From: David Korn
Sent: Friday, August 20, 2010 10:15 AM
To: 3-tracks comments
Subject: Attached Comments from PhRMA

Attached are comments in response to the Federal Register notice on "Enhanced Examination Timing Control Initiative." Please do not hesitate to contact me if you have any questions.

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PhRMA

August 20, 2010

VIA EMAIL: 3trackscomments@uspto.gov

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

Attention: Robert A. Clarke, Deputy Director, Office of Patent Legal Administration

Dear Mr. Clarke,

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 notice on "Enhanced Examination Timing Control Initiative," 75 Fed. Reg. 31763 [Docket No.: PTO-P-2010-0035]. 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 proposals outlined in the notice. 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-2010-0035
August 20, 2010

Comments of the Pharmaceutical Research and Manufacturers of America in Response to the PTO's Request for Comments on Enhanced Examination Timing Control Initiative

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the Patent and Trademark Office ("PTO") Request for Comments on the Enhanced Examination Timing Control Initiative.[1/] 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").[2/] In 2009, the biopharmaceutical sector 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.[3/] The industry's direct contribution to GDP in 2006 was $88.5 billion – more than triple the average contribution of other sectors.[4/]

Like innovators across the spectrum of American industries, pharmaceutical companies rely on patents to protect their inventions and provide an opportunity to recover their research investments. But patents are particularly important to pharmaceutical innovation given the research-intensive nature of this sector and the substantial investment required to discover and develop products that meet FDA approval requirements. [5/]

Bringing new life-saving and life-improving products to people is the central role of our member companies. Because intellectual property is critical to carrying out this mission,

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1/ 75 Fed. Reg. 31763-768 (June 4, 2010).

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

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

4/ *Id*.

5/ Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 JOURNAL OF INT'L ECONOMIC LAW 849-60 (2002). Without patent protection, potential investors would see little prospect of a sufficient return on investment to offset the accompanying financial risk. Barfield, Claude, and Calfee, John. Biotechnology and the Patent System: Balancing Innovation and Property Rights. AEI Press, 2007. It has been estimated that without patent protection, 65% of pharmaceutical products would never have been brought to market, while the average across all other industries was a mere 8%. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, Management Science (Feb. 1986) at 173-181.

PhRMA members particularly appreciate the efforts of the PTO to improve the patent prosecution process and to allow applicants to have more control over examination timing.

I. Comments on the PTO's Enhanced Examination Timing Control Initiative

The PTO has requested comments on its Enhanced Examination Timing Control Initiative, which would institute a three-track examination system.[6/] Under this initiative, for applications filed in the PTO that are not based on a prior foreign-filed application, an applicant would be able to: (1) request prioritized examination (Track I); (2) for non-continuing applications, request a delay of examination lasting up to 30 months (Track III); or (3) obtain processing under the current procedure (Track II).[7/] The PTO's stated objective is to provide applicants with greater control over when their applications are examined and to reduce the overall pendency of patent applications.[8/]

PhRMA supports the PTO's objective and, as a general matter, favors the flexibility provided by an examination system that is not "one-size fits all." PhRMA supports providing applicants with more control over the timing of patent examination because it is likely to result in a better alignment of examination resources with the needs of innovators. However, as explained below, PhRMA has concerns about some aspects of the PTO's proposed three-track system.

1. The PTO Needs To Ensure That Traditional Examination Under Track II Is Not Delayed if the Three-Track System is Adopted

The PTO proposes to institute a cost recovery fee associated with prioritized examination in Track I.[9/] According to the proposal, this fee would be set at a level that would provide the necessary resources to increase the PTO's output so that the aggregate pendency of non-prioritized applications would not increase due to examination of prioritized applications.[10/]

Ensuring that traditional examination under Track II is not delayed is critical. In order to ensure that pendency for non-prioritized applications does not increase under the new three-track system, the PTO needs to establish that the fees associated with prioritized examination are set for, and used solely for, cost recovery of these applications and are not diverted for any other purpose. By targeting the new fees exclusively to the purpose for which they are paid, the PTO can take steps to avoid any depletion of current resources.

The PTO also needs to institute safeguards to ensure that the pendency of applications in Track II does not increase. The PTO should establish meaningful metrics to monitor whether pendency is increasing and have a plan in the event that it does. Without such safeguards, the

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6/ 75 Fed. Reg. at 31764.
7/ *Id*.
8/ *Id*.
9/ *Id*. at 31765.
10/ *Id*.

proposed prioritized examination option could unfairly prejudice and penalize applications in the traditional Track II examination category.

2. Patent Applications That Claim Priority to Foreign-Filed Applications Should Not Be Treated Differently

The PTO's proposal would unfairly penalize applications that claim priority to foreign-filed applications because those applications would not even be placed in the examination queue until the PTO receives a copy of a search report, first office action from the foreign office, and a reply to the foreign office action.[11/] Only once these requirements are met can an applicant request prioritized examination or obtain processing under the current examination procedure.[12/]

As a matter of public policy, applications based on foreign applications should not be unfairly delayed in this manner. Applicants should be able to request prioritized examination for such applications at any time.

The negative treatment for applications that claim priority to foreign applications inherent in the PTO's proposal could lead to retaliatory actions by foreign patent offices against applications that claim priority to U.S. applications and could run afoul of international treaties such as the Paris Convention.[13/] Such differential treatment also might lead to forum shopping, which could result in more applications being filed in the U.S., thereby increasing the PTO's workload and undermining the PTO's objectives.

PhRMA also is concerned about adverse effects on Patent Term Adjustment ("PTA") for applications that claim priority to foreign applications. The PTO is considering a rule to offset positive PTA accrued in an application when an applicant files the required documents after the aggregate average period to issue a first Office action on the merits.[14/] Thus, delays by foreign offices beyond the aggregate average time for the PTO to issue a first Office action on the merits would be an offsetting reduction against any positive PTA accrued by the delay in issuing a first Office action by the PTO.[15/] This PTA proposal would further penalize applications that claim priority to foreign applications because delays in foreign patent offices, over which the applicant has no control, would cause a reduction in PTA in the U.S. In order to avoid negative PTA consequences, applicants might be more likely to file in the U.S. initially, thereby increasing the PTO's workload.

The PTO's proposed treatment of applications based on foreign applications appears contrary to the spirit of the successful Patent Prosecution Highway, in which an applicant that

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11/ *Id.* at 31764.

12/ *Id*.

13/ Paris Convention for the Protection of Industrial Property, *available at* http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html.

14/ 75 Fed. Reg. at 31766.

15/ *Id*.

receives a favorable ruling from one nation's patent office on at least one claim in an application may file a petition to make special and request that the corresponding application filed in the U.S. advance out of turn for examination.[16/] Today, if an applicant does not file a petition to make special, the PTO does not delay examination of the application but rather places the application in the examination queue. The PTO should continue to offer the Patent Prosecution Highway so that search and examination results of foreign patent offices can be utilized in these circumstances and should allow applicants with applications that claim priority to foreign applications to choose Track I or Track II examination at any time.

3. Implementation of the Proposed Three-Track System Needs Further Clarification

Several aspects of the proposed three-track system need further clarification so that patentees can properly evaluate this initiative. For example, it is unclear whether an applicant can elect Track III delayed examination after entering the national stage from a Patent Cooperation Treaty ("PCT") application. Without this option, the proposed Track III does not appear to provide any additional opportunity for delay because applicants currently can choose to delay examination by 30 months in the U.S. by filing a PCT application.[17/]

The PTO also needs to provide additional information on how national stage applications that claim priority to PCT applications will be treated under the proposed three-track system. It is not clear if the PTO will treat these applications as if they were filed first in the U.S. or as if they claim priority to foreign applications. If such applications are to be treated as applications that claim priority to foreign applications, use of the PCT application process would likely be discouraged due to the negative treatment of these applications as discussed above.

II. Conclusion

PhRMA appreciates the PTO's efforts to provide increased flexibility in the patent examination process and the opportunity to offer its perspective on the PTO's proposals. 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.

16/ *See* 75 Fed. Reg. 29312-313 (May 25, 2010); *see also*, "Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the European Patent Office based on Patent Cooperation Treaty Work Products," 1351 Off. Gaz. 208 (Feb. 23, 2010), "Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the Japan Patent Office based on Patent Cooperation Treaty Work Products," 1351 Off. Gaz. 209 (Feb. 23, 2010).

17/ Patent Cooperation Treaty, Article 22(1), *available at* http://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct.pdf.