

From: Hans Sauer [redacted]
Sent: Friday, November 19, 2010 4:49 PM
To: HumanitarianProgram
Subject: BIO comments; reexamination voucher

Dear Madam, Sir:

Please find attached the comments of the Biotechnology Industry Organization on the PTO's proposed *ex parte* reexamination acceleration voucher program, as set forth in the PTO's Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, 75 Fed. Reg. 181, 57261.

Please feel free to contact us at the number below with any questions in this matter.

Respectfully submitted,
Hans Sauer

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The Honorable David Kappos
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Director of the U.S. Patent & Trademark Office
Mail Stop Comments—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATT: Joni Y. Chang

Via e-mail to HumanitarianProgram@uspto.gov

Re: Request for Comments on Incentivizing Humanitarian Technologies
and Licensing Through the Intellectual Property System, 75 Fed. Reg. 181, 57261

Washington, D.C., November 19, 2010

Dear Under Secretary Kappos:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the U.S. Patent & Trademark Office's (USPTO) proposed technology development and licensing initiative set forth in the Office's above-identified Federal Register notice dated September 20, 2010.

Background

BIO is a non-profit organization with a membership of more than 1,100 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. life sciences industry, fueled by the strength of the U.S. patent system, supports more than 7.5 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products such as renewable fuels and bio-based plastics. 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 nutrients, and increasing farm income and economies worldwide. In the energy and environmental sector, biotech innovation is helping to clean our environment and fight global climate change by reducing our dependence on petroleum and fossil fuels. In short,

biotechnology innovation, if supported by appropriate public policies, 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.

BIO's members are acutely aware of the significant unmet needs that exist in the developing world with respect to medical care, food supply, food safety, animal health, sanitation, pollution, and other areas in which biotechnology companies have special expertise. Other sectors of the U.S. economy likewise possess specialized technology that could help address problems that affect impoverished populations in the developing world, for example in the areas of education, environmental conservation, energy, transportation and communication. Technology access alone, of course, cannot solve the many problems that exist in the developing world. Nonetheless, BIO members believe that much is being and more can be done to develop and increase access to products for problems that disproportionately affect people in the developing world, while also increasing access to the range of existing products commonly utilized in the developed world. BIO believes that the biotechnology industry is well-situated to leverage its diversity to contribute to these ends.

BIO's members include a diverse mix of entrepreneurial small biotech companies, large integrated pharmaceutical and agricultural companies, top-tier research institutions, and biotech investment firms, each with their own different expertise and experience that can be used to help address unmet humanitarian needs. Each biotechnology company also has its own unique business model, with different approaches to R&D and commercialization depending on the products at issue and the markets for them. In order to provide innovative technology to the marketplace, strong intellectual property rights are the key to a successful business model. Importantly, each company must in the end become or remain profitable to be able to continue its investment in R&D activities and make innovative products broadly available to patients, farmers, and consumers across the globe. BIO's members believe that the goals of increasing access to biotech products, respecting intellectual property rights, and fostering commercial growth and innovation are mutually supportive.

BIO's members also understand that problems with access to medicines and other biotechnology products in the developing world have very little to do with the patent system, and are generally caused by other factors outside the control of individual stakeholders, such as lack of adequate local manufacturing, delivery, public health and sanitation infrastructure, trade and tariff barriers, regulatory obstacles, lack of market incentives, inequitable local distribution and corruption, diversion of products to more lucrative markets, and a chronic underinvestment in public health, education and environmental conservation. In fact, access issues persist even in countries where there are no patents covering humanitarian products and technologies.

While the patent system cannot be a primary policy lever to address these complex questions above, BIO nonetheless believes that innovative businesses from all sectors of the U.S. economy, including the biotechnology industry, can help improve the lives of underprivileged populations in the developing world. Indeed, BIO member companies have long participated in specific access and licensing initiatives that have informed the policy choices of members of the

industry.¹ Most recently, in May of this year, BIO announced a policy statement containing its Options for Increasing Access to Medicines in the Developing World that it believes should be considered during the development and commercialization of biotechnology products.² Accordingly, BIO commends the USPTO for likewise exploring creative and market-oriented ways to incentivize the development and distribution of humanitarian technologies, a goal that BIO and its members have long shared and are working hard to achieve. In addition, BIO would support efforts to bring together all potential stakeholders to explore various approaches and initiatives.

Comments on the USPTO Voucher Proposal

1. Any program should be technology-neutral

BIO members believe that any acceleration voucher program should not be specific to or particularly geared towards the biotechnology industry. In BIO's view, such a program should be applicable to innovators from all sectors who engage in the creation and dissemination of technology that has the potential to address the needs of impoverished populations in the developing world. Further, BIO is reluctant to endorse an approach that leverages *the patent system* to parse such technologies into those deemed "essential" and those that are not, some worthy of a special examination privilege but not others. Seen this way, the patent system should not permit value judgments between, for example, a novel antiparasitic drug and a novel diabetes drug, between the solar-powered hearing aid and the "\$100 laptop," between sanitation technology and livestock health, or between food safety products and software education tools. The United States Government is free to create technology-specific or problem-specific incentive and reward programs to address developing-country needs in the particular areas of, for example, education, medical care, nutrition, pollution, animal health, transportation, communication, and the like. Such programs would be developed and implemented by agencies with specific technology expertise and legal and policy mandates in these areas. In contrast, the patent system is primarily concerned with furthering the progress of technological innovation, without regard to the applicability of inventions in specific policy areas. Maintaining the strict technology-neutrality of the patent system is critically important to BIO's member companies from an international comparative, trade, and treaty obligation perspective as well. Accordingly, BIO members still have many open questions about the inclusiveness of the proposed program and how its technology-neutrality can be ensured.

¹ For a collection of specific health initiatives, see <http://www.globalhealthprogress.org/>. A searchable database of partnership programs to improve health in developing countries is available at <http://www.ifpma.org/healthpartnerships>; and an in-depth analysis of six public-private tropical infectious disease programs can be found at: <http://www.bvgh.org/LinkClick.aspx?fileticket=867bPGw-kYo%3d&tabid=105>. Reports of ongoing public/private partnerships to promote access and delivery of proprietary agricultural technologies for use by resource-poor smallholder farmers in Sub-Saharan Africa are available at <http://www.aatf-africa.org/>; and a recently-launched international collaboration to develop improved maize varieties for African soils (IMAS) is described at <http://www.cimmyt.org/>.

² [http://www.bio.org/healthcare/innovation/Access to Medicines Policy Statement Final.pdf](http://www.bio.org/healthcare/innovation/Access%20to%20Medicines%20Policy%20Statement%20Final.pdf)

2. Any proposal should ensure USPTO's core mission is maintained and adequately resourced

BIO members have further expressed concern that the proposed program could create a resource-intensive bureaucracy for the review of voucher requests, under which the adjudication of requests, and appeals or petitions from their denial, would consume resources that would better be deployed on the USPTO's core missions. In the same context, it was expressed that voucher awards under the proposed program should not be so common as to negatively impact the timing of regular ex parte reexaminations. By statute, all reexaminations are supposed to be conducted with special dispatch.

3. Value of any proposed vouchers should be maximized, but will remain limited

BIO interprets the USPTO's current proposal as a pro-IP approach that seeks to create an incentive for the creation and licensing of technology that addresses humanitarian needs and that carries both symbolic and actual commercial value. BIO believes that the commercial value of the proposed voucher could be substantial under some situations, but difficult to express in monetary terms at this time.³ Comments received from BIO members indicate that biotechnology companies would value such vouchers in instances where acceleration of a patentee- or third-party-initiated ex parte reexamination is deemed critical. BIO understands and appreciates that the USPTO sought to create the most valuable benefit that it could offer under current statutory authority. Notably, the voucher's value could be further increased within existing statutory authority if it could additionally be used to accelerate, at the patentee/applicant's option, the examination of original patent applications and reissue applications as well as any appeals to the Board of Patent Appeals and Interferences in ex parte proceedings.

Even if the voucher's versatility were increased in these ways, BIO's members have consistently expressed the view that such a voucher's commercial incentive value would probably be less than its symbolic value – that is, BIO members generally believe such a voucher is more likely to operate as a reward for humanitarian development and licensing efforts, rather than an incentive sufficient in and of itself to initiate R&D or licensing activities with the specific aim of benefiting the developing world. Consistent with their “reward” rather than “incentive” function, the USPTO should consider ways to increase the symbolic value of the voucher award.

BIO members also considered whether the proposed program would be likely to differentially benefit smaller or larger innovative companies. Larger companies are more likely to have the intellectual property, the products, the resources, and the funding to engage in the kinds of humanitarian activities that could lead to a voucher award. Larger companies are also more likely to have a need for such vouchers, and the funds to purchase them. Smaller companies, on the other hand, are typically investment-funded and more likely to primarily focus on generating a return for their investors. They may have less relevant IP and may not yet have marketed products. They also are more likely to be concerned about fragmenting their IP by out-licensing

³ BIO members believe that the expected monetary value of an acceleration voucher is so speculative at this time that most declined to provide a dollar estimate. Generally, it appears that the expected commercial value of a voucher, while not negligible in itself, is believed to be very small when measured against the operating budgets of even small biotech companies.

part of it for humanitarian uses if they know that they may have to seek commercial development partners or licensees who prefer unencumbered IP portfolios. On balance, BIO therefore at this time believes that larger companies would be better situated to take advantage of the proposed program.

4. Clarity of standing for voucher use needed

BIO members are seriously concerned that vouchers could potentially be used by third party requesters, or even unrelated third parties, to accelerate the ex parte reexamination of other party's patents without the patentee's consent. The USPTO should clarify that the proposed acceleration vouchers could not be used in this way.

5. Policy options for voucher award process require further discussion

BIO members also raised the question whether the proposed vouchers should be awarded as an entitlement for meeting certain objective criteria, or as a more subjective prize for extraordinary humanitarian licensing efforts. BIO assumes that an entitlement system would entail a set of award criteria that would be promulgated by regulation, and under which voucher requests would be adjudicated and denials appealed. A prize system, on the other hand, would presumably entail the creation of a board inside or outside the USPTO that would award such vouchers according to broad criteria set forth in its charter, under which non-awards could neither be appealed by disappointed patentees, nor awards be contested by third parties.

BIO members are still discussing the benefits and disadvantages of either approach. On the one hand, an entitlement system created through regulation could provide for more legal certainty, predictability, and equal treatment if the award criteria can be defined with sufficient clarity.⁴ It would also, presumably, require the use of administrative resources that are currently deployed elsewhere in the USPTO. A prize system, on the other hand, would appear to be less resource intensive, would be less predictable (a company could not "count on" getting a voucher), and would presumably result in fewer voucher awards overall, thus maximizing the financial and symbolic value of vouchers.

Another important consideration for BIO members relates to the potential international precedent-setting effect of an entitlement vs. a prize system for voucher awards. Under either system, it would not be inconceivable that the establishment of a special examination privilege in the USPTO could inadvertently facilitate the differential treatment of inventions under foreign patent laws, depending on the various policy areas that foreign governments may single out for special treatment. However, relative to a prize system, a *de jure* entitlement system in the USPTO would more likely be perceived as a systemic legal precedent that could open the door to

⁴ Theoretically, if a voucher award were more predictable, it would also be expected to operate as a more efficient *prospective* incentive for patentees who would know which activities would likely lead to a voucher. However, as explained above, BIO members view the incentive value of the proposed voucher as relatively limited. Moreover, it was noted that a voucher entitlement program might at least sometimes create a paradoxical negative effect in instances where patentees might wish to "hold back" their technology until they are sure they can meet the voucher award criteria.

differential patent treatment abroad, and undermine the U.S. Government's advocacy on international patent system technology neutrality. With these considerations in mind, BIO continues its internal deliberations and looks forward to the USPTO's views on the matter.

Conclusion

BIO understands this Federal Register notice to be a first conceptual step in what will be a deliberative process with additional opportunities for public review and comment as more specific details and approaches are proposed. With this understanding, we look forward to engaging further on this effort in partnership with the USPTO and other industries and stakeholders.

Respectfully submitted,

A handwritten signature in cursive script that reads "James Greenwood".

James Greenwood
President & CEO