From: Nathaniel Lipkus [redacted]
Sent: Friday, November 19, 2010 1:26 PM
To: HumanitarianProgram
Cc: [redacted]
Subject: Incentives for Global Health - Submission for Docket No. PTO-P-2010-0066

Attention: Edward Elliott and Quentin Palfrey

Dear Messrs. Elliott and Palfrey:

I am writing on behalf of myself, my colleague Jocelyn Mackie, Professor Thomas Pogge and Incentives for Global Health – the originators of the Health Impact Fund. Thank you so much for including us in your October 27, 2010 session regarding incentivizing humanitarian technologies and licensing through the intellectual property system. Jocelyn and I were delighted to attend.

We attach to this email the submission of Incentives for Global Health in response to your September 20, 2010 request for comments. Please do not hesitate to contact us should you have any questions regarding our submission.

Best regards,

Nathaniel

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November 19, 2010

Commissioner for Patents
P.O. Box 1450
Alexandria, VA
USA 22313-1450

Attention: Joni Y. Chan

Dear Ms. Chang:

Re: Docket No.: PTO-P-2010-0066

Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System

Thank you for the opportunity to provide our views on the USPTO's effort to incentivize dissemination of humanitarian technologies through the intellectual property system. We share the USPTO's view that incentives can help to stimulate more useful and more accessible innovation, and we strongly support the USPTO's effort to creatively advance innovation using IP system incentives.

Incentives for Global Health (IGH) is a not-for-profit organization based out of Yale University and our flagship proposal, which has received much press and attention, is the Health Impact Fund (HIF). The HIF is a new mechanism to incentivize research and development into medicines for diseases which mainly affect those unable to pay high prices. The HIF will pay companies based on the demonstrated health impact of the medicine. Our efforts to develop the HIF have required us to grapple with many of the same issues confronting the USPTO in piloting its humanitarian incentives program.

We enclose feedback on several of the issues posed by the USPTO in the Request for Comments. Above all, we wish to stress three principles to guide the USPTO moving forward:

1. **A Simple, Reliable Method of Assessing Humanitarian Impact:** Humanitarian impact should be evaluated using measures that are generally accepted, such as the Quality-Adjusted Life Year (QALY) for interventions that principally affect health. Humanitarian impact should be assessed using a reliable, predictable methodology so that applicants can anticipate how their submissions will be evaluated.

2. **Consider the 'Last Mile' Problem:** In our view, any incentive offered to commercialize technologies for humanitarian impact should accrue as easily as possible to the commercializing entity. Otherwise, the commercializing entity will have minimal incentive, and other rights-holders may be able to prevent commercialization. This approach will also address the 'last mile problem', often encountered in humanitarian efforts, wherein products do not reach their final

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destination due to downstream access barriers.

3. **Technological, Financial & Geographic Neutrality:** All technologies having humanitarian applications which are effectively delivered to impoverished populations should be considered eligible for the reward. Moreover, no population should be treated more favorably than any other in evaluating humanitarian impact, regardless of the country in which the population is located.

Our full submission is enclosed. We would be pleased to provide further feedback to the USPTO as requested regarding this or any other initiative to expand the USPTO's role in promoting meaningful innovation.

Should you have any questions or comments, please do not hesitate to contact us.

Sincerely,

Thomas Pogge Aidan Hollis Tim Gilbert

Directors, Incentives for Global Health

INCENTIVES FOR GLOBAL HEALTH: COMMENTS ON INCENTIVIZING HUMANITARIAN TECHNOLOGIES THROUGH THE IP SYSTEM

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 voucher from the USPTO?*

   No comment.

2. *FDA priority review vouchers are transferrable on the open market. Should USPTO fast-track ex parte reexamination vouchers similarly be transferrable on the open market?*

   Yes, the fast-track ex parte reexamination vouchers should be transferrable on the open market. Their transferability would maximize their value, and would thus provide the greatest incentive to develop and distribute technologies that address humanitarian needs.

   Fast-track ex parte reexamination vouchers are most valuable to patentees with commercially significant patents, which are the subject of patent litigation. Infringement lawsuits, where hundreds of millions of dollars can be at stake, are often stayed pending the outcome of reexamination proceedings, thereby delaying the resolution of the disputes. The delay can cost the parties involved in the litigation millions of dollars in lost opportunity. For example, the settlement won by Visto Corporation in its patent litigation dispute with Research in Motion in 2009 was delayed by several months, possibly even over a year, due to the pending reexamination of the patents in dispute. After the reexamination was complete, the parties settled the matter globally for $267.5 million. A fast-track ex parte reexamination voucher would have eliminated much of this delay, leading to an earlier damages payment, and thus would have been very valuable to the successful party.

   This value would not be realizable unless the fast-track vouchers are transferable on the open market, because the owners of commercially significant patents do not necessarily have the ability to develop and distribute technologies that address humanitarian needs.

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?*

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The humanitarian issues that qualify for the voucher program should be determined in a neutral manner, consistent with three principles: (a) technological neutrality; (b) geographical neutrality; and (c) financial neutrality. Each principle is described as follows.

A. Technological neutrality – All technologies having humanitarian applications should be considered eligible for the reward, as long as they positively affect impoverished populations. Incentives for humanitarian technologies and licensing should not carve-out specific technologies or end-uses because innovation may occur in unpredictable ways. As long as the humanitarian impact is assessed using a reliable, predictable methodology that allows applicants to anticipate how their submissions will be evaluated, innovation will occur where it benefits impoverished populations. If the humanitarian impact of some technologies cannot be compared with others, they can be grouped into appropriate categorie (e.g. health, economic or environmental impact), which would be eligible for a predetermined number of the total available fast-track reexamination vouchers to be distributed.

B. Geographical neutrality – No population should be treated more favorably than any other in evaluating humanitarian impact, regardless of the country in which the population is located. Impoverished populations exist in both developed and developing countries, albeit in smaller numbers in the former. If the effect of one technology on a smaller population is collectively greater than the effect of another technology on a larger population, as determined by a reliable, predictable methodology, then it should be rewarded accordingly.

C. Financial neutrality – The USPTO's reward should be available to entities that develop and distribute technologies to address the humanitarian needs of impoverished populations, irrespective of whether or not such entities are otherwise benefiting from their efforts. The reward mechanism should incentivize sustainable humanitarian impact – impact which will continue after the reward has been received. Some sustainable humanitarian efforts may profit from their endeavors, but they should not be penalized as a consequence by being ineligible to receive a fast-track reexamination voucher.

   A program created by the Incentives for Global Health - the Health Impact Fund (HIF) - serves as a good illustration of this point. Entities participating in the HIF must forgo monopoly pricing in exchange for a reward based on the health impact of their new medicine. In this way, the HIF will stimulate R&D for life saving pharmaceuticals for the world's poor. These entities would be further incentivised if they were also eligible for fast-track ex parte reexamination vouchers. They should not

have to choose between a reward through the HIF or through the USPTO – both should be available to them if they so qualify.

4. *Other than actual use, how can a patent owner demonstrate that a patented technology would be effective at addressing a particular humanitarian issue? What kinds of expertise would be required to make those judgments?*

Generally, a patent owner could demonstrate in advance that a patented technology would be effective at addressing a particular humanitarian issue if it establishes a factual basis for its prediction, and articulates a sound plan for achieving its predicted humanitarian impact. For a drug product, the patent owner could demonstrate its impact in advance if it uses clinical trial data. However, demonstrating potential impact in advance should only be used as a screening mechanism to determine potential eligibility for the reward; it should not be used to determine the winner of the reward. Determination of the recipients of the fast-track voucher reward should be judged after the patented technology has been used to address humanitarian needs, and after results can be measured.

An adjudication board should be used to perform the preliminary screening function and to determine the recipients of the reward. The adjudication board should be comprised of individuals who are adequately equipped to understand the technologies being judged.

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?*

Yes, the USPTO should consider statements from independent third parties. Allowing third party submissions would make the process more credible.

The submissions of the entities applying for the fast-track voucher reward may include third-party submissions; however, such submissions should not be required to provide them to qualify for a voucher. Requiring applicants to provide third party independent information would complicate the judgment process and would make the process expensive. As long as the third-party information is reviewed for relevance and reliability, it should be considered in assessing entitlement to a voucher.

Requiring additional information could also have the adverse effect of encouraging applicants to found and support seemingly independent third-parties such as non-governmental organizations, which might then be called upon to testify in their favor.

6. *Should certain elements (e.g., neglected diseases, tropical crops, developing countries) of qualifying humanitarian criteria be defined with reference to lists or criteria provided by external organizations experienced in such matters, such as the World Health Organization, National Institutes of Health, Food and Drug Administration, United Nations, or U.S. Agency for international Development? If so, which criteria of other public or private organizations should be followed?*

   No comment.

7. *What actions should be considered to determine whether a patent holder has made significant efforts to increase access to a patented technology? What types of evidence of such actions can be submitted to minimize the burden on both patent owners and the USPTO*

   Measuring the effort required to increase access to a patented technology may not be the right approach to determine eligibility for the USPTO's reward. Little effort may be required by a patent holder to make a technology that has a large humanitarian effect accessible to the public. Therefore, the USPTO should instead look at the resulting effect of a technology on the relevant impoverished populations to determine whether a patent holder, having made that technology accessible, is eligible for the reward. The USPTO should measure the humanitarian effect by using methods that are simple and reliable so that the process is efficient, predictable and accurate. Given that patentees may address different humanitarian needs consistent with the overarching purpose of the voucher program, such as health and environmental needs, different methodologies to assess the resulting impact on the impoverished populations will likely be required.

   One such methodology that can be used to assess the health impact of a drug is the Health Impact Fund's (HIF) assessment matrix, in which health impact is assessed in comparison to the outcome that would have been expected in the absence of the drug. The HIF assessment matrix measures health impact using a standard and internationally recognized method to compare and measure the effectiveness of drugs: quality-adjusted life years (the "QALY"). Many factors are considered when measuring someone's quality of life in terms of health. They include, for example, the level of pain the person is in, mobility and general mood.

   The HIF assessment begins by using existing data to determine the health outcome for patient subgroups in the absence of treatment. The incremental QALY impact is then estimated based on clinical trial data and is included in the matrix. Once the drug is introduced, the company provides information regarding the number of doses/treatments sold and patients and/or physicians are surveyed to determine the health impact. This information is

included in the matrix and the actual incremental health impact is measured. In this way, the resulting humanitarian effect of a drug (i.e. the incentivized technology) can be measured in a simple and reliable manner.

For more information regarding the HIF assessment method, please see Appendix I, "Measuring Health Impact".

8. *How should a patented technology's significance to a humanitarian research project be determined? Should significance mean that the research could or would not have occurred without the use of the patented technology? Would considering economic or logistical factors suffice? Should qualifying research efforts meet certain minimum thresholds (resources, number of researchers involved, involvement from recognized humanitarian groups, etc.) to prevent abuse?*

As discussed above, the key requirement should be an *ex post* demonstration of the effective use of the technology for the benefit of impoverished populations.

9. *For the humanitarian research qualification, what factors should determine whether terms of use are generous? Should it only focus on the cost of the patented technology or consider other factors? What if the granting entity retains any rights over the results of the humanitarian research?*

No comment.

10. *How can the program encompass humanitarian issues affecting impoverished populations in more developed countries in a way that is efficient to administer and deters abuse?*

One way to deter abuse would be to implement safeguards such as randomized end-user and distributor surveys to confirm actual humanitarian distribution of the product, and thereby deter abuse. By using such measures, the USPTO can confirm or reject claims made by entities using minimal independently-gathered information.

An example of an efficient method to survey and obtain information directly from end-users is to collect widely dispersed data on patient's health and product sales (if relevant to the USPTO's judgment for reward eligibility) by using mobile phones. Basic software installed on mobile phones can be used to communicate between patients, doctors, pharmaceutical vendors, and public health officials.

For more information about how a robust mobile payment and data collection system can be designed to enhance transparency and accountability, whilst improving the quality of data available for impact

assessment, see Attachment I, Ravalia and Stern, "The MHIF System Supporting the Health Impact Fund with Mobile Technology".

In particular, how should an applicant demonstrate the existence of an impoverished group and that the product or treatment primarily targets that group?

The product or treatment should not necessarily be required to primarily target an impoverished group. The USPTO may want to make the reward available to products or treatments that also target other groups. Otherwise a patent holder would have to artificially reduce access by more privileged groups to its product in order to be eligible for the voucher – a perverse outcome if the technology otherwise stands to benefit impoverished populations. What matters is the effect achieved for impoverished groups.

Applicants should be required to provide evidence that an impoverished group exists and that they are beneficially affected by the product or treatment. Such evidence will differ according to the field of innovation and the country.

A simple and reliable method to determine whether or not an impoverished group exists would be to integrate it into the methodology used by the USPTO to assess the resulting humanitarian effect of an incentivized technology.

The Health Impact Fund (HIF) assessment matrix, explained above, is one such method. It first determines the existence of an impoverished group in its determination of health impact, and then determines if the product or treatment targets that group. The HIF assessment begins by determining the counterfactual health outcome, i.e. the health outcome a treated individual would most likely have obtained in the absence of the treatment. It is obtained by surveying the treatment methodologies used before the introduction of the product in each country or region. The counterfactual outcome would ideally be estimated for defined patient subgroups, with the subgroups being determined based on their relevance to the product. Subgroups could be defined by patient demographics (e.g. age and sex) and by clinical considerations (e.g., co-morbiditities and severity of symptoms). Ultimately, for each country or region there would be an estimate of a "baseline" or counterfactual outcome for each subgroup.

11. *Should vouchers to accelerate initial examinations 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?*

No comment.

12. *Would non-monetary prizes or awards sponsored by the USPTO recognizing humanitarian efforts encourage greater investment in the field*

Yes, a program offering non-monetary prizes or awards sponsored by the USPTO recognizing humanitarian efforts would encourage greater investment in the field. The keys to a successful program are to utilize a reliable methodology and to provide applicants with a reasonable chance of success.

What criteria should be used for selecting recipients

The selection of potential recipients raises a few issues worth highlighting.

The first issue is whether the reward should be available only in relation to patented technologies used to address humanitarian needs, or whether it should be given in relation to any technology, patented or not, used to address humanitarian needs. While we understand the USPTO's need to tie its incentive system to patents, it is worth noting that requiring patent protection on eligible technologies would fail to take advantage of a distinct benefit held out by rewards as compared to patents, especially in the context of pharmaceuticals: rewards can provide incentives for a broader range of valuable developmental activities than what would qualify as "innovative" under the patent system's proxies.

For more information and a discussion on whether or not a patent requirement for a reward should be in place, see Attachment II, Syed, "Should a Prize System for Pharmaceuticals Require Patent Protection for Eligibility?". As Syed shows, for drugs, what is really critical is recognition of a new use or product by regulatory authorities. However, the Health Impact Fund is not designed to reward "innovation" so much as impact through innovation.

The second issue is whether or not potential recipients of the reward are limited to the legal owners of the technologies used to address humanitarian needs. Technologies are not necessarily deployed and distributed by their owners; this role is often played by commercializing entities. Entities who commercialize technologies will have minimal incentive to deploy and distribute technologies which address humanitarian needs to the end-consumers if they are ineligible for a reward or if an upstream patentee is able to block the reward. Therefore, it is arguable that any incentive offered to commercialize technologies for humanitarian impact should be conferred on the commercializing entity, as long as they possess a license enabling the humanitarian contribution. Such an approach would help solve the last-mile

problem – which occurs when solutions for the poor do not make it far enough down the distribution chain to actually reach the populations in need.

The third issue is to determine how much humanitarian impact is necessary to make an applicant eligible for the fast-track reexamination voucher reward. An applicant may not be willing to expend the time and resources necessary to address humanitarian needs if it is uncertain as to whether or not it will likely obtain a reward. To overcome this issue, the USPTO should consider making the program a two-step process. The first step of the program would involve having the applicant make a proposal for its anticipated humanitarian impact. The USPTO would accept proposals that meet its criteria, up to the number of fast-track vouchers it has available (e.g. based on humanitarian impact, or the number of fast-track vouchers available). The applicant would then do what it promised under the proposal, and the second step of the program would evaluate the outcome as compared to the proposal. If the applicant fulfilled its promise and achieved its level of humanitarian impact, it would be awarded a fast-track reexamination voucher. If the applicant did not fulfill its promise by failing to achieve its level of humanitarian impact, it would not be awarded a fast-track reexamination voucher. In this way, the USPTO's program would adequately incentivize potential recipients and the USPTO would also have certainty in its obligation to provide the rewards.

Appendix "A"
Measuring Health Impact

Method of Measurement: QAL

The health impact of the drug will be measured using a standard and internationally recognized method to compare and measure the effectiveness of drugs: quality-adjusted life years (the "QALY").

Many factors are considered when measuring someone's quality of life in terms of health. They include, for example, the level of pain the person is in, mobility and general mood. The quality of life can range from negative values below 0 (worst possible health) to 1 (the best possible health).

Many organizations including the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom and the Pharmaceutical Benefits Scheme ("PBS") in Australia use the QALY to measure drug effectiveness. However, no organization has yet used the QALY to measure and pay for drugs based on *actual* demonstrated health impact; this is what the HIF will set out to do.

How QALY will be calculate

Step 1: Establish baseline outcomes based on clinical trial data

- An important first step for estimating QALY impact is knowledge of the counterfactual health outcome (i.e. the health outcome in the absence of the treatment). The difference between the counterfactual health status and the actual health status will be the health impact of the drug.
- The counterfactual health outcome will be estimated using existing data, ideally for defined patient subgroups.

Step 2: Estimate incremental QALY impact ("IQI") by patient subgrou

- Based on clinical trials performed before market approval, the estimated expected IQI for each relevant patient subgroup will be established and included into a matrix.

Step 3: Introduce drug; collect consumption and health impact data

- Company will provide information regarding number of doses / treatments sold. HIF and Company will track sales though the distribution system to the retail and, when possible, patient level.
- Prescribers and patients will be randomly surveyed to determine how and by whom the product is being used. Patients, and where applicable, physicians and other health workers will be randomly surveyed to determine the actual health impact of the drug.
- The HIF and Company will collaborate with various stakeholders in the drug distribution chain to obtain this information.

Step 4: Adjust estimated IQI based on collected data to determine actual IQI

- The expected IQI for each patient subgroup, established at Step 2, will be applied to the number of doses/treatments consumed among the respective subgroups; and then adjusted for actual demonstrated health impact, to determine the drug's actual IQI.
- Factors that could impact actual health impact include: unanticipated side effects; off-label use; stage of disease; unanticipated incremental benefits.
- The amount of the reward is based on the resulting incremental health impact of the drug.