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From: Arvie Anderson [mailto:ANDERSON_ARVIE@LILLY.COM]
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Subject: Eli Lilly and Co. Comments on Changes to Practice for Continuing Applications and for the Examination of Claims in Patent Applications

Respectfully Submitted,

Arvie J. Anderson
Patent Counsel, Legal
Eli Lilly and Company
Drop Code 1104
Lilly Corporate Center
Indianapolis, IN 46285
(Phone) (317) 277-7217
(Fax) (317) 276-3861

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
Mail Stop Comments—Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Robert W. Bahr
Senior Patent Attorney
Office of the Deputy Commissioner for Patent Examination Policy

Attn: Robert A. Clarke
Deputy Director
Office of Patent Legal Administration
Office of the Deputy Commissioner for Patent Examination Policy

Dear Under Secretary Dudas:

Eli Lilly and Company appreciates the opportunity to offer comments regarding the U.S. Patent and Trademark Office ("USPTO") proposed rules directed to changes to practice for continuing applications, requests for continued examination practice, and applications containing patentably indistinct claims, published at 71 Fed. Reg. 48 (Jan. 3, 2006), and proposed rules directed to changes to practice for the examination of claims in patent applications, published at 71 Fed. Reg. 61 (Jan. 3, 2006).

General Concerns: Actions in Excess of Authority and Resulting Uncertainty

A substantial question exists regarding whether the rules proposed by the USPTO exceed its statutory rulemaking authority. The USPTO's rulemaking powers are described in 35 U.S.C. § 2(b)(2)(A). This provision provides that the USPTO "may establish regulations, not inconsistent with law." Several of the proposed rules, however, effectively contravene clear statutory provisions. For example, the USPTO's proposal to limit applicants to a single continued application as of right, with the ability to file further applications only upon meeting additional and non-statutory subjective conditions, effectively limits an applicant's right to continued examination which is guaranteed under 35 U.S.C. § 132(b).

Additionally, the USPTO has proposed a limit to the number of claims it will initially examine in an application unless an examination support document ("ESD") is filed. Currently an application may be filed with as many claims as the applicant deems is necessary to fully protect the invention, subject only to the payment of fees for excess claims pursuant to 35 U.S.C. § 41(a)(2). The requirement to file the ESD effectively eliminates the ability to present more than a nominal number of claims for examination. Because applicants would be unduly increasing the opportunities for unenforceability defenses that would later be brought against their patents by submitting the ESD, the proposed rules effectively defeat the statutorily protected right to present as many claims as the applicant regards are necessary to fully protect the invention.

Because judicial challenges to the proposed rules can be expected, a wiser course of action for the USPTO would be to work with its user community and the Congress in an effort to define clear-cut legislative authority for any rulemaking. If a true dialogue were to be commenced, we believe that it could address the issues that the USPTO has raised in its proposed rulemaking, but by moving these efforts in a quite different direction.

Alternative Approaches to Enhancing Efficiency of Patent Examination

Lilly would propose that, in place of the current framework that the USPTO has developed in the proposed rules, consideration be given to commencing a dialogue around the following ideas:

- End "restriction practice." If an applicant presents claims for examination in a patent application, the public should know at the earliest possible time whether a patent will issue on *all* such claims. Notwithstanding all of the focus of the USPTO on limiting the number of claims to be initially filed and the number of "continuation" applications to be permitted as of right, the USPTO does nothing to address the issue of *delays* in patentability determinations on account of restriction practice. The proposed rulemaking does nothing whatsoever to address the long delay that can occur in the search and examination of any subject matter that the examiner deems to be an "independent and distinct" invention. Moreover, it does nothing to address the inefficiency that results when claims to a new technology are divided, creating the opportunity for the inherent inefficiencies that result when different examiners are involved at different times in examining the related claims. A better practice would be for the "independent and distinct" inventions standard to be legislatively changed and/or administratively interpreted to limit restriction requirements to situations where wholly unrelated technology is combined into a single patent application. Implementing this suggestion would, of course, require that the USPTO be given appropriate fee-setting authority by Congress to assure that a fee structure could be implemented that would permit the collection of fees proportionate to the workload required to conduct the unitary examination of all claims in an application. However,

such congressional action could presumably mean that more complex applications with more and more complex claims that would be charged the higher fees would be accorded more patent examiner time for their examination. These steps would greatly advance patent quality, examination efficiency, and the public interest in a prompt determination of patentability for all claims presented for examination.

- Impose a *statutory* timeliness requirement for filing of continuation applications, not an *administrative* limitation on their number. The most fundamental principle that every USPTO rulemaking should advance is that applicants should have a full and fair opportunity to present claims for examination in order to assure the most complete protection for any validly patentable invention disclosed in a patent application. Given recent developments in the patent law, especially in the area of the "doctrine of equivalents," this axiom should be given ever more deference in any rulemaking. When applications are initially filed, applicants should be given wide berth to decide whether those claims appear in one application or multiple applications and whether the claims to the invention should be few or should be substantial in number. For this reason, the USPTO proposals to limit the *number* of continuing applications for patent have engendered significant controversy. For this reason alone, it appears more prudent to explore the imposition by statute of a policy-driven *timeliness* requirement for filing any desired continuing applications. In other words, applicants may choose the number of original applications to be filed, the disclosure to be made in each such application, the number of continuation applications (including continuation-in-part applications) that may be needed, and the number of claims to be made in each and every such application. However, after an early and defined point in time during the statutory twenty-year term, the availability of filing further continuing applications should cease altogether. There are two obvious (and fair and reasonable) candidates for imposing such a timeliness limitation. One is the eighteen-month publication date of the application for patent. The other is the one-year anniversary of the application's eighteen-month publication. Both time markers are driven by the practical and legal complications of using continuation-in-part applications once an application for patent publishes. The latter corresponds to the date the publication of the application becomes a statutory bar against any broadening of claims that might be accomplished through a continuation-in-part application. The former appears reasonable given the complexity of prosecution and risks of invalidity due to intervening prior art that is inherent in any prolonged use of continuation-in-part practice. The timeliness requirement would advance the broader public interest in achieving the earliest possible determination of the full scope of protection that will be afforded to an invention once patent protection is first sought. By not limiting the number of continuing applications, but only their timing, Congress could produce a win-win outcome for inventors and for the public—assuming, of course, that the USPTO can promptly examine applications and make final determinations of patentability once an application for patent has published.

- Continue the practice of "requests for continued examination" as a "safety valve" once continuation applications are unavailable, but limit the RCE practice to defined situations, including where an applicant develops new evidence or arguments in support of patentability. Imposing a "timeliness limitation" and abolishing "restriction requirements" would mean that a patent examiner could pick up a published patent application for examination and proceed to a final determination of patentability for all the application's claims (*i.e.*, through a first action; applicant's response, if needed; and a final action) within a matter of several months. At that point, only three options should exist: an applicant's appeal of any final rejection of claims, an applicant's opportunity for continued examination (*e.g.*, based upon new evidence or arguments developed in support of patentability), or issuance of the patent because all claims have been allowed. If the applicant elects appeal and the appeal is not successful, a similar opportunity for requesting continued examination should exist. By creating *limited* RCE opportunities, together with the existing limited option to seek suspension of examination (*e.g.*, to develop new evidence in support of patentability), the issuance of the patent would not be unreasonably delayed and every inventor would be afforded the fullest and fairest opportunity to fully protect the invention.

- Group together an applicant's related applications for concurrent, coordinated examination by the same patent examiner. Under the patent examination paradigm set out above abolishing divisional applications and post-publication continuing applications, patent examiners could use the USPTO database to identify all of an applicant's related applications for patent at or shortly after the eighteen-month publication has taken place. These would include any continuation, continuation-in-part, and/or original applications for patent with similar disclosures and/or similar claims. Because this would be an administrative device to assure the greatest efficiency in examining all of an applicant's related claims that might be patentably indistinct from one another, it would create none of the concerns over rulemaking in excess of statutory authority. Moreover, it would accomplish the objective of a prompt and final determination of patentability of all claims to an invention, but without imposing new burdens on applicants to identify applications that the USPTO might or might not want to examine in a concurrent and coordinated manner. Thus, this administrative initiative to undertake concurrent and coordinated examination of applications that the Director deems are sufficiently related would entirely obviate rulemaking efforts imposing any new duties upon applicants beyond those already entailed by the existing duty of candor and good faith.

- Provide the necessary statutory framework for applicants to assume greater responsibility in guiding patent examiners through the examination process by creating an incentive for applicants to obtain fully valid patents. Consistent with the USPTO's goal of increasing applicant responsibility in the patent examination process, this requires creating a "safe harbor" from "inequitable conduct" pleadings in patent

litigation where the patent in litigation is determined to be a fully valid one. Such a "valid patent safe harbor" would afford applicants an incentive to work with patent examiners to secure fully valid patents. Without such a safe harbor, the current use of the "inequitable conduct" unenforceability defense in patent litigation renders such efforts at the enhancement of the applicant's role in the patent examination process an untenable option for the applicant. Proposals for applicants to provide additional information and additional analysis for patent examiners multiply the opportunities for allegations of misstatements and omissions of information. This is particularly the case for the type of ESDs described in the proposed rules. Perhaps no single step by Congress could result in improving the efficiency of the patent examination process and the quality of issued patents to a greater extent than enactment of "inequitable conduct" reforms, specifically those proposed by Chairman Lamar Smith in his July 26, 2005 substitute text to HR 2795. As a first step to patent examination efficiency reforms, the USPTO should, therefore, work with the Bush Administration to secure its support for Chairman Smith's initiatives and work for their enactment.

In view of the foregoing, we urge that the USPTO not implement the proposed rules, but seek—through a dialogue with the user community—appropriate legislative solutions to the examination backlog.

In addition, we offer the following technical observations on the proposed rules:

Proposed Rules Limiting Continuation Applications and RCEs

RCEs Should Not Be Treated as Equivalent to Continuations and CIPs Under Section 1.78(d)(1) for the Purpose of Limiting the Rights of Inventors to Seek Claims to Fully Protect an Invention.

The USPTO has postulated that certain continuation practices, even though the USPTO admits they are rarely used by applicants, contribute substantially to the USPTO's examination backlog. Such practices include an applicant's inability to particularly point out and distinctly claim the invention at the time an application is initially filed, the use of multiple continuation applications to delay the conclusion of prosecution, and the maintenance of continuing applications for the purpose of adding claims to later-discovered inventions in parallel technologies. As an alleged incentive to assure that applicants work with patent examiners to efficiently advance prosecution, the USPTO has proposed amendments to 37 C.F.R. §§ 1.78(d)(1) and 1.114, limiting applicants to a single continuation, continuation-in-part ("CIP"), or request for continued examination ("RCE") as of right in each nonprovisional application. The proposed rules would require an applicant to show to the satisfaction of the USPTO that later-filed applications in a multiple-continuing chain are necessary to claim the invention and do not contain unnecessarily delayed amendments, arguments, or evidence that could have been previously submitted. As previously discussed, the USPTO is certain to be

challenged in the courts, if not the Congress, that it has exceeded its rulemaking authority in promulgating rules that actually or effectively limit the availability of continuing applications.

If rules are to be adopted to advance the supposed intent of the USPTO, applying revised section 1.78(d)(1) equally to RCEs, continuations, and CIPs fails to take into account the specific purpose of RCEs. Subjecting RCEs to the same limitations as continuing applications would destroy the efficiency that currently exists under the RCE rules. Unlike continuation and CIP applications that require a virtual restart of the examination process,[1] an RCE provides the opportunity to continue advocacy of the original claim set with the same Examiner.[2,3] As such, RCE practice has emerged as an attractive alternative to filing an appeal in view of two factors: a) the shorter delay before the patent examiner[4] compared to the historically long period of delay during the pendency of an appeal before the Board of Appeals; and b) the economic as well as administrative efficiency of filing an RCE relative to an appeal brief. Stripped of the availability of certain RCE opportunities, such as to obtain entry of amendments after final rejection, to cite late-discovered art in order to meet the ongoing duty of disclosure,[5] or to provide data to support arguments for patentability, the prudent applicant will be forced to appeal all final rejections to preserve a continuation option as of right. The inevitable result will be to recreate an intractable backlog of appeals to the Board, in spite of the recently adopted appeal conference and pre-brief appeal conference programs.

The RCE is specifically designed to increase the efficient continuation of ongoing prosecution. Thus, if the USPTO does move its rulemaking efforts forward, the proposed rules should be amended to create *limited* RCE opportunities, together with the existing limited option to seek suspension of examination. The rules should be amended to allow second and subsequent RCEs for specific purposes, such as: a) citation of newly available prior art; b) entry of new arguments or evidence to overcome a final rejection; and c) amendment of the claims to place them in condition for allowance or in better condition for appeal. This approach gives a better balance between the USPTO's goal of increased efficiency and the applicant's need for flexibility and certainty during patent prosecution.

[1] Manual of Patent Examining Procedure §§ 201.07, 201.08 (8th ed., Rev. 3)(2005) [hereinafter M.P.E.P.].
[2] M.P.E.P. at §§ 201.06(d), 706.07(h).
[3] In amending 35 U.S.C. § 132 under the American Inventors Protection Act, Congress required that the USPTO provide a means for applicants to continue prosecution of applications. 37 C.F.R. § 1.114 was enacted to provide such means.
[4] Because the claims presented are the same or substantially similar to those originally filed, the RCE does not require an additional search by the USPTO. Further, the RCE provides for timely examination, as the examiner must reply within four months, just as if the RCE were a response to any other USPTO action.
[5] 37 C.F.R. § 1.56 (2004).

The Proposed Revisions to Section 1.78(f) Are Unwarranted, Unwise, and Unnecessary, Given the Existing Obligations Under the Duty of Disclosure Under 37 C.F.R. § 1.56 and the Protection of the Public Through the Requirements for Filing Terminal Disclaimers.

The proposed revisions to 37 C.F.R. § 1.78(f) confer a duty of disclosure whenever a non-provisional application is filed on the same date or within two months of one or more other pending non-provisionals, naming at least one inventor in common and being owned or subject to assignment to the same person.[6] Under these circumstances, within four months from the filing date(s), the applicant must identify each related application or patent.

This new requirement is manifestly unnecessary to protect any public interest. Currently, 37 C.F.R. § 1.56 already requires disclosure of any application or patent that is material to patentability.[7] This includes applications that contain claims that create issues of "obviousness-type" double patenting because such applications could result in patents on patentably indistinct inventions. Examination efficiency is not improved by requiring identification of applications and patents that have a common inventor and common ownership, but are otherwise *immaterial* to patentability.

Section 1.78(f)(1) does not require that the applications have related subject matter—only related inventorship and ownership. An inventor may file two applications on vastly different and unrelated inventions—inventions that are not even in the same field of art. Moreover, these applications may be filed by unassociated attorneys. Unless the inventor informs each attorney that he has filed another application within the previous two months, a substantial risk exists that the attorneys will not discover the other filing, especially if the attorneys work for different law firms. The identification process may be further hindered by the fact that the application number often is not available until more than four months have passed.[8] No USPTO efficiency goals would be served by identifying an unrelated, immaterial application, simply because it was filed by the same inventor.

The USPTO has provided no guidance on how an error in identification of applications falling under section 1.78(f)(1) would be handled, that is, how to correct an error in the identification requirements or even whether it is correctable. The proposed rules do not even suggest that the practitioner has a duty to update the record. If the error is not discovered by the practitioner or the inventor, the proposed rules provide no guidance as to the consequences.

[6] Section 1.78(f)(1).
[7] "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the USPTO, which includes a duty to disclose to the USPTO all information known to that individual to be material to patentability . . . ." 37 C.F.R. § 1.56 (2004).
[8] Although this problem might be resolved through the electronic filing system ("EFS"), which provides an application number within days, currently applications containing sequence listings and PCT applications cannot be filed via EFS.

Certainly, any error in identification could be fodder for an inequitable conduct allegation in litigation in the same way that rule 56 has traditionally been used.[9]

The proposed revisions to section 1.78(f)(2) build on the requirements of section 1.78(f)(1) by providing that if the two or more applications contain "substantial overlapping disclosure[s], . . . a rebuttable presumption shall exist that the 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."[10] Neither the case law nor the M.P.E.P. defines "substantial overlapping disclosure."[11] Under current practice, practitioners often disclose compounds (including genes, proteins, host cells, vectors, etc.), processes, formulations/compositions of matter, and multiple methods of use in one case, knowing that continuations can be filed later.[12] However, given the proposed changes relating to continuations and "limitation"[13] of representative claims, it is foreseeable that practitioners will voluntarily divide one application into numerous applications, each relating to a different aspect. Such applications will contain much of the same information, and depending on the definition of "substantial," the disclosures may have "substantial overlap" with each other. However, the claims in these related applications will be completely different, and thus patentably distinct. Yet, proposed section 1.78(f)(2) compels a presumption that at least one claim is patentably indistinct, placing the burden on the practitioner to rebut the presumption "to the satisfaction of the Director." If a petition to the Director is required, then the applicant must make two replies: a petition to the Director and a response to the examiner because "[t]he mere filing of a petition will not stay any period for reply that may be running against the application, nor act as a stay of other proceedings."[14] This will increase cost and burden to the applicant, for the mere purpose of administrative efficiency or convenience[15] to the USPTO.

[9] 37 C.F.R. § 1.56 (2004). *See, e.g., Novo Nordisk Pharms. Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 76 U.S.P.Q.2d (BNA) 1811 (Fed. Cir. 2005); *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 73 U.S.P.Q.2d (BNA) 1593 (Fed. Cir. 2005).

[10] Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48, 55 (Jan. 3, 2006).

[11] "Substantial overlap" is used in two cases: 1) an unpublished opinion, *In re Fujimura*, 130 Fed. Appx. 465, 76 U.S.P.Q.2d (BNA) 1630 (Fed. Cir. 2005); and 2) *Ex parte Karol*, 8 U.S.P.Q.2d (BNA) 1771 (Bd. Pat. Appeals & Interferences 1988). However, no definition or guidance is provided in these cases.

[12] Furthermore, current restriction practice is so varied from examiner to examiner that it is highly unpredictable how claims will be restricted or even whether they will be restricted.

[13] Although not actually a limitation, practitioners will be extremely hesitant to file an examination support document and will do so only when absolutely necessary. Thus, in practice, the proposal is a limitation on the number of claims in an application.

[14] 37 C.F.R. § 1.181(f) (2004).

[15] Note that the Court of Appeals for the Federal Circuit is wary of procedures set in place merely for the "administrative convenience" of the USPTO. *See, e.g., Transco Prods. Inc. v. Performance Contracting Inc.*, 38 F.3d 551, 559, 32 U.S.P.Q.2d (BNA) 1077, 1083 (Fed. Cir. 1994) ("Actions . . . taken by the PTO primarily for administrative convenience[] ***should not increase the burdens on an applicant*** regarding his ability to obtain patent protection.") (emphasis added); *Patlex Corp. v. Mossinghoff*, 771 F.2d 480, 483, 226 U.S.P.Q. (BNA) 985, 987 (Fed. Cir. 1985) (quoting *Cella v. United States*, 208 F.2d 783, 789 (7th Cir. 1953), *cert. denied*, 347 U.S. 1016 (1954); *see also Ohio Bell Tel. Co. v. Pub. Utils. Comm'n of Ohio*, 301 U.S. 292, 304 (1937))

Moreover, the quantity of administrative convenience provided by such a rule is questionable because it will increase the quantity of documents to be reviewed by the Director.

A more preferable approach, described in summary above, would be for the USPTO to use its electronic resources *immediately upon filing* of an application for patent to digest the full text of the patent specification, inventorship designation, and, if applicable, the assignee for the purpose of identifying other applications that it deems sufficiently related such that efficiency of the USPTO might be enhanced by the concurrent examination of all such related applications with one another. In other words, instead of imposing burdens on the applicant (and inherent risks of inequitable conduct arising from possible omissions and misrepresentations) to identify applications with a mechanical relationship to one another, the USPTO could more effectively use its resources to electronically identify applications that it has determined will create examination efficiencies through concurrent examination by the same patent examiner.

The above approach would have particular promise if the filing of continuation applications were time-limited to the publication date of the application and the USPTO eliminated restriction practice. By the time a patent examiner picked up an application for examination, the examiner would have the ability to simultaneously identify and consider all such other potentially related applications. Through rulemaking that should be within the existing statutory authority of the USPTO to encourage examination efficiency, the patent examiner could declare all such applications "concurrent examination applications" and require that a common assignee concurrently prosecute all such applications in a coordinated fashion. Such concurrent prosecution would assure that issues such as "obviousness-type" double patenting would not be overlooked as claims are amended in the concurrent prosecution applications.

Additionally under proposed section 1.78(f)(2), if an applicant submits a terminal disclaimer because two or more nonprovisional applications contain patentably indistinct claims, the applicant must explain to the satisfaction of the USPTO why both applications are necessary. Under proposed section 1.78(f)(3), if the reasoning for two or more applications with patentably indistinct claims supplied by the applicant under section 1.78(f)(2) is not deemed a "good and sufficient reason," then the USPTO "may require elimination of claims from all but one of the applications." The creation of this new bureaucracy is entirely misguided. Unless Congress acts to eliminate the right of applicants to seek multiple patents on patentably indistinct subject matter, the USPTO should not engage in rulemaking that

("Administrative convenience thus appears to be the sole basis for the rule. Although administrative convenience must be considered, 'administrative convenience or even necessity cannot override the constitutional requirements of due process.'"); Tr. of Hr'g for *In re Fisher*, 421 F.3d 1365, 76 U.S.P.Q.2d (BNA) 1225 (Fed. Cir. 2005) (No. 04-1465; Judge speaking to Mr. Walsh, Associate Solicitor for the USPTO) ("I have a feeling that you are [setting the utility standard high] largely for administrative convenience, and I question whether that's the proper motivation.").

differentiates between an inventor who files one patent application with ten claims or ten patent applications that each contains only one of those ten claims. Any adverse impact on the USPTO can be fully ameliorated by creating a simple mechanism that declares the ten applications as "concurrent examination applications." Given that the USPTO would collect multiple filing fees and multiple maintenance fees for each of the multiple applications, the USPTO would be *diminishing*, not enhancing its capacity to promptly examine and issue patents by creating a bureaucracy dedicated to assessment of this type of "good and sufficient reason."

Finally, as the rules have been proposed, in instances where all claims in the concurrent or subsequent nonprovisional application are deemed patentably indistinct, "elimination of claims" will mean elimination of the subsequent application. This is a severe penalty, given the ambiguity of the terms "good and sufficient" and decisions requiring "satisfaction of the Director" are usually non-appealable. Furthermore, the purpose for the restriction on double patenting is to protect the public from "unjustified extension of patent exclusivity beyond the term of a patent."[16] Same invention-type (*i.e.*, statutory) double patenting is already precluded by law.[17] Obviousness-type double patenting can be remedied by filing of a terminal disclaimer,[18] which prevents extension of patent life and thereby protects the public interest. In fact, the use of terminal disclaimers is a preferred remedy, according to case law and the M.P.E.P.:

> A rejection based on a nonstatutory type of double patenting can be avoided by filing a terminal disclaimer . . . . The use of a terminal disclaimer in overcoming a nonstatutory 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.[19]

Notably, both Congress and the Federal Circuit understood that applications which contain patentably indistinct claims might contain "additional developments" that will be useful to public, if disclosed. In light of this public interest, it appears that the only reason for not allowing multiple patents covering similar inventions, even with a terminal disclaimer, would be administrative convenience—a reason that "concurrent examination application"

[16] M.P.E.P. at § 804.
[17] 35 U.S.C. § 101 (2000). *See also* M.P.E.P. at § 804(II)(A).
[18] M.P.E.P. at § 804.02(II).
[19] *Id.* (citing *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. (BNA) 619 (C.C.P.A. 1970); *In re Jentoft*, 392 F.2d 633, 157 U.S.P.Q. (BNA) 363 (C.C.P.A. 1968); *In re Eckel*, 393 F.2d 848, 157 U.S.P.Q. (BNA) 415 (C.C.P.A. 1968); *In re Braithwaite*, 379 F.2d 594, 154 U.S.P.Q. (BNA) 29 (C.C.P.A. 1967); *In re Knohl*, 386 F.2d 476, 155 U.S.P.Q. (BNA) 586 (C.C.P.A. 1967); *In re Griswold*, 365 F.2d 834, 150 U.S.P.Q. (BNA) 804 (C.C.P.A. 1966)). *See also In re Berg*, 140 F.3d 1428, 1436, 46 U.S.P.Q.2d (BNA) 1226, 1233 (Fed. Cir. 1998).

designations would actually reverse. As mentioned above, while administrative convenience is an important consideration, it should not outweigh the public interest.[20]

Proposed Rules Restricting Initial Examination of Claims in an Application for Patent

Clarification Is Needed on the Examination of "Non-Designated" Dependent Claims.

Proposed section 1.75(b)(1) would require an applicant to submit an examination support document that covers each representative claim if either: (1) the application contains, or is amended to contain, more than ten independent claims; or (2) the number of representative claims (*i.e.*, the independent claims plus the number of dependent claims designated for initial examination) is greater than ten. The fate of non-designated claims appears to be addressed in the proposed amendment to 37 C.F.R. § 1.104(b), stating that "[t]he examination of a dependent claim that has not been designated for initial examination may be held in abeyance until the application is otherwise in condition for allowance." This suggests facially that all non-designated dependent claims will be fully examined once the examination of the designated claims is complete and the application is otherwise in condition for allowance. Slides from the USPTO presentations on the rules, however, state that if a representative independent claim is allowed, all of its non-designated dependent claims will be examined for compliance with only 35 U.S.C. §§ 101 and 112.[21] Failure to fully examine all claims deprives applicants of their judicially recognized "right to have each claim examined on the merits."[22] Furthermore, the USPTO's failure to fully examine every claim undermines the presumption of validity afforded an issued patent. The USPTO must clarify whether non-designated dependent claims will be fully examined.

Patents are presumed valid, and each claim within a patent is independently presumed valid, even if other claims within the patent are held invalid.[23] This presumption of validity is a critical element of the value proposition central to the social contract between the applicant and the public. Without a full examination on the merits of all allowed claims, the presumption of validity is seriously undermined.[24] Examination on the merits requires that claims are examined "for compliance with the statutory provisions of Title 35, United States

[20] *See supra* note 15.
[21] PTO Presentation: Summary of Proposed Rule Changes to Continuations, Double Patenting, and Claims, Slide 41.
[22] *In re Weber*, 580 F.2d 455, 458, 198 U.S.P.Q. (BNA) 328, 331 (C.C.P.A. 1978).
[23] 35 U.S.C. § 282 (2004).
[24] M.P.E.P. at § 706 ("An application should not be allowed, unless and until issues pertinent to patentability have been raised and resolved in the course of examination and prosecution, since otherwise the resultant patent would not justify the statutory presumption of validity, nor would it strictly adhere to the requirements laid down by Congress in the 1952 Act as interpreted by the Supreme Court.").

Code, as set forth in sections 100, 101, 102, 103, and 112."[25] Examination of claims for compliance with only sections 101 and 112 is simply not sufficient to assure the presumption of validity currently afforded to issued patents because compliance of an independent claim with the requirements of sections 102 and 103 does not invariable assure compliance of all claims dependent therefrom. For example, a reference may be available as prior art for a non-designated dependent claim not entitled to priority, yet the same reference may not be available as prior art to the designated independent generic claim entitled to an earlier provisional filing date. Examination of the dependent claim for compliance with only sections 101 and 112 could lead to the issuance of an invalid dependent claim on these facts.

In view of the foregoing, the proposed rules must be amended to clearly articulate whether non-designated dependent claims will be fully examined before allowance. If all claims will be fully examined, applicants can be assured of a presumption of validity. If all claims will not be fully examined, applicants will be required to assess whether to risk the liability of filing an examination support document or to limit the application's claim set to ten total claims to assure the presumption of validity during litigation.

The Availability of Terminal Disclaimers Makes New Section 1.75(b)(4) Unnecessary.

The USPTO is proposing new section 1.75(b)(4). Under this section, the USPTO may require elimination of "patentably indistinct claims" from all but one nonprovisional application in certain instances. Such an instance arises in the case when, for example:

1) nonprovisional application ("A") contains a claim that is patentably indistinct from a claim in one or more nonprovisional application ("B") or patent ("C");

2) B or C either names an inventor in common and is owned by the same person as A or is subject to assignment to same person as A;

3) the patentably indistinct claim in A has support under 35 U.S.C. § 112, first paragraph, in B or C.

If the patentably indistinct claims are not eliminated by the patentee, then the USPTO will treat all claims in A, both independent and dependent claims, as "designated" claims for initial examination in each one of applications: A, B, and C.

[25] *In re Harnisch*, 631 F.2d 716, 721, 206 U.S.P.Q. (BNA) 300, 304 (C.C.P.A. 1980); M.P.E.P. at § 706 ("In every art . . . , all of the requirements for patentability (e.g., novelty, usefulness and unobviousness, as provided in 35 USC 101, 102, and 103) must be met before a claim is allowed.").

Several issues arise from the proposed changes to section 1.75(b)(4). First, no guidance is provided regarding the meaning of the term "patentably indistinct"[26] or how claims will be compared to determine whether they are patentably indistinct. Understandably, if claims are patentably indistinct under statutory-type ("same invention type") double patenting, then the required elimination of claims from subsequent applications is warranted. However, if claims are determined to be patentably indistinct under obviousness-type ("nonstatutory") double patenting, then the required elimination of claims is inappropriate.

The terminal disclaimer is the appropriate means for addressing non-statutory double patenting rather than creating unnecessary new rules. "The use of a terminal disclaimer in overcoming a non-statutory 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."[27] Statutorily provided for in the 1952 Patent Act as 35 U.S.C. § 253,[28] terminal disclaimers have been upheld and endorsed by the courts in numerous patent cases.[29] While the elimination of claims appears administratively convenient at first blush, it strikes an inappropriate balance between administrative efficiency and the public interest. The terminal disclaimer, as it is currently applied to non-statutory double patenting, is an adequate means of addressing patentably indistinct claims and preferable to a new rule requiring the elimination of claims.[30]

Further, under the proposed USPTO rule changes, if the claims are deemed to be patentably indistinct and are not eliminated from the subsequent applications, then the USPTO will count all claims as "designated" claims. The application of new section 1.75(b)(4) could easily trigger the requirement to submit an examination support document under proposed section 1.261(a). The examination support document requirement will most likely increase rather than decrease overall USPTO workload because practitioners will try to avoid submitting such a document by filing several applications rather than a single application. In view of these administrative concerns and the fact that an adequate remedy already exists for

[26] Admittedly, the term "patentably indistinct" has been used in case law and the M.P.E.P. in situations relating to double patenting. *See, e.g.*, *Geneva Pharms. Inc. v. GlaxoSmithKline P.L.C.*, 349 F.3d 1373, 68 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2003); *Eli Lilly & Co. v. Barr Labs. Inc.*, 251 F.3d 955, 58 U.S.P.Q.2d (BNA) 1865 (Fed. Cir. 2001); M.P.E.P. at §§ 804-804.02. Notably, the lack of guidance provided for "patentably indistinct claims" is less vague than the lack of guidance for the term "substantial overlap," the term used in revised section 1.78(f), which is not prevalent in either the case law or the M.P.E.P.

[27] M.P.E.P. at § 804.02(II).

[28] *In re Van Ornum*, 686 F.2d 937, 938-39, 214 U.S.P.Q. (BNA) 761, 769 (C.C.P.A. 1982).

[29] *See, e.g.*, *In re Emert*, 124 F.3d 1458, 44 U.S.P.Q.2d (BNA) 1149, 1152 (Fed. Cir. 1997); *In re Lonardo*, 119 F.3d 960, 43 U.S.P.Q.2d (BNA) 1262 (Fed. Cir. 1997); *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q.2d (BNA) 2010 (Fed. Cir. 1993).

[30] In fact, if all claims in a second or subsequent application are deemed patentably indistinct, the entire application would be eliminated.

handling patentably indistinct claims, reconsideration of the new section 1.75(b)(4) is requested.

Alternatives in Markush Claims Are Adequately Determined Using 35 U.S.C. §§ 112 and 101 and the Elimination of Restriction Requirements.

The USPTO suggests counting each alternative in a Markush claim as a separate claim for purposes of § 1.75(b)(1), with the possibility of allowing an applicant to group alternatives in the claim by showing "that each alternative in the claim includes a common core structure and common core property or activity, in which the common core structure constitutes a structurally distinctive portion in view of existing prior art and is essential to the common property or activity." The USPTO has requested comments on how claims written in an alternative form, such as claims in a Markush format, should be counted for purposes of section 1.75(b)(1). The USPTO presumably proposes these ideas to reign in overly-broad Markush claims such as those described in the Town Hall presentation materials.

The USPTO should not promulgate new rules pertaining specifically to Markush claims to deal with this problem, but instead should apply existing patent laws, which emphasize that applicants must provide adequate enablement of an operable invention. Application of 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 101 should be the USPTO's primary means of assuring reasonable proportionality between contribution (*i.e.*, what is actually invented) and reward (*i.e.*, patent claim scope) by barring overreaching by applicants. It is proposed that by encouraging applicants to accurately and specifically define their invention, a Markush claim should be examinable under section 1.75(b)(1) without the need to designate it as more than a single claim.

Counting each alternative as a separate claim will not necessarily decrease application pendency time and appears inconsistent with the public interest in securing a full and complete examination of the claimed subject matter in an application for patent at the earliest possible time after the application has published. It is evident from the USPTO Town Hall Meeting and presentation materials that examination costs and burdens to the public are high for patents that contain exceedingly broad Markush claims to subject matter nowhere described and enabled in the patent specification. Therefore, the USPTO and public policy would be better served by making reasonable and fairly based rejections for lack of enablement whenever possible. Encouraging applicants to adhere more closely to existing 35 U.S.C. § 112, paragraph 1 and 35 U.S.C. § 101 requirements is a far better means of managing the breadth of Markush claims than the more radical change of individualized claim counting schemes and required showings.

Section 112, first paragraph, specifically requires that a patent application contain the manner and process of making and using the invention "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 same."[31] Further, enablement requires the specification to teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.[32] Upon presentation of a Markush claim by an applicant and determination of what the claim scope covers, an examiner must review the entire specification to find support including working examples, tables, schematics and drawings, if necessary, to implement the invention. Comparing the breadth of Markush alternatives with the disclosure will strongly encourage applicants to draw a closer relationship between the claim and the description, thus constraining claim scope.

A disclosure which does not adequately enable the invention claimed with respect to its asserted utility may also be raised in a rejection under 35 U.S.C. § 101.[33] The utility requirement of section 101 mandates that the invention be operable to achieve useful results.[34] "Thus, if the claims in an application fail to meet the utility requirement because the invention is inoperative, they also fail to meet the enablement requirement because a person skilled in the art cannot practice the invention."[35] A section 101 rejection would be particularly warranted where there is good reason to doubt that a useful activity has been determined or demonstrated in fact for the plurality of possible compounds encompassed by a Markush claim. In the most egregious examples, such as the Markush claim examples identified during the USPTO Town Hall meeting, a section 101 inoperability rejection would be warranted. The application of these enablement and utility principles would appropriately constrain Markush claims of undue breadth without counting each alternative as a separate claim.

Further, in practice, counting each alternative as a separate claim will at best have a neutral effect on application pendency time because it is unclear where the increased efficiency will occur in the examination process. If an applicant's claims include a Markush claim from which ten claims are "designated," the USPTO is still obligated to examine the remaining claims, including the Markush claim held in abeyance. Further, it is unclear whether alternatives in a Markush claim would be counted as independent or dependent claims for the purposes of the ten claim designation aspects of 37 C.F.R. § 1.75(b)(1). If counted as

[31] 35 U.S.C. § 112, para. 1 (2000) (emphasis added). *See also Application of Boon*, 439 F.2d 724, 729, 169 U.S.P.Q. (BNA) 231, 235 (1971).

[32] *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d (BNA) 1400, 1404 (Fed. Cir. 1988); To satisfy the enablement requirement of section 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. *Enzo Biochem, Inc v. Calgene, Inc.*, 188 F.3d 1362, 1371-72, 52 U.S.P.Q.2d (BNA) 1129, 1136 (Fed. Cir.), *reh'g and reh'g en banc denied* (1999).

[33] *Ex parte Stevens*, 16 U.S.P.Q.2d (BNA) 1379, 1380, 1990 WL 354529 (Bd. Pat. App. & Interferences 1990). The question of whether a specification provides an enabling disclosure under section 112, first paragraph, and whether an applicant satisfies the utility requirement of section 101 are closely related. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358, 52 U.S.P.Q.2d (BNA) 1029, 1034 (Fed. Cir. 1999), *cert. denied*, 529 U.S. 1037 (2000).

[34] *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d (BNA) 1401, 1412 (Fed. Cir. 1992), *reh'g denied, en banc suggestion declined* (1993).

[35] *In re Swartz*, 232 F.3d 862, 863, 56 U.S.P.Q.2d (BNA) 1703, 1704 (Fed. Cir. 2000).

independent claims, then virtually all Markush claims will trigger an obligation for a showing or submission of an examination support document under section 1.75(b)(1) because most Markush claims will have more than ten alternatives.

The new expression "common core property or activity," unnecessarily introduces a potential deviation from the internationally recognized "unity of invention" standard. The concept of unity of invention is typically applied to determine whether a claim contains unrelated inventions which are truly independent[36] and distinct.[37] A Markush claim is, in essence, a synthetic generic expression of usable members of an invention that will produce a resulting utility. As such, a proper Markush claim is comprised of structurally similar members that possess unity of invention.[38] A Markush claim that possesses unity of invention has traditionally been counted as a single claim. On its face, the USPTO proposed standard appears to be at least partially consistent with unity of invention principles in that "common core structure" imparts structural similarity into the analysis of a Markush claim. However, "essential to common property or activity" is an ambiguous new term which could result in alternatives appearing in a proper Markush group considered as more than a single invention. Substances appearing in a proper Markush group constitute a single invention.[39] Further, unity of invention is deemed to exist among substances which have a common function, and the substances may be recited in a single claim as a Markush group.[40] Seemingly, the USPTO seeks to do what is not otherwise allowable under US and international unity of invention principles, that is, to divide an otherwise proper Markush claim into separate alternatives for examination. This is unnecessary, as existing claim analysis rules and principles, including 35 U.S.C. § 112, first paragraph, 35 U.S.C. § 101 and unity of invention concepts, if applied consistently by the USPTO in the examination process, would foster Markush claims of appropriate breadth without the need to introduce new and potentially internationally inconsistent terms.

Finally, we believe that the USPTO must take as its starting point that its primary purpose is to thoroughly examine for patentability all claims to an invention presented for examination. For that to be a starting point for the USPTO, it means that, for each patent application filed, patent examiners must be accorded sufficient time to complete the

[36] The term "independent" means that "there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design operation or effect," as for example: (1) species under a genus which species are not usable together as disclosed; and (2) a process and apparatus incapable of being used in practicing the process. M.P.E.P. at §§ 806.02, 806.04.

[37] The term "distinct" means that two or more subjects are disclosed as related as, for example: (1) a combination and part (subcombination) thereof; (2) a process and apparatus for its practice; (3) a process and product made, which are each capable of separate manufacture, use or sale as claimed, and are patentable over each other. *Id*. at § 808.02.

[38] 2 Pat. L. Fundamentals § 14.15 (2d. ed.) (2005).

[39] *In re Harnisch*, 631 F.2d 716, 722, 206 U.S.P.Q. (BNA) 300 (C.C.P.A. 1980); *Daniels v. Daum*, 214 U.S.P.Q. (BNA) 911, 915 (Bd. Pat. App. & Interferences 1982).

[40] *Id*.

examination, based upon the size, number and complexity of claims, and scope of pertinent prior art that is material to the examination. That reality, in turn, dictates that the USPTO should have the authority to craft a fee schedule that produces from each patent application the user fee income needed for to this examination process. We believe that this fee-for-service approach would have the inherent benefit of discouraging precisely what the USPTO seeks to discourage—excessive numbers of claims not reasonably needed to fully protect an invention, but are nonetheless filed because the existing fee structure effectively subsidizes their examination.

In summary, consistent with all of our proposals for patent examination efficiency reforms, we would urge that the USPTO look to define its core mission as "if they come, we will build it" in terms creating the needed capacity for patent examination based upon what inventors desire to file and to claim. The corollary to that adage should be "when they come, they will pay for it." Given such a match between the services sought by inventors and services available from patent examiners, the USPTO would be positioned to vindicate the overarching public interest that a full and final determination of patentability of all claims to an invention be expeditiously concluded. The USPTO proposed rules look more to administrative expediency than to the interests of inventors seeking to best protect their inventions and to the interests of the public demanding that the USPTO promptly examine all the inventor's claims and make its final determination of patentability for all of them expeditiously.

We appreciate the opportunity to provide comments on the proposed rules and request reconsideration in view of the points made above.

Sincerely,

Arvie J. Anderson, Reg. No. 45,263
Paula K. Davis, Reg. No. 47,517
Robert D. Titus, Reg. No. 40,206
on behalf of Eli Lilly and Company