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From: Zielinski, Bryan C. [mailto:Bryan.C.Zielinski@pfizer.com]
Sent: Wednesday, May 03, 2006 6:12 PM
To: AB93Comments; AB94Comments
Subject: Pfizer Inc's Submission Regarding The USPTO's Proposed Rule Changes

Dear Sir:

Attached are Pfizer Inc's comments regarding the USPTO's proposed rule changes.

Alan Hesketh
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May 3, 2006

Office of the Deputy Commissioner for Patent Examination Policy
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

Re: Comments On Behalf Of Pfizer Inc In Response To The United States Patent And Trademark Office's Proposed Rule Changes to Examination and Continuation Practice

Gentlemen:

As Vice President and General Patent Advisor for Pfizer Inc, let me express our appreciation for the opportunity to provide comments on the United States Patent and Trademark Office's proposed *Changes to Practice for the Examination of Claims In Patent Applications* (Fed. Reg. Vol. 71 No. 1 page 61, Jan. 3, 2006), and *Changes to Practice for Continuing Applications, Request for Continued Examination Practice, and Applications Claiming Patentably Indistinct Claims,* (Fed. Reg. Vol. 71 No. 1 Page 48, Jan. 3, 2006). Pfizer is the world's largest research-based pharmaceutical company providing innovative pharmaceutical therapies and health-care solutions to allow patients to live longer, healthier, and more active lives. In 2005, Pfizer spent over seven billion dollars in the research and development of new drugs.[1] Patents contribute to Pfizer's research and development efforts by helping to ensure that an appropriate return on investment is achieved for the innovative products invented by Pfizer scientists.

[1] Pfizer Inc *Notice of Annual Meeting of Shareholders, Proxy Statement and 2005 Financial Report,* Consolidated Statements of Income, p. 35.

Pfizer appreciates the demands placed on the PTO in providing valuable patent services to diverse and competing industries. The stated purpose of the proposed rules focuses on the need for increased efficiency and the desire for improving the quality of issued patents. We support the PTO in its efforts "to do a better, more thorough and reliable examination" of patent applications, "ensure that the patent application process promotes innovation," and to "improve the quality of issued patents."

Pfizer supports many of the views expressed by BIO, AIPLA, and IPO regarding the PTO's proposed rules. In particular, Pfizer endorses PhRMA's comments regarding the proposed rules. In the interest of finding common ground with the PTO to achieve the goals stated above, we have outlined below several proposed alternative solutions with the hope of working toward a mutually acceptable solution that ensures that innovators such as Pfizer are provided adequate opportunity to obtain appropriate patents in support of our R&D investments.

Recommended Alternatives to the PTO's Proposed Rule Changes

Pfizer concurs with many of the alternatives proposed by the various industry groups. Many of the proposals set forth below share similarities with those described in industry group submissions.

1. Changes to the USPTO Examiner Production System

One alternative that many trade organizations and commentators have recently noted is the need to modify the current PTO Examiner Production System. Under the current system, an Examiner is awarded production or disposal credits for certain interactions with patent applicants. The current credit system provides Examiners with a motivation to pursue certain examination tactics that are likely to force patent applicants to pursue continuation filings.[2] Examiners accomplish this in a number of ways including issuing inordinately long and complex *formal* rejections. This tactic often leads to at least one formal issue left unresolved which in turn leads to the applicant pursing resolution through the filing of a continuation application. Other tactics that often lead to continuation filings are the allowance of narrow claims at the expense of broader genus or method claims and the issuance of second office actions as final actions.

Pfizer recommends that the PTO consider a graduated credit system that supports a thorough, high quality application review at the beginning of the examination process. Such a system may motivate Examiners to provide a higher quality initial examination, thereby avoiding the introduction of new grounds for rejection in subsequent actions and allowing applicants to resolve patentability issues without the need to pursue one or more continuation applications.

[2] Testimony of Harold C. Wegner responsive to the proposed rulemaking *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*, p.12, electronically submitted as continuingABwegner via AB93Comments@uspto.gov.

2. "Patent Work-Sharing" and Greater Collaboration with European, Japanese and Other Patent Offices to Streamline Practices

There are a number of areas where the PTO may benefit from greater collaboration with select foreign patent offices, particularly those which are also International Searching Authorities (ISAs) under the PCT, such as the EPO and JPO. One approach may include the use or substitution of searches generated by a patent office that is a qualified ISA in foreign equivalent or corresponding international patent applications. Many, or perhaps most, pharmaceutical and biotechnology patent applications are filed internationally, and of those many are subject to prior art searches conducted by EPO, JPO and other searching authorities which are well-respected within the patent practice community. If the PTO were to adopt a system where an applicant could request that a prior search from the EPO, JPO or other selected searching authority (or a prior PCT search), appropriately supplemented and updated, be used instead of having the PTO generate a new search, this would greatly decrease the time and effort expended by the PTO during prosecution. Further, it would be beneficial for the PTO to collaborate with other respected patent offices to share best practices with regard to searching strategies and protocols.

3. Implementation of a Viable and Easy to Use Deferred Examination System

As an alternative to the PTO's proposed changes to 37 CFR §1.78, Pfizer recommends consideration of a system that allows a patent applicant to defer the examination of an original and/or continued examination filing (including continuation, continuation-in-part and request for continued examination filings). While Pfizer generally supports expeditious examination of patent applications, a deferred examination procedure would be preferable to the PTO's proposed limitations on continued examination filings. Given the long regulatory review process associated with drug development, there is typically a long delay between invention and commercialization. Generally, in the pharmaceutical area, certain patent applications, e.g. those eligible for Hatch-Waxman patent term restoration under 35 U.S.C. §156, require immediate examination, but others may not require immediate examination. By implementing a procedure that allows an applicant to defer examination, particularly if patent term adjustment under 35 U.S.C. §154(b) is not negatively impacted, there would be a number of applications temporarily removed from the examination queue and the total number of continued examination filings would decrease. This benefit would be enhanced if applicants were provided an incentive, either through reduced costs or increased patent term adjustment, to defer examination.

4. Graduated Price Structure Based on the Number of Continued Examination Filings

While Pfizer generally does not encourage fee increases, a graduated fee structure related to the number of sequential continued examination filings would be preferable to the PTO's proposed rule limiting such filings. A graduated fee structure would create a disincentive to those simply seeking to keep an application pending. It may also generate more revenue with which to attract, train and retain talented examiners.

5. *Limits on Continued Examination Filings and on the Number of Claims Initially Examined*

If any limit on the number of continued examination filings is imposed, Pfizer submits that a rational compromise should permit the filing of at least three continuation (including continuation-in-part) and/or voluntary divisional applications without showing cause and the right to file unlimited RCE (request for continued examination) applications. Since continuation applications generally represent an effort by applicants to move prosecution forward, such as by submitting comparative test data to support non-obviousness, allowing three continuation applications as of right should provide an adequate opportunity for patent applicants to address the various issues that arise in the course of prosecution. Further, many pharmaceutical patent applications encompass a genus of therapeutically active compounds such that a single application often covers more than one clinical candidate or therapeutic product. However, under the terms of 35 U.S.C §156, a single patent can only be extended once, based on the clinical development and regulatory review associated with a single therapeutic compound. Thus, if significant limits are placed on continued examination filings, the ability of pharmaceutical firms to obtain the full benefit of the Hatch-Waxman patent term restoration provisions for each clinical candidate would be significantly impaired. Moreover, as outlined in PhRMA's submission regarding the PTO's proposed rules, RCE practice generally moves prosecution to allowance without requiring appeals or continuation applications, so limiting this area of continuation practice is unnecessary. On balance, in view of the concerns outlined above, a rule that permits the filing of at least three continuation and/or voluntary divisional applications without showing cause and the right to file unlimited RCE (request for continued examination) applications should meet the objectives of both the PTO and pharmaceutical innovators such as Pfizer.

Another alternative proposal may involve modifying the proposed rules such that petitions to show cause in second and subsequent continuations would not be required where such continuations are: (a) based on parent cases having allowed claims and applicants are refiling to further consider contested claims; (b) based on involuntary divisional applications; (c) based on continuation applications with an abandoned parent application and filed via the PTO's electronic filing system ("EFS"); and (d) any RCE application filed via the EFS.

Further, if any limit is imposed on the number of claims that are subject to initial examination, as the PTO suggests in its proposed changes to 37 CFR §1.75, a rational compromise would be a twenty (20) claim limit rather than the proposed ten claim limit (before triggering the required Examination Support Document). Also, since Markush practice is an essential aspect of pharmaceutical patent practice, any proposal that would count each member of a Markush group as a single claim would likely lead to the filing of several more applications by pharmaceutical firms to ensure that all aspects of pharmaceutical innovation are appropriately patented. Examiner searching in the pharmaceutical area is a generally straightforward process, enabled by computer technology and widely available databases. Rather than decrease efficiency by requiring individual examination of multiple cases, considering a Markush claim as a single claim will maintain efficiency in examination and prosecution. Therefore, in addition to offering a twenty claim limit as a rational compromise, Pfizer also recommends that the PTO not pursue any proposal that is likely to effectively eliminate or significantly limit claims written in Markush-type

format. If the PTO wishes to limit Markush practice in any way, Pfizer recommends that the PTO consider the guidance provided by the PCT in the PCT International Search and Preliminary Examination Guidelines, Part III, Chapter 10, as a point of reference regarding appropriately structured Markush claims.

Finally, as pointed out in BIO's submission regarding the PTO's proposed rules, the PTO's current restriction practice will only exacerbate backlog issues if the PTO's proposed rules are adopted. Pfizer recommends that the PTO consider replacing its current restriction practice with the unity of invention practice that is set forth by the PCT in the PCT International Search and Preliminary Examination Guidelines, Part III, Chapter 10, and adopting the illustrations and examples set forth in parts 10.11 through 10.59 of the guidelines as a point of reference for patent applicants and Examiners as to the claim types and groupings that satisfy the unity of invention principle.

Conclusion

Pfizer wishes to thank the PTO for this opportunity to comment on the agency's proposed rules. We understand the PTO's challenges and hope to find a mutually agreeable solution. Since the current proposals would likely have a significant impact on patent filings in both the pharmaceutical and biotech areas, we have offered alternative proposals with a goal of addressing the PTO's concerns and, at the same time, preserving the opportunity to obtain appropriate patent coverage for the innovative pharmaceutical therapies developed by Pfizer. We encourage the PTO to consider our proposals and engage in additional notice and comment proceedings that include public hearings, in order to ensure a fully transparent process and encourage the broadest possible input from all affected stakeholders.

Sincerely,

Alan Hesketh

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