From:
Sent: Friday, August 13, 2010 1:41 PM
To: Restriction_Comments
Subject: Attached Comments from PhRMA

Attached are comments in response to the "Request for Comments on Proposed Changes to Restriction Practice in Patent Applications." Please do not hesitate to contact me if you have any questions.

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PhRMA

August 13, 2010

VIA EMAIL: Restriction_Comments@uspto.gov

Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Linda S. Therkorn

Dear Ms. Therkorn,

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the views of PhRMA's members in response to the "Request for Comments on Proposed Changes to Restriction Practice in Patent Applications," 75 Fed. Reg. 33584 [Docket No.: PTO-P-2010-0030]. PhRMA's members are leading pharmaceutical research and biotechnology companies devoted to researching and developing new medicines to allow patients to live longer, healthier and more productive lives. PhRMA members lead the way in finding cures and new treatments as well as in developing critically important improvements in existing therapies. Strong patent protection is required in order to promote the innovative research necessary for such advances and to make available to society the benefits of that research.

The enclosed comments include views of PhRMA's members on restriction practice. PhRMA's members appreciate the PTO seeking comments in the area, and would welcome further dialogue with the PTO on the issue.

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

Sincerely,

David E. Korn
Senior Assistant General Counsel

Enclosure

Comments of the Pharmaceutical Research and Manufacturers of America
Docket No.: PTO-P-2010-0030
August 13, 2010

Comments of the Pharmaceutical Research and Manufacturers of America in Response to the Request for Comments on Proposed Changes to Restriction Practice

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments in connection with the Patent and Trademark Office (PTO) Notice, "Request for Comments on Proposed Changes to Restriction Practice in Patent Applications," 75 Fed. Reg. 33584 (June 14, 2010). As the PTO recognizes, restriction practice has a significant impact on users of the patent system, and a continuing dialog with patent applicants will do much to promote the development of efficient practices and support from the patent community.

PhRMA's member companies are leading research-based pharmaceutical innovators devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA's membership ranges in size from small companies to multi-national, multi-billion dollar corporations that employ tens of thousands of Americans, and encompass both research-based pharmaceutical and biotechnology companies.

The research-based pharmaceutical sector is one of the most knowledge-intensive enterprises in the U.S. economy, and is responsible for 80% of the world's global healthcare biotechnology research and development ("R&D").[1] In 2009, the biopharmaceutical industry invested more than $65 billion in R&D. This sector also is the source of high-quality, high-value jobs and economic growth. Analyses show that the industry supported more than 3.2 million jobs, and directly employed more than 686,000 Americans in 2006.[2] The industry's direct contribution to GDP in 2006 was $88.5 billion – more than triple the average contribution of other sectors.[3]

Patents are intellectual property rights that provide a critical incentive to allow pharmaceutical companies and their investors to realize the benefits of their significant investments. They not only stimulate the early-stage discovery and development of new medicines, but also safeguard the sector's ability to carry out the lengthy and costly clinical investigations that are essential for ensuring that those medicines are safe and effective. The research-based pharmaceutical sector faces significant challenges to the discovery, development, testing, production, and ability to commercialize new medical treatments. Adequate, timely, and legally effective protection of intellectual property is an economic prerequisite for securing the R&D investments needed to develop tomorrow's medical advances against the most challenging

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1 Burrill and Company, analysis based on publicly available data, 2009.

2 Archstone. The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels. Washington, DC: Archstone Consulting, 2009.

3 *Id.*

and costly diseases. According to a recent study, when innovation is protected with strong intellectual property, "jobs are created, economies grow, and societies advance."[4]

Bringing new life-saving and life-improving products to patients is the central role of our member companies. Because intellectual property is critical to carrying out this mission, PhRMA members have a strong interest in efforts designed to improve the patent prosecution process and enhance the quality of patents.

Below we provide general observations about restriction practice as well as comments on the discussion points outlined in the PTO's Notice.

I. General Comments

PhRMA's member companies appreciate the need of the PTO to manage its workflow through restriction practice. When used effectively, restriction requirements allow patent examiners and applicants to resolve distinct patentability issues in separate applications. Indeed, several of the PTO's constructive proposals in its Federal Register Notice appear aimed at improving the effectiveness of examination in this regard.

When restriction requirements are imposed arbitrarily, however, the efficiency of patent examination is degraded. As the PTO undertakes efforts to reduce its backlog of unexamined applications, its objective for restriction practice should be to complete the examination of the greatest possible scope of claimed subject matter with a given expenditure of examination resources. Restriction requirements that lead to a proliferation of closely related divisional applications, each involving substantially similar patentability issues, will exacerbate the backlog. The PTO should continually remind its examiners that an essential prerequisite for *any* restriction requirement is that the restricted claims *must* justify the issuance of separate patents.

A concern of cardinal importance to PhRMA's members involves the consistency of restriction practice within the PTO. Individual examiners may view the restriction authority as a procedural tool to manage their workload and thereby impose restrictions based on short-term workload issues, without regard to the long-term implications of segregating claims to related inventions in separate applications. Applicants are given no choice but to acquiesce to a restriction, even though it may reflect divergent views between examiners in the same art unit, or between the examiner of an original application and examiners of later divisional applications, as to how a particular claim set should be restricted. The resulting mismatches and overlaps of claimed subject matter compromise the ability of patentees to license and enforce their patents and complicate the efforts of innovator companies to manage their patent portfolios. Unpredictability in the application of the PTO's restriction authority also frustrates planning and budgeting for intellectual property procurement.

[4] *Id.* at 3.

The PTO should take steps to rectify the unpredictable and often arbitrary nature of restriction practice through substantive and procedural measures. Examiners need to be provided clear guidance regarding not only when it is proper to impose a requirement for restriction, but when it is preferable – both for the applicants who are entitled to have their inventions examined fully, and for the interests of the PTO in managing its workflow and backlog – *not* to exercise the discretionary authority to require patent applicants to restrict their claims. The consistent application of such guidance needs to be encouraged and, as needed, enforced through more effective review of restriction requirements.

PhRMA also encourages the PTO to evaluate adoption of the "unity of invention" practice followed by most other countries to manage the work implicated by a patent application that presents a disproportionate burden on examiner resources. The PTO presently follows unity of invention practices in connection with international applications filed under the Patent Cooperation Treaty (PCT). In addition, the PTO has established worksharing arrangements with other patent examining offices that employ the unity of invention model. The "unity of invention" approach and integrating it into U.S. examination practices should be considered, in view of the PTO's familiarity with the unity standard, its use during examination of international applications, and its application of unity of invention standards in other patent prosecution highway examining authorities.

II. Comments on Specific Issues Identified in the Federal Register Notice

A. Establishing "Serious Burden" to Support Restriction Requirements

The PTO states in the Notice that it is considering changes to the "burden" requirement.[5] In principle, it is appropriate to consider the complexity of measuring compliance with patentability requirements other than those involving prior art. For example, certain issues under 35 U.S.C. § 112 can raise complex scientific and legal questions that require additional time for an Examiner to address during examination of the application. In some circumstances, these considerations may justify requirements for restriction. In others, it may be appropriate for the PTO to use other administrative measures to offset the burden on a particular examiner, such as providing additional examining time for complex cases and/or for particular issues that arise during examination of an application.

If the PTO were to permit Examiners to impose restrictions due to the non-prior art patentability issues presented in an application, any restriction imposed under that authority should be supported by more than a conclusory "showing" that is typical under today's practices. A "serious burden" justification for restriction should not be invoked without a reasoned explanation of *why* the additional amount of work will impose a significant burden on the examiner. In particular, the possibility that an additional rejection *might* apply to one group of claims should generally not be sufficient to support the use of the PTO's restriction authority. The PTO should establish clear and concrete guidance for examiners to use and follow in

[5] 75 Fed. Reg. at 33585.

formulating restriction requirements. Restriction should be based not merely on the possibility that examining more claims will require additional effort, but on the nature of the asserted patentable advance and the unifying features of the contribution it makes to the art.

Current restriction practices suffer from the inherent conflict involved in asking the examiner reviewing an application to exercise restraint in imposing a restriction requirement. If the PTO does adopt a broader definition of "burden" on the examiner than the current definition linked to a search of the prior art, it would be appropriate for a person in the Office other than the examiner handling the application to make determinations concerning the existence of a "serious burden." Without such a safeguard, there is a significant potential for abuse of the expanded authority to impose restriction requirements.

B. More Effective Review of Restriction Requirements

The PTO also in the Notice inquired about practices for higher level review of restriction requirements.[6] As noted above, the lack of consistency in the approaches that different examiners take to restriction practice places significant burdens on patent applicants. It would be desirable for the PTO to implement internal mechanisms for reconciling divergent approaches to restriction in two or more applications when the applicant brings the inconsistency to its attention. For example, the PTO could direct its managers to require examiners to give "full faith and credit" to restriction requirements already imposed in applications that are related either formally, or by similar subject matter arising from a unitary inventive effort. The PTO could also identify "facilitators" to ensure that examiners concurrently reviewing related applications reach and implement a consensus approach to restriction in the applications. The particular mechanisms that PTO management chooses to encourage and ensure consistency are less important than the result of promoting uniform practice.

A procedural bias against reconsidering restriction requirements that are improper – or even simply ill-advised – is built into the PTO's current practice. At present, the earliest opportunity an applicant has to have a reasoned traversal of a restriction requirement considered is when the front-line examiner is preparing a first action on the merits. Typically, examiners view the inclusion of a *pro forma* response to the applicant's arguments as only one component of an action that must be addressed *after* a search has been completed, claim rejections have been formulated, and (often) the applicant has responded on the merits. From the examiner's perspective, there is every practical incentive to decline to reconsider a restriction requirement at that stage of prosecution. More efficient mechanisms for reconsidering the propriety of restriction requirements are needed.

The concept of "second pair of eyes" review should be extended to restriction practice. Immediate review by a supervisor or experienced manager of any reasoned traversal of a restriction that the examiner does not find persuasive, short of a formal petition, should be

[6] 75 Fed. Reg. at 33586.

available. The PTO should undertake such review as a matter of course before the examiner prepares a full action on the merits.

C. Improvements to Markush Practice

The PTO invited thoughts on Markush practice in the Notice.[7] PhRMA welcomes refinements that would encourage examiners to examine different inventions or claims in one application where patentability is resolved on substantially similar grounds, including distinguishing over the same prior art. The PTO should implement its suggestions to group patentably indistinct species together for initial examination and to expand rejoinder practice to include more than a rigidly defined set of relationships between products and processes.

It is appropriate for the PTO to take account of patentability issues other than those based on prior art as it devises procedures for examining Markush claims after elected species have been found allowable. But, any revised procedures must be based on a recognition that certain patentability requirements can only be assessed with respect to the claim as a whole, rather than individual species. For example, it would be improper for the PTO to reject a Markush claim for lack of enablement because it concluded that any single species covered by the claim was inoperative. The PTO is obliged to examine every claim as it is presented. Patentability requirements that relate to the claimed invention as a whole, including most issues under the first paragraph of 35 U.S.C. § 112, should be raised in a first Office action, thus affording the applicant the examination, opportunity to respond, and reexamination required by statute.

Following a determination that an elected species is patentable, the PTO should direct is examiners to consider rejoinder of alternatives within a Markush claim with a view to determine the broadest range of subject matter than can be found allowable. Often, patentability concerns relating to certain non-elected species can be resolved easily by excising some part of the Markush group, a process that may be carried out efficiently by direct communication with the applicant's representative. A rule that the Office will not rejoin *any* nonelected species unless *all* species are allowable will inevitably result in atomizing inventions, resulting in large numbers of divisional applications. Such practices entail the exponential expansion of costs for applicants, as well as commercially unreasonable delays. They also have the effect of requiring the PTO to effectively repeat in each of several divisional applications much of the examination work already done in parent applications.

D. Combinations and Subcombinations

The PTO also referred specifically to situations involving combinations and subcombinations.[8] Restrictions between combinations and subcombinations may be proper when the combinations are patentable for different reasons than the separate components would

[7] 75 Fed. Reg. at 33586.

[8] 75 Fed. Reg. at 33586.

be. However, as illustrated by the PTO's "DNA probe array" example, restriction practice should also take account of the relationships established by the unifying features of the invention, such as providing a solution to the same problem (e.g., detection of particular variants of a gene). To the extent practical, the PTO should adopt practices that would permit the examination of a "reasonable number of subcombinations" with the combination, in a manner analogous to the treatment of generic claims under 37 C.F.R. § 1.146.

III. Conclusion

PhRMA appreciates the PTO's efforts to enhance the quality of patents and the opportunity to offer comments. PhRMA and its member companies are committed to helping the PTO find solutions to the many challenges it faces today and in the years to come. PhRMA encourages the PTO to continue a dialog with the patent user community as it develops specific procedures and guidance for implementing the goals indicated in its Federal Register Notice.