct claims. Some comments questioned whether a requirement to eliminate patentably indistinct claims would apply to all but a single application.

Response: Section 1.78(f)(3) provides that, in the absence of good and sufficient reason for there being multiple commonly owned applications that contain patentably indistinct claims, the Office may require elimination of the patentably indistinct claims from all but one of the applications. The term "may" provides both the Office and applicants with the necessary discretion and flexibility either to eliminate the identified claims found to be patentably indistinct, or to merge multiple applications into one. Substantively, § 1.78(f)(3) is a restatement of former § 1.78(b).

Comment 153: A number of comments stated that requirements to eliminate patentably indistinct claims from all but one of the applications will lead to applicant appeals or petitions before examination resulting in a substantial increase in pendency while consuming Office and applicant resources. Some comments stated that § 1.78(f)(3) requirements will discourage applicants from acknowledging claims that are patentably indistinct and result in increased challenges to double patenting rejections.

Response: As discussed previously, it is envisioned that many applicants will file fewer applications containing patentably indistinct claims unless there is a good and sufficient reason to do so. Because any requirement under § 1.78(f)(3) would be made during examination, there can be no petitions to the Director, or appeals, filed before examination as suggested by the comment. The comment provided no reasoning as to why § 1.78(f)(3) would have the negative impact anticipated by the comment when § 1.78(f)(3) is a restatement of former § 1.78(b).

Comment 154: One comment suggested allowing multiple related applications, keeping the requirement to identify related applications, and adding a requirement for applicant to briefly explain the subject matter claimed in each related application.

Response: The proposed solution would not meet the objectives of these rules and would not prevent the Office from unnecessarily expending the Office's resources in the examination of multiple applications with patentably indistinct claims.

Comment 155: Several comments questioned whether excess claim fees would be refunded upon elimination of patentably indistinct claims pursuant to § 1.78(f)(3).

Response: Applicant may request a refund of any excess claims fees paid on or after December 8, 2004, if applicant cancels the claim before an examination on the merits has been made of the application. *See* § 1.117.

Comment 156: Several comments questioned why there is different language in §§ 1.78(f)(3) and 1.75(b)(4), and questioned whether the language should be the same.

Response: As the comment noted, the proposed provisions that the Office may require elimination of the patentably indistinct claims from all but one of the applications in §§ 1.78(f)(3) and 1.75(b)(4) were duplicative and might have appeared different. In view of the comment, the Office did not adopt the proposed provision that the Office may require elimination of the patentably indistinct claims from all but one of the applications in § 1.75(b)(4). The Office adopted this provision in § 1.78(f)(3) which is substantively a restatement of former § 1.78(b). *See* the discussion of §§ 1.75(b)(4) and 1.78(f)(3).

Comment 157: Several comments requested that implementation of § 1.78(f)(3) be delayed until other rule changes can be evaluated.

Response: Section 1.78(f)(3) is a restatement of former § 1.78(b) which has been in effect since April 30, 1971.

See Conflicting Claims, 36 FR 7312 (April 17, 1971) (final rule).

Comment 158: One comment stated that the patentably indistinct claims in multiple applications are a necessary and desirable component of United States patent law.

Response: The comment did not provide a reason why the need for applicants to have separate applications with patentably indistinct claims outweighs the needs of the Office to reduce the resources exhausted during the examination of different applications with patentably indistinct claims.

Comment 159: One comment stated that § 1.78(f)(3) imposes an overly stringent standard that jeopardizes applicant's ability to ensure patented claims will be held valid if challenged during litigation. One comment stated that the § 1.78(f) changes are based on the presumption that all patentably indistinct claims can be supported and examined in the same application, but that is not always the case.

Response: Section 1.78(f)(3) is a restatement of former § 1.78(b), which previously gave the Office the same discretion to require elimination of patentably indistinct claims in all but one of the pending nonprovisional applications. Therefore, § 1.78(f)(3) does not introduce a new standard as suggested in the comment. Applicant may file multiple applications, but applicant must, in each application, submit a terminal disclaimer in accordance with § 1.321(c) and explain why there are two or more pending nonprovisional applications containing patentably indistinct claims.

Comment 160: One comment suggested allowing applicants to add patentably indistinct claims to an application after determination that an original set of claims is allowable.

Response: Patentably indistinct claims should not be added to an application upon allowance of the original claims, but should instead be presented earlier.

Comment 161: One comment questioned whether it is really a burden on the examiner to search two applications with patentably indistinct claims versus one application with the claims of both.

Response: It is less burdensome to the Office to have patentably indistinct claims in a single application. A related application with conflicting claims would have to be identified, reviewed and analyzed for double patenting issues.

Comment 162: One comment suggested providing for immediate and expedited review of all decisions

relating to new submissions required by § 1.78.

Response: The Office will strive to promptly act on all petitions related to the changes to § 1.78 in this final rule.

Comment 163: One comment suggested that § 1.78(g) should be amended to require that in response to a statutory or obviousness-type double patenting rejection, the Office may require the assignee to state whether the claimed inventions were commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, and if not to indicate which named inventor(s) is/are the prior inventor, unless applicant traverses the rejection.

Response: Section 1.78(g) contains the provisions of former § 1.78(c). The Office believes that these provisions, as well as the information that may be required, are currently sufficient for the Office to achieve its goals with respect to identifying commonly owned cases that come within the provisions of 35 U.S.C. 103(c) or with respect to determining the prior invention.

F. Changes to Practice for Examination of Claims

Comment 164: Several comments supported the concept of representative claims. One comment stated that the rules promote more focused examination, reduce delay and help conserve scarce Office resources, require little effort on the part of most applicants, and still make certain that no patent claims will issue without a complete examination. The comments also expressed support for limiting the number of claims that need to be examined and encouraged the Office to reduce overwhelming numbers of claims in favor of quality examinations. One comment suggested that the Office should adopt a rule that only independent claims are examined.

A number of comments, however, argued in a variety of terms that the “representative claims” examination approach would lead to piecemeal examination and prolonged examination, would require additional searching when features from non-designated dependent claims are added to designated dependent or independent claims, and would lead to additional filings, increased appeals, and less thorough examination. Several comments suggested that the number of claims examined should not be limited *per se* because the line of novelty in a claim family often falls between the broad independent claims and the narrowest dependent claim. One comment stated that the “representative claims” examination approach may

adversely affect the treatment given to dependent claims in court. One comment argued that the Office’s statistics on applications having more than ten independent claims ignore how many total claims had to be presented to lead to those independent claims.

Several comments argued that since excess claim fees have presumably been determined based on the resources necessary to carry out search and examination of all of the claims, it is not appropriate for the Office to neglect to fully search and examine the entire application for which all fees have been paid. One comment stated that there is no basis for limiting the consideration of a dependent claim during examination because under 35 U.S.C. 112, ¶ 4, a dependent claim is treated as a claim that incorporates all the limitations of the preceding claims.

A number of comments argued that the “representative claims” examination approach may be appropriate in other proceedings (such as before the BPAI) or even during examination, but not before first Office action on the merits. One comment argued that statistical data from the appeal stage is misleading because there are fewer issues during an appeal than during prosecution of an application before the examiner. Several comments stated that the BPAI would be forced to perform examination on the merits of the non-representative claims.

A number of comments suggested that the Office should address excessive claiming concerns in a simple and straightforward manner by limiting the number of claims permitted and fully examined under the basic fee structure to, for example, six independent and thirty total numbered claims, and allowing multiple dependent claims that depend on other multiple dependent claims. Several comments suggested that the Office specify that excess claims over a certain number will only be examined if accompanied by an independent search report, rather than burdening all applicants with the requirement to designate claims. Several comments suggested that instead of representative claims, applicants should be allowed to select claims that stand or fall together.

Finally, a number of comments also raised implementation issues, requested clarification concerning implementation issues, or provided suggestions concerning the implementation of the “representative claims” examination approach.

Response: As a result of the public comment, the Office is not adopting the “representative claims” examination approach under which the Office would limit the initial examination of an

application to the “representative claims” (the independent claims and the dependent claims that are expressly designated by the applicant for initial examination). The Office is instead making the presentation of more than five independent claims or more than twenty-five total claims (rather than the presentation of more than ten representative claims) the threshold for invoking the examination support document requirement. Thus, this final rule provides that if the number of independent claims is greater than five or the number of total claims is greater than twenty-five, the applicant must provide additional information to the Office in an examination support document covering all of the claims in the application (whether in independent or dependent form).

Although, the “representative claims” examination approach is not being adopted, the Office disagrees that such an approach amounts to piecemeal examination or that it would be less efficient than the current examination process. Under such an approach, the Office would have examined a claim before applicant could seek review of any rejection of the claim on appeal, regardless of whether the claim was designated or non-designated under the “representative claims” examination approach.

Regarding escalating fees, the Office previously proposed a system of escalating fees and it was overwhelmingly opposed by user groups. The Office has also determined that charging higher fees for large numbers of claims would likely still not result in the desired increase in quality since many applicants would simply pay the higher fees. Furthermore, claim fees are set by statute, not the Office. As discussed previously, 35 U.S.C. 112, ¶ 5, prohibits multiple dependent claims depending on other multiple dependent claims.

Comment 165: One comment stated that examining many claims aids in understanding the invention.

Response: The experience of those who actually examine applications is that examining a large number of claims does not aid in understanding the invention but rather obfuscates the invention. In addition, the issuance of patents containing an excessive number of claims has also long been considered an abuse of the courts and the public, rather than an aid in understanding the invention. See *Carlton v. Bokee*, 84 U.S. (17 Wall) 463, 471–72 (1873) (needless multiplication of nebulous claims deemed calculated to deceive and mislead the public); *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1551

n.6, 10 U.S.P.Q.2d 1201, 1206 n.6 (Fed. Cir. 1989) (presentation of the infringement issue on an overgrown claims jungle to a jury and judge at trial is an unprofessional exercise in obfuscation).

Comment 166: A number of comments argued that more claims are needed to protect an applicant's invention adequately, especially in light of restrictions on the doctrine of equivalents, decisions by the Federal Circuit on unclaimed subject matter, the proposed limitations on continuation practice, and because the complexity of some inventions requires more claims to protect the subject matter appropriately. One comment argued that the effects of prosecution history estoppel and the constraints put on reissue applicants by the recapture doctrine demand a broad range of claims. Several comments argued that the proposed changes disproportionately affect the biotechnology and pharmaceutical industries. One comment argued that in chemical or pharmaceutical applications full protection requires applicant to claim a chemical substance, a composition containing the substance, method of making the substance, the chemical substance prepared by a claimed process and at least one method of use, where there is varying scope within each category of invention. The comments argued that individuals and small businesses would be unable to afford the costs of pursuing their inventions and may be discouraged from using the patent system due to the financial and procedural burdens they must overcome to obtain adequate patent protection of their invention. Several comments argued that the proposed rules would have a disproportionate impact on small entities. One comment stated that in the post-*Festo* environment, patent-drafting techniques would suggest filing a large number of picture claims in multiple statutory classes for easy understanding of the invention by the Federal Circuit. One comment stated that the primary reason why large numbers of claims are filed is that the applicants or their representatives do not want the effort and responsibility of determining the differences between the prior art and the invention, and that another reason is that attorneys who are paid a flat fee for applications attempt to induce a restriction requirement.

Response: This final rule provides that if the number of independent claims is greater than five or the number of total claims is greater than twenty-five (a strategy based upon whether an application contains more than a given number of independent and total

claims), the applicant must provide additional information to the Office in an examination support document under § 1.265. The overall goal of these changes is to promote early presentation of claimed inventions, enhance quality and improve pendency. The rules do not impose a *per se* limit on the number of claims which can be presented to protect applicant's inventions. Rather, applicant may file any desired number and scope of claims necessary to adequately protect the applicant's invention as long as an examination support document is provided before the issuance of the first Office action on the merits of an application that present more than five independent claims or twenty-five total claims.

The Office notes that, during fiscal year 2006, the percentage of small entity applications that exceeded the five independent claim and twenty-five total claim threshold appeared slightly higher than the percentage of total applications that exceeded the five independent claim and twenty-five total claim threshold (24.4 percent as opposed to 23.7 percent). The Office does not consider this slight differential as establishing that the changes in this final rule have a disproportionate economic impact on small entities. While it is possible to engage in a mathematical exercise to exaggerate the significance of any slight differential, these percentages are based upon data that is available in the Office's PALM system for applications filed during the most recent fiscal year, and this slight differential is not sufficient to establish that the changes in this final rule have a disproportionate economic impact on small entities. In addition, there is no apparent reason why small entity applicants would inherently require more claims to adequately cover their inventions. Thus, even higher differences in these percentages could easily be explained by the fact that small entity applicants pay only one-half of the fees that other applicants pay for excess claims. Moreover, the five independent claim and twenty-five total claim threshold adopted in this final rule has a smaller differential than other alternatives suggested in the comments. For example, in fiscal year 2006: (1) 17.1 percent of small entity applicants exceeded a six independent claim and thirty total claim threshold where only 15.7 percent of all applications exceeded a six independent claim and thirty total claim threshold; (2) 10.3 percent of small entity applicants exceeded a six independent claim and forty total claim threshold where only 9.2 percent of all applications exceeded

a six independent claim and forty total claim threshold; and (3) 5.0 percent of small entity applicants exceeded a ten independent claim and fifty total claim threshold where only 4.1 percent of all applications exceeded a ten independent claim and fifty total claim threshold.

The remaining explanations (post-*Festo* patent-drafting techniques, not wanting the responsibility of determining the differences between the prior art and the invention, and attempts to induce a restriction requirement) may be "reasons" why some applicants submit a large number of claims. These reasons, however, do not justify not going forward with a change to the rule of practice to require applicants who place an extensive burden on the Office to help focus examination by providing additional information in the form of an examination support document to the Office.

Comment 167: One comment argued that choosing dependent claims to designate at the outset of prosecution forces applicant to make a threshold decision regarding claim scope without the benefit of analyzing cited prior art following an Office action. Thus, applicants either have to guess, or perform their own prior art search prior to filing, which puts a burden on applicant and results in the need to file a previously unnecessary information disclosure under § 1.56.

Response: The Office is not adopting the proposed "representative claim" approach. Therefore, no designation is required by this final rule. This final rule requires applicants who present more than five independent claims or more than twenty-five total claims to file an examination support document before the issuance of a first Office action on the merits of an application. Applicants are encouraged to conduct a preexamination search and review the references uncovered from the preexamination search so applicants can better understand where their invention fits in the overall patent landscape. Such action would facilitate presentation of claims more likely to be patentable over the closest prior art, thereby alleviating some of the burden on Office resources. Nevertheless, if applicant chooses not to conduct a preexamination search and does not submit an examination support document before the first Office action on the merits of the application, this does not constitute a justification for filing more than five independent claims or more than twenty-five total claims.

Comment 168: One comment stated that it is unclear as to whether all claims, or only independent (or designated) claims, are counted for the purposes of § 1.75(b)(4).

Response: Pursuant to § 1.75(b)(4) as adopted in this final rule, the Office will count all of the claims in copending applications containing patentably indistinct claims (including applications having a continuity relationship) but not in issued patents containing patentably indistinct claims, in determining whether each such application contains more than five independent claims or more than twenty-five total claims and thus whether an examination support document in compliance with § 1.265 is required. Claims withdrawn from consideration under §§ 1.141 through 1.146 or § 1.499 as drawn to a non-elected invention or inventions, however, will not, unless they are reinstated or rejoined, be taken into account in determining whether an application exceeds the five independent claim and twenty-five total claim threshold set forth in §§ 1.75(b)(1), (b)(3), and (b)(4). See § 1.75(b)(5). As discussed previously, this final rule does not implement a “representative claims” examination approach.

Comment 169: One comment stated that the rules do not provide speedy and economical administrative relief when the Office errs in determining whether claims are patentably indistinct, or whether there is adequate support in an application for a claim filed in another application.

Response: As discussed previously, the Office already has timely and efficient procedures in place that provide for an applicant to seek relief with respect to matters subject to appeal (e.g., the rejection of claims) by way of an appeal to the BPAI under 35 U.S.C. 134 and § 41.31 *et seq.*, and to seek relief with respect to actions or requirements not subject to appeal by way of a petition to the Director under § 1.181. For example, if a double patenting rejection is made because the claims of two applications are patentably indistinct, applicant may seek relief by way of an appeal to the BPAI. If the Office issues a notice under § 1.75(b) requiring an examination support document in each of the multiple applications that contain patentably indistinct claims, applicant may seek relief by way of a petition to the Director under § 1.181. A grant of relief in a petition, however, does not preclude a subsequent double patenting rejection.

Comment 170: One comment argued that the rule will create more work for examiners by requiring review of all patents and applications assigned to one assignee of an application under examination, and that if certain examiners fail to do so, the rule will be unfairly applied within the Office. One comment argued that implementation of the rules will have a disproportionate effect on assignees holding small patent portfolios because due to time constraints, examiners will be able to review small patent portfolios more thoroughly than large ones.

Response: The rules do not require examiners to review all patents and applications assigned to the same assignee, but rather require applicant to identify certain commonly assigned applications having a common inventor. See § 1.78(f)(1). Examiners already face the situation of having to evaluate a potentially large number of commonly assigned patents and applications for the purpose of determining whether a prior art or double patenting rejection is warranted. The rules will enable the examiners to do this analysis more thoroughly and in less time, thus enhancing quality and reducing pendency.

Comment 171: One comment argued that implementation of the rules will create an additional area of contention between examiners and applicants, and an additional drain on examiners' time. The comment further argued that the drain will be greater than that associated with double patenting because double patenting rejections can be overcome by filing terminal disclaimers.

Response: No new issues between the examiner and the applicant are introduced by the changes being adopted in this final rule. Rather, the rules allow the examiner to identify and address issues more thoroughly. Furthermore, as a result of the rules, applicants will be made aware of issues earlier in the prosecution, thus giving applicants more time to formulate appropriate responses. Terminal disclaimers will continue to be available for use as appropriate to obviate non-statutory double patenting rejections.

Comment 172: One comment argued that the changes concerning claims are superfluous in view of the rule changes concerning continuation practice, and that a penalty for filing excessive continuations is already provided in the continuations rules.

Response: The changes to the practice for examination of claims will operate in concert with the changes to the practice for continuing applications and requests for continued examination. The changes for the continued examination

filing practice do not by themselves act to lessen the examiner's burden when faced with a large number of claims for examination.

Comment 173: One comment questioned how the Office will implement review of two applications containing claims to the same invention.

Response: If two or more commonly assigned applications contain patentably indistinct claims, the Office will track the applications via the PALM system. The applicant may explain why the claims of one application are patentably distinct from the claims of the other(s). If at least one claim is not patentably distinct and there are a total of more than five independent claims or more than twenty-five total claims in the applications, the applicant will be required to file an examination support document before the first Office action on the merits in each application. Applicant may file a terminal disclaimer to obviate an obviousness-type double patenting rejection.

Comment 174: One comment suggested that the requirement that claims differ substantially according to § 1.75(b) should only apply to independent claims.

Response: The provision that “[m]ore than one claim may be presented provided they differ substantially from each other and are not unduly multiplied” has been set forth in § 1.75(b) even prior to this final rule. The comment provides no reason why the requirement that claims differ substantially from each other and not be unduly multiplied should not also apply to dependent claims.

Comment 175: One comment inquired about designation of claims during reexamination. The comment stated that the rules should not apply to reexaminations of patents granted prior to enactment of the rules.

Response: The changes to § 1.75 adopted in this final rule do not apply to reexamination proceedings. Furthermore, this final rule does not adopt the “representative claims” examination approach (which provided for a designation of dependent claims).

Comment 176: A number of comments argued that the changes limit the protection paid for by applicant.

One comment argued that as a result of the limitation on the number of claims, companies that invest in research and development could be expected to keep more inventions as trade secrets due to the threat posed by “free riders” who make minor modifications in an attempt to avoid infringement.

Response: The patent statute requires that an applicant pay certain filing fees (the filing, search, examination, excess

claims, and application size fees) on filing an application for patent. *See* 35 U.S.C. 41(a). The payment of these patent filing fees does not amount to a purchase of patent protection but are simply to help cover the costs of examination and application processing.

Section 1.75 does not limit the number of claims that applicant can present in an application. Section 1.75(b)(1) permits an applicant to present five independent claims and twenty-five total claims for examination without the need for an examination support document. An applicant who considers five independent claims or twenty-five total claims to be insufficient may present more than five independent claims or twenty-five total claims by submitting an examination support document under § 1.265 before the first Office action on the merits of an application.

Comment 177: One comment suggested that if the rules are implemented, the Office should reduce the examination fee and wait to charge the excess claim fees, or refund the excess claim fees if the application goes abandoned.

Response: The basic filing, search, examination, and excess claims fees are set by statute, which the Office cannot change by rule making. The filing fees are due upon filing of the application and the excess claims fees are due when the claims are presented. *See* 35 U.S.C. 41. Applicant may request a refund of any previously paid search and excess claims fees if applicant expressly abandons an application filed under 35 U.S.C. 111(a) on or after December 8, 2004, by filing a petition under § 1.138(d) before an examination has been made of the application. An “examination has been made of the application” for purposes of § 1.138(d) once there has been a requirement for restriction including an election of species, requirement for information under § 1.105, first Office action on the merits, notice of allowability or allowance, or action under *Ex parte Quayle*. Applicant may also request a refund of any excess claims fees paid on or after December 8, 2004, if an amendment canceling the excess claims is filed before an examination on the merits has been made of the application. *See* § 1.117. An “examination on the merits has been made of the application” for purposes of § 1.117(a) once there has been a first Office action on the merits, notice of allowability or allowance, or action under *Ex parte Quayle*.

Comment 178: One comment argued that the small number of problematic cases with excessive claims that confuse

or obscure the invention can be adequately handled through the use of undue multiplicity rejections.

Response: Undue multiplicity rejections based on 35 U.S.C. 112, ¶ 2, are rare. *See* MPEP § 2173.05(n). The rule changes are designed to provide a more focused quality examination of all applications. The Office would not be able to obtain the desired gains in efficiency and quality by merely relying on the use of undue multiplicity rejections.

Comment 179: One comment argued that the impact of the rules on the backlog will be minimal and referred to the Inspector General Report of 2004 which identified suboptimal incentives for examiners as the cause of the backlogs, not the excess number of claims.

Response: The September 2004 Inspector General Report (Final Inspection Report No. IPE-15722), available at <http://www.oig.doc.gov/oig/reports/2004/USPTO-IPE-15722-09-04.pdf>, concluded that the Office should reevaluate patent examiner production goals, appraisal plans, and award systems. The September 2004 Inspector General Report was not the result of a general study of the causes of the growing backlog of unexamined patent applications, but was the result of a review of only patent examiner production goals, appraisal plans, and award systems. Thus, the September 2004 Inspector General Report does not discuss other causes of the growing backlog of unexamined patent applications (e.g., changes in applicant filing tendencies) and does not warrant the conclusion that the September 2004 Inspector General Report identifies suboptimal incentives for examiners as the sole cause of the growing backlog of unexamined patent applications. In any event, the Office is in the process of reassessing patent examiner production goals, appraisal plans, and award systems as recommended in the September 2004 Inspector General Report. Absent significant changes to the patent examination process, the Office does not consider it reasonable to expect that changes to patent examiner production goals, appraisal plans, and award systems alone will be sufficient to address the growing backlog of unexamined patent applications while maintaining a sufficient level of quality.

Comment 180: One comment argued that the Office admitted to previously abandoning a proposal to limit the number of total and independent claims. The comment argued that if such a proposal was deemed inappropriate, it is difficult to see how

limiting claims before initial examination is also not inappropriate.

Response: The previous proposal was not abandoned because it was deemed inappropriate; rather, it was abandoned because it was unpopular. The Office subsequently sought increases in excess claims fees via legislative change. There was insufficient public support for all the fee increases that the Office considered necessary and the current fees are not adequately addressing the problem of large numbers of claims. The comments submitted in response to the Claims Proposed Rule indicate that many view an approach similar to that proposed in 1998 to be preferable. The changes being adopted in this final rule (in contrast to the changes proposed in 1998) do not place a limit on the number of claims (independent or dependent) that may be presented in an application. These changes adopted in this final rule simply require the submission of an examination support document if an applicant chooses to present more than five independent claims or more than twenty-five total claims in an application. Furthermore, the backlog of unexamined applications has increased from 224,446 at the end of fiscal year 1998 to 701,147 at the end of fiscal year 2006. The Office expects the backlog of unexamined applications to continue to increase without significant changes to the patent examination process. In addition, the average number of claims per application has not decreased since 1998. Thus, the Office does not consider the fact that the changes being adopted in this final rule may not be popular to be an adequate reason for not going forward at this time.

Comment 181: One comment pointed out inconsistencies between proposed § 1.75(b)(3)(iii), which requires a suggested restriction to be drawn to “no more than ten” claims, and the preamble to the proposed rule, which requires the restriction to be drawn to “fewer than ten” claims.

Response: Proposed § 1.75(b)(3)(iii) provided that an applicant may file a suggested requirement for restriction accompanied by an election without traverse of an invention to which there are drawn no more than ten independent claims and no more than ten representative claims. This final rule did not adopt the proposed “representative claims” examination approach, but requires applicant to file an examination support document when the application contains more than five independent claims or more than twenty-five total claims. Under § 1.142(c) as adopted in this final rule, applicant may file a suggested

requirement for restriction accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims.

Comment 182: One comment argued that applicants would circumvent the proposed rules by designating a "picture claim" in all applications, thereby forcing the examiner to perform a complete search and examination, thus obviating any time or effort saved through the proposed changes.

Response: The Office has no objection to an applicant presenting a claim that recites in detail all of the features of an invention (*i.e.*, a "picture" claim) in an application. Nevertheless, the mere fact that a claim recites in detail all of the features of an invention is never, in itself, justification for the allowance of such a claim. See MPEP § 706.

Comment 183: One comment argued that according to *In re Wakefield*, 422 F.2d 897, 164 U.S.P.Q. 636 (C.C.P.A. 1970), applicant should be allowed to determine the necessary number and scope of claims.

Response: The changes adopted in this final rule do not set a *per se* limit on the number of claims that an applicant may file in an application. The applicant is free to file as many claims as necessary to adequately protect the invention. Applicant may present more than five independent claims or more than twenty-five total claims in an application if applicant files an examination support document before the first Office action on the merits of the application. The information provided by the applicant in the examination support document will assist the examiner in understanding the claimed invention, determining the effective filing date of each claim and the claim interpretation before the prior art search, understanding the state of the art and the most closely related prior art cited by the applicant, and determining the patentability of the claims. Thus, the examiner will be able to perform a better examination on the claims.

Comment 184: A number of comments argued that the rules would lessen the applicant's ability to file applications due to budget constraints and would increase costs for counseling applicants to get the best patent protection. One comment argued that the rules will increase applicant's costs to such an extent that individual inventors and small companies will not be able to afford patent protection. Furthermore, the costs to comply with the rules will cause many people with technology that can spur innovation to be frozen out of the patent process.

Response: The current rules will only impact those applications that are filed with more than five independent claims or more than twenty-five total claims. If applicant presents more than five independent claims or more than twenty-five total claims, then applicant will be required to submit an examination support document under § 1.265. If an application is so significant that the applicant must present more than five independent claims or more than twenty-five total claims, then the additional costs should not be a deterrent.

Comment 185: One comment suggested that if the Office were to follow *Muncie Gear Works v. Outboard Marine & Mfg Co.*, late claiming of applications would likely decrease.

Response: In *Westphal v. Fawzi*, 666 F.2d 575, 577 (C.C.P.A. 1981), the Court of Customs and Patent Appeals discredited the idea that *Muncie Gear Works v. Outboard Marine & Mfg. Co.*, 315 U.S. 759 (1942) should be read as announcing a new "late claiming" doctrine. Rather, the Court of Customs and Patent Appeals interpreted the *Muncie Gear Works* holding of invalidity as grounded in the statutory prohibition against new matter.

Comment 186: A number of comments suggested that claims written in alternative form should not be treated differently from other claims, and that the Office should use election of species practice to identify alternatives to be used as representative claims. Several comments stated that claims drafted using Markush or other alternative language should be treated as single claims rather than treating each alternative as a separate claim. One comment stated that if members of Markush groups are counted separately, biotechnology and chemical applicants will file more multiple parallel applications. One comment requested clarification as to whether each element of a Markush claim would be considered to be an independent claim. One comment stated that Markush claims are beneficial to both the Office and applicants, and stated that the proposed changes would unfairly disadvantage members of the pharmaceutical community. One comment suggested that encouraging applicants to adhere more closely to existing 35 U.S.C. 112, ¶ 1 and 35 U.S.C. 101 requirements is a better means of managing the breadth of Markush claims than individualized claim counting schemes and required showings. One comment suggested that the Office should treat a Markush claim as a broad or generic claim. One comment asserted that the Office has

not provided any study or anecdotal evidence that identifies an abuse of Markush practice. One comment stated that the MPEP has never required that individual elements in a Markush group be treated separately, and that it is unfair to an applicant to use up claim designations on the individual elements of a Markush group because a reference teaching one element is applied to all.

Several comments argued that the proposed rule relating to determining the presence of separate claims in a Markush grouping will slow down prosecution, in part due to an increased number of petitions to review.

Response: The Office requested comments on how claims written in the alternative form, such as claims in an alternative form permitted by *Ex parte Markush*, 1925 Dec. Comm'r Pat. 126 (1924), should be counted for purposes of proposed § 1.75(b). See *Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR at 64, 1302 *Off. Gaz. Pat. Office* at 1331. This final rule does not change the practice of the Office with regard to claims containing Markush or other alternative language. That is, a claim containing Markush or other alternative language would be considered as one claim for the purposes of determining whether an application exceeds the five independent claim and twenty-five total claim threshold set forth in § 1.75(b). However, the Office is evaluating changes to Markush practice, which could be implemented in a separate rule making.

The Office is also clarifying second action final practice with respect to using alternative language (*e.g.*, Markush claims). MPEP § 803.02 indicates that if an applicant amends a rejected Markush claim to exclude species anticipated or rendered obvious by the prior art, a second action on the rejected claims can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed under § 1.97(c) with the fee set forth in § 1.17(p). MPEP § 803.02 provides this instruction in the context of the situation in which the examiner has determined that the Markush claim encompasses at least two independent or distinct inventions, has required applicant to make a provisional election of a single species, and has rejected the Markush claim on prior art grounds. This has led to some confusion as to when a second action on the rejected claims can be made final when the examiner has not found that the claim encompasses at least two independent

or distinct inventions and applicant amends a claim to exclude unpatentable alternatives. If a Markush claim or other claim that sets forth alternatives is rejected under 35 U.S.C. 102 or 103 on the basis of prior art that anticipates or renders obvious the claim with respect to any one of the alternatives or on any other basis (e.g., 35 U.S.C. 101 or 112) with respect to any one of the alternatives, a second or any subsequent Office action on the merits may be made final. However, such an Office action may not be made final if it contains a new ground of rejection that is not: (1) Necessitated by applicant's amendment of the claims (including amendment of a claim to eliminate unpatentable alternatives); (2) necessitated by applicant's providing a showing that a claim element that does not use the phrase "means for" or "step for" is written as a function to be performed and does not otherwise preclude application of 35 U.S.C. 112, ¶ 6; (3) based on information submitted in an information disclosure statement filed during the period set forth in § 1.97(c) with the fee set forth in § 1.17(p); or (4) based upon double patenting (statutory or obviousness-type double patenting). The provision in MPEP § 904.02 that a search should cover the claimed subject matter and should also cover the disclosed features which might reasonably be expected to be claimed does not preclude an examiner from making the second or any subsequent Office action on the merits final if the Office action contains a new ground of rejection that was necessitated solely by applicant's amendment of the claims to eliminate the unpatentable species.

Comment 187: A number of comments supported the appropriate use of the proposed requirement in § 1.105(a)(1)(ix) where this information is needed to resolve a reasonable question which is relevant to the determination of a patentability issue before the examiner.

Response: The Office is adopting the change to § 1.105.

Comment 188: One comment argued that the provision in § 1.105(a)(1)(ix) serves no purpose and may be abused. The comment argued that examiners could simply shift the burden on applicant to prove support when there is no basis for making a rejection under 35 U.S.C. 112, ¶ 1. One comment argued that the changes to § 1.105(a)(1)(ix) are unnecessary since examiners already have the power to request such information.

Response: One purpose of the provision in § 1.105(a)(1)(ix) is to assist the examiner in properly examining the application when it is not readily

apparent where the specification of the application provides support under 35 U.S.C. 112, ¶ 1, for a claim or a limitation of a claim. This is information that the applicant should be aware of and should be able to provide to the examiner. The Office considers this authority to be inherent under the patent statute and rules existing prior to this rule change, including the previous version of § 1.105, and thus there is no reason to expect such provision to be abused. The Office agrees that examiners inherently have the authority to request this information. See *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 73 USPQ2d 1409 (Fed. Cir. 2005). The Office is amending § 1.105 to make the authority explicit.

Comment 189: One comment suggested that the Office should encourage examiners to use § 1.105 to require a concise, plain-English explanation of the invention and claim set when the application contains large claim sets or the invention cannot be understood.

Response: The examination support document will assist the examiner when there are large numbers of claims. If the invention cannot be understood, the examiner could use § 1.105 to require an explanation.

Comment 190: Several comments suggested that language should be added to the rules to indicate that the information required by § 1.105(a)(1)(ix) is not to be used to read limitations into the claims.

Response: Such a change is not necessary. It is well established that the meaning of the terms in the claims is to be ascertained in light of the specification but that limitations from the specification are not to be read into the claims. See *Phillips v. AWH Corp.*, 415 F.3d 1301, 1316, 75 U.S.P.Q.2d 1321, 1329 (Fed. Cir. 2005); *In re American Academy of Science Tech Center*, 365 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004); *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Comment 191: A number of comments supported the extension of the Office's refund authority beyond the expiration date of the legislation and encouraged the Office to accelerate implementation of § 1.117.

Response: The Office is working to make the patent fee and fee structure provisions of the Consolidated Appropriations Act, 2005 (Pub. L. 108-447, 118 Stat. 2809 (2004)), permanent. The Revised Continuing Appropriations Resolution, 2007 (Pub. L. 110-5, 121 Stat. 8 (2007)), keeps the patent fee and fee structure provisions of the Consolidated Appropriations Act, 2005,

in effect during fiscal year 2007. The Office is implementing § 1.117 in this final rule.

Comment 192: Several comments questioned whether excess claim fees would be refunded if claims are eliminated pursuant to § 1.78(f)(3).

Response: Applicant may request a refund of any excess claims fees paid on or after December 8, 2004, if an amendment canceling the excess claims is filed before an examination on the merits has been made of the application. See § 1.117. Applicant may also request a refund of any previously paid search and excess claims fees if applicant expressly abandons an application filed under 35 U.S.C. 111(a) on or after December 8, 2004, by filing a petition under § 1.138(d) before an examination has been made of the application.

Comment 193: One comment suggested that the Office should refund eighty percent of the fees for claims that are withdrawn because of a restriction requirement.

Response: The Office does not have the statutory authority to refund the excess claims fees for claims that are still pending in an application where the fees were properly paid. The Consolidated Appropriations Act, 2005, authorizes a refund only for a claim that has been canceled before an examination on the merits has been made of the application under 35 U.S.C. 131. See 35 U.S.C. 41(a)(2)(C). Claims that are withdrawn due to a restriction requirement are still pending in the application. Applicant may cancel the withdrawn claims prior to a first Office action on the merits of the application and request for a refund of any excess claims fees paid on or after December 8, 2004. See § 1.117.

Comment 194: A number of comments noted that since very few examination support documents are likely to be filed, there is not likely to be any opportunity to reduce a patent term adjustment.

Response: The Office is not adopting the changes in this final rule for the purpose of reducing patent term adjustment. The Office simply does not want an applicant to obtain patent term adjustment by delaying compliance with the examination support document requirements.

Comment 195: Several comments argued that it was unfair to reduce patent term adjustment for not complying with the rules for applications pending before the effective date.

Response: Section 1.704(c)(11) as adopted in this final rule is applicable only to applications under 35 U.S.C. 111(a) filed on or after November 1,

2007, or international applications that have commenced the national stage after compliance with 35 U.S.C. 371 on or after November 1, 2007. Thus, other applications for which an examination support document (or other appropriate action) is required would not encounter a patent term adjustment reduction unless the applicant failed to properly reply to an Office notice requiring an examination support document (or other appropriate action) within three months of the date the notice was mailed to the applicant.

Comment 196: One comment argued that § 1.704(c)(11) is contrary to statute because 35 U.S.C. 154(b)(2)(C)(ii) guarantees a minimum of three months to respond before patent term adjustment is lost.

Response: 35 U.S.C. 154(b)(2)(C)(ii) provides that “[w]ith respect to adjustments to patent term made under the authority of [35 U.S.C. 154(b)(1)(B)], an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.” See 35 U.S.C. 154(b)(2)(C)(ii). The patent term adjustment reduction provision of 35 U.S.C. 154(b)(2)(C)(ii) is applicable where the applicant’s failure to engage in reasonable efforts to conclude processing or examination of an application involves a failure to reply to an Office action or notice within three months of the date the Office action or notice is mailed or given to the applicant. 35 U.S.C. 154(b)(2)(C), however, contemplates other circumstances that may constitute an applicant’s failure to engage in reasonable efforts to conclude processing or examination, by further providing that “[t]he Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.” See 35 U.S.C. 154(b)(2)(C)(iii). The provisions of § 1.704(c), including § 1.704(c)(11), are promulgated under the Office’s authority in 35 U.S.C. 154(b)(2)(C)(iii) to prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. For example, an examination support document is required to be filed before the issuance of a first Office action on

the merits when the application contains or is amended to contain more than five independent claims or more than twenty-five total claims. See § 1.75(b)(1). Therefore, § 1.704(c) provides for a reduction of any patent term adjustment when there is a failure to comply with § 1.75(b), e.g., a failure to file an examination support document in compliance with § 1.265 when necessary under § 1.75(b). The Office does not issue a notice requiring an examination support document (or other appropriate action) until the Office has determined that an examination support document is required under § 1.75(b), but applicant failed to submit an examination support document.

Comment 197: Several comments argued that § 1.704(c)(11) would adversely affect small businesses. One comment argued that some patents owned by universities and small biotechnology companies have values of one million dollars per day, and these patents often have hundreds of days of patent term extension. The comment argued that the proposed reductions in patent term would easily cost small businesses one hundred million dollars per year.

Response: An applicant can avoid a reduction in patent term adjustment simply by providing an examination support document in compliance with § 1.265 before the first Office action on the merits or taking other appropriate action (if necessary) in a timely manner.

Comment 198: One comment questioned whether the proposed changes to § 1.75 (the “representative claims” examination approach) as applied to national stage applications violate the PCT. Another comment suggested that the proposed changes to § 1.75 are contrary to PCT Article 17.

Response: As discussed previously, this final rule does not implement a “representative claims” examination approach. Nevertheless, nothing in the PCT or the regulations under the PCT requires a designated Office to examine all claims presented (in any particular order or at a particular stage) in a national stage application. Furthermore, PCT Article 27(6) provides that the national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by such law. Under this final rule, applicant is free to submit as many claims as he or she chooses, as long as applicant files an examination support document before the first Office action on the merits if there are more than five independent claims or more than twenty-five total claims. Article 17 of the PCT concerns

procedures before the international searching authorities. The changes to § 1.75 do not apply to international searching authorities and, accordingly, do not conflict with Article 17.

G. Number of Independent and Total Claims Permitted Without an Examination Support Document

Comment 199: A number of comments argued that the proposed change in the definition of an independent claim for determining the number of designated claims and calculating additional claims fees would be complicated and confusing. A number of comments argued that the statutory classes of invention are not necessarily mutually exclusive. A number of comments expressed the opinion that the proposed changes to the way claims are treated for fee purposes will further burden the Office. One comment stated that it would cause disputes and slow down the examination process. One comment argued that it would likely produce inconsistent results. One comment argued that the rule change makes it very difficult to calculate claim fees for anyone other than a registered practitioner. Several comments opined that as a result of the proposed rule, the fee calculation process would no longer be merely administrative, but would involve a legal opinion. The comments questioned whether fee calculations will be handled by examiners, and what the process for dispute resolution will be. A number of the comments also argued that the change would effectively increase fees.

Response: Designation of claims for initial examination is not required because this final rule did not adopt the “representative claims” examination approach. This final rule, however, requires applicant to file an examination support document in compliance with § 1.265 before the issuance of a first Office action on the merits of an application that contains more than five independent claims or twenty-five total claims, counting all of the claims in any other copending application having a patentably indistinct claim. If an examination support document in compliance with § 1.265 is not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims.

This final rule adopts the proposed changes to § 1.75(b)(2) to provide that a claim that refers to a claim of a different statutory class of invention will also be treated as an independent claim for fee

calculation purposes and for purposes of determining whether an application exceeds the five independent claim and twenty-five total claim threshold under § 1.75(b). Section 1.75(b) (introductory text) as adopted in this final rule clarifies that a dependent claim must contain a reference to a claim previously set forth in the same application, incorporate by reference all the limitations of the previous claim to which such dependent claim refers, and specify a further limitation of the subject matter of the previous claim. See 35 U.S.C. 112, ¶ 4; see also *Pfizer*, 457 F.3d at 1291–1292, 79 U.S.P.Q.2d at 1589–1590. If a claim does not incorporate by reference all the limitations of the previous claim to which it refers, it is not a dependent claim under 35 U.S.C. 112, ¶ 4. It would be proper for the Office to consider such a claim as an independent claim for fee calculation purposes and for purposes of determining whether an examination support document is required. The determination of whether a claim is independent or dependent could be difficult when applicant did not clearly draft the claim as an independent claim or a dependent claim under 35 U.S.C. 112, ¶ 4. Applicant may minimize issues related to fee calculation for claims by drafting claims that are in compliance with 35 U.S.C. 112, ¶ 4, and § 1.75(b) (e.g., not presenting claims that refer to another claim of a different statutory class of invention or claims that refer to another previous claim but do not incorporate by reference all of the limitations of the previous claim). Once a determination of whether a claim is independent or dependent has been made, the fee calculation is simple. If applicant disagrees with the Office's determination that a claim is an independent claim, applicant should provide a showing of how the claim is a dependent claim in compliance with 35 U.S.C. 112, ¶ 4, and § 1.75(b) either in a reply to a notice requiring a claim fee or a request for a refund.

Comment 200: One comment stated that a claim that does not make reference to another claim is an independent claim, and a claim that does make reference to another claim is a dependent claim. One comment stated that the Office cannot charge independent claim fees for dependent claims because to do so would violate statute. One comment questioned how a claim can fail to incorporate by reference all of the limitations of the claim to which it refers, and yet be statutory. The comment suggested that the proposed rule is unnecessary and not supported by the case law cited by

the Office. One comment suggested that the changes to § 1.75(b)(2) (e.g., treating a claim that refers to a claim of a different statutory class of invention as an independent claim for fee calculation purposes and for purposes of determining whether an examination support document is required) might be contrary to judicial precedent set forth in *In re Ochiai*, 71 F.3d 1565, 37 U.S.P.Q.2d 1127 (Fed. Cir. 1995). The comment also argued that these changes would create a “tricky fee structure” and a “trap for the unwary” and would increase the administrative/non-substantive workload on the examiner.

Response: A claim that merely refers to another claim is not a dependent claim in compliance with 35 U.S.C. 112, ¶ 4. A proper dependent claim must also incorporate by reference all the limitations of the claim to which it refers and specify a further limitation of the subject matter in the claim to which the dependent claim refers. Some applicants present claims that refer to a previous claim, but fail to comply with the requirements of 35 U.S.C. 112, ¶ 4. See e.g., *Pfizer*, 457 F.3d at 1291–1292, 79 U.S.P.Q. 2d at 1589–1590. The provisions of § 1.75(b)(2) are consistent with 35 U.S.C. 112, ¶ 4, and judicial precedent including *Ochiai* (the use of *per se* rules in determining nonobviousness under 35 U.S.C. 103). A claim that refers to a previous claim of a different statutory class of invention could require a separate search and patentability determination because the patentability of such a claim might not stand or fall together with the previous claim. For example, if claim 1 recites a specific product, a claim for method of making the product of claim 1 in a particular manner would require a separate patentability determination because in accordance with *Ochiai*, there is no *per se* rule in applying the test for obviousness under 35 U.S.C. 103. Furthermore, a claim that refers to a previous claim of a different statutory class of invention does not comply with 35 U.S.C. 112, ¶ 4, because such a claim does not further limit the subject matter of the previous claim.

Comment 201: A number of comments recommended that the Office issue guidance for use by Office employees as well as the public in distinguishing among statutory classes of invention. One comment stated that it is unclear how “a different statutory class of invention” will be applied. The comment questioned whether the last sentence of § 1.75(b)(2) would apply only to combination method-apparatus claims or whether it might also be applied to regular dependent claims which add additional limitations of a

similar kind such as a method limitation for a method claim or an apparatus limitation for an apparatus claim. One comment stated that § 1.75(b)(2) provides clarification that claims which refer to a claim of a different statutory class would be regarded as independent. One comment stated that § 1.75(b)(2) appears to be a statement of the current state of the law.

Response: The statutory classes of invention are set forth in 35 U.S.C. 101. If a method claim depends from another method claim, incorporates by reference all of the limitations of the method claim from which it depends, and adds additional method limitations, such a claim will be considered as a dependent claim. However, if a method claim refers to a composition claim (e.g., “A method of using the composition of claim 1 comprising * * *”), it will be treated as an independent claim. The Office will issue any guidance as necessary and appropriate for the implementation of the rules.

Comment 202: Several comments argued that § 1.75(b) is a problem for software-based inventions because it is common for applications to include claims to different classes of invention. The comments argued that there is no reason to discourage a claim drawn to one class of invention which depends from a claim drawn to another class when little additional work is required of the examiner to examine both claims, citing the example of a claim drawn to a manufacture which depends from a claim drawn to a process for making a manufacture.

Response: The rule does not discourage an applicant from submitting whatever claims may be considered desirable for protection of the invention, and does not discourage submission of claims to any statutory class of invention. Rather, the rule clarifies how claims will be treated for the purposes of fee calculation and determination whether an examination support document is required under § 1.75(b)(1).

Comment 203: A number of comments argued that ten representative claims are not sufficient for adequate patent protection and suggested various numbers for the representative claim limit including at least twenty claims, twenty-five claims, or at least thirty claims. Several comments suggested twenty claims, with a maximum of three independent claims, as being more consistent with the fee schedule. Several comments suggested that the limit should be six independent and forty total claims. One comment suggested that the limit should be twelve independent claims and fifty total claims. One comment suggested

that the limit should be ten independent claims and sixty total claims. Several comments suggested that there should be no limit. One comment suggested that there should be no limit on dependent claims.

Several comments stated that the rules affect the vast majority of applications that contain an ordinary number of claims, rather than targeting the small number of problem applications with excessive claims. One comment stated that it was unclear why all applicants should be limited to representative claims when approximately ninety percent of all non-provisional applications currently filed contain six or fewer independent claims and forty or fewer total claims. The comment argued that examining forty or fewer claims does not appear to constitute an undue examination burden. One comment suggested that the rule changes should be more narrowly tailored with respect to the technology areas where the inventions are not capable of being adequately protected using only twenty claims. One comment inquired about the need for establishing a separate procedure for examination of claims if only 1.2 percent of applications fall within the category of excess claims. Several comments argued that there is a lack of statistical analysis relating to the number of applications containing more than ten total claims.

Response: The Office notes the concerns expressed in the public comments concerning the proposed "representative claims" examination approach. The Office did not adopt this approach in this final rule. This final rule provides that if the number of independent claims is greater than five or the number of total claims is greater than twenty-five, the applicant must provide additional information to the Office in an examination support document under § 1.265 covering all of the claims in the application (whether in independent or dependent form).

The Office received a significant number of comments suggesting a threshold of six independent claims and thirty total claims. The Office also received a number of comments suggesting independent claim thresholds ranging from three to ten and total claim thresholds ranging from twenty to sixty (or no limit). The comments, however, provided no justification for deeming any particular independent and total claim threshold to be the ideal threshold or even superior to any other possible independent and total claim threshold. The Office arrived at the five independent claim and twenty-five total

claim threshold primarily for the following reasons.

First, a significant number of comments suggested a threshold of six independent claims and thirty total claims, but did not suggest such a threshold if it were not considered sufficient to provide adequate patent protection for an invention.

Second, the majority of applications contain no more than five independent claims and no more than twenty-five total claims. Specifically, over 92 percent of the applications filed in fiscal year 2006 contained no more than five independent claims, and over 78 percent of the applications filed in fiscal year 2006 contained no more than twenty-five total claims. These figures do not take into account that many applications contained claims to more than one distinct invention, and the changes in this final rule permit an applicant to suggest a restriction requirement and elect an invention to which there are drawn no more than five independent and twenty-five total claims. In addition, the majority of applications in every Technology Center contain five or fewer independent claims and twenty-five or fewer total claims. Therefore, there is no support for the position that there are technology areas that are just not capable of being adequately protected with five or fewer independent claims and twenty-five or fewer total claims. Finally, the Office notes that the most common number of independent claims presented in an application is three, and the most common number of total claims presented in an application is twenty.

Third, an applicant may present up to fifteen independent claims and seventy-five total claims via an initial application and two continuation or continuation-in-part applications that are prosecuted serially without providing either an examination support document or a justification as discussed previously. Only about five percent of the applications filed in fiscal year 2006 were in an application family that contained more than fifteen independent claims or more than seventy-five total claims.

Finally, this final rule does not preclude an applicant from presenting more than five independent claims or more than twenty-five total claims. Rather, an applicant may present more than five independent claims or more than twenty-five total claims in an application with an examination support document in compliance with § 1.265 if the applicant considers it necessary or desirable in the particular application. Specifically, this final rule

requires applicant to file an examination support document in compliance with § 1.265 before the issuance of a first Office action on the merits of an application that contains more than five independent claims or twenty-five total claims, counting all of the claims in any other copending application having a patentably indistinct claim. If an examination support document in compliance with § 1.265 is not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims.

Comment 204: A number of comments suggested that the Office should explore the possibility of examining multiple dependent claims that are dependent on other multiple dependent claims to reduce examination burden and better focus the examination process. The comments argued that most foreign countries permit such claims and that this would significantly reduce the number of claims. One comment argued that if the Office adopts representative claims rules, it will move towards the European style of claim sets, but without the benefit of multiple dependent claims and claims stated in the alternative. Several comments expressed the opinion that multiple dependent claims should be encouraged because examining a multiple dependent claim is no more work than examining a single dependent claim.

Response: As discussed previously, the Office did not adopt the "representative claims" examination approach in this final rule. Further, 35 U.S.C. 112, ¶ 5, prohibits multiple dependent claims that are dependent on other multiple dependent claims. Moreover, the examination of multiple dependent claims that are dependent on other multiple dependent claims would be at least as burdensome as if these claims were presented as a plurality of single dependent claims or as permitted multiple dependent claims. The Office disagrees that permitting multiple dependent claims that depend on other multiple dependent claims would reduce the examination burden or better focus the examination process. The Office's experience is that multiple dependent claims are significantly more difficult to search and evaluate than a plurality of single dependent claims. Multiple dependent claims that depend on other multiple dependent claims would be even more burdensome. While the use of multiple dependent claims may be a convenient shorthand mechanism, a multiple dependent claim

is considered to be that number of claims to which direct reference is made therein and must be considered in the same manner as a plurality of single dependent claims. See MPEP

§ 608.01(n), paragraph I. The same would be true for multiple dependent claims that are dependent on other multiple dependent claims.

Comment 205: One comment suggested that there should be a limit of twenty claims in every application with no exceptions and no requirement for an examination support document.

Another comment suggested that the Office should limit the number of claims of any application to twenty or thirty total claims, and two or three independent claims. One comment suggested that there should simply be a hard cap without an option to file an examination support document to have additional claims examined. The comment argued that this would not take away any substantive rights, as long as applicant's right to file continuing applications and requests for continued examination is preserved.

Response: This final rule appropriately balances applicants' interests to have an adequate number of claims to protect their inventions and the need to reduce the large and growing backlog of unexamined patent applications, improve the quality of issued patents, and make the patent examination process more effective. The changes to § 1.75 in this final rule permit an applicant to present five or fewer independent claims and twenty-five or fewer total claims in the application without submitting an examination support document in compliance with § 1.265. The changes to § 1.75 in this final rule also permit an applicant to present more than five independent claims or more than twenty-five total claims if the applicant files an examination support document in compliance with § 1.265.

Comment 206: Several comments suggested that the Office should adjust the fees if excess claims fees are insufficient to permit examination of the claims for which they are paid. One comment suggested that there should be higher fees for claims in excess of ten. Several comments suggested that there should be higher fees for claims in excess of twenty. One comment suggested higher fees for independent claims in excess of three. One comment suggested that there should be a higher fee for independent claims in excess of ten and total claims in excess of fifty. Several comments suggested that there should be escalating fees for increasing numbers of claims. One comment argued that applicants should be

permitted to designate a number of claims, without an examination support document, that varies with the filing fee paid. One comment suggested that applicants should be charged in proportion to the number of designated claims, and that, optionally, an upper bound on the number of claims (*e.g.*, twenty-five total claims, no more than twelve independent claims) could be established.

Response: Excess claims fees are set by statute. See 35 U.S.C. 41(a). The Office sought a legislative change to increase excess claims fees, and while some increases were made in the Consolidated Appropriations Act, 2005, the Office did not obtain the increases that it considered necessary. In any event, the changes adopted in this final rule will help to focus examination and increase quality.

Comment 207: Several comments suggested that excessive claiming should be dealt with on a case-by-case basis, rather than by penalizing all applicants. One comment suggested that the Office should consider strategies under present § 1.105 to address problem applications on a case-by-case basis. A number of comments suggested that the requirement for an examination support document should be imposed on a case-by-case basis, only in those situations that impose a unique burden on the Office.

Response: As discussed previously, the Office is not adopting the "representative claims" examination approach under which the majority of applicants would have been required to either designate dependent claims for initial examination or file an examination support document. The changes adopted in this final rule require the applicant to file an examination support document under § 1.265 only if the applicant presents more than five independent claims or more than twenty-five total claims. If an examination support document in compliance with § 1.265 is not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims. The majority of applications do not contain more than five independent claims or more than twenty-five total claims. Therefore, as a result of the public comment, this final rule adopts an approach that avoids requiring a majority of applicants to make the choice between designating dependent claims for initial examination and filing an examination support document.

Comment 208: One comment suggested that one of the representative claims should be in Jepson format. Another comment suggested that fees should be increased on all non-Jepson claims. One comment suggested that the Office should charge less for claims written in Jepson format.

Response: There is no persuasive explanation as to why Jepson claims should be treated differently from non-Jepson claims. Furthermore, fees are set by statute and the statute does not provide the authority to charge higher or lower fees for Jepson claims.

Comment 209: One comment suggested that there should be an expedited procedure for an application with a limit of five claims, a 1200-word specification, and four drawings, (with the filing fee being \$1000 for a small entity or \$3000 for a non-small entity), where the application could issue as a patent in fifteen months or less. One comment argued that the representative claim proposal should be an option for applicants and those applications with ten or fewer representative claims should be assigned a higher priority for examination. One comment argued that the examination support document should only be used as an optional procedure for an applicant to advance the application out of turn.

Response: The proposed "representative claims" examination approach is not adopted in this final rule. Further, the Office has revised its accelerated examination program with the goal of completing examination within twelve months of the filing date of the application. The application must contain three or fewer independent claims and twenty or fewer total claims, and the applicant must provide an accelerated examination support document and meet a number of other requirements. See *Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination*, 71 FR 36323 (June 26, 2006), 1308 *Off. Gaz. Pat. Office* 106 (July 18, 2006) (notice). However, requiring an examination support or similar document only as an optional procedure for applicant to advance the application out of turn would not result in the desired gains in efficiency and quality.

Comment 210: One comment suggested that if examination is limited to a certain number of claims, the Office should not be allowed to make a restriction requirement that is not linked to the burden of searching. Thus, the comment suggested that where different statutory classes or independent claims within a class do not really impose an additional burden,

they should not be counted against the examination limit.

Response: Under the current restriction practice, the burden of the search and examination in an application is considered before a requirement for restriction is made. See MPEP section 803. This includes where there are different statutory classes of invention or independent claims within a class that do not impose a search burden.

Comment 211: A number of comments argued that the one-month time period to reply to a notification of more than ten representative claims was too short to prepare and submit an adequate examination support document. One comment suggested that the time period should be at least two months with extensions of time being permitted. One comment suggested that the time period should be three months with extensions of time being permitted.

Response: The proposed "representative claims" examination approach is not adopted in this final rule. Under this final rule, applicant is required to provide an examination support document if applicant presents more than five independent claims or more than twenty-five total claims in an application. If an examination support document in compliance with § 1.265 is not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims. The time period provided in the notice requiring an examination support document is only applicable where it appears that the omission of an examination support document was inadvertent. Therefore, applicant should prepare and file an examination support document when applicant presents more than five independent claims or more than twenty-five total claims in an application. Applicant should not rely on the notification from the Office and a new period within which to prepare an examination support document. Nevertheless, the Office is revising this provision to provide a two-month time period that is not extendable under § 1.136(a), which should be sufficient for those situations in which an applicant inadvertently omitted an examination support document.

Comment 212: A number of comments argued that the notice to the applicant under § 1.75(b)(3) would impose costs because it would have to be generated by an examiner and another round of communications would be needed if applicant suggests a

restriction requirement and it is not accepted by the Office.

Response: Since the examination support document is required whenever applicant presents more than five independent claims or more than twenty-five total claims and the notice only applies when it appears that the omission of the examination support document was inadvertent, the Office expects that the number of notices would be relatively low. Furthermore, the Office plans to have a notice under § 1.75(b)(3) generated by someone other than the examiner. While it may be necessary on occasion for the examiner to communicate with the applicant if a suggested restriction requirement is not accepted, this additional communication is far outweighed by the benefits of focused examination and increased quality.

Comment 213: Several comments requested that the Office explain the procedures for how the Office will evaluate a suggested restriction requirement. Some comments questioned how an examiner will approve a suggested restriction requirement. One comment questioned what would occur if the restriction requirement was not accepted by the examiner.

Response: As discussed previously, if the applicant submits a suggested restriction requirement, the suggested restriction requirement is accepted, and there are five or fewer independent claims and twenty-five or fewer total claims to the elected invention, the Office will simply treat the non-elected claims as withdrawn from consideration and proceed to act on the application (assuming the application is otherwise ready for action). The Office action will set out the requirement for restriction under § 1.142(a), e.g., in the manner that an Office action on the merits would contain a written record of a requirement for restriction previously made by telephone. See MPEP section 810.

The refusal to accept a suggested requirement for restriction may result in the examiner making a different restriction requirement or making no restriction requirement. If the examiner makes a restriction requirement (different from the suggested restriction requirement), the applicant will be notified (a notice under § 1.75(b)(3) coupled with a restriction requirement) and given a time period within which the applicant must make an election. In addition, if there are more than five independent claims or more than twenty-five total claims to the elected invention and/or species, the applicant must also: (1) Amend the application

such that it contains no more than five independent claims and no more than twenty-five total claims to the elected invention and/or species; or (2) file an examination support document in compliance with § 1.265 that covers each claim (whether in independent or dependent form) to the elected invention and/or species.

Comment 214: Several comments argued that the rules should provide guidance on how the non-extendable deadline would be treated in the event of a petition or appeal relating to the requirement for an examination support document. Several comments questioned how the notice and time period would be set when there are multiple applications that have patentably indistinct claims that are being considered together for purposes of determining the number of claims in an application.

Response: Applicant may file a petition under § 1.181 if the applicant disagrees with a determination that an application contains more than five independent claims or more than twenty-five total claims, or a determination that an examination support document does not comply with § 1.265. As stated in § 1.181(f), the mere filing of a petition will not stay any time period that may be running against the application. Applicant must file a reply in compliance with § 1.75(b)(3) within the two-month time period to avoid abandonment even when applicant files a petition under § 1.181. If there are multiple applications with at least one patentably indistinct claim, the Office will issue a notice under § 1.75(b)(3) in each application and set a separate time period in each application.

Comment 215: Several comments argued that applicants would file more applications in parallel with fewer claims to avoid having to file an examination support document and this would create more work for the Office.

Response: This final rule provides that if multiple applications contain at least one patentably indistinct claim, the Office will treat the multiple applications as a single application for purposes of determining whether each of the multiple applications exceeds the five independent claim and twenty-five total claim threshold. See § 1.75(b)(4). For example, if one of the claims in an application is patentably indistinct from at least one of the claims in another application, the Office will treat each application as containing the total of all of the claims in both applications when determining whether each application exceeds the five independent claim and twenty-five total claim threshold. This

provision is intended to prevent an applicant from submitting multiple applications to the same subject matter, each with five or fewer independent claims or twenty-five or fewer total claims, for the purposes of avoiding the requirement to submit an examination support document. Furthermore, under § 1.78(f), applicant is required to identify such applications if they: (1) Have filing dates that are the same as or within two months of each other, taking into account any filing date for which a benefit is sought under title 35, United States Code; (2) name at least one inventor in common; and (3) are owned by the same person, or subject to an obligation of assignment to the same person. If the applications also have the same claimed filing or priority date and substantially overlapping disclosures, applicant must rebut a presumption that the applications contain patentably indistinct claims or file a terminal disclaimer and provide good and sufficient reasons why two or more such pending applications are required rather than one. See §§ 1.78(f)(2) and (f)(3).

Comment 216: One comment questioned whether the Office would require an examination support document if a parent application issues as a patent with ten claims and a continuation application is filed with indistinct claims.

Response: The Office has revised § 1.75(b)(4) to provide that if there are multiple applications containing at least one patentably indistinct claim the Office will treat each of such applications as containing the total of all of the claims (both independent and dependent) present in all of the multiple applications containing patentably indistinct claims for purposes of determining whether each such application contains more than five independent claims or more than twenty-five total claims. Under § 1.75(b)(4), the Office will count the claims in copending applications containing patentably indistinct claims (including applications having a continuity relationship) but not in issued patents containing patentably indistinct claims, in determining whether each such application contains more than five independent claims or more than twenty-five total claims and thus whether an examination support document in compliance with § 1.265 is required. As discussed previously, this provision is to preclude an applicant from submitting multiple applications to the same subject matter (with claims that are patentably indistinct), each with five or fewer independent claims or twenty-five or fewer total claims, for the purposes of avoiding the requirement to

submit an examination support document in compliance with § 1.265. Although claims in an issued patent are not counted for the purposes of § 1.75(b)(4), the pending application may still be subject to a double patenting rejection.

Comment 217: One comment questioned how the Office would determine when an examination support document was “inadvertently” omitted.

Response: If the omission of an examination support document is an isolated instance, then generally the omission would be considered inadvertent. Where, however, a particular individual (e.g., applicant or attorney) has a pattern of not including an examination support document when required, then the Office would be less inclined to consider such an omission as being inadvertent. The Office will not generally question whether the omission of an examination support document was inadvertent unless there is a reason to do so.

H. Examination Support Document Requirements

Comment 218: Several comments supported the concept of an examination support document. One comment agreed that the examination support document would help the Office to reduce the backlog.

Response: The Office is adopting the concept of an examination support document in this final rule. Under this final rule, an examination support document is required if applicant presents more than five independent claims or more than twenty-five total claims in an application.

Comment 219: A number of comments argued that the search and analysis necessary to prepare an examination support document would add significant cost to the preparation of an application, that the cost would be significantly more than the \$2,500 predicted by the Office, and that this would significantly disadvantage independent inventors and small businesses. Several comments argued that it would be unaffordable for independent inventors and small entities. Several comments argued that the patentability search done by most practitioners is limited to United States patents and United States published applications and does not generally set forth in detail the patentability of each claim element by element. A number of comments argued that the examination support document was more like a validity search and opinion and included various estimates of the cost of preparing an examination support

document, which ranged from \$5,000 to \$30,000. One comment argued that it would cost a minimum of \$30,000 for a biotechnology application. One comment argued that even if the Office's estimate is accurate, it would cost a small entity applicant \$3,000 to have twenty claims examined, which would be a six hundred percent increase over current costs and would have a significant economic impact.

Response: As discussed previously, the Office has modified the proposed rules with respect to claims. Under the proposed rules, applicants who wished to have more than ten representative claims examined in the initial Office action would have had to file an examination support document. Under the changes in this final rule, applicants may have up to five independent and twenty-five total claims examined in an application without filing an examination support document.

The Office was given feedback that the costs for preparing an examination support document could be anywhere from \$5,000 to \$100,000. No data to support the alleged costs were submitted. Contrary to some of the comments, the Office is not requiring a validity search and opinion. The pre-filing preparation of an application that contains more than five independent claims or more than twenty-five total claims should involve obtaining a patent novelty search, analysis and opinion. Preparation of an examination support document requires that this information be reduced to writing in a particular format.

The Office commissioned a detailed analysis of the final rule's impacts on small entities. This analysis indicated that the cost of an examination support document is likely to be in the range of \$2,563 to \$13,121. This analysis also concludes that this final rule is not expected to result in a significant economic impact on a substantial number of small entities. This final rule does provide an exemption from the requirement (§ 1.265(a)(3)) that an examination support document must, for each reference cited in the listing of the references required under § 1.265(a)(2), include an identification of all the limitations of each of the claims that are disclosed by the reference that applies to applications by a small entity as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). See § 1.265(f).

Comment 220: Several comments argued that the examination support document is substantially more burdensome than the current procedure for accelerated examination because the search and examination support

document must separately address every claim for which examination is sought, and the rule contains substantial additional burdens. One comment argued that the accelerated examination procedure is too onerous as shown by the very small number of applicants who used the procedure, and the examination support document is even more stringent. Several comments argued that a petition to make special is voluntary, not mandatory. Furthermore, such a petition does not foreclose applicant's opportunity to pursue additional inventive subject matter to protect against design-arounds, as would happen in view of the concurrent continuation proposed rule changes.

Response: The Office has reduced the requirements for an examination support document under § 1.265 as adopted in this final rule. The Office proposed to require applicants to provide a detailed explanation of how each independent and dependent claim was patentable over the cited art (proposed § 1.261(a)(4)). Section 1.265(a)(4) as adopted in this final rule requires applicants to provide the same explanation for the independent claims only. The Office also proposed to require applicants to provide statements of utility of the invention as defined in each independent claim (proposed § 1.261(a)(5)). Section 1.265 as adopted in this final rule does not include such a requirement. These changes reduce the requirements for applicants who wish to file an examination support document while still providing examiners with valuable information to assist in the examination of applications.

Furthermore, an examination support document in compliance with § 1.265 is required under § 1.75(b) only when an applicant presents more than five independent claims or more than twenty-five total claims. It is not required in applications that contain five or fewer independent claims and twenty-five or fewer total claims. Thus, the majority of applications would not need an examination support document since a majority of applications contain five or fewer independent claims and twenty-five or fewer total claims.

In addition, the accelerated examination procedure was recently revised. The accelerated examination procedure has more requirements than are contained in § 1.265. *See Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination*, 71 FR at 36323-27, 1308 *Off. Gaz. Pat. Office* 106-09. For example, the accelerated examination support document must also identify any cited references that

may be disqualified as prior art under 35 U.S.C. 103(c) as amended by the Cooperative Research and Technology Enhancement (CREATE) Act (Pub. L. 108-43, 118 Stat. 3596 (2004)).

Comment 221: Several comments argued that due to the cost and "duty to search," the requirement for an examination support document is tantamount to imposing a *de facto* limit on the number of claims in an application.

Response: The Office has not placed a *de facto* limit on the number of claims. If an applicant wants to present more than five independent claims or more than twenty-five total claims, the applicant simply needs to submit an examination support document in compliance with § 1.265 before the first Office action on the merits. As discussed previously, the accelerated examination procedure has more requirements than are contained in § 1.265. However, over four hundred applications have been filed under the revised accelerated examination procedure in the last nine months.

Comment 222: One comment suggested that § 1.265 should be replaced by a requirement that applicant comply with the rules for a petition to make special. Another comment argued that applicants will file a petition to make special after going through the effort and expense to prepare and file an examination support document.

Response: As discussed previously, the Office has recently revised its accelerated examination program with the goal of completing examination within twelve months of the filing date of the application. An application containing more than five independent claims or more than twenty-five total claims would not be eligible for the revised accelerated examination program. Nevertheless, the Office has no objection to every applicant filing his or her application under the revised accelerated examination program.

Comment 223: A number of comments argued that the requirement for an examination support document transfers to the applicant the costs and responsibilities of the examination process for which fees have been paid. One comment questioned why applicant must pay a search fee and perform a search of their own in order to prepare an examination support document. One comment suggested that the Office should consider eliminating the search and examination fee when an examination support document is provided. One comment argued that the excess claims fees that are paid are more than enough to cover the associated extra expense and burden placed on the

Office in examining the excess claims. One comment suggested that the excess claims fee should be increased rather than requiring applicants to submit an examination support document.

Response: Applications which contain a large number of claims absorb an inordinate amount of patent examining resources, and such applications are extremely difficult to process and examine properly. An applicant who presents more than five independent claims or more than twenty-five total claims will be required to assist the Office with the examination by providing an examination support document in compliance with § 1.265. The Office will still conduct a search and examine an application in which an examination support document is filed. Furthermore, the search and examination fees and excess claims fees do not recover the costs of searching and examining an application. The higher cost estimates provided in the comments on the Claims Proposed Rule confirm that the cost of conducting a search and preparing an analysis far exceeds the search and examination fees. The Office, however, cannot increase these fees because they are set by statute.

Comment 224: Several comments argued that the examination support document imposes extra burdens on the applicants that are not performed by the Office since applicants are required to translate any foreign documents not in the native language of the applicant and rejections by the Office do not comply with most of the requirements imposed under the rule.

Response: Examiners frequently obtain translations of foreign documents that they consider to be pertinent. Examiners must obtain a translation of any document that is in a language other than English if the examiner seeks to rely on that document in a rejection. *See* MPEP § 706.02. During examination, examiners cite references that are most closely related to the subject matter of the claims, identify the limitations of the claims that are disclosed by the references being relied upon in a rejection, explain how each of the independent claims are being rejected over the references being applied, and make determinations regarding utility and 35 U.S.C. 112, ¶ 1, support and enablement. The requirements in § 1.265 are intended to assist the examiner with the examination process.

Comment 225: Several comments stated that the costs and requirements of an examination support document would encourage applicants to seek the services of the least qualified searchers.

Response: The Office is not encouraging applicants to seek the services of the least qualified searchers. An applicant who decides to file an examination support document has the option to seek the services of any searcher he or she chooses or to conduct the preexamination search on his or her own. Applicant should have an incentive to hire the most qualified searchers since a better search is more likely to result in a more thorough examination. The requirements of an examination support document are clearly set forth in § 1.265 and an applicant who chooses to file an examination support document must satisfy these requirements. If the preexamination search is poor, then applicant runs the risk that the preexamination search or the examination support document will be deemed insufficient. If the preexamination search or examination support document is deemed insufficient, applicant will be given only a two-month time period that is not extendable under § 1.136(a) in which to file a corrected examination support document to avoid abandonment of the application. See § 1.265(e).

Comment 226: One comment argued that the Office's estimate that the burden imposed by the rule change will equate to an additional one minute and forty-eight seconds to twelve hours was unrealistic for applications having multiple independent claims and hundreds of pieces of prior art to be reviewed.

Response: The one minute and forty-eight seconds to twelve hours response time provided in the notice of proposed rule making covered each activity that may occur during the processing of an application for patent (OMB control number 0651-0031). The specific estimate for an examination support document was twelve hours (which has subsequently been increased to twenty-four hours). While the Office received comments suggesting that the Office's cost estimate for an examination support document was low, these comments provided only conclusory statements and contained few facts or information.

Comment 227: A number of comments argued that it was almost impossible to determine the extent to which the prior art must be searched to satisfy the preexamination search requirement. Several comments argued that there is no way to meet the search requirements. One comment argued that it would be impossible to prove the "non-existence" of more pertinent art. A number of comments argued that the search should not be required to go

beyond the resources that are publicly available in the Office's search room. One comment suggested that the Office's search room would need to be upgraded to allow access to all foreign patents, periodicals and publications as well as all United States patents to meet the examination support document requirements. Several comments argued that applicant would be required to conduct a search that is beyond the scope of the searches performed by examiners and that this was unfair and burdensome to the applicants. Some comments argued that the information that must be identified is significantly more than what the Office provides to an applicant for a search and that a requirement for a statement that applicant has searched on the Office's database, the resources available to examiners, should be sufficient.

Response: The standard for the preexamination search that is required is the same standard that the Office uses to examine patent applications, which is set forth in MPEP §§ 904-904.03. The information that applicant must identify is the same information that the examiner must record in the application file as set forth in MPEP § 719.05. If applicant follows the search guidelines set forth in the MPEP, then the preexamination search should be sufficient. The Office has published patent search templates to define the field of search, search tools, and search methodologies that should be considered when performing a search. The search templates are published on the Office's Internet Web site at <http://www.uspto.gov/web/patents/searchtemplates/>. The Office has requested comments on the patent search templates. See *Request for Comments on Patents Search Templates*, 71 FR 94 (May 16, 2006), 1307 *Off. Gaz. Pat. Office* 22 (Jun. 6, 2006).

The accelerated examination procedure has more requirements than are contained in § 1.265. See *Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination*, 71 FR 36232 (June 26, 2006), 1308 *Off. Gaz. Pat. Office* 106 (July 18, 2006) (notice). Thus, the information concerning the requirements for a preexamination search document under the revised accelerated examination procedure can be applied to fulfill the requirements for a preexamination search under § 1.265. See samples of a preexamination search document and an accelerated examination support document on the Office's Internet Web site at <http://www.uspto.gov/web/patents/accelerated/>.

Finally, a statement that applicant has searched on the Office's database and the resources available to examiners would not be sufficient. A mere statement that the applicant has searched on the Office's database and the resources available to examiners would not identify the field of search, the date of the search, and, for database searches, the search logic or chemical structure or sequence used as a query, the name of the file or files searched and the database service, and the date of the search. See § 1.265(a)(1).

Comment 228: One comment argued that the fact that foreign search reports are not sufficient for the preexamination search or examination support document seemed at odds with the objective of promoting greater reliance on and use of work done by other competent patent offices. One comment questioned whether an international search report is sufficient to satisfy the search requirement, and if it is, then why are foreign patent office searches not sufficient.

Response: Neither foreign search reports nor international search reports are *per se* excluded. If a foreign search report or an international search report satisfies the requirements for a preexamination search set forth in § 1.265, then it would be accepted.

Comment 229: One comment argued that the preexamination search requirement that the search must cover all the features of the designated dependent claims separately from the claim or claims from which the dependent claim depends makes no sense. The comment argued that if a dependent claim adds an element to the combination in an independent claim, a search for prior art references that disclose the additional element separately from the elements of the independent claim is likely to produce many references that have no relation to the invention. The comment suggested that the language of the rule be revised to clarify that the preexamination search must include a separate search for each independent claim and each designated dependent claim.

Response: As discussed previously, the Office did not adopt the "representative claims" examination approach. Under this final rule, if the application contains more than five independent claims or more than twenty-five total claims, applicant is required to file an examination support document in compliance with § 1.265 that covers each of the claims (whether in independent or dependent form) before the first Office action on the merits. If an examination support document in compliance with § 1.265 is

not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims. The Office has revised § 1.265(b) to delete the phrase “separately from the claim or claims from which the dependent claim depends.” Section 1.265(b) as adopted in this final rule requires that the preexamination search must encompass all of the features of the claims (whether independent or dependent), giving the claims the broadest reasonable interpretation. For example, if independent claim 1 recites elements ABC and dependent claim 2 depends on claim 1, incorporates all the limitations of claim 1 and additionally recites element D, then, even if applicant cannot find elements ABC and believes elements ABC to be novel, applicant must still search for element D.

Comment 230: One comment argued that the requirement that the search encompass the “disclosed features that may be claimed” should be deleted because it gives examiners carte blanche to reject preexamination searches on essentially arbitrary grounds.

Response: The Office notes the concerns expressed in the public comment. The Office has modified the proposed provision such that § 1.265(b) as adopted in this final rule does not require that the preexamination search must encompass the disclosed features that may be claimed. For any amendment to the claims that is not encompassed by the examination support document, however, applicants are required to provide a supplemental examination support document that encompasses the amended or new claims at the time of filing the amendment.

Comment 231: Several comments suggested that there should be an exemption from the limits on the number of claims for independent inventors. One comment argued that many individual inventors lack the skills and requisite knowledge to perform an adequate preexamination search and prepare an examination support document.

Response: The applicant of a patent application should have sufficient knowledge of his or her own invention. Performing a preexamination search and preparing an examination support document should be no more difficult than preparing and prosecuting the patent application. Furthermore, applicants can avoid the need to file an examination support document by not presenting more than five independent claims or more than twenty-five total

claims in an application. This final rule, however, provides that a small entity as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) may claim an exemption from the requirement in § 1.265(a)(3) for an identification of all of the limitations of each of the claims that are disclosed by the references cited in the listing of the references required under § 1.265(a)(2). *See* § 1.265(f).

Comment 232: One comment suggested that the Office should hire experienced searchers to perform the searching function.

Response: The Office has recently conducted a pilot using PCT international applications for competitively sourcing search functions to commercial entities, each of which had experience in providing patent searches. The purpose of the pilot program was to demonstrate whether searches conducted by commercial entities could meet or exceed the standards of searches conducted and used by the Office during the patent examination process. The pilot was not proved successful and was concluded after six months.

Comment 233: A number of comments argued that the rules requiring an examination support document are fraught with dangers in the form of inequitable conduct allegations and malpractice. One comment argued that there would be challenges on the sufficiency of the examination support document, the scope of the search of the examination support document, and the timing of the search for the examination support document. A number of comments argued that even a good faith attempt is likely to be attacked on the grounds of inequitable conduct, and that such a duty is contrary to *Frazier v. Roessel Cine Photo Tech., Inc.*, 417 F.3d 1230, 75 U.S.P.Q.2d 1822 (Fed. Cir. 2005). A number of comments argued that the risk of inequitable conduct allegations in litigation would effectively force applicants to file ten or fewer claims, which would deny them the right to adequately protect their inventions. Several comments argued that each patent that includes an examination support document in its file history would be inherently weak given current inequitable conduct practices. Several comments argued that the likelihood of having to defend against inequitable conduct would reduce perceived public confidence in the validity of issued patents. Several comments also argued that the examination support document will increase litigation costs. Several comments also argued that the added costs in terms of the perceived reduction in patent quality and the

potential litigation costs would outweigh any potential speed of examination benefit. One comment argued that forcing applicant's representatives to limit the claims to an arbitrary number is akin to asking them to commit what amounts to malpractice. One comment stated that the rules put applicants in a triple-jeopardy situation for losing patent rights. First, because examiners will not consider all initially filed claims, applicants are put in jeopardy of having to file continuations for unexamined claims. Second, if applicants choose to have more than the threshold number of claims, applicants risk inequitable conduct charges. Third, if only the threshold number of claims is pursued, applicants will be unable to adequately protect their inventions.

Response: Applicants may present as many claims as they feel are necessary to adequately protect their invention. Under this final rule, applicant may present up to five independent claims and twenty-five total claims for examination in an application without providing an examination support document. As discussed previously, the Office has also modified the proposed changes to continuing application practice and continued examination practice to permit an applicant to file two continuation or continuation-in-part applications plus one request for continued examination in an application family, without any justification. Thus, an applicant is permitted to present up to fifteen independent claims and seventy-five total claims for each patentably distinct invention via an initial application and two continuation or continuation-in-part applications that are prosecuted serially without providing either an examination support document or a justification. Applicant may also present additional claims by submitting an examination support document under § 1.265 before the first Office action on the merits.

The changes in this final rule do not force an applicant to carry any affirmative duty that may expose him or her to a greater risk of inequitable conduct. The submission of an examination support document to assist the Office in gathering information for use during examination does not expose an applicant to a greater risk of inequitable conduct. Inequitable conduct is a doctrine based, in part, upon “intent to deceive.” *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178, 33 U.S.P.Q.2d 1823, 1826 (Fed. Cir. 1995). To establish inequitable conduct, a party must provide clear and convincing evidence of: (1) Affirmative misrepresentations of a material fact,

failure to disclose material information, or submission of false material information; and (2) an intent to deceive. *See, e.g., Impax Labs., Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1374, 81 U.S.P.Q.2d 1001, 1006 (Fed. Cir. 2006) (citing *Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365, 1373, 73 U.S.P.Q.2d 1161, 1167 (Fed. Cir. 2004)). Absent such “intent to deceive”, inequitable conduct cannot be proven. Unless the applicant has an “intent to deceive” when submitting an examination support document, the simple submission of an examination support document, even one containing erroneous information, to the Office does not by itself raise an intent to deceive or mislead the Office. *See Frazier*, 417 F.3d at 1236 n.1, 75 U.S.P.Q.2d at 1826 n.1 (the mere submission of erroneous information to the Office does not by itself raise an inference of intent to deceive or mislead). Moreover, frivolous allegations in litigation are subject to professional responsibility rules and Rule 11 of the Federal Rules of Civil Procedure.

Comment 234: A number of comments argued that the Office must create a “safe harbor” that appropriately protects the applicant from inequitable conduct allegations when identifying and characterizing important prior art. Several comments argued that changes to § 1.56 would need to be made to exempt examination support documents from it. One comment argued that legislative reform is needed. Several comments argued that implementation of the examination support document should be delayed until changes to inequitable conduct are made. A number of comments suggested that more meaningful participation by applicants in prosecution of the application requires adequate “safe-harbor” provisions from inequitable conduct.

Response: The Office proposed revising § 1.56 to provide a “safe harbor” to applicants who make a reasonable good faith effort to comply with the proposed requirements. *See Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 FR at 38811–12, 38820, 1309 *Off. Gaz. Pat. Office* at 27, 34. Most of the comments indicated that such a “safe harbor” at best sets out the current state of the law of inequitable conduct, in that a “safe harbor” is unnecessary for applicants who act in good faith (*i.e.*, without an intent to deceive or mislead the Office) because an intent to deceive or mislead the Office is a separate and essential component of inequitable conduct. *See*

e.g., Weatherchem Corp. v. J.L. Clark, Inc., 163 F.3d 1326, 1336, 49 U.S.P.Q.2d 1001, 1009 (Fed. Cir. 1998) (a finding that the patentee acted without any intent to deceive disposes of the inequitable conduct issue), and *Manville Sales Corp. v. Paramount Systems Inc.*, 917 F.2d 544, 552, 16 U.S.P.Q.2d 1587, 1593 (Fed. Cir. 1990) (materiality does not presume intent, which is a separate and essential component of inequitable conduct). The comments also expressed concern that any “safe harbor” would possibly create new requirements with respect to an applicant’s duty of disclosure under § 1.56. It is the Office’s position that an applicant’s duty of disclosure under § 1.56 with respect to an examination support document under § 1.265 is satisfied if an individual as defined in § 1.56(c) acted in good faith to comply with the requirements in § 1.265 for an examination support document. The Office, however, is not adopting changes to § 1.56 in this final rule to provide a “safe harbor” to applicants because such a provision would be unnecessary. The Office notes that patent reform legislation is pending in the 110th Congress before both the Senate and House of Representatives. *See Patent Reform Act of 2007*, S. 1145, 110th Cong. (2007), and *H.R. 1908*, 110th Cong. (2007). The Department of Commerce submitted a letter on May 18, 2007, to the Chairman of the House Subcommittee on Courts, the Internet, and Intellectual Property recommending that H.R. 1908 be amended to address the doctrine of inequitable conduct and unenforceability to ensure that patent applicants are not discouraged from fully and fairly sharing relevant information with the Office.

Comment 235: A number of comments argued that the examination support document would require the applicant to make binding admissions as to the scope of the claims and how they relate to the prior art references and thus force applicant to create prosecution history estoppel and address rejections that would never have occurred during prosecution. Several comments argued that such a requirement shows a complete lack of understanding of the pitfalls that admissions can have in litigation. Several comments argued that such statements can be misinterpreted and distorted in unforeseen ways. One comment argued that this may cause the practitioner to unintentionally and unnecessarily narrow the claims through the effect of prosecution history estoppel, which will decrease the commercial value and the quality of the

patent. Several comments argued that the requirement for an examination support document places applicant in a precarious position of having to provide as much information as possible to support patentability of the claimed invention while avoiding statements that can be easily manipulated in litigation. One comment argued that applicants would be put in a position of having to make statements against interest long before the scope of their invention is realized. One comment argued that requiring applicant to examine his or her own application creates a conflict of interest, which would raise a question of concealment or understatement.

Response: The best way to avoid prosecution history estoppel is by knowing what the prior art is and filing claims that initially define patentable subject matter without having to file an amendment. Conducting a preexamination search and preparing an examination support document will help applicants to draft a better written disclosure and more focused claims, thereby minimizing any prosecution history estoppel.

Comment 236: Several comments argued that the one-month non-extendable time period to respond to a notice requiring a corrected or supplemental examination support document is insufficient. Some comments suggested that a three-month time period, which is extendable up to six months with an extension of time, should be given. Some comments suggested that the time period should be at least three months or extensions of time should be permitted.

Response: The Office notes the concerns expressed in the public comment regarding the time period set forth in a notice requiring a corrected or supplemental examination support document when an examination support document is deemed to be insufficient. The Office has revised the proposed provision such that § 1.265(e) provides a two-month time period that is not extendable under § 1.136(a). The two-month time period should be more than sufficient to correct any minor deficiencies. Applicants, however, should not rely on the two-month time period in § 1.265(e) to prepare an examination support document or a supplemental examination support document. The requirements for an examination support document are clearly set forth in § 1.265. Applicant should prepare the examination support document in compliance with the requirements before presenting more than five independent claims or more than twenty-five total claims. Applicant

should also conduct the preexamination search to encompass all of the disclosed features that applicant expects to claim in order to avoid the need to update the preexamination search. Applicant should file a supplemental examination support document at the time applicant presents any amendment to the claims that is not covered by the previous examination support document. Applicant also has the option of canceling the requisite number of claims (independent or total) that necessitate an examination support document, rather than submitting a corrected or supplemental examination support document. Furthermore, extensions of this two-month time period in § 1.265(e) are available to those for which there is sufficient cause (§ 1.136(b)).

Comment 237: One comment suggested that if applicant's examination support document is deemed insufficient, applicant should be afforded an opportunity to undesignate claims, and if applicant fails to undesignate the claims or file a corrected examination support document, then the examiner should undesignate claims and proceed with examination, rather than holding the application abandoned.

Response: The Office is not adopting the "representative claims" examination approach in this final rule. Thus, designation (or "undesignation") of dependent claims for initial examination is not required in this final rule. Under this final rule, if applicant wants to present more than five independent claims or more than twenty-five total claims in an application, applicant simply needs to submit an examination support document in compliance with § 1.265 before the first Office action on the merits. If applicant files an examination support document and it is insufficient, the Office will notify the applicant and give the applicant the options of either: (1) Filing a corrected or supplemental examination support document in compliance with § 1.265 that covers each of the claims (whether in independent or dependent form); or (2) amending the application such that it contains no more than five independent claims and no more than twenty-five total claims.

Comment 238: One comment argued that applicant should be given the options available under § 1.75(b)(3) and not be limited to submission of a corrected or supplemental examination support document when an examination support document is deemed to be insufficient or in other situations under § 1.265(e) (§ 1.261(c) as proposed).

Response: The Office notes the concerns expressed in the public comment regarding the proposed provision that requires a corrected or supplemental examination support document when an examination support document is deemed insufficient. The Office has modified this proposed provision such that § 1.265(e) provides that if an examination support document is insufficient, the Office will notify the applicant and give the applicant the options of either: (1) Filing a corrected or supplemental examination support document in compliance with § 1.265 that covers each of the claims (whether in independent or dependent form); or (2) amending the application such that it contains no more than five independent claims and no more than twenty-five total claims. However, applicants will not be given the option to submit a suggested requirement for restriction. Such an option would not be appropriate after applicant has already submitted an examination support document.

Comment 239: A number of comments requested clarification on how the Office would use an examination support document. Some comments questioned whether an independent search would be conducted and whether the cited references would be independently evaluated by the examiner. One comment noted that if the examiner simply adopts the results of the search and the conclusions of patentability, there would be a wide variation in quality and thoroughness of the searches performed, and in the quality of analysis of the search results. The comment further argued that if the examiner will perform further searching, then it was difficult to understand how the objective of "sharing the burden" is accomplished, since it would not seem to yield time or cost savings for the Office. Several comments argued that examiners should not give any faith and credit to the information in an examination support document. One comment argued that if the examiner does rely on the external search, the uncertainty of the patent will be increased. Another comment argued that the submission of an examination support document may motivate examiners to skip doing a thorough search, thus leading to lower patent quality. One comment argued that requiring an examination support document was a punitive measure because: (1) The examination support document requires information that is rarely if ever required, such as details

regarding literal support for the claim elements; (2) the Office does not indicate that examiners will receive additional time to review the examination support document; and (3) the Office has not indicated that it will rely on the external search.

Response: Upon taking up an application for examination, the examiner will consider the prior art submitted in an information disclosure statement in compliance with §§ 1.97 and 1.98 (see § 1.97(b)) and those filed with an examination support document in compliance with § 1.265 (required under § 1.75(b)), and make a thorough investigation of the available prior art related to the subject matter of the claimed invention (see § 1.104(a)(1)). The examiner will make an independent patentability determination in view of the prior art on the record, other information in the examination support document, and any other relevant prior art or evidence. The examination support document will assist the examiner in the examination process and the determination of patentability of the claims by providing the most relevant prior art and other useful information. It will help the examiner in understanding the invention and to focus on the relevant issues. The examination support document will also assist the examiner in evaluating the prior art cited by the applicant and in determining whether a claim limitation has support in the original disclosure and in any prior-filed application. The requirement for an examination support document is not a punitive measure, nor is it a substitute for the Office's examination. The information required in an examination support document is to assist the examiner with the more extensive examination of an application having more than five independent claims or more than twenty-five total claims.

The Office has reduced the requirements for an examination support document under § 1.265 as adopted in this final rule. The Office proposed to require applicants to provide a detailed explanation of how each independent and dependent claim was patentable over the cited art (proposed § 1.261(a)(4)). Section 1.265(a)(4) as adopted in this final rule requires applicants to provide the same explanation for the independent claims only. The Office also proposed to require applicants to provide statements of utility of the invention as defined in each independent claim (proposed § 1.261(a)(5)). Section 1.265 as adopted in this final rule does not include such a requirement. These changes reduce the requirements for applicants who

wish to file an examination support document while still providing examiners with valuable information to assist in the examination of applications.

Comment 240: Several comments questioned how the Office would determine if an examination support document is insufficient. Some comments also questioned what would happen if the Office knows of closer prior art than that cited by applicant. One comment questioned whether the examiner could hold the examination support document non-compliant if the examiner objects to the search or the claim scope and also what would be applicant's remedy. Several comments argued that applicants currently disregard §§ 1.56, 1.97 and 1.98 and fail to cite their own work. The comments argued that applicant will cite generic references to comply with § 1.265 and will likely not reveal the most pertinent art. One comment argued that the examination support document requirements are subjective. One comment suggested that the Office should institute a petition process for disputing the requirement for an examination support document or the holding that an examination support document is insufficient. The comment suggested that the requirement should be stayed pending the outcome of the petition, or applicants should at least be given sufficient time for the petition to be heard.

Response: The Office will review an examination support document to determine if it meets all the requirements set forth in § 1.265. As discussed previously, the accelerated examination procedure has more requirements than are contained in § 1.265. The Office has provided guidelines for examination support documents filed under the accelerated examination procedure. The Office's guidelines concerning the accelerated examination support document may be helpful to applicants who are preparing an examination support document under § 1.265. The guidelines under the accelerated examination procedure, search templates, and samples of a preexamination search document and an examination support document are available on the Office's Internet Web site at <http://www.uspto.gov/web/patents/accelerated/>. The Office will provide similar guidelines for examination support documents under § 1.265, including the preexamination search statement, and will post such guidelines on the Office's Internet Web site. These guidelines should minimize subjectivity in evaluating whether an examination support document

complies with the requirements of § 1.265.

Section 1.265(a)(2) requires a listing of references deemed most closely related to the subject matter of each of the claims (whether in independent or dependent form). As discussed previously, the references that would be most closely related to the subject matter of each of the claims include: (1) A reference that discloses the greatest number of limitations in an independent claim; (2) a reference that discloses a limitation of an independent claim that is not shown in any other reference in the listing of references required under § 1.265(a)(2); and (3) a reference that discloses a limitation of a dependent claim that is not shown in any other reference in the listing of references required under § 1.265(a)(2). References that are only relevant to the general subject matter of the claims would not be most closely related as long as there are other references that are more closely related to the subject matter of the claims. Applicant may not exclude a reference from an examination support document simply because the reference was not the result of the preexamination search provided for in § 1.265(a)(1). References, from whatever source, that have been brought to the applicant's attention must be considered in determining the references most closely related to the subject matter of each of the claims. Accordingly, if applicant merely cites generic references and does not cite the most pertinent art (including applicant's own work), then the examination support document would most likely not be compliant with § 1.265. Simply because the Office knows of a closer prior art reference (that is not applicant's own work) than the prior art cited by the applicant is generally not enough to hold a preexamination search insufficient.

An examination support document could be deemed insufficient based on an insufficient search. If the preexamination search or examination support document is deemed insufficient, applicant will be given only a two-month time period that is not extendable under § 1.136(a) in which to file a corrected examination support document or amend the application to contain five or fewer independent claims and twenty-five or fewer total claims to avoid abandonment of the application. See § 1.265(e). Any applicant who disagrees with a requirement for an examination support document or the holding that an examination support document or preexamination search is insufficient may file a petition under § 1.181. As

provided in § 1.181(f), the mere filing of a petition will not stay any period for reply that may be running against the application. The Office will make every effort to decide petitions in a timely manner.

Comment 241: A number of comments argued that it was unfair and inconsistent for the Office to require applicants to produce an examination support document when the Office is not effectively using foreign search reports. One comment argued that since the Office is unwilling to accept a foreign search report or use international search reports prepared by the Office itself, the examination support document would not reduce pendency. Another comment argued that since examiners ignore international search reports they would not consider an examination support document.

Response: The Office will consider any prior art submitted by applicant in an examination support document in compliance with § 1.265 (required under § 1.75(b)) and an information disclosure statement in compliance with §§ 1.97 and 1.98 including those that are filed with a foreign search report or an international search report. Any relevant prior art will assist the examiner in the determination of patentability of the claims. The examiner, however, must make an independent determination of patentability of the claims in the application. The examiner cannot accept the determination of patentability by another examiner in a foreign application or an international application because the patentability standard of a foreign or international application is different than the standard in a U.S. application.

Comment 242: A number of comments argued that the requirement for an examination support document would create more work for the examiner since the examiner would have to determine the adequacy of the examination support document. One comment argued that complex cases would continue to be complex and the Office would just have the additional tasks of determining whether or not an examination support document should be required, and whether or not an examination support document is sufficient. One comment argued that examiners will not have sufficient time to review the examination support documents and that examiners would need more time for reviewing the examination support documents. The comment questioned whether this would take the place of the examiner reviewing the specification. Several

comments argued that determining the adequacy of examination support documents would divert resources from examination and prolong pendency. One comment argued that there would be additional burdens on the examiner in having to impose the requirement for designation of claims, issue communications challenging the sufficiency of the examination support document, perform a different search after claims are amended in response to an Office action, and search and examine the non-designated claims after allowance of designated claims. One comment argued that the number of petitions would increase because of petitions regarding whether an examination support document was needed or defective.

Response: Under this final rule, applicant is required to file an examination support document under § 1.75(b)(1) if applicant presents more than five independent claims or more than twenty-five total claims in an application. If an examination support document in compliance with § 1.265 is not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims. The majority of the applicants would not need to file an examination support document. The requirements of an examination support document are clearly set forth in § 1.265. Applicants should comply with the requirements at the time applicant presents more than five independent claims or more than twenty-five total claims in an application. As discussed previously, any relevant prior art and other information provided in an examination support document will assist the examiner in the examination process and in the determination of patentability of the claims. During the examination process, the examiner will consider all relevant prior art and information, and interpret the claims in light of the specification. The examiner will review the specification even when applicant files an examination support document. Thus, the benefits obtained by the examination support document would outweigh the Office's additional task of determining whether or not it is sufficient or is required.

Comment 243: One comment questioned whether the Office would give examiners less time to examine those applications in which an examination support document is filed and, if not, then how would the workload be reduced.

Response: Changes to patent examiner production goals are beyond the scope of the proposed changes to the rules of practice. Therefore, whether examiners should be given less time to examine certain applications is not discussed in this final rule. The Office expects that these rule changes will result in a more focused quality examination. The information provided in the examination support document will assist the examiner with the more extensive examination of the application. This information will be available to the examiner up front and will include the most closely related references and a detailed explanation of how the claims are patentable over these references. As a result, the exchanges between examiners and applicants should be more efficient and effective, the number of Office actions should be reduced, prosecution should be concluded faster, and the need to file a continuation application or request for continued examination should be reduced. Thus, the Office's workload would be reduced.

Comment 244: Several comments argued that the requirement for the broadest reasonable interpretation of the claims in conducting the search for an examination support document is inconsistent with current case law citing *In re Johnston* and *In re Donaldson* that require the Office to interpret the claims reasonably in light of the specification.

Response: The requirement in § 1.265(b) is consistent with current case law. The current case law requires that during examination the claims must be given their broadest reasonable interpretation consistent with the specification. According to case law, however, the broadest "reasonable" interpretation is necessarily one that is consistent with the specification. *See, e.g., Phillips*, 415 F.3d at 1316, 75 U.S.P.Q.2d at 1329; *In re Morris*, 127 F.3d 1048, 1054, 44 U.S.P.Q.2d 1023, 1027 (Fed. Cir. 1997) ("Some cases state the standard as the broadest reasonable interpretation, others include the qualifier consistent with the specification or similar language. Since it would be unreasonable for the PTO to ignore any interpretive guidance afforded by the applicant's written description, either phrasing connotes the same notion: As an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's

specification.") (citations omitted). Therefore, the reference in § 1.265(b) to giving the claims "the broadest reasonable interpretation" is consistent with case law.

Comment 245: One comment agreed that the requirements relating to the concise statement of utility and the 35 U.S.C. 112 showing is sharing the burden of examining all of the claims in the application, but argued that requiring applicant to characterize the prior art goes too far and is best left to the examiner since it is the examiner's role to review and analyze the prior art for patentability purposes in view of § 1.104. Several comments argued that the burden of the examination belongs with the Office and that it is against the public interest to shift the burden from the examiner to the applicant. One comment argued that the examination support document requirement asks applicant to prove that patent claims are patentable, which is essentially impossible. One comment argued that the only purpose of an examination support document is to force applicants to do what they already should be doing, that is, carefully comparing their claims to every close prior art reference and adding limitations to distinguish the claims.

Response: Ultimately it is the Office's responsibility to determine patentability. Nevertheless, it is appropriate for applicants to provide information regarding an initial review of claims to assist the Office in determining patentability in applications where they feel they need to have more than five independent claims or more than twenty-five total claims. There is no reasonable explanation as to why it is against public interest for an applicant who presents more than five independent claims or more than twenty-five total claims to provide additional information to the Office. The Office is not requiring applicants to prove that their claims are patentable. The Office is simply requiring applicants who present more than five independent claims or more than twenty-five total claims to provide additional information to the Office by conducting a preexamination search and submitting an examination support document. The Office agrees that applicants should be comparing their claims to every close prior art reference and adding limitations to distinguish the claims.

Comment 246: One comment stated the Office should require a showing of precise written description (35 U.S.C. 112, ¶ 1) support for all amendments made by applicants.

Response: Applicant should specifically point out the support for any amendments made to the disclosure. See e.g., MPEP § 2163.06. Furthermore, when applicant adds a new claim limitation in an application that contains more than five independent claims or more than twenty-five total claims, applicant is required to submit a supplemental examination support document that includes a showing of where such new claim limitation finds support under 35 U.S.C. 112, ¶ 1, in the written description of the specification and in any parent application. In addition, the examiner may require the applicant to show where the specification of the application or a parent application provides written description support under 35 U.S.C. 112, ¶ 1, for a new limitation. See § 1.105(a)(1)(ix) (as adopted in this final rule).

Comment 247: One comment argued that the concise statement of utility and the 35 U.S.C. 112 showing required in an examination support document make no sense. The comment argued that cross-referencing each line of the claims back to the specification is a waste of time. One comment argued that applicants should not have to admit what is disclosed, but rather they should only have to admit what is not disclosed.

Response: In view of the comments, the Office is not adopting the requirement that an examination support document contain a concise statement of the utility of the invention as defined in each of the independent claims. The showing of where each limitation of the claims finds support under 35 U.S.C. 112, ¶ 1, however, would be helpful to the examiner. The examiner is responsible for determining whether or not there is 35 U.S.C. 112, ¶ 1, support in the written description for claimed subject matter. If applicant provides this information, it will assist the examiner in the examination of the application by making it easier for the examiner to make the necessary determinations. See *Hyatt v. Dudas*, 2007 U.S. App. LEXIS 15350 (Fed. Cir. Jun. 28, 2007). The applicant should be aware of where each limitation of the claims finds support under 35 U.S.C. 112, ¶ 1, in the written description by virtue of having prepared the application. There is no justification for requiring the examiner to duplicate this effort in an application that exceeds the five independent claim and twenty-five total claim threshold set forth in § 1.75(b).

Comment 248: One comment argued that § 1.265(a)(2) through (a)(4) resurrects provisions that used to be in

the rules, but were amended out of the rules in 1992 when they were found to be unworkable.

Response: The Office proposed a number of changes to the rules of practice around 1990 related to the duty of disclosure and the filing of information disclosure statements. See *Duty of Disclosure*, 56 FR 37321 (Aug. 6, 1991), 1129 *Off. Gaz. Pat. Office* 52 (Aug. 27, 1991) (proposed rule), and *Duty of Disclosure and Practitioner Misconduct*, 54 FR 11334 (Mar. 17, 1989), 1101 *Off. Gaz. Pat. Office* 12 (Apr. 4, 1989) (proposed rule). The Office ultimately adopted changes to the duty of disclosure provisions of § 1.56 and the information disclosure statement provisions of §§ 1.97 and 1.98 (and deleted § 1.99) in 1992. See *Duty of Disclosure*, 57 FR 2021 (Jan. 17, 1992), 1135 *Off. Gaz. Pat. Office* 13 (Feb. 13, 1992) (final rule). The changes adopted in the 1992 final rule concerning the duty of disclosure provisions of § 1.56 and the information disclosure statement provisions of §§ 1.97 and 1.98 did not eliminate, or decline to adopt as final, provisions similar to the provisions of § 1.265(a).

Comment 249: One comment argued that the requirement for an examination support document was contrary to case law (citing *In re Wilder*, 736 F.2d 1516, 222 U.S.P.Q. 369 (Fed. Cir. 1984)) that applicant is not under a duty to search.

Response: Initially, it is noted that *Wilder* does not stand for the proposition that applicant does not have a duty to search. *Wilder* involved a reissue application. That case held that an attorney's statement that his error was a misunderstanding of the scope of the invention arose resulting from a lack of a prior art search was a sufficient explanation to satisfy the requirements of the reissue rule regarding how the error arose. There is some case law, however, that indicates that applicant does not have a duty to search. See *Nordberg, Inc. v. Telesmith, Inc.*, 82 F.3d 394, 397, 38 U.S.P.Q.2d 1593, 1595-96 (Fed. Cir. 1996); *FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 526 n.6, 5 U.S.P.Q.2d 1272, 1275-76 n.6 (Fed. Cir. 1987); *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415, 5 U.S.P.Q.2d 1112, 1115 (Fed. Cir. 1987); *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362, 220 U.S.P.Q. 763, 772 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 821, 224 U.S.P.Q. 520 (1984). In view of these cases, the Office has stated that "[a]n applicant has no duty to conduct a prior art search as a prerequisite to filing an application for patent." See MPEP § 410. The case law, however, only discusses applicant's responsibility under the rules in 37 CFR

Part 1 that were in effect at the time that was relevant to these particular cases. The case law does not stand for the proposition that the Office cannot change the rules in 37 CFR Part 1 to require a preexamination search, either generally or, when an applicant presents more than five independent claims or more than twenty-five total claims in an application. Indeed, commentators have suggested that, especially after *Festo X*, a practitioner who declines to conduct any pre-filing search as a matter of practice may be falling short of the responsibility under 37 CFR part 10 to perform services with competence. See Schneck, *The Duty to Search*, 87 J.P.T.O.S. 689, 696-701 (2005).

Comment 250: One comment argued that an examination support document is not properly compared to an appeal brief since, in an appeal brief, the focus is on the examiner's rejection and interpretation of the references, whereas in an examination support document, applicant is required to provide a search, interpret claims, and identify all issues related to the search results with respect to each element of each claim.

Response: The Office did not compare an examination support document to an appeal brief. The Office simply indicated that the proposed "representative claim" examination approach was similar to the BPAI's representative claim practice. Nevertheless, the Office is not adopting the "representative claims" examination approach in this final rule.

Comment 251: One comment argued that the rule changes, especially the requirement for an examination support document, are not rationally related to achieving the stated goals of improving patent quality and increasing efficiency.

Response: The Office is requiring an examination support document in those cases where applicants feel they need to have more than five independent claims or more than twenty-five total claims because these applications are the most burdensome for the Office. An examination support document will help the Office improve quality and increase efficiency because it will assist the examiner with the examination of the application. It should provide the examiner with the most pertinent prior art and an analysis of that art. Therefore, the changes being adopted in this final rule are related to the goals of improving quality and increasing efficiency.

Comment 252: One comment argued that the examination support document requirement will increase demand for public searchers and this may drain the examining pool and worsen retention.

Response: It is the Office's experience that only a small number of examiners

who leave the Office do so to become public searchers.

Comment 253: One comment argued that practitioners do not draft patent applications to claim subject matter that they believe is not supported by the specification and thus it should be sufficient to merely assert that the claims are supported by the "entire specification."

Response: The purpose of the requirement for a showing of where each limitation of the claims finds support under 35 U.S.C. 112, ¶ 1, is to assist the examiner in determining where the specification provides written description support for each claim limitation. An assertion by the practitioner that the claims are supported by the entire specification would not be of any assistance to the examiner.

Comment 254: Several comments argued that an examination support document should not be required until after the time for issuing a restriction requirement has passed because it is unfair to require applicant to prepare and file an examination support document when claims may be restricted such that fewer than ten representative claims are pending for examination. One comment suggested that a time period should be set in which the examiner must issue a restriction requirement or indicate that there will be none, and then the time period for submission of an examination support document should be set after that.

Response: As discussed previously, an applicant may submit a suggested restriction requirement accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims. See § 1.142(c) and the discussion of § 1.142(c). In this situation, an examination support document will not be required if the suggested restriction requirement is accepted. An examination support document will be required only if the suggested restriction requirement is not accepted, and the application contains more than five independent claims or more than twenty-five total claims, or more than five independent claims or more than twenty-five total claims to the elected invention and/or species if the examiner makes a restriction requirement that is different from the suggested restriction requirement.

Comment 255: One comment suggested that the Office should give assurances that: Like an information disclosure statement, nothing in an examination support document is an

admission of prior art; nothing in the examination support document would be considered as affecting the scope of the claims; and the examination support document would not be published and examiners would make no references to it in correspondence. One comment supported the use of a limited examination support document that would require applicants to identify where in the specification the corresponding structure, material or acts for functional claim elements may be found since this would improve examination efficiency and have minimal effects in litigation.

Response: Providing assurances that the examination support document would not affect the scope of the claims would not be appropriate. The showing of where each limitation of the claims finds support under 35 U.S.C. 112, ¶ 1, in the written description of the specification and the showing that includes the structure, material, or acts in the specification that correspond to each means-(or step-) plus-function claim element that invokes consideration under 35 U.S.C. 112, ¶ 6, may affect the interpretation of the claims. The determination on patentability is made on the entire record of the application. In order to provide a complete application file history, the examiner may find that it is necessary to state on the record any agreement or disagreement with applicant's explanation of how the claims are patentable over the references or applicant's explanation of where each limitation of the claims finds support under 35 U.S.C. 112, ¶ 1, in the written description. The application record is available to the public upon the publication of the application under 35 U.S.C. 122(b) and the issuance of a patent on the application.

Comment 256: One comment suggested that the Office require applicants to provide claim charts that illustrate the differences between claims. The comment also suggested that applicants could be required to identify where support exists in the specification for the claims, or to identify groups of claims that are similar and define similar limitations.

Response: There is no prohibition against applicants submitting claim charts to illustrate the differences between claims. The Office does not consider it necessary at this time to make claim charts a requirement.

Comment 257: One comment inquired why, when claims in excess of ten are designated, a justification for all designated claims must be supplied and not just the number in excess of ten representative claims.

Response: The Office is not adopting the "representative claims" examination approach in this final rule. Under this final rule, applicant is required to file an examination support document when applicant presents more than five independent claims or more than twenty-five total claims in an application. In order to best assist in examination, the examination support document must cover all of the claims (in independent or dependent form) in the application, and not just the independent claims in excess of five or the total claims in excess of twenty-five.

I. The Office's Authority To Promulgate the Changes in This Final Rule

Comment 258: A number of comments argued that the changes to the rules of practice being adopted in this final rule are beyond the Office's rulemaking authority under 35 U.S.C. 2(b)(2). The comments argued that the proposed §§ 1.75(b), 1.78(d), and 1.78(f) are substantive and not procedural in nature because they affect an applicant's right to receive a patent for an invention or an applicant's ability to claim what the applicant regards as the invention.

Response: The Office has the authority under 35 U.S.C. 2(b)(2) to establish regulations, not inconsistent with law, which shall govern the conduct of proceedings in the Office. The "conduct of proceedings in the Office" provision of 35 U.S.C. 2(b)(2) (as well as former 35 U.S.C. 6(a)), however, is not limited to what might be characterized as "procedural" rather than "substantive" rules. See *United States v. Haggart Apparel Co.*, 526 U.S. 380, 387-88 (1999). Simply contending that a regulation is "substantive and not procedural" fails to address the issue because a regulation that relates to application processing within the Office and that is not inconsistent with law falls within the Office's rulemaking authority. See *In re Van Ornum*, 686 F.2d 937, 945, 214 U.S.P.Q.2d 761, 768 (C.C.P.A. 1982) ("Appellants say the regulation is 'invalid on its face' but they do not explain why beyond contending it is 'substantive and not procedural.' We can give no weight to that contention. True, the rule is substantive in that it relates to a condition under which a patent will be granted which otherwise would have to be denied for double patenting. Much of the content of the PTO rules is 'substantive' in this respect. The regulation clearly relates to application processing within the PTO in a manner consistent with statutory and case law, which is its principal business.").

The regulations at issue in this final rule concern application processing

exclusively within the Office. The changes to § 1.75 being adopted in this final rule govern the requirements relating to the examination of the claims in an application, as is provided for in 35 U.S.C. 131. The changes to § 1.78(d) being adopted in this final rule govern the conditions under which an application may contain or be amended to contain a claim under 35 U.S.C. 120, 121, or 365(c) to the benefit of a prior-filed application. The changes to § 1.78(f) being adopted in this final rule govern the requirements relating to the filing and examination of multiple applications by a common owner. The filing of an application for patent, amendment of an application, and the examination of an application are proceedings that take place exclusively within the Office. Therefore, regulations governing requirements relating to the filing, amendment, and examination of an application fall squarely within the Office's authority under 35 U.S.C. 2(b)(2) to establish regulations which "govern the conduct of proceedings in the Office."

The substantive right at issue during the patent examination process involves whether the applicant has met the conditions and requirements under title 35, United States Code, to be entitled to a patent, rather than the ability to file and maintain an unlimited number of continuing applications or requests for continued examination and the ability to refrain from obtaining and providing information pertinent to the examination of the application to the Office. *See, e.g.*, 35 U.S.C. 101 ("[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"). The changes in this final rule do not preclude applicants from obtaining a patent on an invention, discourage, impede, or block an applicant's statutory right to a patent, or stifle inventors' rights to protect their inventions.

The changes to continuing application practice adopted in this final rule do not set a *per se* limit on the number of continuing applications that an applicant may file. That is, applicant may automatically file a first and second continuation application without any justification and may file any number of additional continuation applications as long as he or she justifies each filing by a showing as to why the amendment, argument or evidence sought to be entered could not have been previously presented. Therefore, the changes to the final rule do not affect an applicant's

right to receive a patent for an invention. The modification to continuation practice simply improves the procedures under which an applicant may file a continuation application by focusing and consolidating the examination process. Furthermore, as an alternative, an applicant may choose to file an appeal when confronted with a rejection that he or she feels is improper. The changes adopted in this final rule to the continuing application practice prevent applicants from unnecessarily prolonging prosecution of applications before the Office.

The changes to the examination of claims practice adopted in this final rule do not prevent an applicant from presenting as many claims as are considered necessary or desirable to protect the full scope of the invention. The changes to the examination of claims practice adopted in this final rule simply provide that if an applicant exceeds or contemplates exceeding a specified threshold (five independent claims or twenty-five total claims), the applicant can provide for that eventuality by submitting additional information to the Office in an examination support document in order to facilitate effective examination of the application. The submission of an examination support document does not change the substantive criteria applied during examination (*i.e.*, the statutory standards of patentability set forth in title 35, United States Code) to determine the applicant's entitlement to a patent.

The patentably indistinct claims provisions do not affect applicant's patent rights because once the required explanation of patentable indistinctness has been provided, the claimed invention is examined on the merits and patentability is determined by the Office. The requirement that applicant show that claims are patentably distinct up front is simply a tool to focus and consolidate the examination of multiple applications.

Comment 259: A number of comments suggested that a requirement of a showing to obtain an additional continuation application is contrary to 35 U.S.C. 120, 121, 365, 132(b), and other sections of title 35, United States Code, under which an applicant has a right to file an unlimited number of continuation applications. The comments suggested that: (1) The proposed rules disregard case law, in particular, *In re Hogan*, 559 F.2d 595, 194 U.S.P.Q. 527 (C.C.P.A. 1977), and *In re Henriksen*, 399 F.2d 253, 158 U.S.P.Q. 224 (C.C.P.A. 1968); (2) the Office does not have authority to limit

the number of continuing applications under 35 U.S.C. 2(b)(2) because the proposed rules are inconsistent with the law, and specifically do not "facilitate and expedite the processing of patent applications"; (3) the changes to § 1.78 cut off substantive rights for reasons other than patentability (as set forth in 35 U.S.C. 102, 103 and 112 of title 35, United States Code) and procedural misconduct, and thus are in violation of 35 U.S.C. 131; (4) the changes to § 1.78 are inconsistent with 35 U.S.C. 131 or 132, because the Director does not have the statutory discretion under these provisions to refuse to examine or to reexamine any application; (5) the requirement for a "showing" is contrary to law because the Office has no authority to deny an applicant the right to file a continuation application or a request for continued examination; (6) no justification or legal basis exists for the petition requirements set forth in the rules to get the benefit of an earlier filing date under 35 U.S.C. 120 or 365; (7) the Office has no statutory authority to delete a claim to priority in a continuing application filed according to the statutory provisions; and (8) applicants have a right to file a continuation application, as long as the reason is not improper, unduly successive or repetitive, citing *Godfrey v. Eames*, 68 U.S. (1 Wall.) 317, 325-26 (1864). Other comments, however, suggested that the proposed rules are consistent with both statute and case law given that: (1) The Office is not instituting a *per se* numerical limit on the number of continuation applications that an applicant may file; and (2) applicants are afforded an opportunity to justify by a showing the need to file additional continuation applications.

Response: None of the statutory provisions or case law cited by the comments provides that an applicant may file an unlimited number of continuing applications or requests for continued examination.

None of the statutory provisions related to continuing applications cited by the comment provide that an applicant may file an unlimited number of continuing applications. 35 U.S.C. 120 simply provides that an applicant may claim the benefit of the filing date of a prior-filed application provided that certain conditions are satisfied. 35 U.S.C. 121 provides that if the Director requires that an application containing claims to two or more independent and distinct inventions be restricted to one of the inventions and a non-elected invention is made the subject of a divisional application, the applicant in the divisional application may claim the benefit of the filing date of prior-filed

application provided that the conditions specified in 35 U.S.C. 120 are satisfied. 35 U.S.C. 365(c) provides that an applicant in an international application designating the United States may claim the benefit of the filing date of a prior-filed national application or a prior-filed international application designating the United States, and that an applicant in a national application may claim the benefit of the filing date of a prior-filed international application designating the United States, again provided that the conditions specified in 35 U.S.C. 120 are satisfied.

Since 35 U.S.C. 120, 121 and 365(c) all hinge upon 35 U.S.C. 120, the response focuses on that provision. 35 U.S.C. 120 provides that:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

35 U.S.C. 120 (2000).

35 U.S.C. 120 has been revised significantly since its codification as part of the 1952 Patent Act. 35 U.S.C. 120 as codified in the 1952 Patent Act provided that: “[a]n application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed

application.” 35 U.S.C. 120 (1952). 35 U.S.C. 120 was amended in 1975 to add “or as provided by section 363 of this title” to provide for claims under 35 U.S.C. 120 to the benefit of an international application filed under the PCT (*i.e.*, international applications filed under 35 U.S.C. 363). Pub. L. 94–131, section 9, 89 Stat. 685, 692 (1975). 35 U.S.C. 120 was amended again in 1984 to substitute “by an inventor or inventors named in the previously filed application” for “by the same inventor” for consistency with the changes to the inventorship provisions of 35 U.S.C. 116. Public Law 98–622, section 104(b), 98 Stat. 3383, 3385 (1984). 35 U.S.C. 120 was finally amended in 1999 to give the Director greater authority with respect to setting forth the time period within which claims to the benefit of a prior-filed application must be submitted by adding:

No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

Public Law 106–113, 113 Stat. 1501, 1501A–563 through 1501A–564 (1999). Thus, 35 U.S.C. 120 has never contained any language either expressly or implicitly stating that an applicant may file an unlimited number of continuing applications.

Turning to the legislative history of the 1952 Patent Act, it does not mention whether an applicant may file an unlimited number of continuing applications. The Senate Report simply documents that “[s]ections 120 and 121 express in the statute certain matters which exist in the law today but which had not before been written into the statute, and in so doing make some minor changes in concepts involved.” S. Rep. No. 1979, at 2400 (June 27, 1952). The House Report contains basically the same description for 35 U.S.C. 120. The testimony from hearings before a Subcommittee of the Committee on the Judiciary, House of Representatives, for the 82nd Congress, held on June 13, 14, and 15, 1951, contains the same description for 35 U.S.C. 120 and little else of substance. For example, P.J. Federico testified: “Sections 120 and 121 express in the statute certain things which exist in the law today that have not been written into the statute, and in

so doing make some changes in the concepts involved.” Patent Law Codification and Revision, 82d Cong. 39 (June 13, 1951) (statement of P.J. Federico, Examiner-In-Chief, United States Patent Office). Additionally, as noted in the congressional record for the 1952 Patent Act, 35 U.S.C. 120 codified existing patent practice. 98 Cong. Rec. 7, 9323 (June 28, 1952 to July 7, 1952) (statements of Senators Saltonstall and McCarran). In particular, “[t]he provisions set out in section 120 giving the applicant the benefit of the date of an earlier application by him for the same invention constitute a restatement of the former practice which was not, however, spelled out in the former law.” Charles L. Zinn, *Commentary on New Title 35, U.S. Code “Patents”* 2515.

Secondary sources providing information about 35 U.S.C. 120 also do not offer guidance with respect to whether an applicant may file an unlimited number of continuing applications. The 1952 Patent Act was drafted by: (1) P.J. Federico, Examiner-In-Chief of the Patent Office; (2) Giles S. Rich, then an attorney of some twenty years representing the National Council of Patent Law Associations; (3) Paul Rose, chairman of the laws and rules committee of the American Patent Law Association; and (4) Henry Ashton, a representative of the coordinating committee on revision and amendment of the patent laws of the National Council of Patent Law Associations. *See generally*, Giles S. Rich, *Congressional Intent—Or, Who Wrote the Patent Act of 1952*, Patent Procurement and Exploitation (BNA 1963), reprinted in *Nonobviousness—The Ultimate Condition of Patentability* (John F. Witherspoon ed., 1983) (hereinafter “Rich on Congressional Intent”). Following enactment, Federico gave a series of lectures to teach the patent bar about the new law. Federico’s lectures were transcribed, consolidated, and reprinted for many years in title 35, United States Code Annotated. *See* 35 U.S.C.A. sections 1 to 110 (1954). The Federal Circuit has considered Federico’s Commentary to be “an invaluable insight into the intentions of the drafters of the Act.” *Symbol I*, 277 F.3d at 1366, 61 U.S.P.Q.2d at 1519.

Federico explained that 35 U.S.C. 120 was “not specified in the old statute but was developed by decisions of the courts beginning with a decision of the Supreme Court of 1864, *Godfrey v. Eames*.” P.J. Federico, *Commentary on the New Patent Act*, 75 J. Pat. & Trademark Off. Soc’y 3, 192 (Mar. 1993) (hereinafter “Federico’s Commentary”). After offering this opening statement, he then set forth the three requirements for

a continuation application required by 35 U.S.C. 120 and elaborated on the meaning of each of these three requirements.

Although Federico's Commentary did not expressly mention any limits or conditions on an applicant's ability to file a continuation, it also did not state that the drafters contemplated allowing an applicant to file an unlimited number of continuation applications. Thus, there is nothing which indicates that the drafters intended to permit an applicant to file an unlimited number of continuing applications. What is more, Federico described examples of situations where continuations were used before the codification of the 1952 Patent Act:

Continuing applications are utilized in a number of different situations; for example, in the case of a requirement to restrict an application to a single invention a second application might be filed for the invention excluded from the [sic] first application as explained in connection with the next section of the law, or a second application might be filed for a separable invention even though no requirement was made. A continuing application with the disclosure the same as a first application might sometimes be filed for procedural reasons with the first application thereafter being abandoned. And a continuing application with added subject matter may sometimes be filed when the inventor has additional details relating to the invention which he wishes to disclose in the application; in such cases the second application would be entitled to the date of the first application only as to the common subject matter.

Federico's Commentary, 5 J. Pat. & Trademark Soc'y at 194.

Federico's list, albeit not exhaustive, suggests that patent practitioners used continuing applications in more limited circumstances before the 1952 Patent Act than today. His first example focuses on the divisional-type situation where a continuing (divisional) application is pursued to protect a second invention as a result of a restriction in the initial application. His third example focuses on a continuation-in-part situation where a continuing application is filed to enable an applicant to add subject matter to the application. Only his second example contemplates anything like current continuation practice where a continuing application is filed to pursue protection for an invention disclosed in the initial application. Federico nevertheless explained that the first application to which the continuing application claims priority is abandoned after the continuation is filed.

Federico did not include the then-rare situation in which the first application issued as a patent and the continuing

application was filed to pursue further protection for the invention of the patent on the first application. At the time of the 1952 Patent Act the double patenting doctrine did not permit a patentee to obtain more than one patent on patentably indistinct subject matter. See e.g., *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 199 (1894) (the "a patent" for an invention provision does not permit a patentee to obtain more than one patent on patentably indistinct subject matter). Even after the 1952 Patent Act, the double patenting provision of 35 U.S.C. 101 ("a patent" for an invention), like its predecessor, was interpreted as precluding a patentee from obtaining more than one patent on patentably indistinct subject matter. See, e.g., *In re Ockert*, 245 F.2d 467, 469, 114 U.S.P.Q. 330, 332 (C.C.P.A. 1957)). It was not until 1970 that the Court of Customs and Patent Appeals held that the double patenting provision of 35 U.S.C. 101 precluded only "same invention" double patenting (i.e., two patents containing claims to identical subject matter) and permitted the use of a terminal disclaimer to overcome double patenting unless the application and patent were claiming identical subject matter. See *In re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 617, 622 (C.C.P.A. 1970). Thus, applicants today frequently do not abandon the initial application, but instead prosecute the initial application in parallel with the continuation application. Because of the development of terminal disclaimer practice, the authors of the 1952 Patent Act would not have contemplated a continuing application system under which an applicant would file an unlimited number of continuing applications.

Moreover, both before and long after the 1952 Patent Act applicants did not file long strings of continuation applications as is often done today. Indeed, the Board of Patent Appeals (Board) in *Henriksen* attempted to identify cases involving a series of more than three patents from cases litigated in the courts and patents issued by the Office during the week of April 26, 1966. *Ex parte Henriksen*, 154 U.S.P.Q. 53, 58-59 (Pat. Off. Bd. App. 1966). The Board in *Henriksen* was unable to isolate a single case involving a priority chain longer than three applications, with one exception that the Board nevertheless dismissed because the case was quite old, dating to 1867, and because the factual record was developed under different law. *Id.* at 58, n.2 (referring to the case as "an antique curiosity"). Based on the Board's research, it appears that priority chains

having more than three family members were actually uncommon, if they existed at all, before the 1952 Patent Act. Thus, if anything, the drafters of the Act, seeking to codify existing practice, did not envision that an applicant would use the provisions of 35 U.S.C. 120 to file and maintain an unlimited number of continuing applications.

Following the enactment of the 1952 Patent Act, case law has specifically addressed the imposition of limits or conditions on continuation practice in the two cases cited by the comments (*Henriksen* and *Hogan*). In *Henriksen* and *Hogan*, the Court of Customs and Patents Appeals (C.C.P.A.) overturned rulings by the Board denying an applicant's priority claim to earlier-filed applications. In *Hogan*, the Board sought—without prior warning—to limit the number of continuations by restricting the applicant from claiming priority where the continuation applications covered a pendency period of twenty-four years. In *Henriksen*, the Board took the position that 35 U.S.C. 120 imposed a *per se* limit on the number of permissible continuations.

The changes adopted in this final rule, however, do not set a limit on the applicant's ability to claim the benefit of a prior-filed application regardless of the pendency period, nor do they set a *per se* limit on the number of continuing applications that an applicant may file. See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 50, 1302 *Off. Gaz. Pat. Office* at 1320 ("No limit is placed on the number of continuing applications."). Applicant may automatically file a first and second continuation application and further extend examination by filing a request for continued examination. After these options are exhausted an applicant may also file any number of third and subsequent continuation applications as long as the applicant justifies each filing by a showing that amendment, argument, or evidence sought to be entered could not have been presented earlier. The *Henriksen* court objected to the approach taken by the Board in changing continuing application practice retroactively. The *Henriksen* court objected to the Board changing the interpretation of the provisions of 35 U.S.C. 120 and applying that interpretation to previously filed applications. The *Henriksen* court specifically stated that:

The action of the board is akin to a retroactive rule change which may have the effect of divesting applicants of valuable rights to which, but for the change in Patent

Office position brought about by the board's decision, they were entitled. Nothing appears in the Patent Office Rules of Practice or the Manual of Patent Examining Procedure which sanction such a result.

Henriksen, at 399 F.2d at 261–62, 158 U.S.P.Q. at 231. In *Henriksen* and *Hogan*, the Office had not promulgated any rules, let alone given the public notice of, or an opportunity to respond to, the *ad hoc* limits imposed. By contrast, the Office here is pursuing prospective rule making, having given the public notice of the changes to § 1.78 and an opportunity to comment.

Although the Court of Customs and Patent Appeals in a “post script” mentioned congressional resolution to remedy the abuses associated with continuation applications in both *Henriksen* and *Hogan*, the court seemed more concerned with the openness of the process for effecting change. *Henriksen*, 399 F.2d at 262, 158 U.S.P.Q. at 231. Here, the Office is adopting the prospective and open process missing in *Hogan* and *Henriksen*. The Office has given the public the opportunity to participate in shaping the rules for continuing application practice, received hundreds of comments, and has modified the proposed rules in response to those public comments.

More recent case law demonstrates that an applicant does not have the right to file an endless stream of continuing applications. See *Symbol I*, *supra*, *In re Bogese II*, 303 F.3d 1362, 64 U.S.P.Q.2d 1448 (Fed. Cir. 2002), and *Symbol Techs. v. Lemelson Medical, Educ. & Research Found.*, 277 F.3d 1361, 61 U.S.P.Q.2d 1515 (Fed. Cir. 2002) (*Symbol II*). *Symbol II*, *Bogese II* and *Symbol I* suggest that the Office has the authority to place reasonable restrictions and requirements on the filing of continuing applications, just as it can place reasonable restrictions and requirements on the prosecution of those applications. In addition, the court in *Bogese II* expressly rejected the view that its previous case law (*e.g.*, *Henriksen*) stood for the broad proposition that 35 U.S.C. 120 gave applicants *carte blanche* to prosecute continuing applications in any desired manner. Rather, it held that, while the statute itself provided no limit on the number of applications that may be co-pending, “[n]owhere does [the prior case law] suggest or imply that the PTO must allow dilatory tactics or that the PTO lacks inherent power to prohibit unreasonable delay in prosecution.” *Bogese II*, 303 F.3d at 1368 n.6, 64 U.S.P.Q.2d at 1452 n.6.

By amending the procedures under which an applicant may file

continuation applications, the Office is seeking to encourage the prompt presentation of amendment, argument and evidence in patent prosecution. To do so, the Office has determined that it must, at some point, change the continuing application practice that has facilitated the past dilatory presentation of amendment, argument and evidence that could have been presented earlier. The changes adopted in this final rule allow an applicant the flexibility to choose between filing a continuing application and filing an appeal, but do not permit an applicant to persist indefinitely before the examiner rather than seek an appeal. Therefore, this final rule does not preclude an applicant from obtaining a patent on an invention when requirements of title 35, United States Code, are satisfied. As explained in the Continuing Applications Proposed Rule, the changes to § 1.78 will “make the exchange between examiners and applicants more efficient, get claims to issue faster, and improve the quality of issued patents.” See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 50, 1302 *Off. Gaz. Pat. Office* at 1320.

Like the statutory provisions for continuing applications, the statutory provision for requests for continued examination, namely, 35 U.S.C. 132(b), does not provide that an applicant may file an unlimited number of requests for continued examination. As discussed previously, the provisions of 35 U.S.C. 132(b) were added relatively recently by section 4403 of the AIPA. See Public Law 106–113, 113 Stat. 1501, 1501A–560 (1999). 35 U.S.C. 132(b) provides that:

The Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant. The Director may establish appropriate fees for such continued examination and shall provide a 50 percent reduction in such fees for small entities that qualify for reduced fees under section 41(h)(1) of this title.

35 U.S.C. 132(b) (2000). The Office first implemented the provisions of 35 U.S.C. 132(b) by a final rule in August of 2000 that was preceded by an interim rule in March of 2000. See *Request for Continued Examination Practice and Changes to Provisional Application Practice*, 65 FR 50092 (Aug. 16, 2000), 1238 *Off. Gaz. Pat. Office* 13 (Sept. 5, 2000) (final rule), *Changes to Application Examination and Provisional Application Practice*, 65 FR 14865 (Mar. 20, 2000), 1233 *Off. Gaz.*

Pat. Office 47 (Apr. 11, 2000) (interim rule).

The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), and was incorporated and enacted into law as part of Public Law 106–113. The Conference Report for H.R. 3194, 106th Cong., 1st Sess. (1999), which resulted in Public Law 106–113, does not contain any discussion (other than the incorporated language) of S. 1948. See H.R. Conf. Rep. No. 106–497, at 37 and 1089–174 (1999). A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott. See 145 Cong. Rec. S14,708–26 (1999) (daily ed. Nov. 17, 1999). This section-by-section analysis of S. 1984 provides with respect to 35 U.S.C. 132(b) that:

Section 4403 amends section 132 of the Patent Act to permit an applicant to request that an examiner continue the examination of an application following a notice of “final” rejection by the examiner. New section 132(a) authorizes the Director to prescribe regulations for the continued examination of an application notwithstanding a final rejection. The Director may also establish appropriate fees for continued examination proceedings, and shall provide a 50% fee reduction for small entities which qualify for such treatment under section 41(h)(1) of the Patent Act.

145 Cong. Rec. S14,718.

35 U.S.C. 132(b) does not specify the conditions and requirements for continued examination under 35 U.S.C. 132(b), but rather authorizes the Director to “prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant.” See 35 U.S.C. 132(b). There is nothing in 35 U.S.C. 132(b) that precludes the Office from promulgating regulations that provide for no more than a single request for continued examination under 35 U.S.C. 132(b), or precludes the Office from requiring that any request for continued examination under 35 U.S.C. 132(b) include a showing as to why the amendment, argument or evidence could not have been previously presented.

Comment 260: A number of comments expressed the opinion that any limitation on continuations should be done legislatively by congressional action and not by the Office via rule making. Some comments argued that the Office is usurping the legislative role of Congress by modifying continuation practice via regulation, arguing Congress by inaction tacitly endorses the current practice, and that the Federal Circuit has acknowledged that limiting continuation practice is an issue best left to Congress, citing *Ricoh Co., Ltd. v.*

Nashua, 185 F.3d 884 (Fed. Cir. 1999) (nonprecedential decision). Some comments suggested that the Office should not adopt sweeping changes unless and until Congress acts to address the issues through the pending patent reform legislation, which would ensure consistency with previous legislative acts. Some comments argued that questions regarding the Office's statutory authority to make the proposed changes would likely lead to litigation and a period of uncertainty until the matter can be resolved either judicially or legislatively. Several comments also suggested that the proposed changes to continuation practice will ultimately result in an even larger backlog at the Office should the Federal Circuit hold the proposed changes to be contrary to law, arguing that applicants in the meantime are left in a state of limbo until the courts finally resolve the matter. One comment argued that the Office's stated rationale regarding the public notice function of claims is not consistent with the law and is more appropriately addressed by Congress or the courts. Two comments also suggested that rules limiting the number of continuing applications are unconstitutional because they exceed the rule making authority of the Office, thereby suggesting that the Office should have sought these changes via legislation, not rule making.

Response: The Office is not usurping the legislative role of Congress, but instead acting consistently with the authority given to the Office by Congress. Pursuant to 35 U.S.C. 2(b)(2)(A), Congress has given the Office the authority to establish regulations that "govern the conduct of proceedings in the Office." By the grant of authority in 35 U.S.C. 2(b)(2)(A), "Congress [is understood] to have 'delegated plenary authority over PTO practice' * * * to the Office." *Stevens v. Tama*, 366 F.3d 1325, 1333, 70 U.S.P.Q.2d 1765, 1771 (Fed. Cir. 2004) (quoting *Gerritsen v. Shirai*, 979 F.2d 1524, 1527 n.3, 24 U.S.P.Q.2d 1912, 1915 n.3 (Fed. Cir. 1992)). Therefore, the decision to make these changes via rule making is not an unconstitutional exercise of the Office's rule making authority under 35 U.S.C. 2(b)(2).

Additionally, the provisions of § 1.78, which concern continuing applications, govern proceedings in the Office because they set forth the process by which an applicant can file a continuing application. See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 50, 1302 *Off. Gaz. Pat. Office* at 1320 (noting that

continuation practice is "a procedural device that permits an applicant to amend his application after rejection and receive examination of the 'amended' (or new) application") (citing *In re Bogese I*, 22 U.S.P.Q. 2d at 1824). Specifically, under revised § 1.78, an applicant may automatically file a first and second continuing application and then may file any number of third and subsequent continuing applications as long as the applicant justifies each filing by a showing as to why the amendment, argument or evidence sought to be entered could not have been previously presented. Furthermore, as an alternative, an applicant may choose to file an appeal when confronted with a rejection that he or she feels is improper. The changes adopted in this final rule do not impede or block an applicant's statutory right to a patent.

The Office is responsible for the granting and issuing of patents and has the authority and responsibility to establish regulations that govern the conduct of proceedings in the Office and facilitate and expedite the processing of patent applications. See 35 U.S.C. 2(a)(1) and (b)(2). The Office has the responsibility to take appropriate action in the near term to improve patent quality and pendency issues rather than wait for possible legislative solutions to these issues. The Office is implementing the rule changes via the rule making procedures set forth in 35 U.S.C. 2(b)(2)(A) and 5 U.S.C. 553 by publishing the proposed rules in the **Federal Register** and giving the public the opportunity for comment. Thus, the Office is acting under the broad rule making authority delegated to it by Congress. Were the Office to sit idle and not set forth procedures to govern a continuing application practice that has become problematic, the Office would be ignoring the responsibility imposed on it by Congress in 35 U.S.C. 2(b)(2)(A). Finally, inaction by Congress is not a tacit endorsement of the current continuing application practice (see *United States v. Price*, 361 U.S. 304, 310-11 (1960) ("nonaction by Congress affords the most dubious foundation for drawing positive inferences")), and the Federal Circuit has cautioned against reliance upon nonprecedential decisions such as *Ricoh Co., Ltd. v. Nashua* (see *Symbol I*, 277 F.3d at 1368, 61 U.S.P.Q.2d at 1520, declining to consider the nonprecedential opinions *Ricoh Co., Ltd. v. Nashua* and *Bott v. Four Star Corp.*, 848 F.2d 1245 (Fed. Cir. 1988)).

Comment 261: A few comments suggested that patent reform legislation indicates that the Office does not have the authority to limit the number of

continuing applications, citing *The Patent Reform Act of 2005*, H.R. 2795, 109th Cong. § 8 (2005). One comment specifically suggested that Congress' decision to remove authority to limit continuations from later patent reform legislation indicates that Congress is still debating the issue and that the Office does not have that authority. One comment suggested that Congress' intent is not to limit the number of applications that an applicant may file or the number of inventive concepts that an application may pursue, because that would stifle inventors' rights to protect their inventions.

Response: The Office notes that legislation was pending before the 109th Congress (*The Patent Reform Act of 2005*) which, as introduced on June 8, 2005, contained a provision (section 8) that expressly authorized the Office to limit certain continuing applications. The Office also notes that the House Subcommittee on Courts, the Internet, and Intellectual Property held a hearing on September 15, 2005, on a proposed substitute that did not contain such a provision. No further action, however, was taken on this legislation by the 109th Congress. The Office does not consider this course of events as constituting any evidence of "congressional intent" because the legislation at issue (*The Patent Reform Act of 2005*) was not voted on by either House of Congress, or even a Committee or Subcommittee of either House of Congress. Thus, this change between the legislation as introduced and as amended is at most evidence of the intent of a drafting committee. In any event, the 109th Congress did not enact changes to the provisions of 35 U.S.C. 2(b), 120, 121, 131, 132, or 365. Rather, the provisions at issue were enacted by earlier Congresses. The views of a subsequent Congress have little relevance in determining the intent of an earlier Congress. See *United States v. Southwestern Cable Co.*, 392 U.S. 157, 170 (1968) ("The views of one Congress as to the construction of a statute adopted many years before by another Congress have very little, if any, significance."). This is especially true when the gap is as broad as the one here, spanning more than half a century (*i.e.*, 1952-2005).

Furthermore, this final rule does not stifle inventors' rights because it provides inventors with ample opportunity to present their claims and secure protection for their inventions. In fact, this final rule encourages inventors to fully disclose and fully claim their inventions promptly, on first filing. Applicants may file two continuation or continuation-in-part applications and a

request for continued examination in an application family, without any justification and may file additional continuing applications or requests for continued examination on a showing that the amendment, evidence or argument could not have been earlier presented. Finally, this final rule does not affect the patentability requirement of title 35, United States Code.

Comment 262: A few comments asserted that the doctrine of prosecution *laches*, originally set forth by the Federal Circuit in *Bogese II*, and more recently endorsed by the Federal Circuit in *Symbol II*, does not extend the Office's authority to deny benefit claims to legitimate continuing applications.

Response: The Office is not using the doctrine of prosecution *laches* as a sword to sever an applicant's priority claim. Nor are the changes adopted in this final rule an attempt to codify *Bogese II* or to combat extreme cases of prosecution *laches*. See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 50, 1302 *Off. Gaz. Pat. Office* at 1320. Applicants and practitioners have a duty to refrain from submitting an application or other filing to cause unnecessary delay or needless increase in the cost of prosecution before the Office. See § 10.18(b)(2). Applicants also have a duty throughout prosecution of an application for patent to make a *bona fide* attempt to advance the application. See *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 49, 1302 *Off. Gaz. Pat. Office* at 1319. In *Symbol I*, *Symbol II*, and *Bogese II*, the Federal Circuit recognized that an applicant has a duty of good faith in advancing the prosecution of an application. The Federal Circuit likewise held that an applicant does not have the right to file an endless stream of continuing applications in order to prolong prosecution for the purpose of gaming the system. That is, applicants should not rely on an unlimited number of continuing applications to either correct deficiencies in the claims and disclosure, or to delay the conclusion of examination in a calculated manner. By requiring applicants to show why the amendment, argument, or evidence sought to be entered in a third or subsequent continuing application or second or subsequent request for continued examination could not have been presented earlier, the Office is ensuring that applicants are not unnecessarily prolonging prosecution of the application before the Office.

The possibility that, without justification, a string of continuing applications could last as long as two decades has created inefficiencies and opportunities for the delay of proceedings before the Office that, as a practical matter, can only be addressed by general rule making. Requiring that, at a given stage in the continuing application process, an applicant must make an affirmative showing of need is necessary for the Office to assure an effective examination process. Relying only on a case-by-case approach to address the most egregious cases of abuse would not be sufficient when continued examination filings (other than divisional applications) have grown from less than twelve percent of total filings in 1980 to over twenty-nine percent of total filings in fiscal year 2006. The Federal Circuit specifically indicated in *Bogese II* that the Office has the inherent authority to set reasonable deadlines and requirements for the prosecution of patent applications. See *Bogese II*, 303 F.3d at 1368 n.6, 64 U.S.P.Q.2d at 1452 n.6 (“The PTO is the administrative agency that is ‘responsible for the granting and issuing of patents * * *’ 5 U.S.C. 2 (2000). Like other administrative agencies, the PTO may impose reasonable deadlines and requirements on parties that appear before it. The PTO has inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of applications.”). Thus, consistent with the Office's inherent authority to set reasonable deadlines and requirements for the prosecution of applications, and to improve the effectiveness of the patent examination process, the Office is revising the rules of practice to require that an applicant make an affirmative justification for a third or subsequent continuing application or second or subsequent request for continued examination.

Comment 263: Two comments argued that the proposed rules prevent an applicant from filing even a single continuation application of an application in which a request for continued examination was previously filed, thereby eliminating access to the benefits conferred by 35 U.S.C. 120.

Response: The Office has modified the proposed changes such that an applicant is permitted under this final rule to file a first and second continuation application or continuation-in-part application without any justification, and is also permitted to file a request for continued examination in any one of the initial application, the first continuing

application, or the second continuing application without any justification. Thus, under § 1.78 as adopted in this final rule, an applicant may file two continuation applications without any justification, even if a request for continued examination was previously filed in the initial application.

Comment 264: Several comments suggested that the definition of a “divisional application,” as specified in proposed § 1.78, is inconsistent with 35 U.S.C. 121 because, under proposed § 1.78, a divisional application is limited to only one application, whereas 35 U.S.C. 121 permits applicants to file a divisional application for each invention restricted out. Another comment suggested that 35 U.S.C. 121 permits applications that are both a divisional application and a continuation-in-part application and any rule to the contrary is void.

Response: This final rule defines a “divisional application” as an application “that discloses and claims only an invention or inventions that were disclosed and claimed in a prior-filed application, but were subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the prior-filed application and not elected for examination and not examined in any prior-filed application.” See § 1.78(a)(2). This definition is consistent with 35 U.S.C. 121, which states that the divisional application resulting from a restriction requirement is “entitled to the benefit of the filing date of the original application,” where the “original application” within the context of 35 U.S.C. 121 is the application from which the divisional application has been restricted. Additionally, §§ 1.78(a)(2) and (d)(1)(ii) permit there to be as many divisional applications as there are inventions restricted out of the prior-filed application. Therefore, the changes adopted in this final rule allow an applicant to file a plurality of divisional applications resulting from a restriction requirement in the prior-filed application so that the applicant may obtain examination of the claims that were withdrawn from consideration in the prior-filed application due to the requirement for restriction. Section 1.78(d)(1)(ii) as adopted in this final rule also does not require that any divisional application be filed during the pendency of a single prior-filed application, but permits a divisional application to be filed as long as it meets the copendency requirement of 35 U.S.C. 120. Therefore, the definition of divisional application set forth in

§ 1.78(a)(2) is consistent with 35 U.S.C. 121.

This final rule also permits an applicant to file an application that is in substance both a divisional application and a continuation-in-part application. Specifically, § 1.78(d)(1)(i) as adopted in this final rule permits an applicant to file an application directed both to an invention that was disclosed and claimed, but not elected for examination, in a prior-filed application, and an invention or subject matter that was not described or claimed in the prior-filed application. Such an application would be subject to the conditions applicable to other applications that disclose subject matter that was not disclosed in the prior-filed application (*i.e.*, the conditions applicable to continuation-in-part applications). This is, because such application is not limited to inventions that were subject to a requirement for restriction by the Office in the prior-filed application, but instead includes subject matter not disclosed in the prior-filed application and thus was not subject to any requirement for restriction by the Office in any prior-filed application, it is a continuation-in-part application rather than a divisional application. The provisions of § 1.78(d)(1)(ii) apply to divisional applications that disclose and claim only an invention or inventions that were disclosed and claimed in a prior-filed application, but were subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the prior-filed application and not elected for examination and not examined in any prior-filed application.

Comment 265: A number of comments argued that requiring an applicant to designate a limited number of (ten) representative claims for examination is contrary to statute, specifically, 35 U.S.C. 131 and 112, as well as contrary to *In re Wakefield*, 422 F.2d 897, 164 U.S.P.Q. 636 (C.C.P.A. 1970), because the rules limit an applicant's ability to claim the full scope of his or her invention and that it is the applicant, not the Office, who should determine the proper number of claims that particularly point out and distinctly claim the subject matter that applicants regard as their invention. Two comments argued that the courts have not recognized any statutory authority for rejecting claims as being "unnecessary," citing *Wakefield* where the court held that the forty claims presented in the application at issue were not unduly multiplied. One comment also argued that Congress

intended for each claim to be examined on the merits when it enacted 35 U.S.C. 112, ¶ 2, citing *In re Weber*, 580 F.2d 455, 198 U.S.P.Q. 328 (C.C.P.A. 1978), and one comment suggested that limiting the number of claims to be examined is contrary to 35 U.S.C. 131 because the invention is defined by all of the claims. A few comments suggested that the Office has a duty to examine all of the claims in a patent application when the applicant has paid the search, examination, and claim fees because Congress has authorized dependent claims and specified charges for those claims, and the Office is required to examine all claims, not just the designated ones. A number of comments argued that the Office lacks the statutory authority under 35 U.S.C. 102, 103, 131, and 132 to presume that claims are patentably indistinct by requiring the applicant to designate representative claims from among copending, related applications. Finally, one comment argued that the patent statutes do not permit the Director to examine part of an application or less than the whole invention, and that the Director does not have statutory authority under 35 U.S.C. 2(b)(2) or 112, ¶ 2, to cause an application to be examined only if it does not result in too much work for the examiner, and then if it does, to shift the burden to the applicant to do the search and the examination.

Response: The Office notes the concerns expressed by the public comment concerning the proposed "representative claims" examination approach. The Office also recognizes numerous comments suggested a claim threshold in place of representative claims. The Office took these comments into consideration and is not implementing a "representative claims" examination approach. Instead, this final rule provides that if the number of independent claims is greater than five or the number of total claims is greater than twenty-five (a strategy based upon whether an application contains more than a given number of independent and total claims), the applicant must provide additional information about the claims to the Office in an examination support document to enable the Office to efficiently and effectively examine the application.

Thus, the changes adopted in this final rule do not limit the number of claims that will be examined in an application because an applicant is always free to file as many claims as necessary to adequately protect the invention provided that applicant files an examination support document before the first Office action on the

merits of the application. This final rule simply provides that an applicant who puts a disproportionate burden on examination by presenting more than five independent claims or twenty-five total claims must provide additional information to the Office to facilitate effective examination of the application. The Office, in turn, will ensure that every claim submitted in an application is examined prior to the issuance of a patent. Neither 35 U.S.C. 112 nor 131 provides that an applicant has an unfettered right to submit an unlimited number of claims. In contrast to *Wakefield*, where the Office declined to examine certain claims due to undue multiplicity, the changes adopted in this final rule do not limit the number of claims that will be examined in an application because an applicant is always free to file as many claims as necessary to adequately protect the invention.

While this final rule does not implement a "representative claims" examination approach, that proposal approach was simply a mechanism to focus the examination process and in no way impacted the merits of the examination. Even under a "representative claims" approach, the Office would examine and determine the patentability for every claim in an application before issuing a patent on the application. Thus, a "representative claims" approach would have altered the examination process (*i.e.*, determining when examination of certain claims takes place), but would not have changed the merits requirements of examination (*i.e.*, the statutory standards of patentability).

Comment 266: A number of comments suggested that the rationale presented in the Claims Proposed Rule is contrary to 35 U.S.C. 2(b), 102, 131 and 132, in that the Office is responsible for granting and issuing patents. These comments stated that the examiner bears the initial burden of presenting a *prima facie* case of unpatentability, that the search is not the duty of the applicant but rather is the Office's responsibility under 35 U.S.C. 131, and the rules are inconsistent with the new fee structure which contemplates filing of additional claims with higher fees. A few comments suggested that the examination support document requirement improperly shifts the burden of assessing patentability to an applicant when that burden resides with the Office in the first instance under 35 U.S.C. 102. A few comments asserted that requiring an applicant to submit an examination support document constitutes an abdication of an inherently governmental function,

moves the United States one step closer to a registration system, and places an affirmative duty on an applicant to perform searches, ultimately exposing the applicant to a greater risk of an inequitable conduct challenge.

Response: The changes adopted in this final rule do not mandate the submission of an examination support document. That is, an examination support document is only required if an applicant chooses to present more than five independent claims or more than twenty-five total claims for examination in an application. If an applicant will not present more than five independent claims and no more than twenty-five total claims for examination in any particular application, an examination support document is not required.

The requirement for submission of an examination support document is not an abdication of the examination function, or a shifting of the burden to applicant to make a *prima facie* case of entitlement to a patent. The examination support document simply requires the applicant to provide additional information to the Office so that the Office may more effectively conduct a substantive examination of the application. The Office will examine and determine patentability for every claim in an application before issuing a patent.

Comment 267: A few comments stated that the examination support document requirement transfers the costs of examination to applicants when applicants already pay filing fees.

Response: The changes to § 1.75(b) do not impose any additional Office fees on the applicant. The changes to § 1.75(b) may increase costs for an applicant who presents more than five independent claims or twenty-five total claims in an application. The Office, however, considers it appropriate for applicants who place a disproportionate burden on examination by presenting more than five independent claims or twenty-five total claims to bear these additional costs to facilitate effective examination of the application. In any event, the Office's actual cost of examining an application for patent far exceeds the "filing fees" (*i.e.*, the filing, search, examination, excess claims, and application size fees) charged to applicant. See *United States Patent and Trademark Office Performance and Accountability Report Fiscal Year 2005* at 23 (2005) (Patent Efficiency Table).

Comment 268: Several comments objected to the rebuttable presumption in § 1.78(f)(2) as being contrary to the judicial precedent in other areas of patent law such as obviousness and enablement. One comment suggested

that the patentably indistinct presumption is contrary to 35 U.S.C. 101, which allows a "patent on an invention." One comment objected to the rebuttable presumption as being contrary to the patent statute that states in part that "a person is entitled to a patent unless * * *." The comment suggests that these words in the patent statute evidence that the burden is on the Office to establish a *prima facie* case of unpatentability. A number of comments stated that as part of its statutory duty to determine patentability, the Office has the burden to determine patentable distinctness, and even under the conditions of § 1.78(f)(2), it is improper to shift that burden to applicants. Further, some of the comments argued that the patentably indistinct presumption is contrary to case law because the Federal Circuit has repeatedly held that the burden of showing that the claims recited in copending, related applications are patentably indistinct rests with the Office, citing *In re Kaplan*, 789 F.2d 1574, 229 U.S.P.Q. 678 (Fed. Cir. 1986); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); *In re Epstein*, 32 F.3d 1559, 31 U.S.P.Q.2d 1817 (Fed. Cir. 1994); *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992); and *In re Piasecki*, 745 F.2d 1468, 223 U.S.P.Q. 785 (Fed. Cir. 1984).

Response: The presumption of patentably indistinct claims appearing in multiple applications as set forth in § 1.78(f)(2) of this final rule is not contrary to the cited statutes or case law. Even if the applicant shows that the claims in question are patentably distinct from each other, it does not mean that the claims are also patentable over the prior art. That is, the rebuttable presumption is not a merits determination of patentability. It is simply a procedural tool requiring the applicant to help focus and consolidate the examination process.

When the Office is faced with multiple applications containing overlapping subject matter, it is in the best interest of the applicant, the Office, and the public to ensure that patentably indistinct claims are identified early in the examination process. The applicant is responsible for drafting the application, including the claims, and is in the best position to identify indistinct claims spanning across multiple applications so that they can be consolidated in a single application, or so that the Office will at least be alerted to evaluate them for double patenting. Further, requiring the applicant to ferret out which claims are indistinct from each other is procedural in nature and assists the Office with processing

multiple related applications, but should not be confused with a patentability determination on the merits. Such a procedural requirement is not contrary to statute or case law, but is fully within the Office's authority to regulate the procedure of examination.

Comment 269: One comment suggested that 35 U.S.C. 116 provides for the filing of continuation applications and the Office does not have the authority to make changes.

Response: 35 U.S.C. 116 provides for joint inventorship (35 U.S.C. 116, ¶ 1), application for patent by the remaining inventors in the absence of a joint inventor (35 U.S.C. 116, ¶ 2), and correction of inventorship in an application for patent (35 U.S.C. 116, ¶ 3). 35 U.S.C. 116 does not pertain to continuing applications.

Comment 270: One comment suggested that the changes to § 1.114 violate 35 U.S.C. 133 because the Office would be assuming authority to hold an application "abandoned" even when a *bona fide* reply was timely filed.

Response: 35 U.S.C. 133 provides that: "[u]pon failure of the applicant to prosecute the application within six months after any action therein, of which notice has been given or mailed to the applicant, or within such shorter time, not less than thirty days, as fixed by the Director in such action, the application shall be regarded as abandoned by the parties thereto, unless it be shown to the satisfaction of the Director that such delay was unavoidable." An applicant's reply in prosecuting an application under a final Office action is limited to either appealing in the case of rejection of any claim (§ 41.31 of this title), or amending the claims as specified in § 1.114 or 1.116. See § 1.113(a). The admission of, or refusal to admit, any amendment after final rejection (§ 1.116) will not operate to save the application from abandonment. See § 1.135(b). Therefore, a reply to a final Office action other than an appeal, an amendment after final (§ 1.116) that places the application in condition for allowance, or a request for continued examination in compliance with § 1.114 (including the requirement that any second or subsequent request for continued examination be accompanied by a grantable petition under § 1.114(g)) is not a *bona fide* reply to the final Office action.

Comment 271: A few comments suggested that the Office has a duty to examine all of the claims in a patent application when the applicant has paid the search, examination, and claim fees. The comments also argued that because Congress has authorized dependent claims and specified charges for those

claims, the Office is required to examine all claims, not just the designated ones. One comment also argued that the recently revised fee structure was put in place based on an allocation of resources for search workload on the examiner and therefore the Office is obligated to perform the search and cannot shift the burden to the applicant.

Response: The Office recognizes the concern expressed in the public comments that the “representative claims” examination approach could be perceived as allowing claims to be issued that had not been fully examined. The Office is not adopting the “representative claims” examination approach in this final rule. This final rule instead provides that an applicant who puts a disproportionate burden on examination by presenting more than five independent claims or twenty-five total claims must provide an examination support document to the Office before the first Office action on the merits to facilitate effective examination of the application. An applicant who presents five or fewer independent claims and twenty-five or fewer total claims need not provide an examination support document or other additional information to the Office. In either situation, the Office will ensure that every claim submitted in an application is examined prior to the issuance of a patent.

Further, neither the excess claim fees nor the search fee is directly proportional to actual agency costs. The fee provisions are not a restriction on the agency’s ability to promulgate reasonable regulations governing the application process.

Comment 272: A few comments stated that the rules are arbitrary, capricious, and represent an overly aggressive interpretation of statutes, are beyond the power of the Office permitted under 35 U.S.C. 2(b)(2), expose the Office to legal action under 5 U.S.C. 706(2)(c), and may require the Office to reimburse attorney fees under the Equal Access to Justice Act.

Response: The changes adopted in this final rule are not arbitrary, capricious, an overly aggressive interpretation of the patent statute, or beyond the power of the Office rule making authority under 35 U.S.C. 2(b)(2) for the reasons previously discussed in detail. Concisely put, the Office considers the changes being adopted in this final rule to be an appropriate exercise of its rulemaking authority under 35 U.S.C. 2(b)(2). *See, e.g., Lacavera v. Dudas*, 441 F.3d 1380, 77 U.S.P.Q.2d 1955 (Fed. Cir. 2006), *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 73 U.S.P.Q.2d 1409 (Fed. Cir.

2005), and *Arnold P’ship v. Dudas*, 362 F.3d 1338, 70 U.S.P.Q.2d 1311 (Fed. Cir. 2004).

J. Changes to Internal Practice

Comment 273: A number of comments expressed support for the elimination of the first Office action final practice, and one comment encouraged the Office to adopt a practice of no first action final rejection in any continuing application where the factual record has changed. A number of comments, however, stated that a first action final may be appropriate where no effort has been made to advance prosecution, *e.g.*, by adding to the factual record with additional evidence or amendments to the claims. One comment supported developing rules whereby an applicant’s failure to prosecute could result in the close of prosecution unless adequate and sustained progress is being made in the application.

Response: This proposed change has not been adopted. As discussed previously, this final rule, however, provides that an applicant may file two continuing applications plus a request for continued examination in any one of the initial application or two continuing applications (rather than only one continuing application or request for continued examination as proposed) without any showing. Therefore, the Office is retaining its first action final rejection practice.

Comment 274: Several comments recommended that the Office develop procedures whereby an Office action could not be made final until the examiner was applying the exact same rejection as in the previous Office action, and/or to encourage the Office to issue non-final second Office actions. Several comments suggested reforming examination procedures so that the examiner does not issue a final rejection as long as prosecution is advancing.

Response: The practice suggested by the comments would unduly prolong prosecution, which is counter to the Office’s goal for reducing pendency. Thus, the Office and the applicants need to be efficient to reduce the backlog of applications and most importantly, to meet the public notice function of patent claims as quickly as possible. Further, as one comment recognized, a practice under which an Office action could not be made final until the examiner was applying the exact same rejection would result in an applicant being able to avoid a final Office action by continually amending the claims.

Comment 275: A number of comments proposed that the Office permit amendments after final as matter

of right, and assess a modest fee for the added examination burden. Most of these comments are in the context of a graduated credit system for continuation filings, with more credit being given during the first application and fewer “counts” or less time given in subsequent continuations. Several comments proposed that applicants should be permitted to respond to any new ground of rejection made in the final Office action without having to file a continuation application. Several comments suggested that the examiner should not make an Office action final whenever new art is applied, and one comment suggested an examiner must explain why the new art could not have been located during the first search.

Response: To permit entry of amendments after final as a matter of right would unduly delay prosecution. An applicant may file an amendment to place the application in condition for allowance or in better form for consideration on appeal under § 1.116. Furthermore, a new ground of rejection is only permitted in a final Office action under the limited circumstances. As discussed previously, in this final rule, the Office is revising second action final practice to provide that a second or any subsequent Office action on the merits may be made final, except when the Office action contains a new ground of rejection that is not: (1) Necessitated by applicant’s amendment of the claims, including amendment of a claim to eliminate unpatentable alternatives; (2) necessitated by applicant’s providing a showing that a claim element that does not use the phrase “means for” or “step for” is written as a function to be performed and does not otherwise preclude application of 35 U.S.C. 112, ¶ 6; (3) based on information submitted in an information disclosure statement filed during the period set forth in § 1.97(c) with the fee set forth in § 1.17(p); (4) based upon double patenting (statutory or obviousness-type double patenting); or (5) necessitated by applicant’s identification of the claim or claims in a continuation-in-part application for which the subject matter is disclosed in the manner provided by 35 U.S.C. 112, ¶ 1, in the prior-filed application. Since the applicant is often adding limitations that raise new issues that would require further consideration and/or search, it has long been the Office practice to make the action final at this point. Allowing an expanded practice in this area would undermine the goal of reducing patent pendency.

Comment 276: A number of comments suggested providing examiners with additional time to consider replies after final rejection and

to provide a new full evaluation of the content of those replies.

Response: No changes in after final practice are planned at this time. Under current practice, examiners consider any requests for reconsideration submitted after final rejection in accordance with § 1.116.

Comment 277: A number of comments suggested that the Office require a patentability review conference with others, similar to the pre-appeal conference proceeding, prior to an Office action being made final, in order to address the problem of improper final Office actions and to expedite indication of allowable subject matter. One comment noted that the statistics show that less than half of applications that had a pre-appeal conference are going forward to appeal and indicate that many improper finals are being made. One comment stated that a supervisor should review all first Office actions in a second request for continued examination to determine if prosecution is proper.

Response: The Office recognizes that it is important to make sure the final Office action is proper. The pre-appeal brief conference program is still an ongoing pilot program. The results of that program will help to determine whether the Office replaces it with, or adds, a “pre-final conference” as suggested. Further, the pre-appeal brief conference program is designed for situations in which the applicant believes that the rejections of record are clearly not proper (and is not designed for “close cases”). See *New Pre-Appeal Brief Conference Program*, 1296 *Off. Gaz. Pat. Office* at 67. Thus, data collected during pre-appeal brief conferences (e.g., with respect to re-opening rates) cannot validly be extended to all applications.

In addition, the Office has an ongoing “in process review” of applications to identify problems and trends. Each Technology Center develops ongoing action plans and training each year to address the problems/trends found via the “in process reviews” and the pre-appeal brief conferences. Additionally, the Office will reinforce, during the training on this final rule, issues such as proper final rejection practice, the importance of making proper final rejections, and the importance of indicating allowable subject matter at the earliest possible time. Furthermore, if an applicant believes a rejection was improperly made final, applicant may seek review by filing a petition under § 1.181.

Comment 278: A number of comments stated that the Office should continue and expand ongoing efforts to

hire and retain patent examiners. One comment suggested that “[h]iring should be the centerpiece of the Office’s strategy.” A number of comments stated that the Office has not provided sufficient evidence to show why the Office could not solve the backlog problem by hiring more examiners. One comment argued that the Office should have sufficient funding to pay for additional resources (e.g., more examiners) needed to examine the backlog of applications in view of the recent increase in patent fees. One comment stated that the Office has not supported its assertion that it cannot hire enough examiners to reduce pendency. Another comment stated that the Office should seriously consider hiring retired or former examiners or patent practitioners to be trainers or to assist examiners. In particular, one comment stated retired examiners should be hired to work on specific big applications to reduce the burden on examiners. Another comment stated the Office should hire “generalists” instead of “ultra specialized advanced degree scientists and engineers” to obtain more flexibility in the workforce.

Response: Hiring additional examiners remains an important component of the Office’s overall plan to reduce pendency of patent applications. The Office is committed to the hiring of as many examiners as resources permit. The ability to hire qualified new examiners is affected by many components, such as budget, the economy, the availability of scientists and engineers, and the ability to absorb and train new employees. Furthermore, it will take many years to develop an experienced patent examining corps of sufficient size to address the growing backlog of unexamined patent applications. The Office recognizes that hiring alone will not reduce the backlog of pending applications in the near future. As a result, the Office is actively seeking ways for retaining more employees, such as retention bonuses. The Office continues to become more efficient by implementing many initiatives, such as the current regulatory changes, to reduce pendency.

The Office plans to hire 1,200 examiners each year for the next five fiscal years. See *United States Patent and Trademark Office Fiscal Year 2008 President’s Budget* at 20–21 (2007). This will result in the number of patent examiners increasing from 4,779 at the end of fiscal year 2006 to 7,118 at the end of fiscal year 2012 (accounting for attrition). See *id.* Even with this increase in the size of the Patent Examining Corps, the Office anticipates that average pendency to first Office action

will increase from 22.6 months in fiscal year 2006 to 28.9 months in fiscal year 2012, and that average total pendency will increase from 31.1 months in fiscal year 2006 to 38.6 months in fiscal year 2012. See *id.*

Comment 279: A number of comments stated that the current examiners’ production system in the Office encourages the filing of continuing applications and requests for continued examination. In addition, several comments stated that the production system also encourages more restrictions and unwillingness to consider any after-final amendment. The comments suggested several alternative accounting schemes to encourage examiners to examine more non-continuing applications and provide more thorough first Office actions, including giving less credit for work done in continuation applications, divisional applications and requests for continued examination, giving examiners more credit for first Office actions as opposed to disposals, giving examiners credit for claims disposed as opposed to applications disposed, or giving examiners credit based on numerous application factors such as specification length, technology complexity, number and complexity of the claims, and pertinence of prior art submitted. One comment suggested only having team examination and production goals. One comment suggested the Office should use a performance system, such as the system recently established by the Department of Defense. One comment suggested that examiners should not have any time constraints. Another comment stated the hours per disposal should be decreased to improve production. Several comments argued that timesaving for examiners needs to be tied with an agreement with the Patent Examining Corps to increase productivity and decrease pendency due to the amount of time saved in light of the proposed changes to the examination of claims. One comment argued the rule changes will likely result in less time for the examiners and it is unclear how this will result in more thorough and reliable examination. The comments strongly suggested that any changes to the examiners’ production system should be transparent to the public to install public confidence in such changes.

Response: The Office expects to gain a more focused quality examination as a result of these rule changes. It is expected that these rules will make the exchange between the examiner and applicants more efficient and effective. Issued patents will be examined more

thoroughly, making them easier to evaluate, enforce and litigate. Furthermore, the patents will issue sooner, giving the public a clearer understanding of what is patented. In any event, the Office is in the process of reassessing patent examiner production goals, appraisal plans, and award systems. Absent significant changes to the patent examination process, the Office does not consider it reasonable to expect that changes to patent examiner production goals, appraisal plans, and award systems alone will be sufficient to address the growing backlog of unexamined patent applications while maintaining a sufficient level of quality.

Comment 280: Several comments stated that examiners should be given more production time for certain situations, such as for applications with more than twenty claims, for consideration of over fifteen to twenty cited references and for responding to after-final amendments. One comment stated that primary examiners should be given more time to review a junior examiner's work.

Response: Changes to patent examiner production goals are beyond the scope of the proposed changes to the rules of practice. Therefore, whether examiners should be given more production time for certain situations is not discussed in this final rule. An examination support document in compliance with § 1.265 will assist the examiner in the examination of an application that contains more than five independent claims or more than twenty-five total claims, resulting in a more effective and focused examination. For example, citing the most relevant references and identifying all of the limitations of each of the claims that are disclosed by the references will help the examiner to consider the most relevant prior art more thoroughly. The Office already provides time for training junior examiners and reviewing their work. Furthermore, a sampling of "in process reviews" for each Technology Center helps identify training needs in a focused manner. The Office of Patent Training is thoroughly preparing each new examiner in proper practice and procedure with access to a dedicated trainer for the first eight months; after that, the examiner is placed in a traditional setting with proper supervision and review of his or her work.

Comment 281: A number of comments suggested that the Office could retain more examiners by increasing compensation and offering better working conditions. A number of comments also suggested that if it is

necessary to increase examiner salaries, changes to Title 5 of the United States Code should be requested by the Office. One comment stated that the salary for starting examiners should also be doubled. One comment stated that the Office should seek authority to increase salaries through either existing OPM processes or through restructuring to a quasi-government corporation. One comment suggested charging fees for responding to an Office action and for interviews, and using this money to hire more examiners and pay for retention initiatives. Another comment suggested establishing a salary increase when an examiner passes a test at a number of pay grades. One comment stated that a bonus system should be established. Another comment has suggested increased salary levels for art units with high backlogs. Several comments stated that increased filing fees should go towards increased salary for examiners. One comment explained that the Office could give examiners better working conditions by placing less stress on the more experienced examiners. Another comment suggested the Office should explore more flexible work schedules, including part-time arrangements.

Response: The Office already provides many first rate benefits to its employees. The Office is at the forefront in government for teleworking opportunities for the staff. The Office has also adopted a variety of creative work schedules such as: Maxi-flex, compressed and alternate work schedules, part-time and flex-time for all employees. Additionally, the Office offers paid overtime, compensatory time and credit hours programs. The Office has transitioned into a paperless environment and deployed state-of-the-art technology to its employees. The Office has relocated to a new campus, and provides amenities such as a first class child-care facility, a state-of-the-art fitness center and a cafeteria.

The Office already provides a robust bonus system for examiners that enables one to earn up to ten percent of one's salary per year in bonus compensation. Examiners are already on a special pay scale, with the most recent increase of seven percent for all patent professionals, granted in December 2006. In addition, an examiner receives regular salary increases upon promotions to increasing levels of responsibilities.

Comment 282: Several comments stated the Office should authorize overtime to work on the backlogs. One comment specifically suggested that overtime pay should be 125 percent of the current pay rate, and should only be

available to work on first Office actions on the merits.

Response: Examiners who have been certified as capable of working independently by their supervisors are currently authorized to work overtime. The overtime pay rate is set by statute. See 5 U.S.C. 5542. The Office has recently begun distributing laptop computers to examiners to further encourage overtime.

Comment 283: A number of comments encouraged the Office to consider establishing satellite offices in different areas in the United States to assist in recruiting and retaining of examiners. The comments further explained that satellite offices could tap into a greater pool of potential new examiners, as there would be multiple working locations. In addition, the comments stated that satellite offices could specialize in certain technologies that are prevalent in the area of the satellite office. Another comment pointed out that a satellite office would facilitate more personal interviews, which would expedite prosecution. The comments also stated that salary structures could be adjusted depending on the cost of living within the area surrounding the satellite office.

Response: The Office is considering establishing satellite offices as reflected in the Office's 2007-2012 Strategic Plan.

Comment 284: A number of comments stated that the Office should increase training requirements for examiners in order to improve patent quality and retain more examiners. One comment suggested using any increase in patent fees to provide training. Several comments offered assistance in providing technical and legal training to the examiners. One comment suggested that examiners should receive more training on making proper rejections under 35 U.S.C. 103, and also suggested testing examiners periodically. Another comment stated that examiners' prior art searching is poor, and that the Office is not making efforts to stem poor rejections, which lead to rework. One comment suggested that the Office should train examiners using self-training programs utilizing videos. Another comment stated that training should be outsourced. Several other comments suggested training potential new examiners by creating a patent examination curriculum for universities.

Response: The Office has redesigned the training program of new examiners and increased technical and legal training for other examiners and patent professionals. Currently, the first classes of new hires have completed their training in the new Patent Training Academy program, wherein examiners

go through eight months of intensive training prior to being assigned to an art unit. Mirroring a collegiate environment, examiners are trained in a variety of disciplines, including technology skills, legal skills, and procedural requirements.

For non-first year examiners, the Office has expanded training to include patent law and evidence. Each employee must attend a specified number of training hours in a variety of pertinent legal and technical subjects. Additionally, the Office also offers a Law School Tuition Assistance Program (LSTAP) to qualified employees as an extension of the Office's internal training program. Reimbursements for university technical training courses related to the technology being examined are also available for employees. Creating a partnership between the Office and interested universities to offer an undergraduate course in patent law and examination practice to highlight career opportunities in the intellectual property field is also being investigated.

Comment 285: A number of comments stated that the Office did not address improvements in the internal examination process. One comment alleged that the Office did not consider any changes to address examiners' errors that extend the prosecution. Several comments suggested that the Office should improve the examination process before implementing the rule changes.

Response: The Office is implementing many initiatives including improvements in the internal examination process as well as the rule changes in this final rule. To realize the effectiveness of these initiatives in the near term, the Office is implementing many of them simultaneously. The Office seeks ways to improve internal examination processes by providing training created as a result of internal reviews that identify areas where challenges exist.

Comment 286: Several comments encouraged the Office to take additional measures to improve the quality and clarity of Office actions, in particular first Office actions. One comment stated that examiners should use "plain English" in explaining the rationale behind rejections.

Response: The Office recognizes that the quality of Office actions is of great importance. There are several quality initiatives in place to insure that quality continues to improve. The new Patent Training Academy emphasizes the importance of high quality Office actions. Current interview practice encourages the use of interviews to

clarify the examiner's position, as necessary. The Office also has writing classes available to employees.

Comment 287: Several comments stated that examiners should be encouraged to allow an application, or to point out allowable subject matter, in the first Office action, if appropriate. Several comments also suggested requiring examiners to propose amendments when prosecution reaches a certain point, such as the filing of a second request for continued examination.

Response: The Office has previously adopted, in part, these comments. It is current Office policy to encourage examiners to suggest allowable subject matter as early as possible in the prosecution in order to achieve the Office's goal of compact prosecution. It has long been a standard in the examiner's performance appraisal plan, and it is indeed an indicia of outstanding performance, to indicate allowable subject matter at the earliest time possible. (See also, e.g., MPEP § 707.07(j)(III) EARLY ALLOWANCE OF CLAIMS, "Where the examiner is satisfied that the prior art has been fully developed and some of the claims are clearly allowable, the allowance of such claims should not be delayed"; MPEP § 2106 (II), "Whenever practicable, Office personnel should indicate how rejections may be overcome and how problems may be resolved * * *"; and MPEP § 2164.04, "In other words, the examiner should always look for enabled, allowable subject matter and communicate to applicant what that subject matter is at the earliest point possible in the prosecution of the application.").

Comment 288: There were a number of comments pertaining to the quality review of examiners' work product. A number of comments stated that the Office should limit its "second-pair-of-eyes" review to the work of examiners that have been identified as needing more review in their annual performance appraisal. The comment further explained that the Office should focus more intensive review on an examiner's work if it is the principal cause for the failure to close prosecution on an invention (e.g., by making poor rejections). Another comment suggested eliminating the review of allowed applications and having the "review" examiners work on the backlog. One comment stated that supervisors should review all Office actions for examiners that have fewer than three years experience unless they have passed a proficiency examination. Another comment stated the review should spot

factual issues instead of just legal issues to better improve Office action quality.

Response: The Office already has focused "second pair of eyes" reviews only for those examiners and/or technology areas where it has been determined necessary. Additionally, the Office has an ongoing "in process review" of applications to identify problems and trends. Each Technology Center develops ongoing action plans and training each year to address the problems/trends found via the "in process reviews" and other sources, such as the pre-appeal brief conferences. Supervisors, or their designated primary examiners, currently review all the work of examiners who do not have signatory authority. All of these reviews do encompass both factual and legal issues.

Comment 289: A number of comments stated that examiners should be encouraged or required to conduct more interviews throughout the prosecution, including preexamination interviews and after-final interviews. Several comments suggested that all interviews should include the supervisor of the examiner or a person with signatory authority. Several other comments suggested giving examiners a count, or credit, for an interview, and charging a fee for interviews. Another comment stated that examiners should be trained to give more productive interviews.

Response: Interview practice is set forth in § 1.133 and MPEP §§ 713 through 713.10. Normally, one interview after final rejection is permitted. See MPEP § 713.09. The Office also provides examiners extra time to conduct an interview. In June 2006, this practice was expanded to allow extra time for telephone interviews initiated by applicants or their representatives; it had previously only been available for personal (face-to-face) interviews. The Office conducted a pilot program permitting an interview before the first Office action in applications that were assigned to certain art units in Technology Center 3600. See *Notice of Pilot Program to Permit Pre-First Office Action Interview for Applications Assigned to Art Units 3624 and 3628 and Request for Comments on Pilot Programs*, 1281 *Off. Gaz. Pat. Office* 148 (Apr. 27, 2004). Section 1.133(a)(2) was amended in November of 2005 to permit an interview before the first Office action in any application if the examiner determines that such an interview would advance prosecution of the application. See *Provisions for Claiming the Benefit of a Provisional Application With a Non-English Specification and Other Miscellaneous Matters*, 70 FR at

56121, 56128, 1299 *Off. Gaz. Pat. Office* at 144, 150. As discussed previously, if the examiner, after considering the application and any examination support document, still has questions concerning the invention or how the claims define over the prior art or are patentable, the examiner may request an interview before the first Office action.

Comment 290: One comment stated that the Office should encourage the submission of more useful information disclosure statements, which contain statements of materiality and have provisions to discourage “dumping” of references. Such an information disclosure statement may be filed at a reduced fee amount. Another comment questioned whether the Office has considered a rule that states that duty of disclosure terminates at the close of prosecution.

Response: The Office recently published proposed changes to the information disclosure statement practice which will encourage the submission of more useful information. *See Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 FR at 38812–16, 38820–22, 1309 *Off. Gaz. Pat. Office* at 27–31, 34–36.

Comment 291: A number of comments suggested that the Office should make better use of search and examination reports from other intellectual property offices and PCT search and examination authorities. On the other hand, one comment stated that the Office should not rely on foreign office searches. Several comments further suggested separating the search and examination functions and outsourcing the search function. One comment stated that U.S. and PCT prosecution should be done at the same time.

Response: The Office recognizes the importance of leveraging the search results from other intellectual property offices. One of the specific action plans of the United States Patent and Trademark Office 21st Century Strategic Plan is to share search results with other intellectual property offices. Since the beginning of 2003, the Office, the European Patent Office and the Japan Patent Office (the Trilateral Offices) have participated in search exchange projects aimed at promoting the mutual exploitation of search results. The Office implemented the Patent Prosecution Highway pilot program in July 2006. *See Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the Japan Patent Office*, 1307 *Off. Gaz. Pat. Office* 61 (June 13, 2006). Under the Patent Prosecution Highway pilot

program, an applicant whose claims are determined to be patentable by the Japan Patent Office may request that the corresponding application filed in the Office be advanced out of turn for examination provided certain conditions are met. The Patent Prosecution Highway pilot program allows the Office to exploit the search and examination results of the Japan Patent Office and applicants to obtain corresponding patents faster and more efficiently. Additionally, whenever the Office is designated as the International Searching Authority, both the international application and the application filed under 35 U.S.C. 111(a) are assigned to the same examiner, if possible.

Comment 292: A number of comments stated that all related applications should be assigned to the same examiner, including applications with overlapping disclosures.

Response: The Office will continue to make reasonable efforts to ensure that related applications are assigned to the same examiner, if possible. However, the Office normally assigns divisional applications to the technology area most appropriate for the claimed subject matter. In fact, this is in part why this final rule requires applicants to identify certain related applications. *See* § 1.78(f).

Comment 293: A number of comments suggested creating a new or modified accelerated examination procedure. One comment requested a procedure to permit accelerated examination for applications that enter the national stage under the Patent Cooperation Treaty. Another comment stated that accelerated examination could be available to applications containing ten or fewer representative claims. Another comment suggested allowing accelerated examination if the applicant permits an *inter partes* submission of a prior art statement and applicant provides either an examination report from either the European Patent Office or the Japan Patent Office, or pays a high fee for a special search. One comment stated high technology areas should be given examination priority. Another comment suggested requiring expedited replies in continued examination applications and not giving extensions of time under § 1.136(a). Another comment requested accelerated examination for independent inventors.

Response: The Office has long provided for advancement of examination upon granting a petition to make special. *See* § 1.102 and MPEP § 708.02. The Office also announced a revised accelerated examination

procedure, and the goal is to complete examination within twelve months of the filing date of the application under this program. *See Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination*, 71 FR at 36323–27, 1308 *Off. Gaz. Pat. Office* 106–09. Any applicants, including independent inventors, may participate in the revised accelerated examination program which provides an expedited reply procedure. As discussed previously, under the Patent Prosecution Highway pilot program, an applicant whose claims are determined to be patentable by the Japan Patent Office may request that the corresponding application filed in the Office be advanced out of turn for examination provided certain conditions are met.

Comment 294: Several comments suggested that examiners should strictly follow the guidance set forth in MPEP section 708 and examine applications with the oldest effective filing date first. On the other hand, several comments stated the Office should promote earlier examination of non-continuing applications by giving continuation applications a lower priority in the examination queue.

Response: The Office will continue to follow the guidance set forth in MPEP section 708 pertaining to the order of examination of applications, including that “[e]ach examiner will give priority to that application in his or her docket, whether amended or new, which has the *oldest effective U.S. filing date.*” An exception to this guideline is an application in which examination has been advanced pursuant to § 1.102.

Comment 295: One comment suggested examiners should not just search the claimed invention, but also subject matter that might be reasonably claimed at a later time.

Response: MPEP § 904 sets forth that “[t]he first search should cover the invention as described and claimed, including the inventive concepts toward which the claims appear to be directed.” Additionally, MPEP § 904.02(a) states that “[t]he field of search extends to all probable areas relevant to the claimed subject matter and should cover the disclosed features which might reasonably be expected to be claimed.”

Comment 296: Several comments encouraged the Office to hire efficiency experts, or a task force, to find the best ways to improve the quality and efficiency of examination.

Response: The Office expects these rule changes to improve the quality and efficiency of examination. The Office will evaluate the effectiveness of the rule changes in partnership with the

Office's customers and employees as all gather experience in operating under these adjustments. The Office is currently studying all suggestions, including those in the various studies made of the Office.

Comment 297: One comment requested that the panel involved in a pre-appeal brief conference be required to provide legal and factual reasoning for the decision to both the examiner and the practitioner so as to better make the decision a teaching tool.

Response: The Pilot Pre-Appeal Brief Conference Program has been extended until further notice. *See Extension of the Pilot Pre-Appeal Brief Conference Program*, 1303 *Off. Gaz. Pat. Office* 21, (February 7, 2006) (notice). Since this program is still in the pilot phase, it would be premature to make any changes until a full evaluation of the entire program is completed. Furthermore, the purpose of this program is to provide a quick relief for applications that are clearly not in condition for appeal, so that applicant does not have to go through the expense of preparing and filing an appeal brief. Preparing a written decision of the conference would unduly delay the process.

Comment 298: Several comments stated that the Office should create an Ombudsman position to decide issues regarding examination errors by examiners.

Response: The Office has many effective mechanisms to decide issues regarding alleged "examination errors" by examiners. Practitioners have several options, including but not limited to, responding on the record, calling a supervisor, requesting a pre-appeal brief conference, filing a petition, and filing an appeal.

Comment 299: One comment requested a return to the appeal rules where the examiners are not able to make new grounds of rejection during appeal.

Response: The rules of practice for the appeal process were changed in 2004 to permit a new ground of rejection in an examiner's answer. *See Rules of Practice Before the Board of Patent Appeals and Interferences*, 69 FR 49960, 1286 *Off. Gaz. Pat. Office* 21 (September 7, 2004) (final rule). The approval of the appropriate Technology Center Director, or his or her designee, is needed for such a new ground of rejection, which should be rare. In response to any new ground of rejection made in an examiner's answer, appellant has the options to request that prosecution be reopened and to request that the appeal be maintained under § 41.39(b). There have been no demonstrated problems to

date, thus the Office does not plan to change this practice.

Comment 300: One comment suggested accepting more "variations" in filings to reduce the number of non-compliant notices sent.

Response: The Office waives certain requirements set forth in § 1.121(c) and may accept certain non-compliant amendments. *See Acceptance of Certain Non-Compliant Amendments Under 37 CFR 1.121(c)*, 1296 *Off. Gaz. Pat. Office* 27 (July 5, 2005). Practitioners and applicants, however, are responsible to know the laws and rules relating to prosecuting patent applications and to keep current with any changes. The Office will continue to review common problems that arise, and implement solutions as appropriate.

Comment 301: One comment requested that the Office publish, once a month, a projection of when a new application will be taken up for examination so that applicants can better manage the filing of preliminary amendments.

Response: The Office currently publishes in each issue of the *Official Gazette* the average filing date of the applications that received a first Office action during the preceding three months for each Technology Center Work Group.

Comment 302: One comment suggested that the Office should allow more documents to be filed via the Office electronic filing system. Another comment stated the Office should require electronic filing and that all prosecution be performed electronically.

Response: The Office permits applicants to file many applications, fees, and correspondence (e.g., amendments and replies) electronically via the Office electronic filing system (EFS-Web) with a few exceptions (e.g., Credit Card Authorization Form (PTO-2038), maintenance fees, new plant applications and color plant drawings). There are no plans to make electronic filing mandatory, although special programs (e.g., accelerated examination) do require electronic filing. *See Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination*, 71 FR at 36323-27, 1308 *Off. Gaz. Pat. Office* 106-09.

Comment 303: One comment proposed requiring applicants to give an opinion of the usefulness or commercial potential of the invention.

Response: The Office is not adopting the requirement that an examination support document contain a concise statement of the utility of the invention. An opinion from the applicant on the commercial potential of the invention is

generally unnecessary in determining the patentability of the claimed invention. However, applicant may submit objective evidence of commercial success when applicant seeks to rebut an obviousness rejection under 35 U.S.C. 103. *See* § 1.132 and MPEP § 716.03.

Comment 304: One comment requested prioritizing the order of examination based on such factors as the economic impact and value to society, the quality of the technical description of the invention and the quality of prior art cited. The comment also suggested requiring applicants to state in their application how the invention will be distributed to the public.

Response: It would be very difficult to evaluate and assess these subjective factors for each application filed. In addition, most of this information would not be helpful in determining the patentability of the claimed invention.

Comment 305: One comment suggested creating an electronic search tool that would automatically compare the claim language to prior art and provide complete searches in under ten minutes.

Response: The Office has been evaluating tools to improve the examination practice. Although the Office is routinely seeking ways to improve automated tools, the resources needed for implementation and the applicability of the tools must be considered and weighed. Often, the application of search tools is limited to specific technologies. For example, in many biotechnology applications, the Office employs an Automated Biotechnology Sequence Search System (ABSS) to compare genetic sequences submitted with applications to a number of sequence databases. The Office's Scientific and Technical Information Center (STIC) conducts between 10,000 and 15,000 of these searches a year. Due to the number of requests and because the search runs against multiple databases, ABSS searches can be time-consuming. In other technologies, such as electrical and mechanical arts, STIC provides the option of conducting a Patent Linguistic Utility Service (PLUS) search, which runs significant words from sections of the specification against the full text of the United States Patent and United States Pre-Grant Publication databases. STIC is performing over 20,000 of these searches a year. While these searches are done quickly, limitations in key word searching are not always reliable in finding relevant prior art.

Comment 306: One comment stated that the Office should create a better

search engine so inventors can more easily perform better searches.

Response: The Office continues to explore various ways to disseminate information and improve the searching capabilities of the public. Currently, the Office allows applicants and inventors to search on-line using Patent Full-Text and Full-Page Image Databases (<http://www.uspto.gov/patft/index.html>) and works in concert with eighty-three Patent and Trademark Depository Libraries (<http://www.uspto.gov/go/ptdl/>) throughout the United States to offer the public extension research capabilities. The Office also has a library and tools at the Alexandria campus for the public to use.

Comment 307: One comment suggested that procedures for appeals and petitions should be changed to be less costly and to result in more timely decisions. One comment suggested the Office waive the notice of appeal fee and the appeal brief fee while the applicant awaits a decision on petition to invoke supervisory authority relating to a premature final rejection in an Office action.

Response: Most petition fees are set by regulation. The petition fee amounts that are set by regulation are set at an amount based upon the resources required to handle and decide the petition. See *Changes to Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan*, 69 FR 56482, 56491–93 (Sept. 21, 2004), 1287 *Off. Gaz. Pat. Office* 67, 75–76 (Oct. 12, 2004). The notice of appeal fee and the appeal brief fee are set by statute and cannot be waived. Additionally, the appeal fees recover only a fraction of the Office cost of handling and deciding the appeal.

With respect to petitions, the Office is taking the necessary steps to minimize the backlog and to respond to petitions in a timely fashion. Within the Technology Centers, almost all petitions for relief from improper final rejections or restrictions are answered in a timely fashion. The Office is working to ensure that most of the petitions for relief from improper final rejections or restrictions are decided within four months from when they are filed, and continues to work on ways to make the process consistent across the different Technology Centers. The Office has also taken major steps to eliminate delays with the appeal process. The BPAI has radically reduced the inventory of pending appeals during the last five fiscal years.

The Office also recognizes that it is important to make sure that the finality of any final Office actions is proper. It

is the Office's experience that applicants who seek review of the finality of an Office action also request review of the merits of the rejections contained in the final Office action. The propriety of the finality of an Office action is purely a question of Office practice that is wholly distinct from the merits of the rejections contained in the final Office action rejection. See MPEP § 706.07(c). The propriety of the finality of an Office action is properly raised in a petition under § 1.181, and is not a proper basis for an appeal or complaint to the BPAI during an appeal. See *id.* Likewise, arguments relating to the merits of the rejections contained in the final Office action rejection are properly raised in an appeal to the BPAI, and are not a proper basis for a petition under § 1.181 or for contesting the propriety of the finality of an Office action.

The rules of practice provide that the mere filing of a petition under § 1.181 will neither stay any period for reply that may be running against the application, nor act as a stay of other proceedings. See § 1.181(f). While the Office has put in place procedures to decide the appeals and petitions in a timely manner, the applicant is responsible to continue to prosecute the application consistent with § 1.181(f). Thus, there may be situations in which it is necessary for an applicant to file a notice of appeal to maintain the pendency of an application while a petition under § 1.181 requesting review of the finality of an Office action is being decided. The filing of a notice of appeal, however, does not moot such a petition under § 1.181, so the Office will decide a petition under § 1.181 requesting review of the finality of an Office action even if the applicant has filed a notice of appeal in the application. In such a situation, applicants should also request a pre-appeal brief conference with the filing of a notice of appeal. The pre-appeal brief conference will be conducted and the applicant will be notified of the result of the pre-appeal brief conference before the appeal brief and appeal brief fee must be filed. This should ensure that any petition under § 1.181 requesting review of the finality of an Office action is decided before the applicant must file the appeal brief and appeal brief fee. If the Office determines that the finality of the rejection was premature, the finality of the Office action will be withdrawn and any fees paid for the notice of appeal and the appeal brief can be applied to a later appeal on the same application. See MPEP § 1207.04.

Comment 308: Several comments stated that the Office should exercise

better control over restriction practices. Several comments stated that the Office should encourage claims of different statutory classes to be filed in one application to improve examiner efficiency. One comment asserted that disposal pressures on examiners in the biotechnology area are totally unrealistic and have led to legally ridiculous restriction requirements. Several comments suggested that restriction reform is needed. Several comments suggested that the Office adopt the unity of invention standard. Several comments suggested an interim standard based on current PCT unity of invention practice should be available at the option of the applicant as an alternative to adopting unity of invention practice. Some comments expressed the opinion that current restriction practice in Technology Center 1600 (biotechnology and organic chemistry) requires applicants to file too many continuing and divisional applications. One comment expressed the opinion that current restriction practice is a result of the examiners' production system. Several comments stated that restriction is necessary to avoid abusive filing tactics by applicants seeking to circumvent the proposed regulation of continued examination filings. Several comments suggested that the Office eliminate restriction practice. Another comment stated that if proposed § 1.78(d)(1)(ii) is adopted, the Office should be bound by an initial restriction requirement and § 1.146, authorizing species restrictions, should be repealed. One comment suggested that if restriction practice must be maintained, it should be limited to applications in which two claimed inventions are literally unrelated, and all divisional applications should be examined by the same examiner.

Response: As part of the United States Patent and Trademark Office 21st Century Strategic Plan, restriction reform was studied extensively. See *Request for Comments on the Study of Changes Needed to Implement a Unity of Invention Standard in the United States*, 68 FR 27536 (May 20, 2003), 1271 *Off. Gaz. Pat. Office* 98 (June 17, 2003) (notice). A revision of the study was posted in November 2003, and the study was expanded to include four restriction reform options. See *Notice of the Availability of and Request for Comments on Green Paper Concerning Restriction Practice*, 70 FR 32761 (June 6, 2005), 1295 *Off. Gaz. Pat. Office* 146 (June 28, 2005) (notice) and the extension of the comment period announced at 70 FR 45370 (August 5,

2005) (notice). There were sixteen responders, and there was no consensus as to which of the four options to adopt. In addition, the restriction reform study concluded that a change to unity of invention under PCT Rule 13 under any of the four restriction reform options would significantly increase patent pendency. Thus, the Office is maintaining its current practices with respect to requirements for restriction under 35 U.S.C. 121 or unity of invention under PCT Rule 13.

Technology Center 1600 (biotechnology and organic chemistry) has implemented a comprehensive restriction training plan. This includes training examiners on proper restriction practices, including proper grouping of claims and rationale supporting the restriction requirement, using Art Unit and Work Group specific examples. Training has been ongoing, using materials that are published on the Office's Internet Web site. Feedback from the training to date has been incorporated into the initial patent examining training given to new hires.

Although the Office will continue to assign divisional applications to the technology area most appropriate for the claimed subject matter, they are not necessarily assigned to the same examiner.

Comment 309: Several comments asserted that restriction practice will increase as a result of the rule changes. One comment suggested that the Office needs to coordinate any changes in continuation practice with restriction reform. Another comment expressed the opinion that the proposed rule changes will exacerbate problems with the current restriction practice. One comment suggested that divisional application filings would likely drop in view of designating ten representative claims because examiners usually do not bother to make restriction requirements when they only have a few claims to examine. Another comment stated that an increase in restrictions is a desirable alternative to the rule changes. Another comment argued that current restriction practice adequately limits the claims for examination. The rules would complicate restriction practice resulting in multiple exchanges between the examiner and applicant when designated claims are subject to restriction.

Response: The Office is not adopting the "representative claims" examination approach in this final rule. As noted previously, the Office received comments that restrictions would increase and comments that restrictions would decrease as a result of the changes to the rules. The changes being

adopted in this final rule do not encourage more or fewer restrictions. Thus, the Office is maintaining its current practices with respect to requirements for restriction under 35 U.S.C. 121 or unity of invention under PCT Rule 13. See §§ 1.141, 1.142, and 1.499.

Comment 310: One comment suggested that the Office require all restriction requirements to be made within six months of filing, with no excess claim fees charge until after that period. Another comment stated that excess claims fees should only be determined after any restriction requirement has been made.

Response: In fiscal year 2006, the average pendency to first Office action was 22.6 months for the entire Patent Examining Corps. Therefore, the Office's current first Office action pendency does not allow for an examination of the application to determine whether restriction is appropriate within six months of filing in most applications. Excess claims fees are required by the statutory requirement "on filing or on presentation at any other time." See 35 U.S.C. 41(a)(2). In response to a restriction requirement, applicant may file an amendment canceling the non-elected claims and request a refund of any excess claims fees paid on or after December 8, 2004, for the non-elected claims, if the amendment is filed before an examination on the merits has been made of the application. See § 1.117.

K. Suggestions Relating to Legislative Changes

Comment 311: A number of comments suggested that Congress should adequately fund the Office by making the United States Patent and Trademark Fee Modernization Act of 2005 (H.R. 2791, 109th Cong. (2005)) permanent and eliminating fee diversion. One comment also suggested that Congress provide additional funds (outside of fees collected) to the Office. A number of comments suggested that the fees for continued examination filings in excess of one should be increased (e.g., graduated fee schedule for subsequent filings). A number of comments suggested charging a fee for each priority claim made. One comment suggested that the fee would be proportional to the years of benefit requested. Several comments suggested that the current fee structure encourages continuations since it is cheaper to file multiple applications than to file a large number of claims (e.g., sixty total claims with nine independent claims) in a single application, and that the Office should revisit the fee structure if it wants to encourage filing the claims in

a single application. A number of comments suggested that there should be higher fees on claims exceeding a certain minimal number, which is proportionate to the increased burden on the Office. One comment suggested permitting applicant to pay additional search and examination fees for those who want to submit more than ten representative claims. At least one comment suggested increasing fees based on complexity of the claims and art. One comment suggested that the Office should permit an applicant to file a third or subsequent continuing application with an appropriate higher fee. One comment suggested a three-tiered system: The first tier would allow three independent claims and twenty total claims; the second tier would activate a very high surcharge; and the third tier, in applications of more than ten independent and thirty total claims, would require a showing as to why such additional claims are necessary. Several comments suggested an overall general fee increase, especially for those areas with high workloads. One comment suggested that doubling the basic filing fee, search and examination fees would not be a hardship for applicants. Several comments suggested a number of changes to the fee schedule: Tripling fees for large entities; instituting a graduated fee scale for adding new matter rather than limiting the number of continuation-in-part applications; charging a higher filing fee for an application with greater than five claims and more than 1200 words in the specification; raising fees if more than ten or more than twenty claims are submitted; increasing fees for independent claims in excess of three; increasing fees on all non-Jepson claims; and eliminating search and examination fees if an examination support document is submitted.

Several comments stated that surcharges should be imposed on independent claims in excess of three and total claims in excess of twenty in order to address the problem of applications with excess numbers of claims. Several comments argued that the current fees appear to be having a significant impact in reducing the number of claims filed, that the Office has not fully evaluated that impact, and that the Office should give the fee increase more time to see if it will be effective.

Response: Patent fees are primarily set by statute, and Congress has considerable authority in setting patent fees and funding of the Office. See *Figueroa v. United States*, 466 F.3d 1023, 1031–32, 80 U.S.P.Q.2d 1437, 1443 (Fed. Cir. 2006). Thus, patent fee

and Office funding issues are beyond the scope of the proposed changes to the rules of practice.

In 2002, the Office proposed a patent fee structure that included a graduated excess claims fees schedule and additional fees for continuing applications. The House Subcommittee on Courts, the Internet, and Intellectual Property held a hearing on July 18, 2002, at which patent user groups expressed strenuous opposition to the Office's 2002 proposed patent fee structure. See *The U.S. Patent and Trademark Office: Fee Schedule Adjustment and Agency Reform: Oversight Hearing Before the Subcommittee on Courts, the Internet, and Intellectual Property of the House Committee on the Judiciary*, 107th Cong., 2nd Sess., Final Print Serial No. 92 (2002). The Office was unable to garner public support for a patent fee structure including a graduated excess claims fees schedule or any additional fees for continuing applications. Therefore, the patent fee structure proposed in the United States Patent and Trademark Fee Modernization Act of 2003 (introduced as H.R. 1561) included the former "flat" excess claims fee schedule (with an adjustment to the fee amounts) and no additional fees for continuing applications.

Section 801 *et seq.* of Division B of the Consolidated Appropriations Act, 2005, provided that 35 U.S.C. 41(a), (b), and (d) shall be administered in a manner that revises patent application fees (35 U.S.C. 41(a)) and patent maintenance fees (35 U.S.C. 41(b)) during fiscal years 2005 and 2006. See Public Law 108-447, 118 Stat. 2809 (2004). In essence, the Consolidated Appropriations Act, 2005, made the patent fees set forth in the United States Patent and Trademark Fee Modernization Act effective during most of fiscal year 2005 and all of fiscal year 2006. The Revised Continuing Appropriations Resolution, 2007 (Pub. L. 110-5, 121 Stat. 8 (2007)), kept the patent fee and fee structure provisions of the Consolidated Appropriations Act, 2005, in effect during fiscal year 2007.

Moreover, the examination fee in effect under this legislation does not recover the entire cost of examination. The excess claims fee structure in effect under this legislation does not provide sufficient incentive for all applicants to keep the number of claims in an application at a reasonable number. The application filing fees in effect under this legislation provide no incentive for applicants to keep the number of continuing applications to a reasonable number. Thus, increasing fees, as suggested by many of the comments, is

not, by itself, a sufficient solution for the large and growing backlog of unexamined applications.

Comment 312: One comment suggested permitting applicants to pay an additional search fee for inventions that are restricted.

Response: The Office studied such a proposal and determined that it would result in an unacceptable increase in patent pendency. See *Green Paper Concerning Restriction Practice* at 14-18 (2005). The *Green Paper Concerning Restriction Practice* is available on the Office's Internet Web site at: <http://www.uspto.gov/web/patents/greenpaper.htm>. Thus, the Office is not pursuing such a change to patent practice.

Comment 313: One comment suggested that fees for small entities should be maintained and that fees for others should be increased.

Response: The Office believes that Congress has set an appropriate discount for fees paid by small entities. 35 U.S.C. 41(h)(1) currently provides for a fifty percent reduction in patent fees charged under 35 U.S.C. 41(a), (b), or (d)(1) for applicants who qualify as a small entity under 35 U.S.C. 41(h)(1), and 35 U.S.C. 41(h)(3) further provides a seventy-five percent reduction in the filing fee charged under 35 U.S.C. 41(a)(1)(A) for small entity applicants who file their applications electronically. The Office notes that small entity applicants file excess claims and continuing applications at virtually the same rate as other (non-small entity) applicants.

Comment 314: One comment suggested that if a specification is a poor-quality literal or machine translation of a non-English language application, the examiner should be permitted to reject the specification as indefinite and provide a time period for applicant to provide a better quality translation.

Response: The goal of the changes in this final rule is to increase quality and decrease pendency of patent applications. To assist the Office in meeting that goal, applicants should file applications that are in condition for examination, or provide corrections no later than the time they are taken up for examination. It should not be necessary for the Office to issue an Office action rejecting or objecting to an application due to informalities. However, if a specification is a poor quality literal translation of a non-English application, the examiner has the authority to object to the specification.

Comment 315: One comment suggested that the Office adopt a "utility model" type of patent as used in

Australia in which a patent issues without a search being done, and a search is only conducted when the patent is enforced.

Response: The Office is currently studying the concept of alternative types of patents, thus allowing an applicant to select a patent product based upon the applicant's needs. See *Draft 2007-2012 Strategic Plan* (Objective 2 of Goal 1). A copy of the Office's draft proposed five-year (2007-2012) strategic plan can be found at <http://www.uspto.gov/web/offices/com/strat2007/>. However, implementing such a practice would need legislative changes.

Comment 316: One comment indicated that Congress recently endorsed and expanded opportunities for double patenting via the CREATE Act (Cooperative Research and Technology Enhancement Act (Pub. L. 108-43, 118 Stat. 3596 (2004))).

Response: The legislative history of the CREATE Act (Cooperative Research and Technology Enhancement Act (Pub. L. 108-43, 118 Stat. 3596 (2004))) indicates that Congress appreciated that the CREATE Act would result in additional double patenting situations. See H.R. Rep. No. 108-425, at 6 (the Office may require a terminal disclaimer when double patenting is determined to exist for two or more claimed inventions for any application for which the applicant takes advantage of the "safe harbor" provision in 35 U.S.C. 103(c) as amended by the CREATE Act). Congress' acknowledgment of the possibility of double patenting is not, however, an expression of support for applicants to intentionally submit claims that would result in a double patenting situation. Instead, it shows that the Congress is aware of the problems created by multiple patents covering the same or substantially the same invention, and expects the Office to address these issues.

Comment 317: Several comments suggested eliminating the two-year limit for filing a broadening reissue. One comment suggested amending the "reissue" or "reexamination" statute to permit broadening of claims at any time for a number of reasons such as: (1) To replace continuing applications which are now being filed to avoid the two-year statutory period for broadening patent claims; (2) to allow correction of simple drafting mistakes which may not be caught before the patent issues; and (3) to provide certainty to industry. The comment stated that to encourage participation by patentee, legal (as opposed to equitable) intervening rights should be provided that are linked to the date of the amendment. Also, such an amendment should provide for

intervening rights after eighteen months to patent applications as well as patents to put an end to the submarine patent situation.

Response: The suggested changes to reissue or reexamination practice are not consistent with the Office's goals of increasing quality and reducing pendency. The Office, nevertheless, appreciates that continuing application practice may currently be used improperly to avoid the two-year bar and the broadening "error" requirement of the reissue statute (35 U.S.C. 251). The changes to continuing application practice in this final rule will reduce a patentee's ability to end-run the reissue statute via continuing application practice.

Comment 318: One comment suggested instituting a tiered search and examination procedure, which provides for a refund of the examination fee if applicant decides to abandon the application after the search but before the examination. If applicants can save money by abandoning applications no longer deemed viable, applications will drop out of the application process, thereby freeing up valuable Office examination resources to focus on quality examination of the remaining applications, as well as reducing pendency.

Response: The current fee legislation authorizes the Office to refund the search fee but not the examination fee if the applicant chooses not to pursue an application after it has been filed. See 35 U.S.C. 41(d)(1)(D). This provision has been implemented in § 1.138(d). Under § 1.138(d), applicant may file a petition for express abandonment before an examination has been made of the application to obtain a refund of the search fee and excess claims fee paid in the application. The feedback received by the Office indicates that the examination fee is too low to provide any additional incentive for an applicant to withdraw from the examination process and seek a refund.

Comment 319: One comment suggested charging more money for voluminous IDS submissions, and additional surcharges for particular technologies where "second pair of eyes" review has had a significant impact on examination quality at an increased cost to the Office.

Response: The Office is addressing the problem of large IDS submissions in a separate rule making. See *Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 FR at 38812-16, 38820-22, 1309 *Off. Gaz. Pat. Office* at 27-31, 34-36. As for increasing fees for particular technologies where "second pair of

eyes" review has had a significant impact on examination quality at an increased cost to the Office, Office funding is subject to appropriations by Congress, and charging additional fees will not necessarily provide more funding for the Office. See *Figueroa*, 466 F.3d at 1031, 80 U.S.P.Q.2d at 1442 (there is no requirement that the revenue resulting from patent fees be appropriated to fund the Office). Furthermore, the limitation currently facing the Office is not a lack of funds to hire new examiners, but rather the ability to hire and train new examiners in the numbers necessary to lower patent pendency while maintaining patent quality.

Comment 320: One comment suggested modifying the relevant statutes to bar a continuing application or request for continued examination after thirty months from the filing date (other than a divisional application, which would be given a different period). The comment also indicated that continuation-in-part applications filed more than thirty months after the initial application should be barred under 35 U.S.C. 102(b) based on the eighteen-month publication of the initial application.

Response: First, the statutes cannot be modified without legislative action by Congress. Further, this final rule provides applicant sufficient opportunities to present claims during the prosecution of the initial application, two continuing applications, and a request for continued examination without justification. The prosecution of these applications and the request for continued examination will most likely extend more than thirty months from the earliest claimed filing date, particularly in certain areas such as biotechnology. The changes as adopted in this final rule appropriately balance an applicant's need for opportunities to present claims and the Office's need to utilize its examining resources more efficiently to reduce the backlog of unexamined applications and improve quality.

Comment 321: One comment suggested developing a practice where new matter can be added to an existing application with a request for continued examination. The comment explained such a practice would eliminate the need to file continuation-in-part applications, would not take the application out of the examining queue, and would be more efficient because the same examiner, rather than different examiners, would examine the application, and would also avoid double patenting issues.

Response: A request for continued examination is not a new application, but is instead a means to continue examination of an existing application. Thus, such a change could not be made, because 35 U.S.C. 132(a) prohibits introduction of new matter into an application. Furthermore, even if 35 U.S.C. 132(a) did not prohibit such a practice, such a practice would create problems in determining the filing date of the new matter.

Comment 322: One comment suggested that the Office should seek the authority from Congress to limit the number of claims in any particular application.

Response: The Office is not seeking to limit the number of claims in an application. Instead, the Office aims to improve the quality of examination. The changes to § 1.75 in this final rule permit an applicant to present up to five independent claims and twenty-five total claims in the application without submitting an examination support document in compliance with § 1.265. The changes to § 1.75 in this final rule also permit an applicant to present more than five independent claims or more than twenty-five total claims if the applicant submits an examination support document in compliance with § 1.265. If an examination support document in compliance with § 1.265 is not filed before the issuance of a first Office action on the merits of the application, the application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims. Thus, the changes being adopted in this final rule are not placing a limit on the number of claims.

Comment 323: One comment suggested that the Office should permit all claims to be filed in an application without any excess claims fees, and then after restrictions are made, calculate the needed fee for "additional claims" so applicants are not penalized by paying claims fees twice.

Response: An applicant can request a refund for excess claims canceled prior to a first action on the merits. See § 1.117. Thus, an applicant does not need to pay claim fees twice, if applicant cancels the non-elected claims in reply to a restriction requirement.

Comment 324: One comment suggested providing for the addition of dependent claims after allowance for a reduced fee with the requirement that applicant identify support for the claims in the specification.

Response: The comment did not provide an explanation as to how such a strategy would reduce pendency and promote quality. Even assuming

applicant would file less claims under this suggested practice, examination of the newly added claims after allowance would be required. Thus, it is not clear how the suggested strategy would serve these goals more effectively than the changes being adopted in this final rule.

Comment 325: One comment suggested to bar, by statute, more than three independent claims and ten total claims, provided that amendments may be made in the regular course of prosecution and after grant to end claim gaming. The comment further indicated that the proposed rule changes will be subject to administrative challenge, leading to several years of uncertainty and chaos.

Response: A number of comments indicated that there are situations in which more than three independent claims and more than ten total claims are needed. Thus, the Office recognizes that it would be inappropriate to seek such legislation to place an absolute limit on the number of claims at this juncture.

Comment 326: One comment suggested that reducing the filing and maintenance fees would reduce filings. The comment stated that the backlog has gotten so large due to the increases in excess claims fees, there has been a tendency among practitioners to segment applications into multiple related filings, each having twenty or so claims. This segmenting, the comment explains, has significantly increased the number of filings within the Office.

Response: It is unclear how reducing fees would reduce the number of filings. The experience of the Office is that reducing patent fees would not lead to reduced filings.

Comment 327: One comment suggested including a patent term reduction while an application remains pending.

Response: Section 1.704 currently provides for reduction of patent term adjustment for processing delays attributable to the applicant.

Comment 328: One comment suggested moving to a first-to-file system.

Response: As part of global patent law harmonization efforts, the Office has sought public comment on whether the first to invent (used in the United States) or the first inventor to file (used in the remainder of the world) standard in determining the right to a patent represented a "best practice" for a harmonized global patent system. See *Request for Comments on the International Effort to Harmonize the Substantive Requirements of Patent Laws*, 66 FR 15409 (Mar. 19, 2001) (request for comments). The Office is

continuing to consider the issues related to the first to invent versus the first inventor to file standard in determining the right to a patent in the context of international harmonization efforts.

Comment 329: One comment suggested elimination of all forms of continuing applications except divisional applications.

Response: The changes to continuing application practice adopted in this final rule seek a balanced approach between the needs of applicants for patents and the goals of the Office to increase quality and decrease pendency.

Comment 330: One comment suggested reducing the shortened statutory period for an applicant's response to three months without any extension of time. One comment suggested implementing a thirty-day reply period for both the Office and applicants.

Response: The Office is considering whether it should change the shortened statutory period for Office actions on the merits to less than three months.

Comment 331: Several comments expressed support for publication of all applications. One comment suggested limiting secrecy of a patent application to one month. One comment suggested that some form of intervening rights legislation might better address the problem of repetitive filings. One comment suggested elimination of 35 U.S.C. 135(b). One comment suggested amending 35 U.S.C. 271 so that a variety of claim forms are not necessary for direct infringement to be found, arguing that current 35 U.S.C. 271 is the reason why software-based inventions require claims to different statutory classes, thus increasing the number of claims in an application. One comment suggested that the Office should work with Congress to legislatively overturn *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 71 U.S.P.Q.2d 1065 (Fed. Cir. 2004), to promote the use of dependent claims and not construe the rewriting of an objected to dependent claim in independent form narrowly under the doctrine of equivalents. One comment suggested granting rights to regulate the use of an Internet patent to the assignee and the enforcement of such regulation would be based on a fee and would not include the right to prevent others from using the invention.

Response: The changes suggested by the comments are beyond the scope of the proposed changes to the rules of practice. It is not clear, however, how the changes suggested by the comments would address the increased usage of continuing application practice or have

an appreciable impact on quality or pendency.

L. Effective Date of the Changes in This Final Rule

Comment 332: One comment stated that the Office does not have any authority to promulgate retroactive rules because the Administrative Procedures Act does not confer such power on the Office. Several comments asserted that Congress never expressly authorized the Office to promulgate retroactive rules, citing *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265 (1994) and *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). A number of comments also suggested that the retroactive effect of proposed rule § 1.78 is contrary to judicial precedent, citing *Henriksen and Hogan*. Several comments argued that applying the changes to § 1.75 retroactively would be unfair to the applicants and a violation of due process because applicants were not given sufficient notice of the changes when they filed applications. Lastly, one comment argued that applying the rule changes to pending applications is an unconstitutional denial of due process.

Response: The Office is not engaging in retroactive rule making. This final rule has a prospective effect only. The Office's decision to grandfather only pending applications in which a first Office action on the merits was mailed before November 1, 2007 (the effective date of the changes in this final rule) with respect to the changes to § 1.75 does not constitute retroactive rule making. Likewise, the Office's decision to grandfather only continuing applications and requests for continued examination that were filed before the effective date of the final rule with respect to §§ 1.78 and 1.114 (with a provision that allows for at least "one more" continuation application or continuation-in-part application of an application filed before the publication date of this final rule) does not constitute retroactive rule making.

"A statute [or regulation] does not operate 'retroactively' merely because it is applied in a case arising from conduct antedating the statute's enactment." *Landgraf*, 511 U.S. at 255. Rather, a statute (or regulation) is retroactive if it takes away or impairs vested rights acquired under existing law, creates a new obligation, imposes a new duty, or attaches a new disability with respect to transactions already completed. See *Landgraf*, 511 U.S. at 269. The filing of an application for patent does not create a vested right or amount to a transaction already completed. See *Community TV, Inc. v. FCC*, 216 F.3d 1133, 1143 (D.C.

Cir. 2000) (the Federal Communications Commission is free to alter the criteria for consideration of pending "upgrade" applications because the mere filing of an application does not vest the applicant with a legally cognizable expectation interest); *Chadmore Communs. v. FCC*, 113 F.3d 235, 240–41 (D.C. Cir. 1997) (the mere filing of an application does not vest an applicant with a legally cognizable expectation interest). In addition, the Office is not changing the substantive criteria of patentability. The Office is simply revising the procedures an applicant must follow for presenting more than five independent claims or more than twenty-five total claims in an application, and for seeking continued examination of an application via a continuation application, continuation-in-part application, or a request for continued examination. See *Landgraf*, 511 U.S. at 275 (changes in procedural rules may generally be applied in actions arising before the change without raising retroactivity concerns).

Finally, this final rule does not raise constitutional due process concerns. This rule change does not preclude an applicant from filing an application or receiving a patent containing any number of claims. Rather, the changes to § 1.75 in this final rule simply revise the procedures for presenting more than five independent claims or more than twenty-five total claims. As for the changes to § 1.78 in this final rule, the filing of an application does not vest an applicant with a due process right to obtain continued examination via a continuation application, continuation-in-part application, or a request for continued examination for purposes of presenting amendments, arguments, or evidence that could have been submitted prior to close of prosecution in the initial application (or the prior-filed application).

Comment 333: A number of comments suggested that the Office should not retroactively affect any pending applications when adopting the changes to § 1.78. Specifically, the comments disagreed with the Office's decision to apply the changes to § 1.78 to any applications filed on or after the effective date of the final rule, which would result in an applicant being able to file only one continuation or continuation-in-part application (and not "one more" continuation or continuation-in-part application) on or after the effective date of the final rule without meeting the requirements specified in § 1.78(d)(1)(i) or (d)(1)(iii) or including a petition under § 1.78(d)(1). The comments argued that the changes would retroactively affect

the prosecution of many pending applications, particularly those that are continued examination filings, precluding any opportunity for subsequent continued examination filings. A number of comments also argued that retroactively affecting the pending applications would be unfair to applicants because it would deprive applicants of timely notice of the rule changes and it would be a violation of due process. Several comments argued that retroactively affecting the pending applications would require applicants to review the pending applications to determine whether to file additional continuing applications to preserve the patent rights of unclaimed subject matter or restricted inventions and to file many continuing applications before the effective date. The comments further argued that this would increase the cost of prosecution and the Office's backlog of applications. One comment estimated the cost of reviewing the pending applications to be 180 million dollars based on 600,000 pending applications. A number of the comments suggested that the changes should be applicable only to claiming the benefit of applications filed on or after the effective date (*i.e.*, the changes should be applicable only to non-continuing applications filed on or after the effective date). One comment suggested that the changes to § 1.78 should apply to applications filed on or after the effective date with an exception for any applications that have a filing date earlier than one year from the effective date. One comment suggested that in the determination of the number of continued examination filings permitted without a petition and a showing, the Office should count only the continued examination filings filed on or after January 3, 2006. One comment suggested that the Office should permit applicants to file one more continued examination filing on or after the effective date.

Response: This final rule provides that an applicant is not required to meet the requirements set forth in § 1.78(d)(1) if: (1) The application claims the benefit under 35 U.S.C. 120, 121, or 365(c) only of nonprovisional applications or international applications filed before the publication date of this final rule in the **Federal Register**; and (2) there is no other application filed on or after the publication date of this final rule in the **Federal Register** that also claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such prior-filed nonprovisional applications or international applications. This will provide applicants with "one more"

continuation application or continuation-in-part application of an application that was filed prior to the publication date of this final rule in the **Federal Register** without a petition and showing. Thus, applicants are also permitted to file a divisional application in compliance with § 1.78(d)(1)(ii) of an application that was filed prior to the effective date of this final rule without a petition and showing.

The rules of practice currently provide that by presenting any paper (including any continuation application, continuation-in-part application, or request for continued examination) to the Office, the party presenting the paper is certifying that to the best of the party's knowledge, information and belief, formed after an inquiry reasonable under the circumstances, that the paper is not being presented for any improper purpose, such as to harass someone or to cause unnecessary delay or to needlessly increase the cost of prosecution before the Office. See § 10.18(b)(2)(i). Thus, as part of the reasonable inquiry, the Office expects a party to review applications to ensure that the desired amendments, arguments, or evidence that can be submitted during the prosecution of the prior-filed (or before the close of prosecution in the) application are submitted rather than waiting to make such submission in a later-filed continuation application. Therefore, it is unclear why the final rule would impose any significant additional cost on applicants.

Comment 334: Several comments suggested that if the Office adopts the proposed changes to § 1.78, the Office should publish the final rule well in advance of the effective date to provide sufficient time for applicants to adjust their prosecution strategies in any pending applications. A few comments further suggested a time period of six months to one year between the publication of the final rule and the effective date. Furthermore, a few comments suggested that the changes to § 1.78 should be implemented in phases. One of the comments provided an example that the changes would initially apply only to non-continuing applications filed on or after the effective date, and then six months after the effective date, the changes would apply to applications that have an effective filing date more than four years before the effective date.

Response: This final rule has been published well (more than sixty days) in advance of the November 1, 2007, effective date of the changes in this final rule. As previously discussed, this final rule permits applicants to file "one

more” continuation or continuation-in-part application of an application that was filed prior to the publication date of this final rule in the **Federal Register** without a petition and showing, and to file (at least) “one more” divisional application in compliance with § 1.78(d)(1)(ii) of an application that was filed prior to the effective date of this final rule without a petition and showing. The Office published the Continuing Applications Proposed Rule and the Claims Proposed Rule in the **Federal Register** on January 3, 2006, which set forth proposed changes to the practice for continued examination filings, patent applications containing patentably indistinct claims, and examination of claims in patent applications. Applicants have been provided with a time period of more than one and a half years from the publication date of the proposed rules to the effective date of this final rule, and a time period of more than sixty days from the publication of the final rule to the effective date. Therefore, applicants should have sufficient advance notice of the rule changes.

Comment 335: One comment suggested a transitional practice for divisional applications, permitting benefit claims to be added only to applications filed on or before the effective date in serial divisional applications.

Response: Section 1.78(d)(1)(ii) as adopted in this final rule permits an applicant to file a divisional application of an application for the claims to a non-elected invention that has not been examined if the application was subject to a requirement for restriction. The divisional application need not be filed during the pendency of the application subject to a requirement for restriction, as long as the copendency requirement of 35 U.S.C. 120 is met. Thus, applicant may file the divisional application during the pendency of the application that was subject to a requirement for restriction or the pendency of any continuing application of such an application.

Comment 336: A number of comments suggested that the changes to § 1.75 should apply only to applications filed on or after the effective date. A number of comments disagreed with the Office’s decision to apply the changes to § 1.75 to applications filed before the effective date. Several comments further argued that the cost of “retroactively” applying the rule changes would be enormous to applicants, especially to small entities, because most applicants would be required to review their pending applications for compliance with the new requirement. Several

comments estimated the cost to be 100 to 120 million dollars to designate representative claims in pending applications, and one comment estimated the cost to be 180 million dollars. Several comments argued that small entities are less able to absorb expenses associated with reviewing and revising pending applications. This could prevent small entities from prosecuting pending applications. Several comments argued that because applicants already paid the increased claims fees under the Consolidated Appropriations Act, 2005, in the pending applications for the Office to examine all of the claims, the new requirements would constitute a taking by the Federal Government. Several comments also argued that applicants did not anticipate the additional costs in reviewing and amending the applications for compliance with the new requirements.

Response: The Office has revised § 1.75 to provide that if an application contains more than five independent claims or more than twenty-five total claims, the applicant must submit an examination support document in compliance with § 1.265. Of the applications currently awaiting examination for which claim data is available in PALM (which is over ninety percent of the applications for which preexamination processing is complete), about thirty percent contain more than five independent claims or more than twenty-five total claims. Therefore, the Office’s decision to grandfather only pending applications in which a first Office action on the merits was mailed before November 1, 2007 (the effective date of the changes in this final rule) with respect to the changes to § 1.75 will not affect the majority of applications that are currently pending before the Office. In addition, the changes in this final rule do not preclude an applicant from filing an application or obtaining a patent containing any number of claims, but simply changes the procedures for applications containing more than five independent claims or more than twenty-five total claims. Therefore, there is no support for the proposition that the changes in this final rule amount to a “taking” by the government. Additionally, § 1.117 as adopted in this final rule provides that if an amendment canceling a claim is filed before an examination on the merits has been made of the application, the applicant may request a refund of any excess claims fee paid on or after December 8, 2004 (fees paid under the

Consolidated Appropriations Act), for such claim.

Comment 337: One comment suggested that if the changes to § 1.75 are retroactively applied to applications filed before the effective date, the Office should automatically consider certain claims as representative when applicant fails to designate claims within the time period set forth in a notice requiring the designation of representative claims. One comment inquired about requiring applicants to take action on applications in the backlog within the first month following enactment of the proposed rules. One comment suggested that the Office should send a notice giving applicant three months (extendable to six months) within which to designate the representative claims in each pending application and, if necessary, to file an examination support document.

Response: As discussed previously, this final rule does not adopt the “representative claims” examination approach. Under this final rule, applicant is permitted to present more than five independent claims or more than twenty-five total claims if applicant files an examination support document before a first Office action on the merits of an application. The Office does not expect that most applicants will need to take any action to comply with the changes to § 1.75 in this final rule within the first month following the effective date of this final rule because the majority of applications contain five or fewer independent claims and twenty-five or fewer total claims. The Office will provide an applicant who filed a nonprovisional application under 35 U.S.C. 111(a) before November 1, 2007, or a nonprovisional application that entered the national stage after compliance with 35 U.S.C. 37 before November 1, 2007, and who would be affected by the changes in the final rule, with an opportunity to submit: (1) An examination support document; (2) a new set of claims such that the application contains five or fewer independent claims and twenty-five or fewer total claims; or (3) a suggested restriction requirement. Specifically, the Office will issue a notice setting a two-month time period that is extendable under § 1.136(a) or (b) within which the applicant must exercise one of these options in order to avoid abandonment of the application. The Office, however, may combine such a notice with a requirement for restriction, in which case the applicant must make an election responsive to the restriction requirement and, if there are more than five independent claims or more than twenty-five total claims drawn to the elected invention, the applicant must

also: (1) File an examination support document in compliance with § 1.265; or (2) amend the application such that it contains five or fewer independent claims and twenty-five or fewer total claims drawn to the elected invention. Thus, if such a notice is combined with a requirement for restriction, the applicant does not have the option of replying to such notice with a suggested restriction requirement under § 1.142(c).

M. Miscellaneous

Comment 338: One comment suggested that the changes to § 1.78 are contrary to the purpose of the Bayh-Dole Act.

Response: The Bayh-Dole University and Small Business Patent Procedures Act (Pub. L. 96-517, 94 Stat. 3015-28 (codified at 35 U.S.C. 200 *et seq.*)), concerns patent rights in inventions made with federal assistance. Specifically, 35 U.S.C. 200 provides that:

It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

The changes to § 1.78 adopted in this final rule do not concern patent rights in inventions made with federal assistance and do not impinge upon any of the policies or objectives set forth in 35 U.S.C. 200. The changes in this final rule do not treat patent applications resulting from federally supported research differently from other patent applications. The policy objectives of the Bayh-Dole Act do not encourage or condone more favorable treatment of patent applications resulting from federally supported research. *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 929, 69 U.S.P.Q.2d 1886, 1896 (Fed. Cir. 2004) (none of the eight policy objectives of the Bayh-Dole Act encourages or condones less stringent application of the patent laws to universities than to other entities).

Comment 339: A number of comments suggested that to help reduce the backlog of pending applications the Office should provide a procedure under which an applicant may request deferral of examination of the application.

Response: The rules of practice currently have a procedure under which an applicant may request deferral of examination. Specifically, § 1.103(d) permits deferral of examination for up to three years from the earliest filing date for which a benefit is claimed under title 35, United States Code. The Office publishes any application in which a deferral of examination under § 1.103(d) is requested. The entire period of deferral is a reduction under § 1.704(c)(1) of any patent term adjustment.

Comment 340: A number of comments suggested variations of the deferral of examination procedure under § 1.103(d), including, *inter alia*, providing for automatic deferral of examination, extending the period of deferral, allowing third party requests for examination of deferred applications, eliminating any negative impact on patent term adjustment resulting from deferral, adopting deferral of examination procedures used in other countries such as Japan and Canada, tying the period of deferral to the actual filing date of the application rather than the claimed benefit date, and establishing deferral fees based on the length of deferral.

Response: The deferral of examination procedure set forth in § 1.103(d) was used in fewer than two hundred applications since November 29, 2000 (the effective date of § 1.103(d)). The Office did not propose any changes to the deferral of examination procedure in the notices of proposed rulemaking published on January 3, 2006, in the **Federal Register**. In view of the comments received on the deferral of examination procedure, the Office is studying whether changes (*e.g.*, the maximum deferral period, third party request for examination, and patent term adjustment) to the deferral of examination procedure would be appropriate.

Comment 341: Several comments opposed third party participation, but suggested that the Office could move toward providing a post-grant opposition period, similar to that currently offered in Europe, during which the public could oppose issued patents and make prior art submissions so the patent could receive a post-grant review.

Response: Legislation regarding post-grant opposition and related

participation by third parties is currently pending before Congress. If enacted, the Office will implement the legislation accordingly.

Comment 342: A number of comments suggested expanding the opportunity under § 1.99 for third parties to submit prior art references in applications; for example, up to a first Office action.

Response: The Office has proposed changes to § 1.99 that would extend the period for submission of information from two months after pre-grant publication of the application to six months after pre-grant publication of the application, or mailing of a notice of allowance, whichever occurs first. *See Changes To Information Disclosure Statement Requirements and Other Related Matters*, 71 FR at 38816, 38822, 1309 *Off. Gaz. Pat. Office* at 31, 36.

Comment 343: One comment questioned applicant's recourse if a third party submission was filed in his or her application.

Response: Applicant's recourse would be the same as it currently is when a third party submits patents or publications pursuant to § 1.99 in a published patent application. Applicant will have an opportunity to comment on any patents or publications relied upon by the examiner in a rejection of applicant's claims. Note, however, 35 U.S.C. 122(c) prohibits third party protests.

Comment 344: Several comments suggested that prior art submissions by third parties should be required to conform to current information disclosure statement rules. These comments also suggested that either statements of relevance for each submitted document, or arguments why the claims are unpatentable in view of the cited documents, should accompany the submissions.

Response: Prior to the publication of a patent application, a third party may file prior art submissions in compliance with the requirements of § 1.291 in the application. After the publication of the application, § 1.99 only permits a third party to file up to ten patents or publications per submission. Section 1.99 does not permit the third party to file comments regarding the documents, or comments regarding the patentability of the claims in view of the documents. Additionally, permitting a third party to file an explanation of relevance would rise to the level of a protest, which is prohibited by 35 U.S.C. 122(c).

Comment 345: Several comments suggested allowing a third party to request examination of an application upon paying a fee during a time frame such as between thirty-six and forty-

eight months from the application filing date. One comment suggested permitting third parties to request accelerated examination of long-pending applications by submitting documents required for accelerated examination.

Response: Under the current patent laws and regulations, it is not proper for a third party to be involved in the examination of an application owned by another which includes seeking to accelerate the examination of an application that is properly awaiting its turn to be examined. Permitting a third party to advance prosecution of an application may be considered in the future for those instances in which an applicant has requested deferral of the examination. However, at this time, the Office has not elected to amend § 1.103(d) to permit such action, in order to further study the issue and to provide the public additional opportunity to comment.

Comment 346: One comment suggested the use of authorized third party prior art searches.

Response: Patents or publications filed by a third party in compliance with § 1.99 may be entered in the file of a published application. Examiners may use any of these references in a rejection, if appropriate.

Comment 347: Several comments were critical of the Office's position that the proposed changes to the practice for continuing applications, request for continued examination, and applications containing patentably indistinct claims will not create any additional work for the applicant.

Response: The changes being adopted in this final rule will not require any additional submissions for the majority of patent applications. Prosecution, however, may be more compact since the number of continuing applications and requests for continued examination permitted without any justification is being limited. Nevertheless, the changes being adopted in this final rule will result in more effective and efficient examination without any additional work on the part of the majority of applicants.

Comment 348: Several comments recommended that the Office should conduct a public hearing before adopting the rule changes. One comment suggested that the Office should issue a green paper or advance notice of proposed rule making to receive more input and perform a cost-benefit analysis on the rule changes. One comment recommended that the Office should form a patent practice advisory committee, consisting of volunteers from the patent bar, for the

purpose of studying problems experienced by the Office and proposing solutions that would be tailored to address those problems. The comments recommended that the Office should bring together all the relevant parties, including the Office, patent practitioners, patentees, litigators, and judges, to arrive at a solution that benefits all parties in the patent system.

Response: 35 U.S.C. 2(b)(2)(B) directs the Office to follow the procedures set forth in 5 U.S.C. 553 in adopting changes to the rules of practice, and 35 U.S.C. 3(a)(2)(B) directs the Office to consult with the Patent Public Advisory Committee when proposing or adopting changes to the rules of practice that change user fees or are subject to notice and comment under 5 U.S.C. 553. The Office published notices of proposed rule making pursuant to 5 U.S.C. 553(b) in advance of this final rule, provided an extended comment period to give interested persons an opportunity to submit written data, views, or arguments pursuant to 5 U.S.C. 553(c), and has published this final rule at least thirty days in advance of its effective date pursuant to 5 U.S.C. 553(d). The Office also consulted with the Patent Public Advisory Committee prior to publishing the notices of proposed rule making and this final rule. The Office also conducted four public meetings to obtain feedback from the public on the proposed changes which resulted in the changes being adopted in this final rule: (1) The first in Chicago, Illinois, on February 1, 2006; (2) the second in Berkeley, California, on February 28, 2006; (3) the third in Houston, Texas, on March 22, 2006; and (4) the fourth in Alexandria, Virginia (at the Office's Carlyle campus) on April 25, 2006. The number of comments submitted in response to the notices of proposed rule making indicates that interested persons and organizations have been given ample opportunity to provide input on the changes being adopted in this final rule.

IV. Rule Making Considerations

A. Administrative Procedure Act

This notice adopts changes to the rules of practice that concern the process for applying for a patent, namely, continuing applications and requests for continued examination practices, the treatment of applications containing more than a set number of independent or total claims, and the treatment of multiple applications containing patentably indistinct claims. The changes being adopted in this notice do not change the substantive criteria of patentability and do not

effectively foreclose the applicant's opportunity to make a case on the merits (*i.e.*, the changes being adopted in this final rule continue to provide patent applicants with numerous opportunities). Therefore, these rule changes involve interpretive rules, or rules of agency practice and procedure. *See Bachow Communs., Inc. v. FCC*, 237 F.3d 683, 690 (DC Cir. 2001) (rules governing an application process are "rules of agency organization, procedure, or practice" and exempt from the Administrative Procedure Act's notice and comment requirement); *see also Fressola v. Manbeck*, 36 USPQ2d 1211, 1215 (D.D.C. 1995) ("it is extremely doubtful whether any of the rules formulated to govern patent or trade-mark practice are other than 'interpretive rules, general statements of policy, * * * procedure, or practice.'") (quoting C.W. Ooms, *The United States Patent Office and the Administrative Procedure Act*, 38 Trademark Rep. 149, 153 (1948)). Accordingly, prior notice and an opportunity for public comment were not required pursuant to 5 U.S.C. 553(b)(A) (or any other law), and thirty-day advance publication is not required pursuant to 5 U.S.C. 553(d) (or any other law). Nevertheless, the Office sought public comment on proposed changes to these rules of practice to obtain the benefit of such input prior to adopting the changes to the rules of practice in this final rule.

B. Regulatory Flexibility Act

As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 (or any other law), neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are required. *See* 5 U.S.C. 603. Nevertheless, the Office published notices of proposed rule making setting forth the factual basis for certification under the Regulatory Flexibility Act and sought public comment on that certification. *See Changes to Practice for the Examination of Claims in Patent Applications*, 71 FR at 66, 1302 *Off. Gaz. Pat. Office* at 1333, and *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, 71 FR at 56–57, 1302 *Off. Gaz. Pat. Office* at 1325. For the reasons set forth herein, the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that the changes in this final rule will not have a significant economic impact on a

substantial number of small entities. See 5 U.S.C. 605(b).

This final rule provides that: (1) A third or subsequent continuation or continuation-in-part application or any second or subsequent request for continued examination must include a showing as to why the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution after a first and second continuation or continuation-in-part application and a request for continued examination; (2) any divisional application be the result of a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the prior-filed application; (3) an application that contains or is amended to contain more than five independent claims or more than twenty-five total claims must include an examination support document under 37 CFR 1.265 that covers each claim (whether in independent or dependent form) before the first Office action on the merits; and (4) multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and a common assignee include either an explanation as to how the claims are patentably distinct, or a terminal disclaimer and explanation as to why patentably indistinct claims have been filed in multiple applications.

In response to the Office's certification in the notices of proposed rule making, the Small Business Administration Office of Advocacy (SBA-Advocacy) submitted a comment contending that the proposed changes are likely to have a significant economic impact on a substantial number of small entities, including small businesses and small independent inventors. SBA-Advocacy recommended that the Office conduct a supplemental Initial Regulatory Flexibility Analysis before publishing a final rule.

The Office's analysis of the proposed rules indicated that the rules would not have a significant economic impact on a substantial number of small entities. The Office considered all public comments addressing small entities, including those submitted by SBA-Advocacy. In response to these comments, this final rule incorporates a number of revisions designed to further reduce the number of small entities affected by the changes and the impacts on small entities. These changes in this final rule vis-à-vis the proposed rules that reduce small entity impacts are as follows: (1) This final rule adopts an examination support document

requirement threshold of five independent claims or twenty-five total claims, rather than ten representative claims; (2) this final rule provides that small entities as defined by the Regulatory Flexibility Act are exempt from the requirement that an examination support document must, for each cited reference, include an identification of all of the limitations of each of the claims that are disclosed by the reference; (3) this final rule adopts a continued examination filing petition threshold of two continuing applications (continuation or continuation-in-part applications), plus a request for continued examination in any one of the initial or two continuing applications, rather than one continuation application, continuation-in-part application, or request for continued examination; (4) this final rule does not require that a divisional application be filed during pendency of initial application; and (5) this final rule provides for at least "one more" continuation or continuation-in-part application after the effective date, regardless of the number of previous continued examination filings.

In addition, the Office commissioned a detailed analysis of the impacts of this final rule on small entities. The analysis concludes that this final rule is not expected to result in a significant economic impact on a substantial number of small entities. The analysis measured economic impact in terms of annualized incremental cost as a percentage of revenue. The analysis indicated that the incremental cost (not annualized) would be between \$2,563 and \$13,121 for an entity who would be required to file an examination support document, a petition for an additional continued examination filing, or both. The analysis presumed that an economic impact greater than three percent of annualized incremental cost as a percentage of revenue was a significant impact. The analysis indicated that no small entities fell into this category. The analysis also presumed that an economic impact greater than one percent of annualized incremental cost as a percentage of revenue was a more moderate impact. The analysis indicated that fewer than one percent of small entities fell into this category. The analysis also presumed that a substantial number of small entities are affected if more than twenty percent of small entities are impacted. The analysis indicated that about 1.0 percent of small entities would be affected by the requirement to submit an examination support document, that about 2.7 percent of

small entities would be affected by the requirement to submit a petition for an additional continued examination filing, and that about 0.3 percent of small entities would be affected by both the requirement to submit an examination support document and the requirement to submit a petition for an additional continued examination filing. A copy of the report containing this analysis is available on the Office's Internet Web site at <http://www.uspto.gov>.

As a result of this analysis, the Office has determined that it is appropriate to make a certification that the changes being adopted in this final rule would not have a significant economic impact on a substantial number of small entities. The Office has revised the final rule requirements, as discussed previously, to further reduce economic impacts on small entities.

SBA-Advocacy commented that while the Office asserts that preparation of the examination support document should cost about \$2,500, small entities contend that completing an examination support document will be more costly, time consuming and restrict their ability to prosecute patents vigorously. SBA-Advocacy also commented that small entity representatives have provided feedback that completion of an examination support document could cost from \$25,000 to \$30,000.

The Claims Proposed Rule referenced a \$2,500 figure covering a patent novelty search, analysis, and opinion, as reported in a 2003 survey conducted by the American Intellectual Property Law Association (AIPLA). The Office agrees with the comments that this figure is probably less than the cost of an examination support document in most situations. Therefore, the Office has further analyzed costs based on the modified examination support document requirements applicable to small entities. The analysis models cost variability based on the number of claims the examination support document must address, and on whether or not a prior art search was conducted when the application was prepared. Based on this analysis, the Office estimates that the examination support document costs for small entities will range from \$2,563 up to \$13,121, although this latter figure assumes the examination support document must address as many as fifty independent claims or three hundred and fifty total claims. Only a small number of small entities, however, will be required to prepare an examination support document, and nearly all of these will incur costs towards the lower end of the range. Thus, the Office does not expect the final rule to result in a

significant impact on a substantial number of small entities.

SBA-Advocacy commented that small entity representatives have asserted that, taken together, the two proposed changes would increase the cost of application preparation and hinder the patent prosecution process.

As discussed previously, the Office commissioned a detailed analysis of the impact of the final rule on small entities. The analysis explicitly considered the combined cost of both proposed rules (which have been combined into a single final rule). The analysis concludes that the final rule is not expected to result in a significant economic impact on a substantial number of small entities.

SBA-Advocacy commented that small entity representatives have raised concerns that the proposed changes will significantly impact the most valuable and commercially viable patents because those types of patents typically involved a higher number of continuations.

The Office notes that there are studies espousing the position that many commercially valuable patents are the result of a continuing application, or of a second or subsequent continuing application. However, these studies do not support the position that the applicants could not have obtained these commercially valuable patents but for the availability of an unlimited number of continuing applications. That is, these studies do not show that these commercially valuable patents could not have been obtained via two or fewer continuing applications prosecuted with a reasonable amount of foresight and diligence. Thus, these studies do not demonstrate that these commercially valuable patents happen to be the result of a continuing application or of multiple continuing applications for any reason other than simply because the prosecution tactics employed in the applications underlying these patents were based upon the availability of an unlimited number of continuing applications.

The analysis commissioned by the Office specifically considered the claim that the most valuable and commercially viable patents are those types of patents that typically involved a higher number of continuations. The Office ultimately rejected the claim that this final rule will preclude applicants from being able to obtain a patent on the most valuable and commercially viable patents due to the speculative nature of the nexus drawn between the availability of an unlimited number of continuing applications and an

applicant's ability to obtain these commercially valuable patents.

SBA-Advocacy commented that small entity representatives have indicated that limiting applicants to ten representative claims would make it very difficult to properly identify a potential patent, could create future liability concerns, and would weaken potential patents.

The final rule requirements apply to patent applications with more than five independent claims or more than twenty-five total claims, rather than ten representative claims. As discussed previously, applicants with more than five but less than fifteen independent claims, or more than twenty-five but less than seventy-five total claims, to an invention are able to prosecute their application in a manner that does not trigger the claims or continuations requirements. Specifically, an applicant may do this by submitting an initial application containing up to five independent claims and up to twenty-five total claims, and then adding a similar number of claims in each of two continuation applications (or two continuation-in-part applications, or one continuation application and one continuation-in-part application) permitted without a petition. Moreover, even for those applications that will require an examination support document, the requirement does not "limit" applicants to any particular number of claims. Applicants may continue to submit as many claims as necessary to appropriately claim their inventions, even if doing so required them to prepare and submit an examination support document.

SBA-Advocacy commented that small entity representatives have contended that limiting continuation applications and examinations would inhibit their ability to enhance their applications, significantly increase costs through new fees, and force small entities to seek review through the very expensive appeals process. Small entity representatives thus assert that limiting the number of continuations could severely weaken small entities' ability to protect their patents.

The Office analysis indicates that the continued examination filing requirements adopted in this final rule will not lead to significant cost increases nor will it have a significant economic impact on a substantial number of small entities. The requirements are necessary to ensure that patent applications are of reasonable quality and that applicants pursue their patents in good faith. The excessive use of continued examination filings has been a major factor in the

growing backlog of unexamined applications. With respect to having to use the appeals process in place of additional continued examination filings, if an applicant disagrees with the examiner's rejections, the applicant should file an appeal rather than filing a continuation application or a request for continued examination, for reasons discussed in detail in the statement of considerations for the final rule. The Office believes that applicants should have sufficient opportunity to place the application in condition for appeal during the prosecution of the initial application, two continuing applications, and a request for continued examination. An applicant who considers this to be insufficient may file a third or subsequent continuing application or second or subsequent request for continued examination with a petition showing why the amendment, argument, or evidence sought to be entered could not have been previously submitted.

SBA-Advocacy commented that the proposed changes will affect a substantial number of small entities, and that the two proposed changes to the rules reshape the basic rights of any small entity that files a patent application.

The Office agrees that the final rule places new requirements on the current patent application process. However, the Office's analysis indicates that the rule will not have a significant economic impact on a substantial number of small entities. In fact, only a small proportion of small entities will be affected by the changes in this final rule.

SBA-Advocacy commented that small entity representatives have contended that the definition of small entity that the Office uses in its certification is for calculating filing fees and excludes any small entity that has a contractual arrangement involving the invention with a larger company. SBA-Advocacy commented that small entity representatives have further asserted that small business size standards for Regulatory Flexibility Act purposes do not include this restriction so the number of small businesses affected is likely to be larger than stated in the certification.

The Regulatory Flexibility Act permits an agency head to establish, for purposes of Regulatory Flexibility Act analysis and certification, one or more definitions of "small business concern" that are appropriate to the activities of the agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment. See 5

U.S.C. 601(3) and 13 CFR 121.903(c). Pursuant to this authority, the Office has established the following definition of small business concern for purposes of the Office conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations: A small business concern for Regulatory Flexibility Act purposes for patent-related regulations is a business or other concern that: (1) Meets the Small Business Administration's definition of a "business concern or concern" set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely, an entity: (a) Whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition. See *Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR 67109, 67112 (Nov. 20, 2006), 1313 *Off. Gaz. Pat. Office* 60, 63 (Dec. 12, 2006) (notice). Prior to establishing this definition of small business concern for purposes of the Office conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations, the Office consulted with the Small Business Administration Office of Advocacy and published such a definition for public comment. See *Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations*, 71 FR 38388 (Jul. 6, 2006), 1309 *Off. Gaz. Pat. Office* 37 (Aug. 1, 2006) (notice). The Small Business Administration small entity size standards set forth in 13 CFR 121.802 excludes any business concern that has assigned, granted, conveyed, or licensed any rights in the invention to an entity which would not qualify for small entity status.

Nevertheless, in analyzing the provisions of the final rule, the Office explicitly considered a sensitivity analysis that assumed all patent applicants qualified as small entities. Even under this sensitivity analysis, this final rule is not expected to result in a significant impact on a substantial number of small entities.

SBA-Advocacy suggested that with respect to the continued examination filing requirements, the Office should

increase the number of permissible continuing applications.

The final rule changes the continued examination filing petition threshold from a single continuation application, continuation-in-part application, or request for continued examination as proposed to two continuing applications (continuation or continuation-in-part applications), and a single request for continued examination in any one of the initial or two continuing applications.

SBA-Advocacy suggested that with respect to the continued examination filing requirement, the Office should consider increasing the fees for additional continuation applications.

Currently, patent application and excess claims fees are set by statute (35 U.S.C. 41(a)). In 2002, the Office proposed a patent fee structure that included a graduated excess claims fees schedule and additional fees for continued examination filings. As discussed previously, however, the Office was unable to garner sufficient support from patent user groups for a patent fee structure including a graduated excess claims fees schedule or any additional fees for continued examination filings. Therefore, the Office did not pursue this alternative.

SBA-Advocacy suggested that with respect to the continued examination filing requirement, the Office should defer review of subsequent continuation applications.

The Office considered expanding the deferral of examination provisions to allow a longer deferral of examination period. The Office currently has a provision (37 CFR 1.103(d)) under which an applicant may request deferral of examination for up to three years from the earliest filing date for which a benefit is claimed. As discussed previously, the Office is studying whether changes (e.g., the maximum deferral period, third party request for examination, and patent term adjustment) to the deferral of examination procedure would be appropriate.

SBA-Advocacy suggested that with respect to the claims requirements, the Office should expand the number of representative claims included in initial review.

The Office has revised the final rule to change the examination support document threshold from ten representative claims to five independent claims or twenty-five total claims. As discussed previously, however, applicants with more than five but less than fifteen independent claims, or more than twenty-five but less than seventy-five total claims, to an invention are able to prosecute their

application in a manner that does not trigger the claims or continuations requirements.

SBA-Advocacy suggested that with respect to the claims requirements, the Office should provide expedited review of applications that contain ten or fewer representative claims. The Office has considered the suggestion to provide expedited examination to applications containing less than a set number of claims. As discussed previously, the Office currently has an accelerated examination program for applicants who limit the number of claims in their applications (to no more than three independent claims and no more than twenty total claims) and who also provide an accelerated examination support document. Therefore, the Office did not pursue this alternative in the final rule.

SBA-Advocacy suggested that with respect to the claims requirements, the Office should not apply the regulation to the backlog of pending unexamined applications.

The Office has considered not applying the claims requirement to pending applications that have not yet been examined to minimize the impact on small entities. The examination support document threshold being adopted in this final rule (i.e., more than five independent claims or more than twenty-five total claims) means that most small entity applications will not be impacted by the final rule or the decision to apply the final rule to the backlog of unexamined applications. Given the current backlog of over 700,000 unexamined applications, a decision to not apply the changes to the backlog of unexamined applications would mean that it would be calendar year 2010 before the Office would see any benefit from the change, and that the Office (and applicants) would be in a transition state until late calendar year 2011. Therefore, this suggestion was not adopted in the final rule.

The Office also received a number of additional comments from the public generally asserting that the Office did not comply with the requirements of the Regulatory Flexibility Act in certifying that the changes in this rule making will not have a significant economic impact on a substantial number of small entities. The comments stated that: (1) In light of the fact that several large companies support the proposed changes it is questionable whether the rule changes are truly neutral towards small companies and that a bias in favor of large companies and against small entities could be in violation of the Regulatory Flexibility Act; (2) the Office's certification did not adequately

address the impact of the proposed rules on small entities, and the Office failed to provide a credible factual basis to justify its certification that the proposed rules would not have a significant economic impact on a substantial number of small entities in compliance with 5 U.S.C. 605(b); (3) the rule changes would have a significant economic impact on a substantial number of small entities seeking patents due to the additional costs associated with preparing an application, establishing the required showing under 37 CFR 1.78(d)(1)(vi) and 1.114(g), and supplying an examination support document in compliance with 37 CFR 1.265, and would hinder the abilities of small entities to enhance their applications and protect their inventions; (4) the definition of small entities used by the Office in its certification of the proposed rules is for the purpose of paying reduced patent fees and excludes any application from a small business that has assigned, granted, conveyed, or licensed any rights in the invention to an entity which would not qualify for small entity status; (5) the Office should prepare an initial Regulatory Flexibility Analysis and republish the proposed rules before issuing any final rule to enable the Office to closely examine the impact on the affected small entities, encourage small entities to comment on additional information provided by the analysis, identify viable regulatory alternatives to the proposed rules, and demonstrate the Office's compliance with the Regulatory Flexibility Act; (6) the Office did not describe any viable alternatives to the proposed rules to provide regulatory relief to small entities as required under 5 U.S.C. 603(c); (7) the rule changes would be invalid and vulnerable to challenges under 5 U.S.C. 611 if the Office fails to comply with the requirements of the Regulatory Flexibility Act; and (8) the Office should exempt small entities from complying with the proposed rules to avoid further scrutiny under the Regulatory Flexibility Act.

The Office has received comments from some large entities that the changes being adopted in this final rule have a bias against large entities, and has received comments from small entities that the changes being adopted in this final rule have a bias in favor of large entities. The changes being adopted in this final rule are neutral towards both small entities and large entities. That several large entities support the changes being adopted in this final rule is more likely indicative of a willingness to take a systemic view

with respect to the need to take more significant steps to address patent quality and pendency.

As discussed previously, the Office commissioned a detailed analysis of the final rule's impact on small entities. As a result of this analysis, the Office has determined that it is appropriate to make a certification that the changes being adopted in this final rule would not have a significant economic impact on a substantial number of small entities. Therefore, the Office is not required to conduct a Regulatory Flexibility Analysis.

Pursuant to 5 U.S.C. 605(b), the requirements in 5 U.S.C. 603 and 604 for an initial and final Regulatory Flexibility Analysis (including identification of viable regulatory alternatives to the proposed rules) do not apply if the agency head certifies that the changes will not have a significant economic impact on a substantial number of small entities. In accordance with 5 U.S.C. 605(b), the Deputy General Counsel for General Law of the United States Patent and Trademark Office has certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed changes would not have a significant economic impact on a substantial number of small entities.

The Office considers this rule making to be in compliance with the requirements of the Regulatory Flexibility Act. Thus, the possibility of legal action does not warrant a decision to delay proceeding with the changes being adopted in this final rule to allow for preparation of an initial and final Regulatory Flexibility Analysis, or to completely exempt small entities from complying with the changes being adopted in this final rule.

C. Executive Order 13132 (Federalism)

This rule making does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

D. Executive Order 12866 (Regulatory Planning and Review)

This rule making has been determined to be significant for purposes of Executive Order 12866 (Sept. 30, 1993), as amended by Executive Order 13258 (Feb. 26, 2002) and Executive Order 13422 (Jan. 18, 2007).

E. Executive Order 13175 (Tribal Consultation)

This rule making will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal

governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

F. Executive Order 13211 (Energy Effects)

This rule making is not a significant energy action under Executive Order 13211 because this rule making is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

G. Executive Order 12988 (Civil Justice Reform)

This rule making meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

H. Executive Order 13045 (Protection of Children)

This rule making is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

I. Executive Order 12630 (Taking of Private Property)

This rule making will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

J. Congressional Review Act

Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), the United States Patent and Trademark Office will submit a report containing this final rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the Government Accountability Office. The changes in this final rule will not result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this final rule is not a "major rule" as defined in 5 U.S.C. 804(2).

K. Unfunded Mandates Reform Act of 1995

The changes in this final rule will not result in the expenditure by State, local,

and tribal governments, in the aggregate, or by the private sector, of 100 million dollars or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 *et seq.*

L. National Environmental Policy Act

This rule making will not have any effect on the quality of environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 *et seq.*

M. National Technology Transfer and Advancement Act

The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are inapplicable because this rule making does not contain provisions which involve the use of technical standards.

N. Paperwork Reduction Act

This final rule involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information involved in this final rule has been reviewed and approved by OMB under OMB control number 0651-0031. This final rule provides that: (1) A third or subsequent continuation or continuation-in-part application or any second or subsequent request for continued examination must include a showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution after a first and second continuation or continuation-in-part application and a request for continued examination; (2) an application that contains or is amended to contain more than five independent claims or more than twenty-five total claims must include an examination support document under 37 CFR 1.265 that covers each claim (whether in independent or dependent form) before the issuance of a first Office action on the merits; and (3) multiple applications that have the same claimed filing or priority date, substantial overlapping disclosure, a common inventor, and a common assignee must include either an explanation of how the claims are patentably distinct, or a terminal disclaimer and explanation of why patentably indistinct claims have been filed in multiple applications. The United States Patent and Trademark

Office has resubmitted an information collection package to OMB for its review and approval because the changes in this notice do affect the information collection requirements associated with the information collection under OMB control number 0651-0031.

The title, description and respondent description of the information collection under OMB control number 0651-0031 is shown below with an estimate of the annual reporting burdens. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Number: 0651-0031.

Title: Patent Processing (Updating).

Form Numbers: PTO/SB/08, PTO/SB/17i, PTO/SB/17p, PTO/SB/21-27, PTO/SB/24B, PTO/SB/30-32, PTO/SB/35-39, PTO/SB/42-43, PTO/SB/61-64, PTO/SB/64a, PTO/SB/67-68, PTO/SB/91-92, PTO/SB/96-97, PTO-2053-A/B, PTO-2054-A/B, PTO-2055-A/B, PTOL-413A.

Type of Review: Approved through September of 2007.

Affected Public: Individuals or households, business or other for-profit institutions, not-for-profit institutions, farms, Federal Government and State, Local and Tribal Governments.

Estimated Number of Respondents: 2,508,139.

Estimated Time Per Response: 1 minute and 48 seconds to 24 hours.

Estimated Total Annual Burden Hours: 3,724,791 hours.

Needs and Uses: During the processing of an application for a patent, the applicant or applicant's representative may be required or desire to submit additional information to the United States Patent and Trademark Office concerning the examination of a specific application. The specific information required or which may be submitted includes: information disclosure statement and citation, examination support documents, requests for extensions of time, the establishment of small entity status, abandonment and revival of abandoned applications, disclaimers, appeals, petitions, expedited examination of design applications, transmittal forms, requests to inspect, copy and access patent applications, publication requests, and certificates of mailing, transmittals, and submission of priority documents and amendments.

Comments are invited on: (1) Whether the collection of information is necessary for proper performance of the functions of the agency; (2) the accuracy of the agency's estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be

collected; and (4) ways to minimize the burden of the collection of information to respondents.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to: (1) The Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10202, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Patent and Trademark Office; and (2) Robert A. Clarke, Director, Office of Patent Legal Administration, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and recordkeeping requirements, Small Businesses.

■ For the reasons set forth in the preamble, 37 CFR part 1 is amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

■ 1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

■ 2. Section 1.17 is amended by revising paragraph (f) to read as follows:

§ 1.17 Patent application and reexamination processing fees.

* * * * *

(f) For filing a petition under one of the following sections which refers to this paragraph: \$400.00

§ 1.36(a)—for revocation of a power of attorney by fewer than all of the applicants.

§ 1.53(e)—to accord a filing date.

§ 1.57(a)—to accord a filing date.

§ 1.78(d)(1)(vi)—for a continuing application not provided for in §§ 1.78(d)(1)(i) through (d)(1)(v).

§ 1.114(g)—for a request for continued examination not provided for in § 1.114(f).

§ 1.182—for decision on a question not specifically provided for.

§ 1.183—to suspend the rules.

§ 1.378(e)—for reconsideration of decision on petition refusing to accept

delayed payment of maintenance fee in an expired patent.

§ 1.741(b)—to accord a filing date to an application under § 1.740 for extension of a patent term.

* * * * *

■ 3. Section 1.26 is amended by revising paragraphs (a) and (b) to read as follows:

§ 1.26 Refunds.

(a) The Director may refund any fee paid by mistake or in excess of that required. Except as provided in § 1.117 or § 1.138(d), a change of purpose after the payment of a fee, such as when a party desires to withdraw a patent filing for which the fee was paid, including an application, an appeal, or a request for an oral hearing, will not entitle a party to a refund of such fee. The Office will not refund amounts of twenty-five dollars or less unless a refund is specifically requested, and will not notify the payor of such amounts. If a party paying a fee or requesting a refund does not provide the banking information necessary for making refunds by electronic funds transfer (31 U.S.C. 3332 and 31 CFR part 208), or instruct the Office that refunds are to be credited to a deposit account, the Director may require such information, or use the banking information on the payment instrument to make a refund. Any refund of a fee paid by credit card will be by a credit to the credit card account to which the fee was charged.

(b) Any request for refund must be filed within two years from the date the fee was paid, except as otherwise provided in this paragraph, or in § 1.28(a), § 1.117(b), or § 1.138(d). If the Office charges a deposit account by an amount other than an amount specifically indicated in an authorization (§ 1.25(b)), any request for refund based upon such charge must be filed within two years from the date of the deposit account statement indicating such charge, and include a copy of that deposit account statement. The time periods set forth in this paragraph are not extendable.

* * * * *

■ 4. Section 1.52 is amended by revising paragraph (d)(2) to read as follows:

§ 1.52 Language, paper, writing, margins, compact disc specifications.

* * * * *

(d) * * *

(2) *Provisional application.* If a provisional application is filed in a language other than English and the benefit of such provisional application is claimed in a nonprovisional application, an English language translation of the non-English language

provisional application will be required in the provisional application. See § 1.78(b).

* * * * *

■ 5. Section 1.53 is amended by revising paragraphs (b) and (c)(4) to read as follows:

§ 1.53 Application number, filing date, and completion of application.

* * * * *

(b) *Application filing requirements—Nonprovisional application.* The filing date of an application for patent filed under this section, except for a provisional application under paragraph (c) of this section or a continued prosecution application under paragraph (d) of this section, is the date on which a specification as prescribed by 35 U.S.C. 112 containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75, and any drawing required by § 1.81(a) are filed in the Patent and Trademark Office. No new matter may be introduced into an application after its filing date. A continuing application, which may be a continuation, divisional, or continuation-in-part application, may be filed under this section if the conditions specified in 35 U.S.C. 120, 121, or 365(c) and § 1.78 are met.

(1) A continuation or divisional application that names as inventors the same or fewer than all of the inventors named in the prior application may be filed under paragraph (b) or (d) of this section. A continuation or divisional application naming an inventor not named in the prior application must be filed under paragraph (b) of this section. See § 1.78(a)(2) for the definition of a divisional application and § 1.78(a)(3) for the definition of a continuation application.

(2) A continuation-in-part application must be filed under paragraph (b) of this section. See § 1.78(a)(4) for the definition of a continuation-in-part application.

(c) * * *

(4) A provisional application is not entitled to the right of priority under 35 U.S.C. 119 or 365(a) or § 1.55, or to the benefit of an earlier filing date under 35 U.S.C. 120, 121 or 365(c) or § 1.78 of any other application. No claim for priority under 35 U.S.C. 119(e) or § 1.78 may be made in a design application based on a provisional application. No request under § 1.293 for a statutory invention registration may be filed in a provisional application. The requirements of §§ 1.821 through 1.825 regarding application disclosures containing nucleotide and/or amino acid sequences

are not mandatory for provisional applications.

* * * * *

■ 6. Section 1.75 is amended by revising paragraphs (b) and (c) to read as follows:

§ 1.75 Claim(s).

* * * * *

(b) More than one claim may be presented provided they differ substantially from each other and are not unduly multiplied. One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. A dependent claim must contain a reference to a claim previously set forth in the same application, incorporate by reference all the limitations of the previous claim to which such dependent claim refers, and specify a further limitation of the subject matter of the previous claim.

(1) An applicant must file an examination support document in compliance with § 1.265 that covers each claim (whether in independent or dependent form) before the issuance of a first Office action on the merits of the application if the application contains or is amended to contain more than five independent claims or more than twenty-five total claims. An application may not contain or be amended to contain more than five independent claims or more than twenty-five total claims if an examination support document in compliance with § 1.265 has not been filed before the issuance of a first Office action on the merits of the application.

(2) A claim that refers to another claim but does not incorporate by reference all of the limitations of the claim to which such claim refers will be treated as an independent claim for fee calculation purposes under § 1.16 (or § 1.492) and for purposes of paragraph (b) of this section. A claim that refers to a claim of a different statutory class of invention will also be treated as an independent claim for fee calculation purposes under § 1.16 (or § 1.492) and for purposes of paragraph (b) of this section.

(3) The applicant will be notified if the application contains or is amended to contain more than five independent claims or more than twenty-five total claims but the applicant has not complied with the requirements set forth in paragraph (b)(1) or (b)(4) of this section. If the non-compliance appears to have been inadvertent, the notice will set a two-month time period that is not extendable under § 1.136(a) within which, to avoid abandonment of the application, the applicant must comply

with the requirements set forth in paragraph (b) of this section.

(4) If a nonprovisional application contains at least one claim that is patentably indistinct from at least one claim in one or more other pending nonprovisional applications, and if such one or more other nonprovisional applications and the first nonprovisional application are owned by the same person, or are subject to an obligation of assignment to the same person, the Office will treat the claims (whether in independent or dependent form) in the first nonprovisional application and in each of such other pending nonprovisional applications as present in each of the nonprovisional applications for purposes of paragraph (b) of this section.

(5) Claims withdrawn from consideration under §§ 1.141 through 1.146 or § 1.499 as drawn to a non-elected invention or inventions will not, unless they are reinstated or rejoined, be taken into account in determining whether an application exceeds the five independent claim and twenty-five total claim threshold set forth in paragraphs (b)(1), (b)(3), and (b)(4) of this section.

(c) Any dependent claim which refers to more than one other claim ("multiple dependent claim") shall refer to such other claims in the alternative only. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. For fee calculation purposes under § 1.16 (or § 1.492) and for purposes of paragraph (b) of this section, a multiple dependent claim will be considered to be that number of claims to which direct reference is made therein. For fee calculation purposes under § 1.16 (or § 1.492) and for purposes of paragraph (b) of this section, any claim depending from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in that multiple dependent claim. In addition to the other filing fees, any application which is filed with, or is amended to include, multiple dependent claims must have paid therein the fee set forth in § 1.16(j). A multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered.

* * * * *

■ 7. Section 1.76 is amended by revising paragraph (b)(5) to read as follows:

§ 1.76 Application data sheet.

* * * * *

(b) * * *

(5) *Domestic priority information.* This information includes the application number, the filing date, and

relationship of each application for which a benefit is claimed under 35 U.S.C. 120, 121, or 365(c). This information includes the application number and the filing date of each application for which a benefit is claimed under 35 U.S.C. 119(e). Providing this information in the application data sheet also constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and § 1.78(b)(3) or § 1.78(d)(3), and need not otherwise be made part of the specification.

* * * * *

■ 8. Section 1.78 is revised to read as follows:

§ 1.78 Claiming benefit of earlier filing date and cross-references to other applications.

(a) *Definitions*—(1) *Continuing application.* A continuing application is a nonprovisional application or an international application designating the United States of America that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed nonprovisional application or international application designating the United States of America. An application that does not claim the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed application is not a continuing application even if the application claims the benefit under 35 U.S.C. 119(e) of a provisional application, claims priority under 35 U.S.C. 119(a)-(d) or 365(b) to a foreign application, or claims priority under 35 U.S.C. 365(a) or (b) to an international application designating at least one country other than the United States of America.

(2) *Divisional application.* A divisional application is a continuing application as defined in paragraph (a)(1) of this section that discloses and claims only an invention or inventions that were disclosed and claimed in a prior-filed application, but were subject to a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the prior-filed application, and were not elected for examination and were not examined in any prior-filed application.

(3) *Continuation application.* A continuation application is a continuing application as defined in paragraph (a)(1) of this section that discloses and claims only an invention or inventions that were disclosed in the prior-filed application.

(4) *Continuation-in-part application.* A continuation-in-part application is a continuing application as defined in paragraph (a)(1) of this section that discloses subject matter that was not disclosed in the prior-filed application.

(b) *Claims under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application.* A nonprovisional application, other than for a design patent, or an international application designating the United States of America may claim the benefit of one or more prior-filed provisional applications under the conditions set forth in 35 U.S.C. 119(e) and paragraph (b) of this section.

(1) The nonprovisional application or international application designating the United States of America must be filed not later than twelve months after the date on which the provisional application was filed. This twelve-month period is subject to 35 U.S.C. 21(b) and § 1.7(a).

(2) Each prior-filed provisional application must name as an inventor at least one inventor named in the later-filed application. In addition, each prior-filed provisional application must be entitled to a filing date as set forth in § 1.53(c) and the basic filing fee set forth in § 1.16(d) must have been paid for such provisional application within the time period set forth in § 1.53(g).

(3) Any nonprovisional application or international application designating the United States of America that claims the benefit of one or more prior-filed provisional applications must contain or be amended to contain a reference to each such prior-filed provisional application, identifying it by the provisional application number (consisting of series code and serial number). If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence(s) following the title.

(4) The reference required by paragraph (b)(3) of this section must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed provisional application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-

filed provisional application. Except as provided in paragraph (c) of this section, failure to timely submit the reference is considered a waiver of any benefit under 35 U.S.C. 119(e) of the prior-filed provisional application. The time periods in this paragraph do not apply if the later-filed application is:

(i) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or

(ii) An international application filed under 35 U.S.C. 363 before November 29, 2000.

(5) If the prior-filed provisional application was filed in a language other than English and both an English-language translation of the prior-filed provisional application and a statement that the translation is accurate were not previously filed in the prior-filed provisional application, applicant will be notified and given a period of time within which to file the translation and the statement in the prior-filed provisional application. If the notice is mailed in a pending nonprovisional application, a timely reply to such a notice must include the filing in the nonprovisional application of either a confirmation that the translation and statement were filed in the provisional application, or an amendment or supplemental application data sheet withdrawing the benefit claim, or the nonprovisional application will be abandoned. The translation and statement may be filed in the provisional application, even if the provisional application has become abandoned.

(c) *Delayed claims under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application.* If the reference required by 35 U.S.C. 119(e) and paragraph (b)(3) of this section is presented in a nonprovisional application after the time period provided by paragraph (b)(4) of this section, the claim under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application may be accepted if submitted during the pendency of the later-filed application and if the reference identifying the prior-filed application by provisional application number was unintentionally delayed. A petition to accept an unintentionally delayed claim under 35 U.S.C. 119(e) for the benefit of a prior-filed provisional application must be accompanied by:

(1) The reference required by 35 U.S.C. 119(e) and paragraph (b)(3) of this section to the prior-filed provisional application, unless previously submitted;

(2) The surcharge set forth in § 1.17(t); and

(3) A statement that the entire delay between the date the claim was due under paragraph (b)(4) of this section and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional.

(d) *Claims under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filed nonprovisional or international application.* A nonprovisional application (including an international application that has entered the national stage after compliance with 35 U.S.C. 371) may claim the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America under the conditions set forth in 35 U.S.C. 120 and paragraph (d) of this section.

(1) A nonprovisional application that claims the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must satisfy the conditions set forth in at least one of paragraphs (d)(1)(i) through (d)(1)(vi) of this section. The Office will refuse to enter, or will delete if present, any specific reference to a prior-filed application that is not permitted by at least one of paragraphs (d)(1)(i) through (d)(1)(vi) of this section. The Office's entry of, or failure to delete, a specific reference to a prior-filed application that is not permitted by at least one of paragraphs (d)(1)(i) through (d)(1)(vi) of this section does not constitute a waiver of the provisions of paragraph (d)(1) of this section.

(i)(A) The nonprovisional application is either a continuation application as defined in paragraph (a)(3) of this section or a continuation-in-part application as defined in paragraph (a)(4) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than two prior-filed applications; and

(B) Any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than one other nonprovisional application, not including any nonprovisional application that satisfies the conditions set forth in paragraph (d)(1)(ii), (d)(1)(iii) or (d)(1)(vi) of this section.

(ii)(A) The nonprovisional application is a divisional application as defined in paragraph (a)(2) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed application that was subject to a requirement to comply with the

requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121; and

(B) The divisional application contains only claims directed to an invention or inventions that were identified in such requirement to comply with the requirement of unity of invention or requirement for restriction but were not elected for examination and were not examined in the prior-filed application or in any other nonprovisional application, except for a nonprovisional application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such divisional application and satisfies the conditions set forth in paragraph (d)(1)(iii) or (d)(1)(vi) of this section.

(iii)(A) The nonprovisional application is a continuation application as defined in paragraph (a)(3) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a divisional application that satisfies the conditions set forth in paragraph (d)(1)(ii) of this section;

(B) The nonprovisional application discloses and claims only an invention or inventions that were disclosed and claimed in such divisional application;

(C) The nonprovisional application claims the benefit under 35 U.S.C. 120, 121, or 365(c) of only the divisional application, any application to which such divisional application claims benefit under 35 U.S.C. 120, 121, or 365(c) in compliance with the conditions set forth in paragraph (d)(1)(ii) of this section, and no more than one intervening prior-filed nonprovisional application; and

(D) The divisional application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than one other nonprovisional application, not including any other divisional application that satisfies the conditions set forth in paragraph (d)(1)(ii) or any nonprovisional application that claims the benefit under 35 U.S.C. 120 or 365(c) of such other divisional application and satisfies the conditions set forth in paragraph (d)(1)(iii) or (d)(1)(vi) of this section.

(iv)(A) The nonprovisional application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed international application designating the United States of America, and a Demand has not been filed and the basic national fee (§ 1.492(a)) has not been paid in the prior-filed international application and the prior-filed international application does not claim the benefit of any other nonprovisional application or international application

designating the United States of America;

(B) The nonprovisional application is either a continuation application as defined in paragraph (a)(3) of this section or a continuation-in-part application as defined in paragraph (a)(4) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three prior-filed applications; and

(C) Any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two other nonprovisional applications, not including any nonprovisional application that satisfies the conditions set forth in paragraph (d)(1)(ii), (d)(1)(iii) or (d)(1)(vi) of this section.

(v)(A) The nonprovisional application claims benefit under 35 U.S.C. 120 or 365(c) of a prior-filed nonprovisional application filed under 35 U.S.C. 111(a), and such nonprovisional application became abandoned due to the failure to timely reply to an Office notice issued under § 1.53(f) and does not claim the benefit of any other nonprovisional application or international application designating the United States of America;

(B) The nonprovisional application is either a continuation application as defined in paragraph (a)(3) of this section or a continuation-in-part application as defined in paragraph (a)(4) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of no more than three prior-filed applications; and

(C) Any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such nonprovisional application has its benefit claimed in no more than two other nonprovisional applications, not including any nonprovisional application that satisfies the conditions set forth in paragraph (d)(1)(ii), (d)(1)(iii) or (d)(1)(vi) of this section.

(vi) The nonprovisional application is a continuing application as defined in paragraph (a)(1) of this section that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a prior-filed application, is filed to obtain consideration of an amendment, argument, or evidence that could not have been submitted during the prosecution of the prior-filed application, and does not satisfy the conditions set forth in any of paragraphs (d)(1)(i) through (d)(1)(v) of this section. A petition must be filed in such nonprovisional application that is accompanied by the fee set forth in § 1.17(f) and a showing that the

amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application. If the continuing application is an application filed under 35 U.S.C. 111(a), this petition must be submitted within four months from the actual filing date of the continuing application. If the continuing application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this petition must be submitted within four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the international application.

(2) Each prior-filed application must name as an inventor at least one inventor named in the later-filed application. In addition, each prior-filed application must either be:

(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) A nonprovisional application under 35 U.S.C. 111(a) that is entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) for which the basic filing fee set forth in § 1.16 has been paid within the pendency of the application.

(3) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application, or international application designating the United States of America, that claims the benefit of one or more prior-filed nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date. The reference must also identify the relationship of the applications (*i.e.*, whether the later-filed application is a continuation, divisional, or continuation-in-part of the prior-filed nonprovisional application or international application). If an application is identified as a continuation-in-part application, the applicant must identify the claim or claims in the continuation-in-part application for which the subject matter is disclosed in the manner provided by the first paragraph of 35 U.S.C. 112 in the prior-filed application. If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be

amended to contain such reference in the first sentence(s) following the title.

(4) The reference required by 35 U.S.C. 120 and paragraph (d)(3) of this section must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed application. Except as provided in paragraph (e) of this section, failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (d)(3) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to the prior-filed application. The time periods in this paragraph do not apply if the later-filed application is:

(i) An application for a design patent;

(ii) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or

(iii) An international application filed under 35 U.S.C. 363 before November 29, 2000.

(5) The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior-filed application. The identification of an application by application number under this section is the identification of every application assigned that application number necessary for a specific reference required by 35 U.S.C. 120 to every such application assigned that application number.

(6) Cross-references to other related applications may be made when appropriate. Cross-references to applications for which a benefit is not claimed under title 35, United States Code, must be located in a paragraph that is separate from the paragraph containing the references to applications for which a benefit is claimed under 35 U.S.C. 119(e), 120, 121, or 365(c) that is required by 35 U.S.C. 119(e) or 120 and this section.

(e) *Delayed claims under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filed nonprovisional application or international application.* If the reference required by 35 U.S.C. 120 and

paragraph (d)(3) of this section is presented after the time period provided by paragraph (d)(4) of this section, the claim under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filed copending nonprovisional application or international application designating the United States of America may be accepted if the reference identifying the prior-filed application by application number or international application number and international filing date was unintentionally delayed. A petition to accept an unintentionally delayed claim under 35 U.S.C. 120, 121, or 365(c) for the benefit of a prior-filed application must be accompanied by:

(1) The reference required by 35 U.S.C. 120 and paragraph (d)(3) of this section to the prior-filed application, unless previously submitted;

(2) The surcharge set forth in § 1.17(t); and

(3) A statement that the entire delay between the date the claim was due under paragraph (d)(4) of this section and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional.

(f) *Applications and patents naming at least one inventor in common.* (1)(i) The applicant in a nonprovisional application that has not been allowed (§ 1.311) must identify by application number (*i.e.*, series code and serial number) and patent number (if applicable) each other pending or patented nonprovisional application, in a separate paper, for which the following conditions are met:

(A) The nonprovisional application has a filing date that is the same as or within two months of the filing date of the other pending or patented nonprovisional application, taking into account any filing date for which a benefit is sought under title 35, United States Code;

(B) The nonprovisional application names at least one inventor in common with the other pending or patented nonprovisional application; and

(C) The nonprovisional application is owned by the same person, or subject to an obligation of assignment to the same person, as the other pending or patented nonprovisional application.

(ii) The identification of such one or more other pending or patented nonprovisional applications if required by paragraph (f)(1)(i) of this section must be submitted within the later of:

(A) Four months from the actual filing date in a nonprovisional application filed under 35 U.S.C. 111(a);

(B) Four months from the date on which the national stage commenced

under 35 U.S.C. 371(b) or (f) in a nonprovisional application entering the national stage from an international application under 35 U.S.C. 371; or

(C) Two months from the mailing date of the initial filing receipt in such other nonprovisional application for which identification is required by paragraph (f)(1)(i) of this section.

(2)(i) A rebuttable presumption shall exist that a nonprovisional application contains at least one claim that is not patentably distinct from at least one of the claims in another pending or patented nonprovisional application if the following conditions are met:

(A) The nonprovisional application has a filing date that is the same as the filing date of the other pending or patented nonprovisional application, taking into account any filing date for which a benefit is sought under title 35, United States Code;

(B) The nonprovisional application names at least one inventor in common with the other pending or patented nonprovisional application;

(C) The nonprovisional application is owned by the same person, or subject to an obligation of assignment to the same person, as the other pending or patented nonprovisional application; and

(D) The nonprovisional application and the other pending or patented nonprovisional application contain substantial overlapping disclosure. Substantial overlapping disclosure exists if the other pending or patented nonprovisional application has written description support under the first paragraph of 35 U.S.C. 112 for at least one claim in the nonprovisional application.

(ii) If the conditions specified in paragraph (f)(2)(i) of this section exist, the applicant in the nonprovisional application must, unless the nonprovisional application has been allowed (§ 1.311), take one of the following actions within the time period specified in paragraph (f)(2)(iii) of this section:

(A) Rebut this presumption by explaining how the application contains only claims that are patentably distinct from the claims in each of such other pending nonprovisional applications or patents; or

(B) Submit a terminal disclaimer in accordance with § 1.321(c). In addition, where one or more other pending nonprovisional applications have been identified, the applicant must explain why there are two or more pending nonprovisional applications naming at least one inventor in common and owned by the same person, or subject to an obligation of assignment to the same

person, which contain patentably indistinct claims.

(iii) If the conditions specified in paragraph (f)(2)(i) of this section exist, the applicant in the nonprovisional application must, unless the nonprovisional application has been allowed (§ 1.311), take one of the actions specified in paragraph (f)(2)(ii) of this section within the later of:

(A) Four months from the actual filing date of a nonprovisional application filed under 35 U.S.C. 111(a);

(B) Four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in a nonprovisional application entering the national stage from an international application under 35 U.S.C. 371;

(C) The date on which a claim that is not patentably distinct from at least one of the claims in the one or more other pending or patented nonprovisional applications is presented; or

(D) Two months from the mailing date of the initial filing receipt in the one or more other pending or patented nonprovisional applications.

(3) In the absence of good and sufficient reason for there being two or more pending nonprovisional applications owned by the same person, or subject to an obligation of assignment to the same person, which contain patentably indistinct claims, the Office may require elimination of the patentably indistinct claims from all but one of the applications.

(g) *Applications or patents under reexamination naming different inventors and containing patentably indistinct claims.* If an application or a patent under reexamination and at least one other application naming different inventors are owned by the same party and contain patentably indistinct claims, and there is no statement of record indicating that the claimed inventions were commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, the Office may require the assignee to state whether the claimed inventions were commonly owned or subject to an obligation of assignment to the same person at the time the later invention was made, and if not, indicate which named inventor is the prior inventor.

(h) *Parties to a joint research agreement.* If an application discloses or is amended to disclose the names of parties to a joint research agreement under 35 U.S.C. 103(c)(2)(C), the parties to the joint research agreement are considered to be the same person for purposes of this section. If the application is amended to disclose the names of parties to a joint research

agreement, the identification of such one or more other nonprovisional applications as required by paragraph (f)(1) of this section must be submitted with such amendment unless such identification is or has been submitted within the four-month period specified in paragraph (f)(1) of this section.

(i) *Time periods not extendable*: The time periods set forth in this section are not extendable.

■ 9. Section 1.104 is amended by revising paragraphs (a)(1) and (b) to read as follows:

§ 1.104 Nature of examination.

(a) *Examiner's action*. (1) On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes, rules, and other requirements, and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.

* * * * *

(b) *Completeness of examiner's action*. The examiner's action will be complete as to all matters, except that in appropriate circumstances, such as misjoinder of invention, fundamental defects in the application, and the like, the action of the examiner may be limited to such matters before further action is made.

* * * * *

■ 10. Section 1.105 is amended by adding a new paragraph (a)(1)(ix) to read as follows:

§ 1.105 Requirements for information.

(a)(1) * * *

(ix) *Support in the specification*: Where (by page and line or paragraph number) in the specification of the application, or any application the benefit of whose filing date is sought under title 35, United States Code, there is written description support for the invention as defined in the claims (whether in independent or dependent form), and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention, under the first paragraph of 35 U.S.C. 112.

* * * * *

■ 11. Section 1.110 is revised to read as follows:

§ 1.110 Inventorship and date of invention of the subject matter of individual claims.

When more than one inventor is named in an application or patent, the Office may require an applicant, patentee, or owner to identify the inventive entity of the subject matter of each claim in the application or patent when necessary for purposes of an Office proceeding. Where appropriate, the invention dates of the subject matter of each claim and the ownership of the subject matter on the date of invention may be required of the applicant, patentee or owner. *See also* §§ 1.78 and 1.130.

■ 12. Section 1.114 is amended by revising paragraphs (a) and (d), and by adding new paragraphs (f), (g), and (h), to read as follows:

§ 1.114 Request for continued examination.

(a) If prosecution in an application is closed, an applicant may, subject to the conditions of this section, file a request for continued examination of the application accompanied by a submission, the fee set forth in § 1.17(e), and if required, a petition under paragraph (g) of this section accompanied by the fee set forth in § 1.17(f), prior to the earliest of:

(1) Payment of the issue fee, unless a petition under § 1.313 is granted;

(2) Abandonment of the application; or

(3) The filing of a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. 141, or the commencement of a civil action under 35 U.S.C. 145 or 146, unless the appeal or civil action is terminated.

* * * * *

(d) If an applicant files a request for continued examination under this section after appeal, but prior to a decision on the appeal, the request for continued examination will also be treated as a request to withdraw the appeal and to reopen prosecution of the application before the examiner. An appeal brief (§ 41.37 of this title), a reply brief (§ 41.41 of this title), or related papers will not be considered a submission under this section.

* * * * *

(f) An applicant may file a request for continued examination under this section in an application without a petition under paragraph (g) of this section if the conditions set forth in at least one of paragraphs (f)(1), (f)(2), or (f)(3) of this section are satisfied:

(1) A request for continued examination under this section has not previously been filed in any of:

(i) The application;

(ii) Any application whose benefit is claimed under 35 U.S.C. 120, 121, or 365(c) in such application; and

(iii) Any application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

(2) The application is a divisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), and a request for continued examination under this section has not previously been filed in any of:

(i) The divisional application; and

(ii) Any application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such divisional application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

(3) The application is a continuation application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of a divisional application and satisfies the conditions set forth in § 1.78(d)(1)(iii), and a request for continued examination under this section has not been filed in any of:

(i) The continuation application;

(ii) The divisional application; and

(iii) Any other application that claims the benefit under 35 U.S.C. 120, 121, or 365(c) of such divisional application, not including any nonprovisional application that satisfies the conditions set forth in § 1.78(d)(1)(ii), (d)(1)(iii) or (d)(1)(vi).

(g) A request for continued examination must include a petition accompanied by the fee set forth in § 1.17(f) and a showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution in the application, except as otherwise provided in paragraph (f) of this section.

(h) The filing of an improper request for continued examination, including a request for continued examination with a petition under paragraph (g) of this section that is not grantable, will not stay any period for reply that may be running against the application, nor act as a stay of other proceedings.

■ 13. Section 1.117 is added to read as follows:

§ 1.117 Refund due to cancellation of claim.

(a) If an amendment canceling a claim is filed before an examination on the merits has been made of the application, the applicant may request a refund of any fee under § 1.16(h), (i), or (j) or under § 1.492(d), (e), or (f) paid on or after December 8, 2004, for such claim. If an amendment adding one or more claims is also filed before the application has been taken up for examination on the merits, the Office may apply any refund under § 1.117 to any excess claims fees due as a result of such an amendment. The date indicated on any certificate of mailing or transmission under § 1.8 will not be taken into account in determining whether an amendment canceling a claim was filed before an examination on the merits has been made of the application.

(b) If a request for refund under this section is not filed within two months from the date on which the claim was canceled, the Office may retain the excess claims fee paid in the application. This two-month period is not extendable. If an amendment canceling a claim is not filed before an examination on the merits has been made of the application, the Office will not refund any part of the excess claims fee paid in the application except as provided in § 1.26.

■ 14. Section 1.136 is amended by revising paragraph (a)(1) to read as follows:

§ 1.136 Extensions of time.

(a)(1) If an applicant is required to reply within a nonstatutory or shortened statutory time period, applicant may extend the time period for reply up to the earlier of the expiration of any maximum period set by statute or five months after the time period set for reply, if a petition for an extension of time and the fee set in § 1.17(a) are filed, unless:

- (i) Applicant is notified otherwise in an Office action;
- (ii) The reply is to a notice requiring compliance with § 1.75(b) or § 1.265;
- (iii) The reply is a reply brief submitted pursuant to § 41.41 of this title;
- (iv) The reply is a request for an oral hearing submitted pursuant to § 41.47(a) of this title;
- (v) The reply is to a decision by the Board of Patent Appeals and Interferences pursuant to § 1.304 or to § 41.50 or § 41.52 of this title; or
- (vi) The application is involved in a contested case (§ 41.101(a) of this title).

* * * * *

■ 15. Section 1.142 is amended by revising paragraph (a) and adding new paragraph (c) to read as follows:

§ 1.142 Requirement for restriction.

(a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action may require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.

* * * * *

(c) If two or more independent and distinct inventions are claimed in a single application, the applicant may file a suggested requirement for restriction under this paragraph. Any suggested requirement for restriction must be filed prior to the earlier of the first Office action on the merits or an Office action that contains a requirement to comply with the requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 in the application. Any suggested requirement for restriction must also be accompanied by an election without traverse of an invention to which there are no more than five independent claims and no more than twenty-five total claims, and must identify the claims to the elected invention. If the suggested requirement for restriction is accepted, the applicant will be notified in an Office action that will contain a requirement for restriction under paragraph (a) of this section. Any claim to the non-elected invention or inventions, if not canceled, is by the election withdrawn from further consideration.

■ 16. Section 1.145 is revised to read as follows:

§ 1.145 Subsequent presentation of claims for different invention.

If, after an Office action on the merits on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant may be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143 and 1.144.

■ 17. Section 1.265 is added to read as follows:

§ 1.265 Examination support document.

(a) An examination support document as used in this part means a document that includes the following:

(1) A statement that a preexamination search in compliance with paragraph (b) of this section was conducted, including an identification of the field of search by United States class and subclass and the date of the search, where applicable, and, for database searches, the search logic or chemical structure or sequence used as a query, the name of the file or files searched and the database service, and the date of the search;

(2) A listing of the reference or references deemed most closely related to the subject matter of each of the claims (whether in independent or dependent form) in compliance with paragraph (c) of this section;

(3) For each reference cited, an identification of all of the limitations of each of the claims (whether in independent or dependent form) that are disclosed by the reference;

(4) A detailed explanation particularly pointing out how each of the independent claims is patentable over the cited references; and

(5) A showing of where each limitation of each of the claims (whether in independent or dependent form) finds support under the first paragraph of 35 U.S.C. 112 in the written description of the specification. If the application claims the benefit of one or more applications under title 35, United States Code, the showing must also include where each limitation of each of the claims finds support under the first paragraph of 35 U.S.C. 112 in each such priority or benefit application in which such support exists.

(b) The preexamination search referred to in paragraph (a)(1) of this section must involve U.S. patents and patent application publications, foreign patent documents, and non-patent literature, unless the applicant justifies with reasonable certainty that no references more pertinent than those already identified are likely to be found in the eliminated source and includes such a justification with the statement required by paragraph (a)(1) of this section. The preexamination search referred to in paragraph (a)(1) of this section must be directed to the claimed invention and encompass all of the limitations of each of the claims (whether in independent or dependent form), giving the claims the broadest reasonable interpretation.

(c) The listing of references required under paragraph (a)(2) of this section as part of an examination support document must include a list identifying each of the cited references

in compliance with paragraphs (c)(1) and (c)(2) of this section, a copy of each reference if required by paragraph (c)(3) of this section, and each English language translation if required by paragraph (c)(4) of this section.

(1) The list of cited references must itemize U.S. patents and U.S. patent application publications (including international applications designating the U.S.) in a section separate from the list of other references. Each page of the list of the cited references must include:

(i) The application number, if known, of the application in which the examination support document is being filed;

(ii) A column that provides a space next to each cited reference for the examiner's initials; and

(iii) A heading that clearly indicates that the list is part of an examination support document listing of references.

(2) The list of cited references must identify each cited reference as follows:

(i) Each U.S. patent must be identified by first named patentee, patent number, and issue date.

(ii) Each U.S. patent application publication must be identified by applicant, patent application publication number, and publication date.

(iii) Each U.S. application must be identified by the applicant, application number, and filing date.

(iv) Each foreign patent or published foreign patent application must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.

(v) Each publication must be identified by publisher (e.g., name of journal), author (if any), title, relevant pages of the publication, date, and place of publication.

(3) The listing of references required under paragraph (a)(2) of this section must also be accompanied by a legible copy of each cited reference, except for references that are U.S. patents or U.S. patent application publications.

(4) If a non-English language document is being cited in the listing of references required under paragraph (a)(2) of this section as part of an examination support document, any existing English language translation of the non-English language document must also be submitted if the translation is within the possession, custody, or control of, or is readily available to any individual identified in § 1.56(c).

(d) If an information disclosure statement is filed in an application in

which an examination support document is required and has been filed, the applicant must also file a supplemental examination support document addressing the reference or references in the manner required under paragraphs (a)(3) and (a)(4) of this section unless the information disclosure statement cites only references that are less closely related to the subject matter of one or more claims (whether in independent or dependent form) than the references cited in the examination support document listing of references under paragraph (a)(2) of this section.

(e) If an examination support document is required, but the examination support document or preexamination search is deemed to be insufficient, or the claims have been amended such that the examination support document no longer covers each of the claims, applicant will be notified and given a two-month time period that is not extendable under § 1.136(a) within which, to avoid abandonment of the application, the applicant must:

(1) File a corrected or supplemental examination support document in compliance with this section that covers each of the claims (whether in independent or dependent form); or

(2) Amend the application such that it contains no more than five independent claims and no more than twenty-five total claims.

(f) An examination support document, or a corrected or supplemental examination support document, is not required to comply with the requirements set forth in paragraph (a)(3) of this section if the examination support document is accompanied by a certification that any rights in the application have not been assigned, granted, conveyed, or licensed, and there is no obligation under contract or law to assign, grant, convey, or license any rights in the application, other than a security interest that has not been defaulted upon, to any entity other than:

(1) A business or other concern:

(i) Whose number of employees, including affiliates, does not exceed 500 persons; and

(ii) Which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under paragraph (f)(1)(i) of this section.

(2) A not-for-profit enterprise which is independently owned and operated and is not dominant in its field; or

(3) A government of a city, county, town, township, village, school district, or special district, with a population of less than fifty thousand.

■ 18. Section 1.495 is amended by revising paragraph (g) to read as follows:

§ 1.495 Entering the national stage in the United States of America.

* * * * *

(g) The documents and fees submitted under paragraphs (b) and (c) of this section must be clearly identified as a submission to enter the national stage under 35 U.S.C. 371. If the documents and fees contain conflicting indications as between an application under 35 U.S.C. 111 and a submission to enter the national stage under 35 U.S.C. 371, the documents and fees will be treated as a submission to enter the national stage under 35 U.S.C. 371.

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■ 19. Section 1.704 is amended by redesignating paragraph (c)(11) as (c)(12) and adding new paragraph (c)(11) to read as follows:

§ 1.704 Reduction of period of adjustment of patent term.

* * * * *

(c) * * *

(11) Failure to comply with § 1.75(b), in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is the later of the filing date of the amendment resulting in the non-compliance with § 1.75(b), or four months from the filing date of the application in an application under 35 U.S.C. 111(a) or from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in an application which entered the national stage from an international application after compliance with 35 U.S.C. 371, and ending on the date that an examination support document in compliance with § 1.265, an election in reply to a requirement under § 1.142(a), 1.146 or 1.499 resulting in compliance with § 1.75(b), an amendment resulting in compliance with § 1.75(b), or a suggested restriction requirement in compliance with § 1.142(c), was filed;

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Dated: August 2, 2007.

Jon W. Dudas,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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