From: Suerie Moon [redacted]
Sent: Friday, November 19, 2010 5:18 PM
To: HumanitarianProgram
Subject: Comments from the Medicines Patent Pool

Dear Edward and colleagues at USPTO,
I am pleased to submit for your consideration comments from the Medicines Patent Pool on the reexamination voucher initiative. Please do not hesitate to contact me if we can provide any further information or clarification. We wish you success in realizing this important initiative,

Best wishes,
Suerie

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Comments of the Medicines Patent Pool

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]

Introduction

The Medicines Patent Pool thanks the USPTO for the opportunity to provide comments on its important initiative, "Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System." If structured well, the humanitarian fast-track *ex parte* reexamination voucher (henceforth "the Voucher," for brevity) could have an important effect on the willingness of patent-holders to license their technology in a way that facilitates availability and access in the developing world. The proposed incentive raises a number of issues and challenges, many of which are reflected in the detailed questions contained in the USPTO's Request for Comments. Before turning to these questions, we preface our comments with our general conclusion:

Many of the complex questions that arise regarding the optimal design of the Voucher require different factors to be weighed judiciously. For example, early-stage research-related technology could be of great potential public health benefit, but there would likely be a great deal of uncertainty regarding its on-the-ground impact – how could the potential benefit be weighed against the uncertainty of the outcome? In addition, it is perhaps impossible to devise rules in advance to weigh the value of a particular technology against the importance of the problem being addressed, against who would benefit, against a range of other variables. For example, technology A could make a small impact against a serious problem affecting children, while technology B could make a major impact against a relatively less pressing problem affecting adults. How should the two technologies be weighed against each other? Or, the patent-holder for technology A could make modest provisions to improve access and availability in a few developing countries, while the patent-holder for technology B could make much more generous and effective arrangements – how should each be evaluated? After some deliberation, we have concluded that the level of complexity and uncertainty involved suggests that setting hard-and-fast rules for Voucher qualification in advance is likely to be inappropriate and administratively burdensome.

Rather, we suggest the USPTO consider convening an expert committee with individual members from global and national bodies with relevant expertise to weigh carefully the various possible factors that may determine which patent-holder is awarded a Voucher. The committee's decisions would be governed by

the principles and criteria established by USPTO, but have considerable flexibility to weigh the multiple relevant variables. The following criteria could be considered:

1. Scope of problem addressed by technology
2. Severity of problem addressed by technology
3. Vulnerability of population addressed (e.g. children, rural populations, those living in extreme poverty)
4. Significance of contribution (i.e. importance of the technology and on-the-ground impact)
5. Scope of activities enabled by the license
6. Absence of unduly restrictive provisions in the license that would undermine the overall objectives
7. Additional efforts made by patent-holders to ensure widespread access to the technology (e.g. technology transfer initiatives)

In order to achieve political legitimacy and earn the public trust, such a committee should include a wide range of stakeholders (including affected populations), avoid conflicts of interest, and operate in a transparent fashion regarding the criteria, decision-making processes, and conclusions of its deliberations. Furthermore, given the many areas of technology potentially encompassed by the Voucher program and the vast range of expertise required to make sound judgments, the committee is likely to benefit from "crowd-sourcing" by accepting written comments and submissions from a wide range of actors on a given patent/technology/license under consideration for the Voucher. The committee could serve, furthermore, as an incubator for creative thinking within the US government on ways to contribute to innovation, and to expand access to knowledge and technologies in developing countries.

In order to keep the value of the Voucher sufficiently high to influence patent-holder behavior, the USPTO could set a fixed number of Vouchers to be awarded per year - in effect, as a prize - and further be made specific to each area of technology (e.g., three for pharmaceuticals, three for agriculture, five for clean energy, etc) as deemed appropriate by the particularities of each field. Establishing a small, fixed number of Vouchers and the criteria by which they will be granted could create a 'race to the top' whereby potential recipients compete with each other to adapt their licensing practices on as many of the criteria as possible in order to maximize their chances of receiving the Voucher. Such a system would avoid the pitfall (envisaged in question 8) that patent-holders may only do the minimum necessary to cross a particular threshold to qualify for the Voucher.

In general, it will be important to avoid creating perverse outcomes, such as the reinforcement of weak patents through hurried reexaminations or encouraging more widespread patenting in developing countries.

Finally, two key risks have been identified with the analogous US FDA priority review voucher program that bear mentioning here[1]: first, a priority review obligation may put additional burden on the agency and

[1] See Kesselheim, A. S. (2008). Drug Development for Neglected Diseases -- the Trouble with FDA Review Vouchers. *New England Journal of Medicine, 359*(19), 1981-1983. doi:10.1056/NEJMp0806684 Available: http://dx.doi.org/10.1056/nejmp0806684; and Moe, J., Grabowski, H., Ridley, D. (2009). FDA Review Vouchers. *New England Journal of Medicine, 360*(8), 837-838. Available: http://www.nejm.org/doi/pdf/10.1056/NEJMc086492

thereby extend the waiting time for other applicants; second, the accelerated deadline may negatively affect the quality of regulatory decisions. In order to minimize the risk of these consequences in the PTO initiative, a reasonable fee could be charged to applicants to cover or defray the additional costs to PTO of administering the program, the total number of Vouchers could be kept relatively small,[2] and all reexamination decisions made under the Voucher could be reviewed for quality (as is current practice for a random sample of patent examiner decisions on initial examination).

Response to Questions:

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?*

   The FDA PRV system currently does not require voucher recipients to make their medicines available or affordable in developing countries; rather, it rewards the development of the product. (the grant of its first voucher, moreover, has been criticized[3]). The USPTO Voucher should be used to incentivize patent-holders to take *additional* steps to make their technologies widely accessible (defined as available and affordable) in developing countries. This is an area in which the US FDA PRV system falls short, and where the PTO system could help to remedy a gap in the existing system. Furthermore, the list of diseases included in the US PRV is itself incomplete (for example, Chagas disease and pediatric HIV infection are currently excluded[4]) and likely to be a small subset of the humanitarian problems to be targeted by the PTO. Any special link between the FDA PRV and the PTO program could inadvertently privilege the diseases included in the FDA list, such that other conditions would potentially be disfavored in consideration for the Voucher. Therefore, we do not recommend that a recipient of the PRV automatically receive a PTO Voucher.

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?*

   Currently, FDA PRVs are transferable once, which is likely to limit the value of the Voucher. While there is legislation that has been proposed to allow unlimited transfers (sale and re-sale), Congress has not yet passed this legislation (Creating Hope Act S.3697 (2010)). The PTO Voucher should be transferable on the open market an unlimited number of times in order to maximize its value. Furthermore, although the USPTO's Request for Comments appears to contemplate that the Vouchers may only be used by patent owners requesting *ex parte* reexamination of their own patents, it may be worth considering whether the value of the Vouchers could be further enhanced

[2] From 2005 to 2009, there were roughly 500-700 determinations per year made on requests for reexamination. Arguably, 5-10 reexamination requests given priority review through the Voucher would not significantly impact waiting times for other requests.

[3] See Anderson, T. (2009). Novartis Under Fire for Accepting New Reward for Old Drug. *The Lancet, 373*(9673), 1414. doi:10.1016/S0140-6736(09)60804-7. Available: http://dx.doi.org/10.1016/s0140-6736(09)60804-7

[4] The Creating Hope Act S.3697 proposes to add Chagas disease and rare pediatric diseases to the FDA list, but has not yet been passed by Congress.

if any party were eligible to purchase and/or use the Vouchers to request a third party *ex parte* reexamination of a patent. Given that, as the Request for Comments indicates, the "patent owner would not be required to waive any current statutory and procedural rights, and would have the same time periods for filing responses and other communications as under the existing procedure," allowing the Vouchers to be used for third party reexamination requests may not unduly prejudice the rights of patent owners.

PTO could also consider limiting the applicability of Vouchers to the field of technology in which they have been granted. Such a measure could help make the value of the Voucher somewhat commensurate with the effort required to gain the Voucher. In other words, a Voucher earned through the licensing of a pharmaceutical-related patent could only be used for reexamination of another pharmaceutical-related patent. The suggestion to limit transferability by field of technology rests on the assumption that investments required to obtain a patent are, in general, higher in some fields (e.g., pharmaceuticals) than others (e.g., climate change technology, seed varieties), although there may be important exceptions to this general assumption. Such restrictions on transferability would help to prevent a potential 'flooding of the market,' in which Vouchers received from the licensing of lower-cost technologies would be traded on the market and applied to higher-cost technologies, thereby reducing the incentive of owners of higher-cost technologies to engage in the desired licensing behavior. In particular, the Medicines Patent Pool believes it would be important to ensure that the Voucher created an incentive for *pharmaceutical* patent-holders to grant voluntary licenses through this program.

It could be very useful for USPTO to commission a study to model the value of the reexamination Voucher in various fields of technology, as was done for the FDA PRV.[5] In addition, further clarity on the period of time reexamination proceedings currently take would be useful (from the request for comments, it seems the USPTO currently takes on average 19-20 months to respond to reexamination requests, but this figure does not seem to include the average time that patent-owners or third-parties take to respond to the proceedings); according to our calculations, such proceedings may take up to 18-20 months of time (for patent-owner or third-parties) and on average 19-20 months (for USPTO action), for a total of 37-40 months without the Voucher, and 24-26 months with the Voucher, or roughly a 1/3 reduction in duration.

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?*

   We restrict our comments here to the area of pharmaceuticals and public health. Within this field, all public health conditions should be considered for the Voucher; as health conditions and available technologies change constantly. Grant of the Voucher should be based on the assessment of a number of criteria, including the severity and scope of the public health problem, and the degree to which the patented technology contributes to addressing it. Such judgments are

[5] See the estimates generated for the FDA PRV in: Ridley, D. B., Grabowski, H. G., & Moe, J. L. (2006). Developing Drugs for Developing Countries. *Health Affairs (Project Hope), 25*(2), 313-324. doi:10.1377/hlthaff.25.2.313

complex and difficult to make based on a single parameter; therefore, the expert committee (described above) should be given the freedom to consider all public health problems that may arise, and to render a reasoned judgment on why a particular set of patents/technologies received the 'prize' Vouchers.

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?*

   It may be difficult to predict how a specific technology will be used, particularly in the earlier stages of its development or deployment. In the area of pharmaceuticals for HIV, for example, a promising drug may be approved by the FDA but reach relatively few people in developing countries unless it is recommended by the WHO in its treatment guidelines. Or, the effectiveness of a product may only be demonstrated after a significant time lag. Because of the difficulty of assessing the concrete impact of a particular technology in advance, and the potentially wide range of expertise required to make a reasonable assessment, we recommend the use of an expert committee to make such judgments. The committee could set higher standards for evidence of effectiveness as a technology reaches maturity, for instance, while relaxing such standards for earlier-stage technologies, provided that they hold the potential for significant impact.

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?*

   Third party submissions should be welcomed as a way of expanding the knowledge base available to the expert committee appointed by PTO to award the reexamination Vouchers. This principle is especially important given the potentially wide-range of relevant technologies, and the fast pace of innovation in a number of fields. In order to build trust in the system and to avoid perceptions of undue influence, such submissions should be made publicly available.

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?*

   While pre-defined lists offer the benefit of clarity, they often lag behind evolving on-the-ground conditions. The expert committee should be allowed to make reference to lists generated by institutions with norm-setting mandates, such as the WHO or CDC, but not be overly bound by such lists. The PTO initiative has the potential to influence and *accelerate* the availability of technologies early in their development; doing so will require that the expert committee have the freedom to be responsive and forward-looking in their assessments of a technology and/or public health problem, which may often mean going beyond pre-defined lists.

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?*

   In the field of pharmaceuticals, the Medicines Patent Pool has analyzed existing licensing practices and developed a set of license terms and conditions that we believe would demonstrate significant effort by patent-holders to increase access to a technology. In most cases, medicines are made more affordable through robust competition among multiple producers manufacturing at acceptable levels of quality. Based on this principle, we suggest that licenses for pharmaceutical-related patents be measured against the following yardstick:

   - Include wide geographical scope (e.g., licenses available in all countries defined as low or middle-income by the World Bank)
   - Enable follow-on research & innovation
   - Include quality-assurance provisions
   - Are licensed on a non-exclusive and non-discriminatory basis
   - Are licensed at reasonable royalty rates
   - Are transparent on licensing conditions (e.g., licenses made publicly available)
   - Are transparent on patent rights (e.g., lists of territories in which patent rights are held made publicly available)
   - Facilitate technology transfer and development of innovative capacity in developing countries

   Evidence that the patent-holder had licensed the relevant technology on humanitarian terms could be submitted to USPTO in the form of the executed license agreement. Further evidence on availability and affordability of the product, technology transferred, or other relevant concerns could be submitted by the applicant, licensees, or credible third-parties.

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?*

   There is tremendous variation between technologies, relevant humanitarian problems, research approaches and needs. As noted above, the complexity of judging the significance of a given technology or license suggests that an expert committee would be a better approach than setting too many conditions *a priori*. In order to prevent abuse, the committee should be asked to consider input from the general global public, and to operate in a transparent manner regarding the criteria, evidence, and rationale used to reach its decisions.

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?*

A wide range of factors could be considered by the expert committee in weighing the impact of a particular patent or technology on a broader research agenda, including the importance of the technology, the problem that is addressed, the scale of investments made, the degree of freedom granted to carry out follow-on research, and the extent to which research data and other relevant information is shared.

The granting entity could retain rights over the results of humanitarian research, provided that such rights did not impinge unduly on further research and/or access to the end-product.

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

    The definition of an impoverished or vulnerable population and/or humanitarian issue is likely to change with time and context. Therefore, as noted above, we encourage USPTO to give the expert committee a wide degree of latitude in determining what comprises an appropriate problem or beneficiary population, within a set of broad guidelines. By tasking the committee to select the best (three to five) licenses in a given year, the USPTO can help to raise the bar for both the type of research carried out to address humanitarian issues and the ways in which patents are managed to ensure widespread access to the fruits of such research.

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?*

    It would be useful to understand better the impact of existing legislative provisions for accelerated initial examination in the areas of HIV/AIDS, cancer, and green technology (i.e., 708.02 Petition to Make Special).[6] We would welcome further information from USPTO on its assessment of such policies and their impact on R&D investment and end-user access to technologies.

    Other pro-business strategies the USPTO could engage in include improving the user-friendliness of the patent system as it relates to humanitarian technologies. One of the difficulties in navigating the patent system, particularly in developing countries, is the lack of reliable and transparent data regarding patent status. In the field of pharmaceuticals, the Orange Book has contributed to improving the transparency of the patent system in the US by listing the US patents relevant to a given pharmaceutical product. In an effort to improve the usability and transparency of the patent system internationally, the European Patent Office has mapped the landscape of patents relevant to climate change-related technologies. The USPTO could carry out similar efforts on a range of

[6] See "708.02 Petition to Make Special [R-6] – 700 Examination of Applications." Available at http://www.uspto.gov/web/offices/pac/mpep/documents/0700_708_02.htm.

technologies relevant for improving human well-being in developing countries, including but not limited to pharmaceuticals.

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?*

    If the Voucher program is designed as a prize system, as suggested above, the grant of a Voucher could be seen as an "award" in and of itself, which recognizes the patent-holder's licensing policy as one of the best in the field. In addition, USPTO could grant other such awards to recognize patent-holders that make significant contributions to improving human well-being and access to their technologies. The criteria for such awards could be similar to those proposed on page 1 for receipt of the Voucher.

Conclusions

The Medicines Patent Pool welcomes the initiative of the USPTO to improve access to important technologies, such as pharmaceuticals, in developing countries. If designed well, we believe the Voucher could have an important impact on the willingness of patent-holders to generate innovation with potential benefits for populations in low- and middle-income countries, and contribute to ensuring that the fruits of scientific progress are accessible to those who need them. We hope the Voucher initiative will encourage pharmaceutical patent-holders to share their patents with the Medicines Patent Pool. We remain available to provide further information or clarification of these comments, and to share our experiences in developing pro-access licensing terms and conditions as our work progresses.

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