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Attached is a response to the request for comments on the humanitarian initiative proposed by the USPTO.

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November 19, 2010

Response to Federal Register Notice Docket No. PTO-P-2010-0066
Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System

Submitted by: **Dennis C. Liotta, Ph.D, Stephen D. Sencer, J.D., Liza S. Vertinsky, Ph.D, J.D., Susanne Hollinger, Ph.D., J.D. of Emory University**

Summary

Emory University strongly supports efforts aimed at advancing the development and distribution of technologies to address humanitarian needs and encourages the USPTO in its efforts to promote the same. Many universities have given considerable thought to encouraging humanitarian activities through licensing and have come up with certain requirements as part of their licensing practices and in our opinion the USPTO's proposal can provide additional leverage in securing licensing terms with humanitarian goals. Although the financial requirements of developing new technologies to address humanitarian needs likely far outweighs the incentive of the USPTO's proposed voucher, we believe the voucher should be viewed within the context of global efforts within the administration to encourage development of such technologies. Further, we recognize that the proposed voucher could encourage the repurposing of technologies for humanitarian needs and suggest that the USPTO strengthen its program to promote the same.

Overview

On September 20, 2010, the USPTO requested comments on its proposal to issue a “fast track ex parte reexamination” voucher as an incentive to stimulate technology creation or licensing that addresses a humanitarian need. Under the proposed program, a patent holder demonstrating humanitarian uses of a patented technology would be issued a voucher which entitled it to “fast-track” proceedings in any pending *ex parte* reexam. Such a voucher would entitle the applicant to have the next action in a pending *ex parte* reexam move to the front of the examiner’s queue and for the total time of USPTO review for that reexam to be six months or less (when possible).

The proposed voucher would issue based on an analysis of whether an organization engaged in intellectual property practices that qualify as “humanitarian” use or research. Whether there is “humanitarian use” is subject to four principles: whether subject matter addresses a recognized humanitarian problem; whether the technology can be effectively used to solve such a problem; whether the technology is available to impoverished populations; and whether the applicant has made significant efforts to increase access to the technology. Whether the technology has been used for “humanitarian research” includes an analysis of whether the patented technology makes a significant contribution to research on a problem primary affecting impoverished populations; and whether the patented technology was made available to researchers. In both cases, the USPTO has requested comments as to a workable test to apply such principles.

Response

The goal of this program is laudable, however we suggest that implementation may be difficult under the current scope, and we suggest that certain modifications would better address the stated goals of the program.

1. Expand the scope of the Proposed Voucher

We believe the USPTO is in a good position to encourage the development of technologies that have dual uses by encouraging patent holders to allow third parties access to their patents for service of underserved markets. We suggest that the USPTO strongly consider expanding the scope of the proposed voucher to include not only *ex parte* reexamination, but to allow acceleration of any *ex parte* action in any pending or issued patent or patent application. This expansion will make the voucher more appealing to the general business community and allow such vouchers to be more readily transferable on the open market.

We suggest that the program be separated into two components:

- a) an “acceleration voucher” that provides acceleration of any pending *ex parte* proceeding and can be requested by any entity which makes a significant humanitarian contribution; and
- b) accelerated examination of any patent application for which the applicant agrees to be bound by humanitarian licensing provisions.

The first component would function much like the proposed voucher, but instead of focusing on the use of a specific patented technology for humanitarian use, it would act more like the FDA voucher program which provides a voucher that can be used to accelerate agency review for any application. Such a program would promote early patenting by an applicant without the risks that are inherent in providing examination support documents and pre examination searches, as currently required. We understand that there are certain concerns that such a program would potentially increase the backlog at the USPTO, however as long as the voucher is given only for significant humanitarian contributions (see below), we do not believe that the volume would cause a serious burden on the USPTO examining corps.

The second suggested component would function much as the current USPTO “Green Technology Pilot Program,” in that an entity could “opt in” to a requirement that they provide access to the technology for certain purposes while continuing exploitation of the technology in the marketplace. The goal of this program is to promote open access to existing technologies, particularly dual purpose technologies, and allow entities beyond the patent holder to pursue these technologies for humanitarian purposes. To “opt in,” an entity would have to agree to enter into a standard form, non-exclusive license for use of the technology described in the patent application during development or in distribution to certain countries, as long as any sale is ‘at cost.’ This proposal is well aligned with the administrative identity of the USPTO, as an applicant would donate patent rights that are issued by the USPTO (and potentially also other patent offices). Certain concerns are raised with this proposal such as how many vouchers a single entity could receive but we suggest that these can be addressed with terms in the humanitarian license that are slightly unfavorable to the patent owner, such as terms that allow a third party to own all intellectual property resulting from the use of the patents.

2. Third Party Review Process

Regardless of the type of incentive provided, a key component that needs to be addressed to make the voucher program feasible is a method for identifying how an entity would be entitled to a voucher. We believe that the USPTO is struggling with this component in part because of the breadth of work it intends to encourage.

As noted above, one method is to provide a voucher for an entity that agrees to humanitarian licensing. In our opinion, this type of voucher should be applicable *only* to the patent application in which it is provided. Further, we suggest that such a voucher only be available if there is also a showing by the applicant that the patented technology has an actual humanitarian potential. This is consistent with the requirements being promoted by the USPTO in its Green Technology initiative and can be administered by the USPTO.¹

If, on the other hand, a more generally applicable voucher, based on “humanitarian use” or “humanitarian research” is issued, we suggest that this voucher be given to any entity that can prove that it has significantly affected a humanitarian problem, regardless of whether this effect is with a patented technology. We also suggest that the USPTO consider issuing a voucher not to a particular technology but instead to a “program”, thus allowing applicants to obtain a single voucher for significant efforts in a particular area of research or development.

We note that the scope of the program is so broad that meaningful criteria are difficult to establish. However, to the extent that the USPTO continues to promote a broad reaching program rather than focusing, for example, on neglected tropical diseases (NTDs) as was done at the FDA, we strongly suggest a more structured program to review the grounds upon which such a voucher should issue.

In our opinion, the USPTO is not ideally suited to review whether an entity meets the criteria of “humanitarian” use or research. Not only is this not an area of expertise by the USPTO, but given the breadth of the program, entities may qualify based on different effort levels, depending on the type of technology. For example, although approval of a new drug for a NTD would likely be sufficient, it is not clear that building a water purification plant in a community would be. This may depend on the needs of the community and the financial, political and human costs associated with building the plant, which only an expert in the area would be familiar with.

We suggest that the USPTO consider asking an agency with expertise in the area to provide comprehensive guidelines on what proof of efficacy or access would be needed, depending on the type of technology. Further we suggest the USPTO consider establishing a panel of experts in global health issues to review the requests for voucher. This panel could be structured similarly to an NIH study section, with each panelist serving a specific term and asked to meet on a periodic basis to review voucher applications.

Should a tradable voucher be issued, we recommend a high standard to be met for obtaining one. Things such as FDA approval of drug for use in treating neglected disease are likely to meet this requirement, but a clinical trial that examines effectiveness of drugs in underserved markets may only meet the requirements in certain instances.

¹ We note that the burden on the USPTO for administration of any of these programs is high and suggest a review of the internal FTE requirements of any of these programs. A clear identification of the cost of this program would assist in a proper review of what programs would be appropriate.

Comments on specific questions:

1. Should recipients of the FDA voucher automatically receive a humanitarian fast-track voucher from the USPTO?

- As noted above, although we suggest a review panel to rate which technologies should be given such a voucher, it seems logical that any entity that meets the requirements under 21 USC 360n would have sufficiently contributed to meet the USPTO requirements. We see no problem in issuing two vouchers to an entity based on such a significant contribution, and indeed believe that enough of these type of recognitions when put together may be sufficient to provide a true incentive for technology development.

2. Should USPTO fast-track vouchers be transferable on the open market?

- We strongly believe that the transferability of such vouchers would increase their value and therefore encourage the USPTO to allow their transferability.

3. What humanitarian issues should qualify for the voucher program?

- As noted above, we believe that the breadth of humanitarian issues proposed by the USPTO is so broad that it makes administration of this program difficult to conceptualize. That being said, we applaud the USPTO for taking such a far reaching approach. To the extent that the USPTO stays with a broad definition of the humanitarian issues being addressed, we suggest that the USPTO either reach out to an agency with expertise in global issues or assemble a panel of experts to provide a specific list of criteria for qualification. We also suggest that the USPTO investigate a staggered approach in which it initiates the program with a focus on NTDs, which are well defined and impact can be measured, and then pursue additional scope in an expansion program.

4. Other than actual use, how can a patent owner demonstrate that a patented technology would be effective at addressing a particular humanitarian issue?

- As we discuss above, we suggest that the USPTO not focus on the development of the ‘patented’ technology but instead focus more generally on a technology “program” that is being promoted by a patent holder. To the extent that the USPTO stays with a broad definition of the humanitarian issues being addressed, we suggest that the USPTO either reach out to an agency with expertise in global issues or assemble a panel of experts to provide a specific list of criteria for qualification

5. Should the USPTO consider statements from independent third parties on the effectiveness or actual use of an invention to address humanitarian needs?

- As noted above, we suggest that the USPTO collaborate with entities that have more expertise in these issues to provide certain criteria for acceptance, and that the USPTO assemble a review board or panel of experts in the area that meet periodically to review these applications.

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?

- As noted, we suggest that the USPTO reach out to at least one, and preferably more than one, of these agencies to identify listings of criteria that should be reviewed for inclusion.

This listing should be provided to applicants to allow these to assemble useful submissions for review.

7. What actions should be considered to determine whether a patent holder has made significant efforts to increase access to a patented technology?

- As noted, we suggest review by an independent panel of experts to establish what actions should be considered sufficient to qualify for such a voucher. Because of the breadth of the proposed program, it would be virtually impossible to identify these criteria in the abstract and they almost by definition require individual review.

8. How should a patented technology's significance to a humanitarian research project be determined?

- One major concern is that a project that is intended to address a humanitarian concern must be separable from one which has merely a tangential connection to the area. Although it would be extremely difficult to establish that a research program would not have occurred but for the voucher, it is not hard to show that the research has as one of its objectives an area that is under-researched and that has importance for understanding and addressing humanitarian problems.

9. For the humanitarian research qualification, what factors should determine whether terms of use are generous?

- We suggest that such a research qualification could have at a minimum a right to use for research purposes and a right to practice to serve markets in low income countries. We also suggest that the granting entity be required to grant rights to any results of the humanitarian research as part of the initial grant.

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?

- As noted above, to the extent that the USPTO provides detailed guidelines for application submission and provides review of these applications by a panel of experts in the area, we believe that there would be little potential for abuse. Further, although the administration of the program will likely require some significant commitment before implementation, once guidelines and panels are established, the USPTO would likely have a relatively low burden in maintaining the program.

11. Should vouchers to accelerate initial examination rather than reexamination be offered for technologies addressing humanitarian needs?

- As noted, we believe that expanding the applicability of the voucher to any ex parte proceeding, including initial examination would increase its value. We further suggest that a separate program be instituted that allows an entity to expedite initial examination on any application when it agrees to open access terms on that patent. To discourage entities from abusing this license, we recommend terms such as that the third party would own any resultant work and inventions.

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

- We are not certain of the benefit to such a prize.