

From: Vincent Garlock [mailto:vgarlock@aipla.org]

Sent: Friday, November 19, 2010 1:23 PM

To: HumanitarianProgram

Cc: Clarke, Robert (OPLA); Chang, Joni; Albert Tramosch; Todd Dickinson; James Crowne; Hill, David

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

Dear Rob and Joni,

On behalf of the American Intellectual Property Law Association (AIPLA), please see the attached letter from Executive Director Q. Todd Dickinson, containing AIPLA's response to the Request for comments regarding Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System.

I would appreciate receiving an acknowledgment of this submission and thank you in advance for your consideration of these comments.

All best wishes,

Vince Garlock

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November 19, 2010

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Comments on “Request for Comments on Incentivizing Humanitarian
Technologies and Licensing Through the Intellectual Property System”
75 Federal Register 57261 (September 20, 2010)

Dear Under Secretary Kappos:

The American Intellectual Property Law Association (AIPLA) appreciates the opportunity to offer comments on the Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, 75 Fed. Reg. 57261 (“the Notice”). The proposal to offer fast-track reexamination as an incentive for creating technologies and licensing behavior that address humanitarian needs raises important concerns. The current proposal, however, is unlikely to achieve the desired results, and may create the undesirable impression that reexamination is a necessity because issued patents are inherently unreliable or defective. As discussed below, a much more positive incentive, such as accelerated, careful examination of initial patent applications (and possibly reissue applications) would better advance the expressed interests of the proposal.

AIPLA is a national bar association whose more than 16,000 members are primarily lawyers and other patent practitioners in private and corporate practice, in government service, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property.

The PTO has proposed to offer a fast-track *ex parte* reexamination voucher to patent holders demonstrating humanitarian uses of patented technologies. The voucher could be used on any patent owned by the patent holder or transferred on the open market. Although *ex parte* reexamination proceedings are expected to be conducted with special dispatch by the PTO (35 U.S.C. § 305), fast-track processing would be given the highest priority with a stated expectation that the current 19–20 month period for a reexamination would be reduced to about 6 months.

As an initial concern, AIPLA would prefer that the current delays in PTO “special dispatch” reexamination processing be addressed, rather than create a “fast-track” option that would further tax the resources of the current reexamination system. Reexamination was once envisioned as a relatively quick, low-cost alternative to litigation. Recent statistics, however, show that reexamination is increasingly used as a component of a more comprehensive litigation strategy. Many patent owners, particularly small entities, do not favor the current reexamination, as it is perceived (rightly or wrongly) as a system used by their opponents to destroy patent rights.

The patent system itself, offering all of the benefits of a carefully examined, issued patent, is a very significant positive incentive for the development of new technologies, including those contributing to humanitarian efforts. It is difficult to see how an offer to “fast-track” reexamination of such an issued patent would be viewed as an incentive to develop those technologies, particularly for small entities. AIPLA believes that the PTO should focus on providing an incentive for developing humanitarian technologies with a more positive focus.

The Notice makes reference to a program of the U.S. Food and Drug Administration (FDA) that offers fast-track review vouchers to entities that develop drugs to treat neglected tropical diseases, and to recent legislative proposals on rare childhood diseases that can use incentives in the existing systems to encourage the development of humanitarian technologies. In the past, the PTO offered accelerated examination of patent applications directed to treatments and cures for HIV/AIDs and cancer—a practice that was discontinued in favor of accelerated examination requirements aimed more at assisting the PTO than assisting in the development of these much needed technologies. See MPEP 703.02(X) and 703.02(a)(I). A PTO program with such a positive focus on the direct needs of inventors, namely, an accelerated, careful examination of their initial patent applications (and possibly reissue applications), offers a much more tangible and useful incentive for those developing technologies with humanitarian uses. Accordingly, the USPTO should implement incentives for humanitarian contributions that emphasize the positive aspects of the examination system.

Further, offering a fast-track reexamination voucher as an “incentive” suggests that every examination leading to the grant of an original patent is so open to question, or is potentially so flawed, that reexamination of issued patents is a necessary and justified step in every case to determine whether an inventor should be accorded any rights at all. Rather than providing a reward for a humanitarian contribution, this program is very likely to send the wrong signal to Congress, the public, and the courts.

The proposal also leaves open the appropriate test for defining the “humanitarian use” that would be a threshold requirement for the accelerated reexamination, as the questions raised by the PTO demonstrate. In fact, it seems impractical for the PTO to attempt to define the parameters for determining humanitarian use, or to develop the metrics required to measure the various socio-economic factors that may be used to make those assessments. Since it is doubtful that the PTO has the resources or the expertise to independently make evaluations of this type, it is suggested that the PTO rely on other agencies (e.g., the FDA) to identify those technologies that should be subject to special incentives for humanitarian or other purposes.

The PTO has identified several questions to be addressed by those submitting comments. AIPLA has addressed the more general questions only (1, 2, 11 and 12).

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?

As described above, AIPLA does not favor fast-track reexamination as an appropriate incentive for stimulating the development of humanitarian technologies. However, the reward of an accelerated patent application examination voucher to recipients of an FDA voucher would be an appropriate incentive that the PTO could offer. Several of our members have questioned whether any PTO reward would have any impact on a patent owner's decision to develop or make available humanitarian technology at something less than a reasonable market price. It is possible, however, that an additional or alternative positive benefit derived from such a decision, such as accelerated examination, could offer some incentive to those patent owners.

The reliance of this proposal on the FDA's identification of worthwhile technologies would have the additional benefit of avoiding any significant resource allocation to this effort by the PTO. Not only would the PTO avoid the difficult determination of whether certain contributors are "humanitarian," it would avoid placing that additional burden on the reexamination unit, which is challenged to process reexamination proceedings with the statutorily mandated "special dispatch." Moreover, if the reexamination unit is forced to give special consideration to one reexamination proceeding, the other pending proceedings, which may have equal or greater significance than the "accelerated" reexamination, will be delayed even further. That is not a desirable result by any measure.

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

If accelerated examination is selected as the suitable reward, then there does not appear to be any harm in making that option transferable on the open market. If the PTO ultimately adopts its recent proposal of making accelerated examination available for a fee, then such an implementation would place a practical limit on the value of an accelerated examination voucher on the open market.

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?

Yes, vouchers to accelerate initial examination of an original (and possibly reissue applications) would be a more appropriate incentive to develop technologies addressing humanitarian needs.

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?

While it is doubtful that non-monetary prizes or awards would play a significant role in any decision to make an investment in humanitarian technologies, those that elect to make such an investment are likely to favor recognition of their efforts. The criteria to select recipients of such recognition should be the same as those for obtaining an accelerated examination voucher.

We appreciate the opportunity to provide these comments on the Notice regarding the Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System, and would be pleased to answer any questions our comments may raise. We look forward to participation in the continuing development of rules applicable to PTO patent practice.

Sincerely,

A handwritten signature in black ink, appearing to read "Q. Todd Dickinson", with a long horizontal flourish extending to the right.

Q. Todd Dickinson
Executive Director
AIPLA