-----Original Message-----
From: David Korn [mailto:DKorn@phrma.org]
Sent: Tuesday, May 02, 2006 6:21 PM
To: AB94Comments
Subject: Attached Comments from PhRMA

Attached are comments on both the proposed "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications containing Patentably Indistinct Claims" and the proposed "Changes to Practice for the Examination of Claims in Patent Applications." Please do not hesitate to contact me if you have any questions.

Sincerely,

David E. Korn
Assistant General Counsel
Pharmaceutical Research and Manufacturers of America
950 F St., N.W.
Washington, D.C. 20004
Phone: 202-835-3509
Fax: 202-715-7033
Email: dkorn@phrma.org

David E. Korn
Assistant General Counsel

PhRMA

May 2, 2006

VIA EMAIL – AB93Comments@uspto.gov
AB94Comments@uspto.gov

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
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Robert W. Bahr, Esq.
Senior Patent Attorney
Robert A. Clarke, Deputy Director
Office of Patent Legal Administration

Dear Under Secretary Dudas:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the views of PhRMA's members on the proposed "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims," 71 Fed. Reg. 48 [Docket No.: 2005-P-066], as well as the proposed "Changes to Practice for the Examination of Claims in Patent Applications," 71 Fed. Reg. 61 [Docket No.: 2005-P-067]. PhRMA's members are leading pharmaceutical research and biotechnology companies, devoted to inventing and making available medicines that allow patients to live longer, healthier and more productive lives. PhRMA members lead the way in finding new cures, as well as in developing critically important improvements in existing therapies. Strong patent protection is required in order to promote the ongoing research of PhRMA members. This research, in turn, further promotes pharmaceutical innovation and benefits society.

The enclosed comments express the concern of PhRMA's members that the proposed rules would not achieve the laudable goals of improving office efficiency and patent quality, but instead would harm the interests of legitimate patent stakeholders. As set forth in the enclosed comments, PhRMA is concerned that, if implemented, the proposals would significantly limit,

and in some cases altogether preclude, the ability of PhRMA's members to obtain and enforce legitimate patent rights - patent rights that are necessary to recoup and justify the extraordinary costs of research and development of life saving medicines. For these and other reasons that are further elaborated in the enclosed comments, PhRMA urges you to reconsider the PTO's proposed rule changes regarding Continuing Applications and the Examination of Claims.

PhRMA's members understand that the PTO's goals in proposing these rules are to improve Office efficiency and the quality of issued patents. PhRMA's members support these underlying goals, and would welcome further dialog with the PTO with these goals in mind.

Please feel free to contact me with any questions or concerns you may have.

Sincerely,

David E. Korn

Enclosure

PhRMA

Comments of the Pharmaceutical Research and Manufacturers of America on Proposed Rules Regarding Continuation Practice and Claims Practice

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA members alone invested an estimated $39.4 billion in 2005 in discovering and developing new medicines, a 6.5% increase over 2004 R&D expenditures.[1] In 2005, PhRMA member companies invested a record 19.2 percent of domestic sales on U.S. R&D. *Id.* The societal benefits from such investment are undeniable. "New medicines generated 40 percent of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000."[2]

According to a recent report issued by PhRMA together with the National Organization for Rare Disorders (NORD) and the Genetic Alliance (GA), America's pharmaceutical research companies have made great strides in fighting rare diseases, with more than 160 new medicines to treat rare or "orphan" diseases approved by the FDA over the last decade.[3] According to the National Institutes of Health, more than 6,000 rare diseases affect a total of 25 million Americans. One in every ten Americans receives a diagnosis of rare disease. And, according to the FDA, 85-90% of rare diseases are serious or life-threatening, making the search for new treatments and cures all the more important. *Id.*

Moreover, entirely new compounds account for only a part of overall innovation. Like technological progress in general, pharmaceutical innovation is frequently cumulative and incremental. Albert Wertheimer et al., *Too Many Drugs? The Clinical and Economic Value of Incremental Innovations, in Investing in Health: The Social and Economic Benefits of Health Care Innovation* 77, 78 (Irina Farquhar et al. eds., 2001). The value of such incremental improvements should not be discounted. By enabling a choice between therapies that can be tailored for individual patients, diseases, or symptoms, a diverse array of related drugs and treatment formulations can significantly improve both medical results and patients' quality of life. Wertheimer et al., *supra*, at 78-79.

---

[1] Press Release, PhRMA, R&D Investments by America's Pharmaceutical Research Companies Near Record $40 Billion in 2005 (Feb. 13, 2006), *at* http://www.phrma.org/news_room/press_releases/r%26d_investments_by_america%92s_pharmaceutical_research_companies_nears_record_%2440_billion_in_2005/.

[2] PhRMA, *Pharmaceutical Industry Profile 2006*, p. 64, *at* http://www.phrma.org/files/2006%20Industry%20Profile.pdf.

[3] "A Decade of Innovation: Advances in the Treatment of Rare Diseases," (Apr. 20, 2006), *at* http://www.phrma.org/files/PhRMA%20Rare%20Diseases%2006.pdf.

PhRMA's members appreciate the importance of innovation – whether fundamental or incremental – to technological progress and social well-being. They also have an intimate appreciation of the importance of patent rights. In an industry where research and development is expensive and competition is fierce, strong patent protection is necessary for PhRMA's members to be able to recoup the costs of their investments. *See* Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries, in Science and Cents: Exploring the Economics of Biotechnology* 87, 88-92, 99-101 (John V. Duca & Mine K. Yücel eds., 2003). Commentators have suggested that without confidence in the availability and enforceability of such protection, the amount of such investment – and the pace of pharmaceutical improvements – would slow dramatically. *See* Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, at ch. 3, p. 11 & n. 48 (Oct. 2003) (reporting an estimate that, without patent protection, pharmaceutical innovation "would decrease by approximately 60%"); *see also* Grabowski, *supra*, at 88.

PhRMA is writing to comment on the proposed "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims," 71 Fed. Reg. 48 [Docket No.: 2005-P-066], and on the proposed "Changes to Practice for the Examination of Claims in Patent Applications," 71 Fed. Reg. 61 [Docket No.: 2005-P-067]. Both Notices of Proposed Rulemaking were published in Volume 71 of the Federal Register on January 3, 2006. PhRMA believes that any proposed PTO practice reform should focus on addressing perceived and actual abuses of patent office practice, and should not harm legitimate patent stakeholders. In particular, PhRMA agrees with the PTO that any proposed reform should focus on making the PTO more efficient, and improving the quality of issued patents.

But PhRMA believes that the proposed rules fail that test. Rather than enhance efficiency, they will further delay the process by promoting an increase in the number of original applications and appeals while injecting needless uncertainty about the prospects for approval of a continuation petition. This in turn will significantly harm the interests of legitimate applicants, including PhRMA members, who need a speedy approval process and who employ continuation practice in a *bona fide* effort to advance prosecution. The proposed changes are particularly pernicious with respect to requests for continued examination, where existing fees and filing requirements already provide a high barrier against abuse.

Continued examination is of particular importance to PhRMA's members, who would be disproportionately and adversely affected by the proposed changes. The proposed rules discriminate against the pharmaceutical industry because of the lengthy development cycle that is required to bring a new pharmaceutical product to market. PhRMA's members will be disproportionately affected because the proposed rules will restrict legitimate practices that occur in the later stages of prosecution, which typically coincides with important strategic decisions made in a pharmaceutical product's development cycle.

PhRMA's members invest billions of dollars annually in incremental research to develop therapeutic compounds having improved specificity, greater potency and reduced side effects.

As applicants, PhRMA's members are frequently confronted with demands by patent examiners for preclinical and clinical data to support claims to these specific pharmaceutical compounds, as well as claims to the broader class or genus of compounds that will often have been described in an earlier application. At the time of filing a patent application, the type of data demanded by examiners usually does not exist. Existing continuation practice permits PhRMA members in this situation to file continuation-in-part applications to introduce these data, and thereby protect their legitimate interests in such improved compounds and the broad class of compounds. The proposed changes to continuation practice could severely reduce and in some cases eliminate this entirely.

Moreover, and more fundamentally, PTO is simply without authority to change 140 years of patent law -- enshrined in statute for almost 60 years -- through regulatory fiat. Congress has afforded continuation applicants a right to the original filing date if certain requirements are met; only Congress may decide to further limit the availability of continuation applications.

PTO PROPOSED RULES

The PTO proposes that "second and subsequent continued examination filings, whether a continuation application, a continuation-in-part application, or a request for continued examination, be supported by a showing as to why the amendment, argument, or evidence presented could not have been previously submitted."

The PTO also proposes to amend the definition of "divisional application" as limited to an application that "discloses and claims only an invention or inventions that were disclosed and claimed in the prior-filed application, but were subject to a requirement of unity of invention under PCT Rule 13 or a requirement for restriction under 35 U.S.C. 121 and not elected for examination in the prior-filed application." As such, the PTO proposal limits a divisional application to a previously claimed invention, and no longer permits voluntary divisionals. The PTO also proposes that a divisional application (as newly defined) may claim the benefit of only a single prior-filed application.

The PTO proposes that "when an applicant (or assignee) files multiple applications with the same effective filing date, a common inventor and overlapping disclosures, the Office will presume that the applications contain patentably indistinct claims." In such situations, therefore, the PTO proposes that applicants "include either an explanation of how the claims are patentably distinct, or a terminal disclaimer and an explanation of why there are patentably indistinct claims in multiple applications."

The PTO proposes to delay examination of most dependent claims until an application is in condition for allowance, and to permit the PTO to limit its initial examination to representative claims including all independent claims and those dependent claims designated by an applicant. With the objective of reducing the PTO's examination burden, the proposed rule would limit an applicant to no more than 10 independent claims in any application, or to no more than 10

"representative" claims, i.e., the independent claims plus the number of dependent claims designated for initial examination.

To obtain examination of more than ten claims (whether independent or "representative"), an applicant would be required to submit an "examination support document" including a statement that a search was conducted and an explanation of the search, an information disclosure statement, an explanation of how the claims are patentable over the references cited, a statement of utility, and a showing of where each claim limitation is supported in the written description. The proposed rule would impose this burden on any applicant for normal examination of more than 10 claims. Moreover, failure to supply an examination support document "when necessary" would result in a reduction by the PTO of any patent term adjustment to which an application might otherwise be entitled.

THE PTO DOES NOT HAVE SUFFICIENT AUTHORITY TO IMPLEMENT THE PROPOSED RULES

Under established law, the proposed rule on continued examination practice is contrary to statute and thus exceeds the statutory authority of the PTO. The sole authority for the proposed rule cited in the preamble is 35 U.S.C. § 2(b)(2), a subsection providing that, in certain circumstances, the PTO "may establish regulations, *not inconsistent with law.*" (Emphasis added). Neither this general grant of rulemaking authority nor any other statutory provision speaks directly to the PTO's authority to regulate or limit the use of continued examination filings. The proposed rule does not comply with the substantive elements of the patent laws set forth by Congress and, accordingly, exceeds the PTO's authority under § 2(b)(2).

Continued examination filings are a longtime practice approved by the Supreme Court for more than 140 years. In *Godfrey v. Eames*, 68 U.S. (1 Wall) (1864), the Supreme Court held that a patent applicant who filed a revised version of his application the same day he withdrew the original application was entitled to the original filing date. Congress ultimately enshrined this court-developed practice in the federal code in 1952. 35 U.S.C. § 120. *See* Chisum, *Patents* § 13.02. As amended in 1984, § 120 provides:

> 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.

Thus, under Section 120, an applicant is entitled to the filing date of a prior application if the applicant meets certain conditions enumerated in the statute itself. Specifically, "[i]f the continuation application meets the requirements of continuity of disclosure, copendency, cross-referencing, and identity of inventorship, it will gain the benefit of the filing date of the prior application in determining patentability and priority." Chisum, § 13.01.[4]

Over the years, despite some concerns about continuation practice and resulting delays in the examination of patent applications, the courts have consistently ruled that Congress alone can change the requirements and framework of continuation practice by limiting continuation applications. *In re Ernst Johan Jens Henriksen*, 399 F.2d 253 (C.C.P.A. 1968), presented the question whether § 120 could be read to "limit an applicant to the benefit of the filing date of the second preceding application in a chain of copending applications." *Id.* at 254. The Patent Office Board of Appeals had so held. The Court of Customs and Patent Appeals, the predecessor to the Federal Circuit, reversed:

> [U]nder [§ 120], in view of its longstanding interpretation by the Patent Office and the patent bar, there is no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest in a chain of copending applications, provided the applicant meets all the other conditions of the statute.

Id. In reaching this conclusion, the court conducted a thorough examination of all possible support for the contrary view.

The court rejected the argument that the text of § 120 itself required the reading advanced by the Board, and found nothing in the legislative history to support the limits the Board sought to impose. Turning to practical considerations, the court found that in "practice prior to" the enactment of § 120, "an applicant was not limited to a chain of three copending applications for the purpose of claiming an early effective filing date." *Id.* at 259. As further support, the court cited relevant treatises that reflected no limits on the number of continuation applications under § 120. *See id.* at 260 n.17 (citing 2 Robinson, *The Law of Patents* 204 (1890) ("It is immaterial how many of these substituted applications may be filed or for how long a period such efforts to obtain a patent may be continued."); 1 Rogers, The Law of Patents 21 (1914) (". . . and that no number of successive applications indicates an intention to abandon; but that, in reference to the

---

[4] Under the Uruguay Round Agreements Act, effective since June 8, 1995, a continuation application merely preserves, rather than extends, the original exclusivity period. This is because the Act provides that a patent term is twenty years from the date of *filing*, with limited exceptions. Uruguay Round Agreements Act, Pub. L. No. 103-465, 1994 U.S.C.C.A.N. (108 Stat.) 4809-5053.

question of abandonment, all such may be regarded as one application, the ones subsequent to the first being known as 'continuing' applications.")). And it remarked upon the absence of case law to the contrary prior to the statute. Indeed, from early decisions, the Supreme Court "has not seemed to question the right of the later-filed application to rely on an earlier-filed application, nor has it questioned—although the point does not seem to have arisen – the right to rely on more than two successively preceding applications." *Id.* at 260. It also found that no case since the enactment of the statute supports the position adopted by the Board of Appeals.

Critically, the court agreed with the dissenters in the Patent Office Board of Appeals that only Congress has the power to address any policy problems occasioned by this set of statutory provisions, specifically holding that neither the Board of Appeals nor the federal courts can modify what Congress has set forth. "It is our view, as the judiciary, that it is for the Congress to decide, with the usual opportunity for public hearing and debate, whether such a restriction as sought by the board is to be imposed." *Id.* at 262; *see also id.* ("[T]he cure . . . rests with Congress, not with us. If a restriction is to be imposed, it must be based upon law, legislatively or judicially expressed.") This holding, including specifically the determination that any change must come from Congress, was reiterated a decade later in *In re Hogan,* 559 F.2d 595, 604 n.13 (C.C.P.A. 1977) ("The 24 years of pendency herein may be decried, but a limit upon continuing applications is a matter of policy for the Congress, not for us.").

The PTO's attempt to impose similar limits in the proposed rule is likewise foreclosed. The proposed rule would limit a patent applicant's right to submit continued examination filings to one such filing, requiring approval of a petition by the applicant for any subsequent filings. The PTO cites no specific statutory authority supporting the power it asserts to impose this new burden on patent applicants. Section 120, which lays out the requirements for such a filing, forecloses additional requirements; the statute states that filings meeting the requirements "*shall* have the same effect, as to such invention, as though filed on the date of the prior application." (emphasis added). Moreover, in practice, the new petition requirement under the proposed rule could well serve as far more than a procedural hurdle to subsequent filings. The proposed rule fails adequately to outline how the petition requirement is to be applied, leaving open the possibility that they serve to limit outright continued examination filings. As demonstrated by *Henriksen* and *Hogan,* it would violate Congress's affirmative command to deny the original filing date to an applicant who meets the statutory requirements on the ground that he failed to meet an additional, agency-created hurdle. To the extent the petition requirement fails to limit such filings it will serve only to increase the burdens of the application process without serving a legitimate purpose; to the extent it substantively curtails applications that would otherwise be entitled by statute to the original filing date, it is ultra vires.[5]

[5] Nor do the statutory defects of the proposed rule end with § 120. The very idea of a petition to accompany any subsequent continued examination filings appears to give the PTO an element of discretion in whether to review applications that the statute does not envision. *See, e.g.,* 35 U.S.C. § 131 ("The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefore.").

In examining challenges to agency rules, courts must "hold unlawful and set aside agency action" that is arbitrary, capricious, an abuse of discretion or contrary to law. 5 U.S.C. § 706(2). The Supreme Court outlined the framework for judicial review in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984). Under the first step of *Chevron*, courts must consider "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If Congress has done so, "that is the end of the matter," and the question for the court is simply whether the regulation comports with congressional intent. *Id.* If, however, "the statute is silent or ambiguous with respect to the specific issue," then, under the second step of *Chevron*, "the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. Because Congress has spoken directly to the requirements for continuation applications, the analysis of the proposed rule here at issue stops at the first step of the *Chevron* analysis: The rulemaking authority of the PTO cannot be employed to fashion policy and correct perceived inadequacies in ways that violate the law. The proposed rule therefore is ultra vires, plainly exceeding the authority of the PTO under § 2(b)(2).

THE PROPOSED RULES WILL NOT MAKE THE OFFICE MORE EFFICIENT OR IMPROVE THE QUALITY OF ISSUED PATENTS

Even if the PTO has sufficient authority to implement the proposed rule changes, PhRMA does not believe that the present proposals will make the PTO more efficient or improve the quality of issued patents.

PTO Rationale for Proposed Rules

The PTO asserts that the proposed rule changes will reduce the backlog of unexamined applications (and, by extension, the resulting pendency of each application) because "each continued examination filing, whether a continuing application or request for continued examination, requires the United States Patent and Trademark Office (Office) to delay taking up a new application and thus contributes to the backlog of unexamined applications before the Office." The PTO also asserts that "[i]n [an unlimited] string of continued application filings, the exchange between examiners and applicants becomes less beneficial and suffers from diminishing returns as each of the second and subsequent continuing applications or requests for continued applications or requests for continued examination in a series is filed."

With respect to the presumption that applications having the same effective filing date, a common inventor, and overlapping disclosures are presumed to contain patentably indistinct claims, the PTO asserts that "[t]he 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," and that "it will be the applicant's responsibility to assist the Office in resolving double patenting situations rather than taking no action until faced with a double patenting rejection."

The PTO's position on its proposal to limit the number of claims it will examine in an application is that this rule change will "allow the Office to do a better, more thorough and

reliable examination since the number of claims receiving initial examination will be at a level which can be more effectively evaluated by an examiner."

Negative Consequences of PTO Proposed Rules

Continued Application Practice

The proposed rules limiting continued examination will have little or no impact on the backlog of unexamined applications. By the PTO's own calculations, only about 3.7 percent (or 11,790 out of 317,000) of applications filed in fiscal year 2005 were a second or subsequent continuation or continuation-in-part application, and only about 3.1 percent (or 9,925 out of 317,000) were a second or subsequent request for continued examination. Targeting a decrease in what is admittedly a very small percentage of current applications will not reduce the backlog.

In fact, the proposed rules could create an incentive for applicants to increase the number of original application filings, because applicants will want to ensure that all subject matter is sufficiently examined and prosecuted to issue. Implementation of the proposed rules could also result in an increased number of appeals to the Board of Patent Appeals and Interferences and the federal courts. The PTO has not detailed how it intends to handle these increased filings, which will further increase total pendency time.

Nor has the PTO detailed how the proposed changes will have any favorable impact on ensuring patent quality. In particular, the PTO has not detailed any proposal to reevaluate the examiner quota system, standards governing the circumstance under which a final rejection can be made, or the standards for submission of an amendment, argument, or evidence in response to a final rejection. To truly increase Office efficiency, there must be a sufficient nexus between the examiner quota system and the amount of work required to examine a continued application compared to an original application. Simply put, examiners must not have an undue incentive to issue a final rejection or otherwise necessitate a continued application filing.

The proposed rules also fail to acknowledge that in most cases, continued application practice is a *bona fide* attempt by a legitimate applicant to advance prosecution. For example, the submission of newly identified prior art or comparative testing data, the addition of new matter in the case of a continuation-in-part application, and the initial acceptance of narrow claims with the option to pursue broader claims are all *bona fide* attempts to advance prosecution that are regularly employed by legitimate patent stakeholders. The current exchange between examiner and applicant allows for a non-adversarial resolution of complex issues to the mutual satisfaction of both the examiner and the applicant, without being unduly limited by an arbitrary cutoff.

This is particularly the case for continued application practice with respect to a request for continued examination. RCEs are used to expedite prosecution by providing the applicant with an opportunity for further amendment and/or argument as a matter of right. Examiners typically act quickly to process an RCE. RCE practice often advances prosecution to allowance, thus

avoiding the requirement for appeals or continuation applications. No limitation is necessary to prevent abuse of the RCE process, because of the significant fees associated with the RCE filing, and because the RCE filing requires a submission that necessarily demonstrates the applicant's *bona fide* attempt to advance prosecution. Accordingly, while PhRMA opposes the proposed rule changes in their entirety, PhRMA is particularly opposed to the proposed rule changes to the extent that they encompass RCEs.

PhRMA is also particularly troubled by the PTO's proposed requirement that an applicant requesting a second or subsequent continuing application must petition the Office with a showing of why "the amendment, argument, or evidence presented in the continuation could not have been submitted in the earlier filed, parent application." The proposed petition process will introduce its own inefficiencies. For example, the PTO has not described how it intends to process these petitions. This uncertainty could discourage applicants from filing a petition and further burden the appeals procedure. In addition, PhRMA is concerned that the proposed standard for approval of the petition is unclear, may be difficult to meet, and may require applicants to argue against their interests. If the standard is too restrictive, the result will be the *de facto* elimination of second or subsequent continuation practice.

The proposed rules would also restrict the legitimate practice of drafting claims to cover a competitor's product, or to provoke an interference based on an allowed claim, in a pending continuation application. This long-standing practice was reaffirmed by the Federal Circuit in *Kingsdown Medical Consultants, Ltd. v. Hollister, Inc.*, 863 F. 2d 867, 874 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989):

> [T]here is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; 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.

While PhRMA recognizes that this practice has been subject to perceived abuses in certain extreme cases, there are other mechanisms for dealing with abusers who have no legitimate interest in advancing prosecution. Placing restrictions on continuation application filings will prevent applicants from protecting what the Federal Circuit has held to be legitimately patentable subject matter.

Divisional Application Practice

In addition to the limit on the number of continuation applications, the proposed rules allow for divisional filings, but only if the divisional is filed directly off of a parent application that has been subjected to a restriction requirement. This requirement is also likely to result in a significant increase in the current backlog of unexamined applications, because applicants will have no choice but to file and prosecute all of the restricted subject matter in divisional

applications prior to the expiration of the parent application in order to obtain the same degree of protection for their inventions as is afforded to them under the current rules of practice.

For example, it is not uncommon in the pharmaceutical, chemical and biotechnology arts to receive a five- to ten-way restriction requirement as a first office action in an application. Many applicants are highly unlikely to have the financial resources to file and prosecute five to ten divisional applications simultaneously, but are instead more likely to prosecute the restricted groups in sequence, depending on the relative importance of each group as dictated by the course of research. Under the PTO proposal, however, an applicant will have no choice but to file an application directed to the subject matter of each restricted group prior to the expiration of the parent application. Accordingly, in response to the hypothetical five- to ten- way restriction requirement, the applicant will be forced to file five to ten separate applications in short order. These sheer numbers dictate that the proposed change will only further increase the PTO's backlog, and require a significant up-front monetary investment by applicants in the form of PTO fees. This estimate is also likely to be a conservative one. Anecdotally, some practitioners report having received restriction requirements designating 50 or more groups, which, following the logic of the proposed rules, would require the filing of 50 new divisional applications prior to expiration of the parent application.

In addition, the proposed divisional practice affects PhRMA's members disproportionately because of the pharmaceutical industry's long product development cycle. If the proposed rules are implemented, the decision of whether to file any divisional application would come earlier in the development cycle, and would require an applicant to make this decision with less information in order to avoid a loss of rights.

The proposed rules regarding divisional applications also eliminate the filing of voluntary divisionals, i.e., those divisionals that may be initiated by the applicant other than in response to a restriction requirement (or unity of invention requirement in the PCT). Voluntary divisionals serve a useful purpose in advancing *bona fide* prosecution, and allow applicants to protect inventions that in hindsight prove to be useful, but may not have been claimed initially. Any limitation on divisionals, and particularly on voluntary divisionals, will result in the unintended dedication of disclosed but patentable subject matter to the public merely due to the timing of the filing.

Double Patenting Practice

Again, the proposed rule is not expected to impact a large percentage of applications, so the implementation of this rule will not significantly alleviate the burden of examination on the PTO, or have a significant impact on the backlog of unexamined applications. In fact, the proposed rule is also likely to increase the PTO's burden, because an applicant will likely appeal cases where the PTO does not accept the applicant's rebuttal of the double patenting presumption, or concludes that the explanation accompanying the terminal disclaimer is not persuasive. The proposed rebuttable presumption is not appropriate because it is inconsistent

with the examiner's burden of initial examination, and may place an undue burden on applicants to make statements that may be against their interest.

Limiting the Number of Claims Examined

The proposed rule is not likely to reduce PTO backlogs or application pendency times, because arbitrarily limiting an applicant to ten independent claims, when coupled with the onerous requirement for an examination support document to justify examination of additional claims, will instead drive applicants to file more applications of narrower scope in order to adequately protect their inventions. Moreover, the PTO offers no objective support for its rationale that fewer claims will result in "better, more reliable examination." The proper goal of examination of patentable inventions is allowable claims that clearly define the metes and bounds of the embodiments of an applicant's novel and non-obvious contributions to the art, and this goal is not necessarily correlated with any particular number of independent or dependent claims. Indeed, more claims may be preferable in many applications to facilitate an examiner's (and the public's) understanding of the specific embodiments of an applicant's invention. Because the PTO intends that its rule changes will apply retroactively, the cost to applicants with pending applications containing more then ten claims will be enormous. The expense of attorney time required to contact clients to identify ten representative claims, and to prepare and file a designation letter with the PTO, could be staggering considering that as many as some 600,000 applications are now awaiting examination.

Requirement for an Examination Support Document

The PTO's proposed requirement that an applicant submit an Examination Support Document (ESD) to obtain initial examination of more than ten claims places applicants in an untenable position and will prove unworkable. When considered in conjunction with existing inequitable conduct law as applied in patent litigation in the federal district courts, the presence of an ESD in an application prosecution file history poses a downside risk that far outweighs the cost.

According to the proposed rules, the applicant will be responsible for designing and carrying out a prior art search, and this would expose the patentee in subsequent patent litigation to a charge of inequitable conduct based on an inadequate search, where additional art comes to light during the litigation (often as the result of heroic and expensive searches by the accused infringer). Moreover, the proposed rules require that an applicant search for every limitation of the claims being examined, leaving the applicant open to the charge that one or more claim limitations was not reflected, or was inadequately reflected, in the search strategy. Because the proposed rules require the applicant to report the date on which the search was conducted, he or she could expect to be accused of performing the search too early, to avoid finding and disclosing more recent art. Under the proposed rules, the applicant is tasked with searching "disclosed features that *may* be claimed" (emphasis added). Claimed features often change over the course of prosecution, as the examiner cites art against the claims during prosecution, and the applicant amends his or her claims to distinguish them. If the applicant fails, even innocently, to search for

each and every feature that may be claimed, he or she can expect to be attacked if the litigated claim recites a feature not covered in the initial search.

The proposed rules specifically preclude an applicant from relying on an independent prior art search carried out by a foreign patent office, requiring the applicant to review the search and to essentially warrant that it meets the requirements of the rules. This requires that an applicant analyze the documents cited in the search, decide which are the most relevant, and present them to the PTO in an information disclosure statement (IDS). Any error by the applicant in carrying out this newly shifted burden, whether inadvertent or not, will prove fertile ground for an inequitable conduct attack, and will place yet another cloud over the legitimate rights of patentees under the PTO's proposed rules. Any statement required of an applicant characterizing the art or the applicant's invention is likely to be asserted in subsequent litigation to have estoppel effect. In effect, the PTO, by this proposed rule change, would shift the burden of examination from the PTO to the applicant, in such a manner that any mistake an applicant might make, for any reason, will undermine the validity of any resulting patent. As a result, applicants may not utilize the ESD procedure if it were to be implemented, and the PTO will fail to achieve the desired improvements.

Markush Practice Effectively Eliminated

PhRMA's members will be disproportionately disadvantaged by the effective elimination of so-called Markush claiming practice that is implicit in the PTO's request for "comments on how claims written in the alternate form, such as claims in an alternative form permitted by *Ex parte Markush* . . . should be counted for purposes of proposed § 1.75(b)(1)."[6] The PTO Notice goes on to posit two alternatives: (1) whether the Office "should simply count each alternative in the claim as a separate claim for purposes of § 1.75(b)(1);" or (2) whether the Office should "count each alternative in the claim as a separate claim for purposes of § 1.75(b)(1) unless the applicant shows 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 (*see* MPEP 1850)."

A Markush-type claim recites alternatives in a format such as "selected from the group consisting of A, B and C." *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925); Manual of Patent Examining Procedure (MPEP) § 803.02. Markush-type claims are often used in the pharmacy, pharmacology and biology arts, among others, *Id.*, and PhRMA's members would be inordinately disadvantaged if the proposed changes to Markush practice were implemented. The Markush-type claim has benefited both the PTO and applicants, because it has been proven over many years to permit efficient search and examination of claims that, when allowed, provide reasonable protection for an applicant's invention.

[6] § 1.75(b)(1) provides for an Examination Support Document (ESD), discussed *supra*.

The two alternative treatments of Markush claims under § 1.75(b)(1), to which the PTO implicitly limits debate, could effectively eliminate Markush practice, as it exists today. Alternative 1 could essentially impose a tax on certain types of inventions, including those of PhRMA's members; a tax that does not exist to a substantial extent with respect to most other types of inventions. Alternative 2 would improperly shift the burden from the PTO to applicants seeking to avoid this unwelcome tax, unnecessarily exposing them to many of the risks discussed above with respect to the proposed ESD practice. Neither of these alternatives would be acceptable, and either could lead to increased backlogs for the PTO, increased risks and costs for applicants. Effectively eliminating Markush practice, as the PTO appears determined to do, would be ill advised and counter-productive for all concerned.

ALTERNATIVE PROPOSALS

The PTO should consider alternative proposals that will have a direct impact on efficiency and improving patent quality, including better training for examiners, streamlined search and examination procedures, a deferred examination system, and a graduated fee structure.

PTO examiners must be provided with sufficient training in order to develop the skills that are required to thoroughly examine the claims submitted in each patent application. Examiners should be trained to sufficiently evaluate all of the claims in an application from the outset, and need to be provided with the resources required to conduct and evaluate a comprehensive prior art search. In addition, the Examiner quota system should be revised to more directly reflect the amount of work required to generate a first office action as compared to a second or subsequent office action in a particular application, as well as the effort required to examine a continued application compared to an original application.

The PTO should also make effective use of searches conducted in counterpart applications as a starting point for examination. For example, applications filed in the US via the PCT national phase have a search report, as well an IPER, or a written opinion for applications filed after the adoption of the Enhanced International Search System. These searches and examination reports should be considered as a starting point for the US examination in the relevant applications to increase examiner efficiency. The PTO should also work cooperatively with the patent offices of other nations to carry out search and examination services for national applications. PhRMA believes that cooperation with other patent offices, along with focused training of PTO examiners on the interpretation of prior art search results, will produce a more efficient examination by allowing examiners to concentrate their efforts on the substantive analysis of an application. Increased cooperation with the patent offices of other nations will lead to a more effective exploitation of search and examination results in the PTO.

The PTO should consider the implementation of a deferred examination system, on at least a temporary basis, as a practical way to reduce the application backlog at the PTO, provide greater value to PTO customers, and limit the issuance of multiple patents in certain situations. A deferred examination system, similar to the system in effect for many years in Japan, would give an applicant the option of delaying examination for a period of years (as long as seven years

in the past in Japan and currently as long as three years). This would reduce the number of applications being substantively handled by the office. Further, it would allow applicants time to determine whether a particular invention was economically viable prior to committing additional resources, and tapping the resources of the PTO, to undertake the process of substantive examination. This deferral option would also allow applicants to more fully investigate the state of the particular technology prior to substantive prosecution, and would increase the overall efficiency of the examination process.

It is expected that the pendency of all applications would drop if deferred examination were implemented, because substantive examination would typically not begin until after the deferral period (which would not count against pendency) had elapsed. In addition, a portion of applications filed could be expected to be abandoned by applicants during the deferral period, without the expenditure of PTO resources on substantive examination, further reducing the burden on the PTO. A deferred examination system would be consistent with the public notice function of the patent system, because it would not affect existing pre-grant publication, which occurs at eighteen months from the first priority date in the great majority of cases. Adoption of a deferred examination system would reduce the application backlog at the PTO and improve the quality of the patent system, without unnecessary adverse effects on legitimate stakeholders. Deferred examination would also be a positive and useful step toward harmonization of the world's major national patent systems.

The benefits of a deferred examination system suggest that it merits consideration by the PTO. If such a system is adopted, the PTO may wish to consider also implementing a procedure for accelerated examination. This could benefit applicants and the PTO alike by permitting rational allocation of PTO resources preferentially to patent applications directed to inventions believed to be of particular commercial importance. The PTO may also wish to consider permitting third party requests to accelerate examination of patent applications after a certain period of pendency where there has been no filing of an examination request by the applicant.

The PTO may wish to consider implementing an increased graduated fee structure for continuing applications. The PTO should allow continuing applications as of right, but could consider charging incrementally higher filing fees, search fees, and/or claims fees, to the extent that such fees are directly related to the costs, for third and later continuing applications. An incrementally higher continuing application fee structure could provide incentive for applicants to limit the number of continuing application filings and achieve the benefit of efficient examination, but would still allow applicants an opportunity to pursue subsequent filings if warranted.

CONCLUSION

PhRMA wishes to express its appreciation to the PTO for this opportunity to comment for the record on the agency's proposed rulemaking. PhRMA and its members are committed to actively contribute to finding solutions to the many challenges facing the PTO today and in the years to come. The PTO's proposed changes to patent application practice and procedure would

be far-reaching and are controversial, and PhRMA believes that it is not alone in viewing many of these proposals as less than well-suited to achieving the improvements to the patent examination system that are necessary and desirable. PhRMA would encourage the agency to consider extending the dialog with stakeholders, through additional notice and comment proceedings that include public hearings, in order to ensure a fully transparent process and encourage the broadest possible input. PhRMA would also welcome the opportunity to meet with the PTO in order to develop reforms that would focus on making the PTO more efficient and improving the quality of issued patents.

May 2, 2006