

Comments from Public Health Civil Society Organizations

In response to:

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

Department of Commerce, United States Patent and Trademark Office

Docket No. PTO-P-2010-0066

November 19, 2010

The United States Patent and Trademark Office (USPTO) is considering creating a new mechanism to “Incentivize Humanitarian Technologies and Licensing through the Intellectual Property System.”

In a September 20, 2010 Federal Register Notice, the USPTO proposes a pilot program to grant vouchers to create incentives for technologies and licensing behavior that address humanitarian needs. The vouchers would enable applicants to obtain an accelerated *ex parte* re-examination of any patent they own, or could be transferred on the open market.

The undersigned organizations offer the following comments pursuant to the Federal Register Notice. Although we recognize the voucher program may apply to a broad range of humanitarian technologies, this submission focuses on medical innovation, particularly pharmaceuticals and diagnostic technologies.

Firstly, we would like to congratulate the USPTO for considering new mechanisms to encourage innovation and licensing of technologies for humanitarian purposes. The USPTO’s proposal recognizes implicitly that the patent system as presently implemented fails to adequately serve the needs of neglected populations around the world. New mechanisms are needed to incentivize technological advances responsive to the needs of developing countries, and to ensure that these technological advances can provide meaningful benefits to disadvantaged populations. This is notably true for technological advances to protect and promote public health.

The voucher program must be carefully designed if it is to deliver real humanitarian benefits, and avoid becoming a public giveaway of valuable rewards for little in return. Further, if the mechanism is improperly designed or implemented it could have unintended, harmful consequences that would undermine its purported benefits.

Our submission provides a series of recommendations that would ensure the voucher program provides the greatest incentive potential for humanitarian technological innovation and access, including in particular through open patent

licensing and technology transfer to developing countries. We would like to offer the following nine recommendations, which are discussed in greater detail below.

The voucher program should:

- Ensure policy coherence with U.S. global commitments on public health, innovation and intellectual property.
- Ensure that the incentive mechanism is designed to motivate innovation and dissemination of technologies responding to a wide range of diseases and health concerns.
- Ensure that the program provides significant incentives, potentially by limiting the number of vouchers provided, as with a prize.
- Ensure an effective accessibility and affordability strategy.
- Favor humanitarian open licensing and technology transfer practices that include a wide geographical scope, including all developing countries.
- Institute a system to meaningfully ascertain the humanitarian value of the technology and dissemination mechanisms.
- Ensure that the mechanism does not incentivize unnecessary patenting.
- Prevent abuses of a system established under the voucher program.
- Ensure continued transparency.

RECOMMENDATIONS:

A. Ensure policy coherence with U.S. global commitments on public health, innovation and intellectual property.

The voucher program is more than an incentive mechanism and will be judged by more than the individual contributions it generates for global public health. The guidelines will also frame existing US policy-making on intellectual property, innovation and public health. The program could help establish models for effective humanitarian incentives and licensing practices, or on the contrary, establish a model that rewards inventions and terms of access that contribute little or potentially have harmful effects.

We expect the USPTO to seek consistency and coherence with U.S. government commitments on public health, innovation and intellectual property. These commitments include the WTO Doha Declaration on TRIPS and Public Health; the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property; the WIPO Development Agenda; and the recent announcement by the U.S. National Institutes of Health of a contribution of intellectual property to the Medicines Patent Pool.

The voucher program should demonstrate policy coherence with U.S. international commitments to support access to medicines and health technologies, and to incentivize the development of new tools.

B. Ensure that the incentive mechanism is designed to motivate innovation responding to a wide range of diseases and health concerns.

The voucher program should be applicable to humanitarian inventions that improve prevention, diagnosis and treatment for a broad scope of diseases and health concerns. This would be different from the approach of the FDA Priority Review Voucher (PRV) program, which is currently limited to a list of neglected tropical diseases (NTDs) hand-picked by policymakers.

Access to medicines initiatives must not be limited to a specific list of diseases. This view has been reaffirmed internationally, for example by the Doha Declaration on TRIPS and Public Health, which applies to all public health concerns. This is important particularly as the disease profile of developing countries has and will continue to evolve. For instance, developing countries need access to appropriate and affordable medicines to treat and prevent both communicable and non-communicable diseases.

Practically, the U.S. Government cannot accurately list the existing or future diseases of greatest importance to developing countries. This risks excluding crucial diseases.

Even in attempting to address only NTDs, the FDA's PRV program, for instance, excluded significant NTDs, including Chagas disease, the largest parasitic killer in the Americas.

C. Ensure that the program provides significant incentives, potentially by limiting the number of vouchers provided, much like a prize.

The USPTO proposal may be most likely to fulfill its humanitarian mission and have greater economic value if designed as a prize-like incentive where a limited number of vouchers are granted every year. This would tend to increase the value of each voucher. It would also stimulate competition to demonstrate the most significant humanitarian innovation and the best terms of access and dissemination. Competition would help promote a "race to the top" among different applicants.

Nevertheless, under a prize system it is important that the USPTO maintain rigorous minimum standards for the award of any voucher. The Expert Committee described below could help elaborate a checklist of possible humanitarian criteria and initiatives that could be considered as a starting point to assist in the effective evaluation of proposals under the voucher program.

Some possible humanitarian criteria and initiatives under the checklist could include the following:

- 1) Where relevant, a commitment by the applicant to license resulting technologies to the Medicines Patent Pool Foundation or similar collective management mechanisms,
- 2) Strategies to promote the open sharing of knowledge and data that accompany the relevant invention, including the open publication of results in free publications available on the Internet, the sharing of compound libraries and other practices,
- 3) Where possible, commitments to enable transfer of technology to all interested public sector institutes and laboratories.

The checklist should be considered non-exhaustive and made public (and also seek public comment). It should provide direction to the applicants on the kinds of initiatives that would be predictably rewarded under the USPTO program but should not limit priorities and ideas that emerge from applicants. Finally, for any application, there must be guidelines that prevent any abuse of the voucher program and that establish sensible minimum criteria that all applications must meet.

D. Ensure an effective accessibility and affordability strategy

It is crucial to ensure that humanitarian technologies are practically accessible, usable and affordable for people that need them. The USPTO program should require applicants to have a clear and effective accessibility and affordability strategy to ensure broad access in the developing world, establishing clear access criteria for the invention that are tied not only to products but also to the results of the research. The access criteria could be different for early stage and late stage development products.

Some steps that the USPTO can take to encourage an effective accessibility and affordability strategy include:

- Require open licensing of the technology; or/and
- Require fulfillment of a market penetration test of the technology proving that the products have reached patients at sufficient quantity, affordability, and quality.

E. Favor humanitarian open licensing and technology transfer practices that include a wide geographical scope, including all developing countries.

The USPTO program should acknowledge the importance of transfer of technology and generic competition as the proven method to ensure long term and sustainable humanitarian access initiatives. In this sense, the voucher program should favor and incentivize open licensing practices.

Both access considerations and economic realities urge that humanitarian licensing practices that are rewarded with a fast-track voucher include a wide geographical scope, including all developing countries. The U.S. Government has already committed, under the WTO Doha Declaration on TRIPS and Public Health, that safeguards and flexibilities under the TRIPS Agreement are applicable to all countries.

The US Government has recently acknowledged the importance of a wide geographic scope for licensing humanitarian inventions under the terms of the license agreement between the National Institutes of Health and the Medicines Patent Pool Foundation with respect to key patents for the anti-retroviral medicine darunavir. This license agreement is applicable to all developing countries including middle-income economies.

F. Institute a system to meaningfully ascertain the humanitarian value of the technology and dissemination mechanisms.

The innovation must be useful to developing countries in order for the humanitarian incentive and dissemination practices to be worthwhile; and the humanitarian dissemination practices must be effective. A system must exist to ensure that both these criteria are met prior to the award of a fast track re-examination voucher.

USPTO expertise rests with the review of patent applications and the granting of patents when patentability criteria are met. The assessment of humanitarian initiatives is not naturally within the USPTO's mandate or area of expertise. Similarly, the evaluation of the utility of the technology for developing countries is not within the expertise of the USPTO. Therefore, the USPTO should establish a process to meaningfully ascertain the humanitarian value of the patented technology and dissemination mechanisms. This should include (1) delegating evaluation of the utility of the innovation and access practices to an expert committee with sufficient expertise, diversity and independence, and also (2) providing an opportunity for public comment for each application under review.

Members of the expert committee could include representatives of competent US government agencies, civil society, patients' groups, and potentially international organizations like WHO and UNDP, among other relevant stakeholders. It is important that clear regulations to avoid conflicts of interest are put in place and made public.

Review of applications by a credible expert committee would heighten confidence in the humanitarian value and real-world applicability of winning technologies and access practices. This would provide a significant non-monetary benefit to successful voucher applicants. It would allow them to attract additional interest for their invention, including humanitarian interest, by referencing the committee's confidence and highlighting the prestige of the committee's approval. In some cases, this might lead to opportunities to further disseminate or improve upon a winning technology. The use of independent experts could therefore increase interest in the voucher program, supplement the monetary value of vouchers, and encourage efforts to make humanitarian technologies accessible. The expert committee's work should be supplemented by an opportunity for public comment prior to the award of a voucher.

G. Ensure that the mechanism does not incentivize unnecessary patenting.

The USPTO proposal should do nothing to incentivize or strengthen unnecessary patenting of technologies. Thus, the voucher program should not be limited only to rights holders seeking to rapidly affirm the validity of a patent. Instead, the design of the program should assist in the elimination of low-quality patents or overly broad claims. Specifically, the USPTO should also allow voucher holders to initiate fast-

track *third-party* patent reexaminations. The expansion of the voucher to third-party initiated patent re-examinations could also increase the value of the vouchers by attracting more bidders, including the same actors who may also use the voucher program to rapidly reaffirm the validity of an existing patent.

H. Prevent abuses of the system.

The voucher program should be designed as a pure incentive program to incentivize the development of both meaningful technological innovations and significant humanitarian dissemination practices. In order to achieve this goal, the mechanism should try to eliminate abuses that may arise.

For instance, patent holders should not be able to apply for a humanitarian voucher if the invention has already been used or licensed for the humanitarian purpose that the applicant is seeking under a new application and does not offer additional and important humanitarian benefits. Improvements to existing technologies that do not confer a new purpose should not be eligible for vouchers.

Also, the USPTO should ensure that companies with many patents do not merely donate low-value patents in order to accelerate the re-examination of high-value ones. The proposed competitive prize mechanism plus minimum standards for voucher awards can help prevent such a giveaway.

The potential for abuse will always exist. Under the FDA PRV program, Novartis, the Swiss pharmaceutical company, obtained a voucher for registering with the US FDA an old anti-malarial medicine – Coartem – that had already been registered, sold, and used around the world for years. The USPTO program must eliminate these and similar efforts to “game” this new initiative. A prize-based approach awarding scarce vouchers to the most meritorious proposals may help limit the risks of gaming the system. An independent review mechanism and an opportunity for public comment prior to the award of a voucher may also help to eliminate the risk of abuse.

I. Ensure continued transparency.

We welcome the efforts of the USPTO to promote transparency throughout the development of the incentive program, including the public and written consultations concerning the design of the first pilot voucher initiative. We hope that these efforts establish a precedent for the operation of the voucher program. We encourage the USPTO to establish appropriate channels for open, inclusive, and continuous participation.

In particular, as the process advances and becomes more defined, our organizations hope that consultation with civil society, and the broader public, would include input on the following key issues:

- 1) The system that the USPTO will establish for evaluating the humanitarian value of applications under the voucher program;
- 2) The design and membership of the independent expert committee and the establishment of clear rules to avoid conflict of interest;
- 3) Minimum standards under the voucher program concerning utility and access; and
- 4) The scope of diseases which humanitarian inventions can be designed to address.

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