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To: HumanitarianProgram

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Subject: Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System

Attached please find the Comments of the Institute of Intellectual Property and Social Justice submitted in response to the USPTO request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System.

<http://www.federalregister.gov/articles/2010/09/20/2010-23395/request-for-comments-on-incentivizing-humanitarian-technologies-and-licensing-through-the>

Respectfully submitted,
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INSTITUTE FOR INTELLECTUAL PROPERTY & SOCIAL JUSTICE, INC.

*ADVANCING IDEAS
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IIPSJ Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System

November 15, 2010

I. Commenter Information

These comments are submitted by the Institute for Intellectual Property and Social Justice (IIPSJ) at the Howard University School of Law in response to the United States Patent and Trademark Office's Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, as published in the Federal Register, Vo. 75, No. 181, p. 57261-57262, Monday, September 20, 2010 (FR Doc. 2010-23395). These responses were prepared by Bryant L. Young, IIPSJ Chair of Institute Development and Advancement, and Shiveta Sooknanan, IIPSJ Research Fellow in Residence.

The Institute for Intellectual Property and Social Justice (IIPSJ) was founded in 2002 to address the social justice implications of intellectual property law and practice both domestically and globally. IIPSJ's work ranges broadly and includes scholarly examination of intellectual property law from the social justice perspective; advocacy for social-justice aware interpretation, application, and revision of intellectual property law; efforts to increase the diversity of the those who practice IP law; and programs to empower historically and currently disadvantaged and under-included groups to exploit IP effectively.

II. Scope of IIPSJ's Comments

IIPSJ comments on the following questions:

1. The FDA awards priority review vouchers to entities that develop drugs which treat a tropical disease under 21 U.S.C. 360n. Should recipients of this FDA voucher automatically receive a humanitarian fast-track *ex parte* reexamination?
3. What humanitarian issues should qualify for the voucher program? Neglected diseases, debilitating health conditions in developing countries, chronic hunger, widespread public health problems such as lack of sanitation or potable water, and/or other issues predominantly affecting impoverished populations? Can these be defined with reference to existing humanitarian aid organizations?
5. Should the USPTO consider statements from independent third parties (particularly humanitarian organizations or researchers) on the effectiveness or actual use of an invention to address humanitarian needs? Should such submissions be required to qualify for a voucher?

11. Should vouchers to accelerate initial examination rather than reexamination be offered for technologies addressing humanitarian needs? Are there other pro-business strategies that the Department of Commerce or the USPTO should pursue in future programs to incentivize humanitarian research and development and/or best practices for intellectual property with humanitarian uses?

12. Would non-monetary prizes or awards sponsored by the USPTO recognizing humanitarian efforts encourage greater investment in the field? What criteria should be used for selecting recipients?

III. Summary of Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System

Infectious diseases such as malaria, cholera, dengue and tuberculosis continue to plague developing countries and it is estimated that such diseases kill millions of people per year. Research and development (R & D) of drugs and vaccines for infectious diseases affecting developing countries is limited mainly because developing countries have small budgets, weak patent protection, and poor patients who can pay only low prices for drugs or simply cannot afford them.¹ For-profit pharmaceutical companies have little economic incentive for investing resources into the R & D of drugs and vaccines for these diseases.² As a result, the growing importance of intellectual property to developing countries cannot be overstated. Humanitarian-related technologies are especially indispensable.

The United States Patent and Trademark Office (USPTO) is proposing to incentivize the creation and wider distribution of humanitarian technologies by making patent holders eligible for a voucher entitling them to an accelerated re-examination of a patent.³ Eligible technologies include "treatments for tropical diseases, diagnostic medical tools, crops with higher yields or better nutritional value, and treatments for sanitation or clean water."⁴ IIPSJ proposes that an approach that incorporates the following attributes will serve social justice while protecting intellectual property:

- (1) Recipients of the U.S. Food and Drug Administration (FDA) priority review voucher should automatically receive a humanitarian fast-track *ex parte* reexamination voucher from the USPTO;
- (2) The USPTO should consider humanitarian issues in determining who qualifies for the voucher program and should seek the assistance of humanitarian aid organizations in making the determinations;
- (3) The USPTO should consider statements from independent third parties (particularly humanitarian organizations or researchers) on the effectiveness or actual use of an invention to address humanitarian needs, but such submissions should not be required to qualify for a voucher;
- (4) Vouchers to accelerate the entire examination process should be offered for technologies addressing humanitarian needs, as opposed to merely accelerating the initial examination or a reexamination; and

¹ Matheny, J, Smith, B, Courtney, & Mair, M. Drug and Vaccine Development for Infectious Diseases: The Value of Priority Review Vouchers. *Clinical Pharmacology & Therapeutics* 85, 571 (2009).

² Sonderholm, J. In Defence Of Priority Review Vouchers. *Bioethics* 23, 414 (2000).

³ Press Release, 10-41, http://www.uspto.gov/news/pr/2010/10_41.jsp (Sept. 20, 2010).

⁴ *Id.*

(5) Non-monetary prizes or awards sponsored by the USPTO recognizing humanitarian efforts may encourage greater investment in the field and in any event can be used to publicize the program.

IV. IIPSJ's Extended Comments

1. Reexamination voucher

Recipients of the U.S. Food and Drug Administration (FDA) priority review voucher should automatically receive a humanitarian fast-track *ex parte* reexamination voucher from the USPTO. The FDA's Priority Review Voucher (PRV) Program was "designed to encourage development of new drug and biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world."⁵ There has been little progress in the development of drugs for tropical diseases because such diseases are found primarily in poor and developing countries with small budgets, weak patent protection, and patients who cannot afford the drugs.⁶ Past FDA incentives such as government and foundation funding for R & D, the Orphan Drug Act provisions, and purchase agreements such as advance market commitments have been inadequate in encouraging the development of new drugs to treat tropical diseases.⁷ The FDA's PRV program proposes to address this problem and encourage R & D for drugs and vaccines for tropical diseases.

The FDA approves any medical drug for the U.S. market with the review process taking approximately eighteen months.⁸ A PRV stimulates R & D by: (1) expediting the FDA review process and cutting the review time down to about six months; (2) enabling an R & D company to start marketing and selling its products at an earlier stage than it would have been able to under standard conditions; (3) allowing a developer to hold the PRV or sell it to another firm; and (4) entitling a holder of the voucher to priority review of any drug in its portfolio that would otherwise receive standard review.⁹

Since the USPTO proposes incentivizing humanitarian technologies, the agency should utilize the premise of the FDA's PRV Program; in particular, there should be higher priority in the application review process. The FDA program and the proposed USPTO program are similar in that the treatment of tropical diseases is an eligible technology common to both. As a patent is generally sought in conjunction with seeking approval for a new drug, providing recipients of an FDA voucher a humanitarian fast-track *ex parte* reexamination voucher would be rational and prudent.

3. Consideration of Humanitarian Aspects

Humanitarian issues that should be considered in qualifying for the voucher program include:

- (1) the extent of government funding for drugs and vaccines;
- (2) the extent of patent protection that the developing country allocates to drugs and vaccines; and

⁵ Guidance for Industry: Tropical Disease Priority Review Vouchers, <http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0530-gdl.pdf> (last visited Nov. 11, 2010).

⁶ Matheny et al., *supra* note 1.

⁷ *Id.*

⁸ Sonderholm, *supra* note 2.

⁹ *Id.* at 414-415.

(3) whether there is an effective plan to ensure that patients get the drugs and that the drugs are administered properly.

In making these assessments, the USPTO should seek the assistance of humanitarian aid organizations. IIPSJ emphasizes aspects of intellectual property law and practice that impact the participation of historically and currently disadvantaged and under-included groups in the economic, cultural and social benefits of developing, exploiting, and enjoying the fruits of intellectual property. To ensure that disadvantaged and under-included groups in developing countries are not exploited, IIPSJ believes that the USPTO should consider various humanitarian issues in determining who should qualify for the voucher program.

As stated in the Federal Register, some humanitarian issues that should be examined include: neglected diseases, debilitating health conditions in developing countries, chronic hunger, and widespread health problems such as lack of sanitation or potable water. Additionally, humanitarian issues can also include: (1) whether the country has a marginal budget; (2) the extent of government funding of developing countries with respect to R & D of drugs and vaccines for tropical diseases; (3) the extent of patent protection that the government in a developing country has allocated to patent protection of drugs and vaccines for tropical diseases; (4) the percentage of patients who can afford only low cost drugs or who cannot afford the drugs at all; and (5) whether the developing country has an effective plan to ensure that the patients get the drugs and that the drugs are administered in the proper manner.¹⁰ As to the last matter, the USPTO should determine whether there is a physical transportation infrastructure and whether the government in the developing country has a plan for drug distribution and health care personnel so as to ensure that the drugs are properly administered.¹¹

To ensure that the USPTO is not overburdened by researching these issues, it should elicit the assistance of humanitarian aid organizations, such as the World Health Organization (WHO), that are likely to have on hand information and data on the various humanitarian issues outlined.

5. Consideration of Submissions by Independent Third Parties

The USPTO should consider statements from independent third parties (in particular humanitarian organizations or researchers) on the effectiveness or actual use of an invention to address humanitarian needs, but such submissions should not be required to qualify for a voucher. The USPTO already accepts submissions of prior art from the general public. According to 35 U.S.C. § 301, the USPTO allows anyone at anytime to “cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on patentability of any claim of a particular patent.” One can also file a request for reexamination by the USPTO of any patent claim on the basis of prior art cited under 35 U.S.C. § 301.

Statements from independent third parties, particularly humanitarian organizations or researchers, should be received and considered if relevant to the discussion of the effectiveness or actual use of the invention to address humanitarian needs. For instance, aid organizations such as UNICEF, the Red Cross, and the Red Crescent, would be able to provide highly relevant information as non-profits with their missions being international in scope. However, submission of statements should *not* be required to qualify for a voucher since there is no guarantee that third parties will actually submit statements, or that high quality statements that are constructive or relevant will in fact be submitted.

¹⁰ Sonderholm, *supra* note 2, at 416.

¹¹ *Id.*

11. Vouchers for Accelerating Examination

Vouchers offered for technologies addressing humanitarian needs should be used to accelerate the entire examination process, not merely the initial examination or a reexamination. Currently, accelerated examination is available for certain types of patent applications such as those in green technology. According to the Manual of Patent Examining Procedure (MPEP) § 708.02(a), an application can be “filed with a petition to make special under the accelerated examination program” if “the claimed subject matter is directed to environmental quality, the development of conservation of energy resources, or countering terrorism.” Humanitarian technologies are fundamental worldwide and absolutely essential in developing countries. Both green technologies and humanitarian technologies will have a lasting global impact. The modified voucher incentive would allow a business to obtain a patent in another technology in an expedited manner. This incentive should encourage other businesses with diverse technological specializations to invest their expertise and resources in broadening the range of beneficial innovations.

Another option to consider to incentivize humanitarian R & D is the reduction of fees for patent applications in humanitarian technologies, such as allowing a business to pay small-entity fees in exchange for a reduced patent term. This option should entice businesses to invest their resources in engineering technology to benefit individuals from developing nations.

12. Non-monetary prizes or awards

Non-monetary prizes or awards sponsored by the USPTO recognizing humanitarian efforts could encourage greater investment in the field. Public recognition is an effective and beneficial means to promote investment in humanitarian technologies. A publicly held awards ceremony, along with the presentation of a plaque, is a prime example. Other non-monetary prizes or awards can include recognition through internet publication on the USPTO's website, electronic distribution of an official newsletter, and other electronic media outlets. Notably, the National Science Foundation in partnership with the White House bestows the President's Medal of Science, a non-monetary award, to individuals deserving of special recognition for their contributions to knowledge in science and engineering. Although the principal impetus driving a business endeavor is typically that of financial gain, a business entity's goodwill and generosity can lead to a better public perception, which may in turn provide financial rewards, as well as other incentives and long-term benefits.

The criteria used by the USPTO in selecting recipients of non-monetary prizes or awards ought to include but should not be limited to: (1) the impact of the invention on the health and well-being of people; (2) whether the prospective recipient has entered into low or no-cost licenses to manufacture the invention; (3) whether the prospective recipient has assigned its patent rights to an international aid organization; and (4) whether the prospective recipient has reduced the patent term through voluntary abandonment by dedicating the invention to the public domain.

V. Conclusion

IIPSJ fully supports this initiative and sees great potential for partnering among governments, private for-profit businesses, and NGOs to incentivize humanitarian technologies and licensing through the intellectual property system. To address the problem of the limited R & D of drugs and vaccines for infectious diseases affecting developing countries, (1) recipients of the FDA voucher should automatically receive a humanitarian fast-track ex parte reexamination voucher, (2) humanitarian issues and statements from independent third parties should be considered, (3)

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vouchers to accelerate the entire examination process should be offered for technologies addressing humanitarian needs, and (4) non-monetary prizes or awards be granted.

To be effective, programs should focus on what is practical and doable more than on what is merely desired. Programs should take into account in real and significant ways the varying circumstances of the target groups and the various competencies of those providing appropriate services. The need is large and pressing. Nonetheless, to succeed, a program must be finely tuned to the particular aims and circumstances in each setting.

Respectfully submitted:

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