From: Andrew Robertson [redacted]
Sent: Friday, November 19, 2010 12:36 PM
To: HumanitarianProgram
Subject: ATTN: Joni Y. Chang - BVGH USPTO comment on fast track reexamination voucher

Dear Joni Chang,

Please find attached the comments from BIO Ventures for Global Health in response to your ***Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System*** **[Docket No. PTO–P–2010–0066]**.

Please let us know if you have any questions. We look forward to tracking this program as it progresses, and offer our support.

Best,

Andrew Robertson

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November 18, 2010

Division of Dockets Management (HFA-305)
United States Patent and Trademark Office
Commissioner for Patents

Re: Docket No PTO-P-2010-0066
Subject: "Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System"

Dear Commissioner:

Thank you for the opportunity to comment on the pilot proposal put forward by the United States Patent and Trademark Office, "*Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System*." These comments are provided on behalf of BIO Ventures for Global Health (BVGH), a non-profit organization whose mission it is to save lives by accelerating the development of novel biotechnology-based drugs, vaccines, and diagnostics, in order to address the unmet medical needs of the developing world. The promotion of innovation in neglected tropical disease (NTD) research is an issue of focus for BVGH, and one we believe we can address through a unique perspective consisting of expertise in global health policy, biomedical science, and the biopharmaceutical industry.

The USPTO should be commended for pursuing this pilot program to impact humanitarian causes through novel incentives. BVGH has significant experience designing, shaping, and promoting incentives that reward companies that invest in combating diseases of the developing world. Fast-track *ex parte* reexamination vouchers are an interesting and inventive way to provide a behavior-changing incentive to address humanitarian needs. If designed and implemented properly, BVGH believes that this program holds the potential to serve as an important part of a package of incentives that work to stimulate innovation and practices towards humanitarian ends.

Addressing global health issues and other humanitarian needs requires the innovative power of the private sector. The biotechnology and pharmaceutical industries play a critical role in advancing innovation and finding new solutions to diseases that plague the world's poorest nations. In the developed world, biotechnology has revolutionized the health care available to patients over the past 30 years, saving countless lives and improving quality of life. However, while biomedical advances in countries like the U.S. and Japan have increased the average life span to 70 or 80 years, the life span of some low-income countries is less than half this number.

Advancing groundbreaking scientific research for neglected tropical diseases (NTD) of the developing world relies on reducing the cost of research, as well as advocating for the reward incentives biopharmaceutical companies need to justify taking a risk on new drug, vaccine, and diagnostic development. To this end, BVGH engages the biopharmaceutical industry and advances NTD research by 1) increasing biopharmaceutical and global health innovator partnerships; 2) designing and advocating for market-based incentives for research and development; and 3) synthesizing and disseminating critical information and quantitative analyses. Our extensive network includes leaders in academic fields, global health, business, and partnerships with over 700 biotechnology companies, product-development-partnerships (PDPs), and global health leaders.

Among our active projects to increase private-sector investment in global health, BVGH works closely with global health partners, the U.S. government, and the biopharmaceutical industry to shape and promote the **U.S. FDA Priority Review Voucher** (PRV). The PRV is a transferable voucher awarded to a company that receives FDA approval for a new vaccine or drug that prevents or treats a neglected tropical disease, such as malaria, tuberculosis, or intestinal worms. A PRV entitles the bearer to priority review for a future new drug application that would not otherwise qualify for priority review — potentially shaving off between four and 12 months from the standard FDA review process. The benefits associated with this accelerated time to market are estimated to be worth between $50-$500 million, depending on variables such as the condition the drug is designed to treat, and the actual time saved from the FDA review process.

We are submitting the following comments and suggestions with the hope that this USPTO pilot program will become a strong incentive in engaging the private sector to address humanitarian issues, such as global health and, specifically, NTDs. Our comments are based primarily on our experience with the PRV program, its implementation, and industry response. Further, BVGH recognizes that this proposed program is in its early stages of development. With this in mind, BVGH offers three main recommendations to the USPTO on their proposal to institute a fast-track *ex parte* reexamination voucher pilot program for humanitarian needs:

1. The USPTO should establish transparent, clearly-defined criteria for earning a fast-track *ex parte* re-examination voucher as an essential step towards encouraging participation by the private sector;

2. The USPTO should develop a mechanism for ongoing consultation with key stakeholders

during the design, implementation, and administration of the pilot program; and

3. The USPTO must allow vouchers to be fully transferable to maximize the value of the incentive program and promote adoption by industry stakeholders.

Recommendation #1: The USPTO should establish transparent, clearly-defined criteria for earning a fast-track *ex parte* reexamination voucher as an essential step towards encouraging participation by the private sector.

To begin, it is essential that the USPTO launch the pilot program with a commitment to transparency and clearly-defined criteria for earning a voucher. Private, for-profit companies rely, in part, on the ability to avoid risk and predict outcomes of business strategies. Clearly-defined criteria can help address these interests, and signal to companies exactly what is required in order to receive a voucher. As such, reducing the level of subjectivity in deciding whether a company has earned a voucher is necessary to engage participation by the private sector.

Transparency concerns impact the debate as to whether this program should be considered a "prize" or an "entitlement." Prize-based incentives that are awarded only to the "best" humanitarian practices are inherently linked to increased subjectivity in the judging process. For example, the determination as to whether a treatment for malaria is more socially valuable than a device to transport water effectively over long distances requires a difficult comparison, and is essentially a subjective process contingent on the particular values of the judges. BVGH believes that under these conditions for selection, the incentive scheme will not create significant private sector investment to address humanitarian needs.

In contrast, however, an "entitlement" approach to this pilot program allows for much more certainty. Under an entitlement model, if a company undertakes humanitarian practices that meet a certain set of criteria, they are entitled to receive a voucher. Under this approach, companies can plan accordingly, invest the appropriate time and resources that reflect the value of the voucher, and adjust business strategies in response to the program. Further, while the "prize" model may compel a "race to the top," incentivizing greater innovation through competition, the entitlement model can achieve a similar effect by establishing more ambitious criteria for receiving a voucher. By developing transparent, demanding yet achievable criteria for earning an *ex parte* reexamination voucher, the USPTO can create a challenging incentive scheme that is also accepted by industry stakeholders.

Linking the USPTO's pilot program to the FDA's PRV program, for example by awarding a fast-track *ex parte* reexamination voucher for licensing practices that benefit research in one of the "PRV-eligible" diseases, would increase transparency of the program. The FDA's PRV program has established relatively clear rules and criteria to earn a PRV, including a clear list of sixteen diseases that are associated with PRVs. These sixteen diseases are well-recognized and understood by biopharmaceutical companies and the global health community, with little ambiguity. Further, the FDA program also contains clear criteria regarding the novelty requirements and class of drugs and vaccines that are eligible for PRVs; the USPTO pilot program would also need to adopt clear criteria

for receiving a voucher, such as donating a non-exclusive patent license to an internationally recognized patent pool or for use in a developing country. Without clearly-defined criteria, many companies that currently view the PRV as an incentive to invest in NTD product development would otherwise consider it as too high-risk to pursue seriously.

However, it should be noted that the *process* for updating the requirements for earning a voucher must also be clear and transparent. This is an important component that has been overlooked in the FDA's PRV program. For example, FDA has not yet defined a method for updating the list of PRV-eligible diseases, despite having the administrative authority to do so. As a result, Chagas disease, one of the largest parasitic killers in South America and a recognized neglected tropical disease by the World Health Organization (WHO), is still not on the list of PRV-eligible diseases, and the process for adding it has not been communicated to stakeholders. As a result, the program does not fully align with the interests of the global health community.

Recommendation #2: The USPTO should develop a mechanism for ongoing consultation with key stakeholders during the design, implementation, and administration of the pilot program.

In addition to maintaining principles of clarity and transparency, the implementation and administration of any program of this nature must be conducted with on-going input from industry stakeholders. While voucher programs can have the potential to change stakeholder behavior, such as increase investment in NTD research by the private sector, the FDA PRV program has demonstrated how implementation and administrative policies can threaten any incentive program.

During the administration of the PRV program, the FDA has instituted conditions on the end-use of vouchers that discourage use by industry. For example, companies are required to issue a 365-day advanced notice to the FDA before using a voucher for priority review. In other words, companies are required to predict a year in advance whether phase III clinical trial outcomes will be successful, and whether profits earned through advanced drug sales would benefit from FDA priority review. This is a difficult task for companies, since clinical trials are often unpredictable and the data collected requires subsequent interpretation. As a result, the utility of the voucher is decreased, and the potential value of the voucher is reduced significantly because of the layered discounting for risk.

Further, industry feedback regarding the voucher program could provide significant benefits to the global health and humanitarian interests involved. In the context of the FDA's PRV program, this feedback would provide up-to-date information regarding advances in drug discovery, as well as relevant communication of strategies to treat particular diseases. For example, regarding diseases such as malaria and tuberculosis, the true "innovation" in current drug development is through combination treatments, such as experimenting with dosages and delivery methods. These innovations are not eligible for a PRV, however, since one or more of the active ingredients involved has already been FDA approved. Consultation between the FDA and industry stakeholders can help

identify potential drug leads, therapeutic strategies, and innovations with serious potential benefits to global health, and can help the FDA leverage the PRV to bring these innovations into practice.

The USPTO should take note and implement their proposed program in close coordination with industry stakeholders. BVGH would recommend a mechanism for soliciting feedback from industry stakeholders, such as creating a standing industry working group to help guide the implementation of the USPTO pilot program, and to help identify technologies that could yield benefits towards humanitarian causes. As the program grows, this ongoing consultation can help ensure the fast-track *ex parte* reexamination voucher program can be implemented in a manner that is workable for industry stakeholders, while still pursuing humanitarian ends.

Recommendation #3: The USPTO must allow vouchers to be fully transferable to maximize the value of the incentive program and promote adoption by industry stakeholders.

Vouchers must be fully transferable in order to maximize the economic value of the incentive. At present, the FDA administration of the PRV program allows for only one transfer or sale for every PRV issued. This limitation hampers the end-user market for the vouchers, in particular by restricting the vouchers from being acquired by those who would buy them at the highest price. Further, capping the number of transfers discourages participation by small biotech companies in the PRV program, as they may not be able to find a profitable use for the voucher once obtained.

Transferability allows vouchers to reach those who can derive the most social or financial value from them. For example, without transferability, companies that meet the criteria for obtaining a voucher will also be required to use the voucher for *ex parte* reexamination of a patent within their own portfolio. However, a developer who earns a voucher may have little or no need for a fast-track *ex parte* review. Reselling the voucher allows these developers to monetize them and gain a financial payoff.

Further, unlimited transferability helps commoditize the vouchers and develop a secondary market. Secondary markets carry several important advantages, such as reduced costs associated with finding a buyer for vouchers, and reduced risk associated with obtaining a voucher. Secondary markets also allow for voucher trading through intermediary third parties; another activity that serves to raise the value of and decrease the risk associated with obtaining a voucher. These advantages associated with secondary markets will increase the attractiveness of the incentive scheme.

Finally, transferability of vouchers plays an important role in signaling to developers the market value of the voucher. Specifically, the ability to buy, sell, and trade fast-track *ex parte* reexamination vouchers would reduce speculation as to the real-world value of the voucher by providing examples of real-world price points. This speculation can pose a significant deterrent towards private sector adoption. In the context of FDA's PRV program, the PRV is estimated to be worth between $50 million and $500 million. Many industry stakeholders have expressed their hope that Novartis—

the only recipient of a PRV to date—would sell their voucher to help demonstrate its real-market value. Without a real-world example of voucher resale, the vast range of possible values for the voucher has made the PRV less attractive as an incentive, and has discouraged the creation of new investment in the development of drugs or vaccines for NTDs.

The need for these price signals is even more vital to the USPTO's proposed pilot program, as the fast-track *ex parte* reexamination voucher holds value to industries outside of drug development. In contrast to PRVs, which can only be earned and used by biopharmaceutical companies, a fast-track *ex parte* reexamination voucher may be of significant value to industries such as high-tech, software, agriculture, energy, and many others. Consequentially, the value of the fast-track *ex parte* reexamination voucher would likely vary significantly between these industries. Without examples of market exchanges to signal the value of vouchers, holders of vouchers would be forced to rely on economic predictions across industries and substantial guesswork.

Summary

BVGH fully recognizes and appreciates the USPTO's interest in creating incentives to promote investment in technologies to meet humanitarian needs. Our recommendations offered reflect BVGH's extensive expertise in incentives that address challenges in global health and NTD research. We believe that our recommendations can help to shape a more robust, workable program that is accepted by industry stakeholders while serving broader humanitarian interests. If designed and implemented properly, this pilot program can serve as an important component of the small but growing number of available incentives to drive investment in some of the most daunting health and development issues faced today.

Respectfully submitted,

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11/18/10