

December 11, 2009

The Hon. David Kappos
Under Secretary of Commerce for Intellectual Property;
Director of the USPTO
Att. Elizabeth Shaw
Mail Stop OIPPE
United States Patent and Trademark Office
P.O. Box 1450
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Via e-mail to IP.Policy@uspto.gov

Re: Request for Comments and Notice of Roundtable on Work Sharing for Patent Applications, 74 FR 202, 54028

Dear Under Secretary Kappos:

The Biotechnology Industry Organization (BIO) thanks you for the opportunity to participate in the USPTO's November 18 Roundtable on Work Sharing for Patent Applications. See 74 FR 202, 54028 (Oct. 21, 2009). This submission is intended to complement BIO's statements made during the Roundtable.

BIO is an industry organization with a membership of more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 States and a number of foreign countries. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The U.S. biotechnology industry, fueled by the strength of the U.S. patent system, supports more than 7 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products. In the health care sector alone, the industry has developed and commercialized more than 300 biotechnology drugs and diagnostics and there are over 370 products in the pipeline. In the agricultural field biotechnology innovations are simultaneously increasing food supplies, reducing pesticide damage to the environment, conserving natural resources of land, water and

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nutrients, and increasing farm income and economies worldwide. Biotechnology innovation, if allowed to progress, has the potential to provide treatments for some of the world's most intractable diseases and address some of the most pressing agricultural, energy and environmental challenges facing our society today.

Given the rising global demand for biotechnology-based products, BIO members commonly apply for patent protection for innovative products not only in the USPTO, but also in the patent granting authorities of our major trading partners and in many rapidly-industrializing countries. In fact, the majority of original nonprovisional patent applications filed by BIO members today will eventually result in multiple related applications pending in the USPTO, the JPO, the EPO, and other foreign patent offices. BIO members are thus well familiar with the patchwork of international patent systems, under which the same basic application is today subjected to multiple searches and examinations in different jurisdictions. Many BIO members feel that coordinating, monitoring, and responding to often duplicative examination work products causes significant expenses and prosecution delays without contributing measurably to the quality of ultimately-issued patents. BIO thus welcomes international work-sharing initiatives that are designed to reduce duplication of examination work, expedite patent prosecution, and lead to a more equitable distribution of examination burden among the international patent offices.

The Patent Prosecution Highway (PPH):

To date, BIO members have only infrequently taken advantage of expedited prosecution under the various bilateral PPH agreements and pilot programs. In fact, as of November 2009, the small number of PPH requests received by Technology Center 1600 trails those received by all other TCs by a wide margin, representing less than 5% of the more than 2,000 PPH requests received to date. Several factors may contribute to this conspicuous underrepresentation of biotechnology and pharmaceutical applications in the USPTO's PPH docket. First, in an international comparison, the United States is overwhelmingly the largest originator of internationally-filed biotechnology and pharmaceutical patent applications. Indeed, it appears that U.S. dominance as an originator of international patent applications is nowhere as pronounced as in the biomedical arts.¹ Since PPH requests are only possible for applications in

¹ For example, for the 2001-2005 timeframe, the 2008 WIPO World Patent Report lists the following numbers of foreign-filed patent families, by country of origin (top 2 countries):

Technology / Originating country	United States	Japan
Biotechnology	32,139	7,094
Pharmaceuticals	43,317	7,738
Instruments -- Medical Technology	57,902	17,611
Telecommunications	34,627	39,479

which the USPTO is not the Office of First Filing (OFF), one would expect some degree of underrepresentation of biomedical patent applications, which predominantly originate in the USPTO (assuming that U.S. originators typically file first in the USPTO).

Second, it is BIO's understanding that PPH requests in the USPTO are most suitable for applications which claim direct foreign priority under the Paris Convention. Among BIO members, however, the by far most common foreign filing route is that under the PCT, and the majority of biotechnology applications pending in the USPTO as the office of second filing (OSF) are expected to be national stage PCT filings. In other words, of the fraction of biotechnology applications that do not originate in the USPTO, most will be ineligible for expedited prosecution under the PPH.

Third, it appears that the benefits of the PPH will be most pronounced in areas where examiners can make use of prior art-related work product, i.e. examination in the USPTO may benefit from a foreign examiner's search, and from any narrowing claim amendments made to comply with novelty and inventive step requirements. More so than in other technology areas, however, biotechnology claim scope is often constrained not so much by prior art as it is by other statutory requirements such as patent-eligibility or sufficiency of technical description. Thus, an international application family with the same original claims, having the same art cited against it in different patent offices, can result in granted claims of vastly different scope and form. A biotechnology claim in a foreign OFF may be clear of the prior art, and still face objections or rejections that force narrowing amendments or constraining claim formats by operation of foreign law. For example, it is very difficult or impossible to obtain pharmaceutical genus claims or medical treatment claims in some foreign Offices of First Filing, when such claims would be permissible in the USPTO. In such cases, BIO members may be hesitant to file PPH requests and prosecute claims in the USPTO that were previously narrowed not due to colliding prior art, but due to the strictures of foreign substantive patent law.

BIO members have also expressed uncertainty about the requirement that the claims of the U.S. PPH application "sufficiently correspond" to the claims that were allowed in the foreign OFF. Foreign patent offices often require that biotechnology claims be drafted in particular ways to make them formally compliant with foreign law, a practice most apparent in the area of medical treatment methods. For example, a claim to "a method of treating a patient having

Semiconductors	20,431	48,369
Instruments - Optics	18,012	54,278
Machine tools	9,207	11,257

See: WIPO World Patent Report 2008, Tab. F2 at p. 42, available at:
http://www.wipo.int/export/sites/www/ipstats/en/statistics/patents/pdf/wipo_pub_931.pdf

disease X, comprising administering an effective amount of compound Y” would be permissible in the USPTO, but would be considered nonstatutory in the JPO, the EPO, and many other foreign offices. To meet the foreign requirement of industrial applicability, the applicant in the OFF may be required to amend the claim to the Swiss-type format “use of compound Y in the manufacture of a medicament for the treatment of disease X.” Conversely, a biotech applicant may be able to obtain a composition-of-matter claim in the OFF reciting a “compound X for use in treating condition Y,” but face problems in the USPTO if compound X was previously known. In either case, it is profoundly unclear how the PPH requirement of ‘claim correspondence’ would operate in expedited U.S. prosecution.

Although the above-described factors conspire to make expedited prosecution under the PPH a rarely-used option in biotechnology cases today, BIO believes that the current PPH process can be a valuable time- and cost-effective prosecution alternative for selected applications. Opening the process more to national-stage filings under the PCT would additionally help in making many more biotechnology applications eligible for the PPH. Appropriate use of the PCT search and examination work product at the national stage would better ensure that work done at the international stage does not get repeated at the national stage. Indeed, an applicant’s ability to obtain expedited prosecution of a national-stage application based on PCT work product may, over time, create systemic incentives to more often request supplementary international searches in hopes of obtaining a favorable Chapter I Written Opinion, or to more often demand international preliminary examination under Chapter II. Ultimately, however, the currently-existing international patchwork of non-prior art-related legal requirements, such as formal compliance with statutory subject matter eligibility, sufficiency of description, the operation of U.S. restriction practice and the like, will remain as impediments to broader use of the PPH in the biotechnology arts until substantive harmonization efforts bring about more international uniformity. In the meantime, the USPTO should consider to which extent a “clean” foreign prior art search could serve as a basis for expedited examination in the USPTO even when there is no *literal* correspondence between the pending claims and those that were searched in the foreign OFF. The requirement that the foreign claims must have been found to be allowable could be qualified in situations where foreign objections or rejections are specific to foreign law and do not relate to colliding prior art.

Strategic Handling of Applications for Rapid Examination (SHARE)

It is BIO’s understanding that SHARE, unlike expedited prosecution under the PPH, would be an Office-driven prioritization program that would not operate at the applicant’s election. As the Office explained the SHARE program during the November 18 roundtable,

applications for which the USPTO is the OFF would be prioritized in the examination queue, with the goal of decreasing overall pendency, improving quality, and reducing redundant work. The Office was silent on what would happen to applications for which it is not the OFF. BIO notes that the USPTO's examination resources are finite and, by its own assessment, strained beyond capacity. It is therefore possible that prioritized examination of first-filed applications could cause increased delays in the processing of second-filed applications.

BIO members are still trying to gage the many potential implications raised by the SHARE concept. In general, a better understanding of how the EPO's PACE and the JPO's JP-FIRST programs operate would be informative for BIO's members, as would any information from the ongoing PTO-KIPO SHARE pilot program. Also, very few details on how the PTO plans to design and implement the SHARE program are as yet available. As an initial observation, however, BIO would be hesitant to support, without more, a general policy under which the USPTO would systematically delay examination of second-filed applications pending the search and examination results of the foreign OFF. At a minimum, it would need to be ensured that the corresponding foreign first-filed applications are equally prioritized for examination in the OFF. Otherwise, systemic examination delays from the foreign OFF would be imported into the USPTO along with the OFF's examination work product. Also, as far as distinguishing between all first-filed applications and those first-filed applications that were subsequently filed abroad, the USPTO should consider whether giving priority to first-filed applications that were subsequently also filed abroad would negatively impact domestic small entity applicants or industries that predominantly seek only U.S.-only patent protection. Systematically delaying examination of second-filed applications could also disproportionately impact foreign applicants in the form of longer pendency, increased patent term adjustment, and lead to more freedom-to-operate uncertainty for U.S.-based businesses.

Thus, BIO believes that a SHARE program should not operate as a *de facto* deferred examination system for applications for which the USPTO is the OSF. While BIO is open to discussions about a well-structured *optional* deferred examination system as part of a suite of other quality- and efficiency-enhancing measures, BIO has explained previously that any deferred examination program in the USPTO would need to be deliberately crafted to ensure transparency and legal certainty, and include safeguards against misuse. See BIO's Comments on the USPTO February 12, 2009 Roundtable on Deferred Examination (cite). If SHARE were to operate as a *de facto* deferral system without being designed as such, multiple unintended consequences could follow.

BIO also notes that many foreign offices permit deferral of searching and/or substantive examination without distinguishing between first- and second-filed applications. For example,

substantive examination need not be requested until 24 months in the UK IPO, 3 years in the JPO and SIPO, 5 years in the KIPO and CIPO, and 7 years in the German PTO. If SHARE were implemented without regard to the presence or absence of an examination request in the corresponding foreign first-filed application, deferral periods in the OFF would effectively be engrafted onto the U.S. examination process. Accordingly, when allocating an application for 'prioritized' or 'non-prioritized' examination under SHARE, the Office may need to take into account whether an examination request has been filed in the corresponding foreign application in the OFF.

In recognition of SHARE's potential for additional examination delays in applications where it is the OSF, the Office has raised the question whether such applications should be eligible for patent term adjustment (PTA) in instances where waiting for foreign search and examination results would normally cause compensable delays under 35 U.S.C. 154. BIO reiterates its understanding that SHARE, at present, is intended as an Office-driven process under which examination priority would be determined according to the foreign/domestic-first filing status of an application, not by the applicant's choice. BIO believes that examination delays that are not attributable to applicant behavior in the USPTO should not be a basis for subtractions from PTA periods to which the applicant would otherwise be entitled. Many applicants cannot "choose" to file their applications first or second in the USPTO because foreign filing laws may force first-filing in the country where the invention was made or where the applicant resides. And even where the applicant has a choice of filing first in the USPTO, legitimate business reasons may compel first-filing in a foreign office. Care must be taken to not doubly prejudice such applicants in the form of longer pendency and patent term adjustment debits. Accordingly, SHARE must be consciously designed to avoid discrimination in practice against foreign inventors who elect or are compelled by domestic law to file first in their home countries, and to ensure compliance with U.S. obligations to afford national treatment to nationals of other member states under Article 2(1) of the Paris Convention and Article 3(1) of TRIPS. BIO believes that factoring SHARE-related examination delays into the PTA calculus would be fraught with many uncertainties, raise fairness concerns from the perspective of both domestic and foreign applicants, and probably collide with Section 154 in its current form. The Office should invite more, and deeper discussion of this topic as it continues to develop the SHARE concept.

Conclusion

BIO recognizes that the Office needs flexibility to better structure and prioritize its workflow, and to create applicant incentives to engage in expedited prosecution programs. An unrelenting pendency backlog and overextended examination resources make international

worksharing a matter of great importance. Accordingly, the information needs of the patent user community with respect to both the PPH and, in particular, SHARE, are significant. BIO hopes to learn more from the PTO in the coming months and remains committed to participating in further consultations and to assist the Office in designing, planning, and implementing its international work sharing initiatives in a way that benefits both the Office and the biotechnology patent user community.

Respectfully submitted,



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