

Comments from Public Health Civil Society Organizations

In response to:

United States Patent and Trademark Office's "Humanitarian Pilot Proposal"

March 4, 2011

The undersigned organizations would like to thank the USPTO for this continued opportunity to comment on its proposed program to "Incentivize Humanitarian Technologies and Licensing through the Intellectual Property System." We previously submitted comments on this proposed pilot program on November 19, 2010 and have attached them to these comments as Appendix 1 and Appendix 2.

New mechanisms are needed to promote technological advances, including accessibility and affordability of these advances, for disadvantaged populations, and we are pleased that the USPTO is working to create new incentives. The USPTO's "Humanitarian Pilot Proposal" incorporates several positive aspects and we congratulate the USPTO in seeking to include these components in its pilot program.

In particular, we are supportive of the elements of the Humanitarian Pilot Proposal that:

- Set forth a pilot that will be run as a prize competition. (Section 1)
- Include a structure with an external selection committee comprised of experts in the field of humanitarian issues with assurance that conflicts of interest must be avoided. (Sections 1(c) – 1(d))
- Take a broad approach with regard to technological and geographic neutrality, permitting inventions from any field of technology to qualify, as well as allowing any impoverished population to be included in the program. (Section 3(d)(i)-(ii))

We appreciate the efforts of the USPTO to include these components in its proposal.

We would also like to offer the following additional comments on the pilot program.

Expanding the program to include the opportunity to use a voucher to accelerate reexamination of low-quality or overly broad patent claims.

Section 2(c) notes that, "Vouchers can only be used by the voucher holder to accelerate one of their own patent cases," preventing the voucher holder from using the award for third-party patent reexamination. Section 2(c) of the proposal would prevent a voucher holder from using its voucher to initiate a third-party patent reexamination seeking to invalidate a low-quality patent or overly broad claim.

By expanding the program to allow fast-track third party reexamination, the USPTO could potentially increase the value of the voucher by attracting bidders who not only want to advance their own case, but also those seeking to challenge a particular patent.

We also note that one of the most compelling and important criticisms of the patent system is the regrettable but predictable issuance of patents of low quality. Thus, not only does an exclusion limit the usefulness and value of the voucher, it provides a bias in favor of patents that never should have been granted in the first place, by excluding from its benefits an important mechanism to eliminate such patents.

Mandating continued transparency to provide the public with information regarding the applications, prizes, value of the voucher, and impact of the awards.

We value the opportunity to submit comments regarding the USPTO’s pilot voucher program and the continued efforts by USPTO to engage stakeholders in the development and design of this initiative. Transparency is a crucial component of the program and we recommend that the proposal be amended to add provisions requiring:

- Applications for the prizes be made available to the public.
- The decisions, evidence and rationale used by the expert committee in awarding a voucher to a patent-holder be made available to the public.
- Amount of money a voucher holder receives from transferring its prize on the open market should be made available to the public so that the value of the voucher may be assessed.
- Impact that the voucher has on the acceleration of the re-examination or appeals process be assessed and made public.
- Allowing open third-party comment on prize applications that will be evaluated by the expert committee evaluating the application.

The current proposal already takes some steps to promote transparency, but these elements can be strengthened. For example, while Section 2(e) notes that “Voucher holders *should* publicly report the compensation received in a transfer to enable market valuation of the vouchers,” (emphasis added), the word “should” suggests that voucher holders can make the determination to make the information public or not. This section would be made stronger by replacing the word “should” with the word “must,” thereby requiring public disclosure.

Additionally, while Section 3(e) of the proposal does envision third-party statements supporting the prize application, this provision appears to allow only those comments solicited by applicants. The pilot proposal could improve this point by allowing all third-party comments—both supporting and criticizing the prize applications—rather than solely those solicited by patent-holders. Accepting open third-party comments improves the channels of information by allowing experts in the field to submit their knowledge regarding particular applications. This will be particularly important to groups working in the public health field, where some voluntary licensing activities described by patent owners as humanitarian have been described by public health groups as insufficient, narrow or even in some cases, anti-competitive and possibly in violation of foreign or U.S. competition laws.

Defining qualifying humanitarian use and promoting open licensing.

In considering what is a “humanitarian issue” or “recognized humanitarian issue,” inventions that address nutrition, access to knowledge, and other needs that concern the quality of life should be included as qualifying for the voucher. In the area of public health, the USPTO should consider as qualifying projects licensing actions that expand access to any important health related technologies for any diseases or conditions by any impoverished population, no matter where they live. We stress this primarily because of past efforts by some to limit certain access expanding initiatives to a limited number of diseases, and because the FDA priority review voucher is limited to particular diseases. Additionally, limits may fail to anticipate emerging humanitarian challenges that could benefit from innovative solutions. We oppose limits on the basis of diseases or conditions. The more important criteria should be: does the invention have the possibility of improving the health of the impoverished population? USPTO could limit abuse by following our above recommendation – namely to invite third party statements from any interested stakeholder, in lieu of limiting comments to those approved by applicants.

Additionally, it is crucial to ensure that humanitarian technologies are practically accessible, usable and affordable for those who need them. We encourage the USPTO to consider requiring applicants to provide open licensing of the technology or require fulfillment of a market penetration test of the technology proving that the products have reached patients in a sufficient quantity, at an affordable price, and of high quality.

We are supportive of USPTO’s efforts to implement this pilot program and appreciate this opportunity to comment on its revised proposal.

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