From: Kevin Fisher [mailto:kevin@avac.org]
Sent: Tuesday, November 23, 2010 9:03 AM
To: HumanitarianProgram
Subject: Fast track re-examination voucher for humanitarian uses

Dear Dr. Chang:

Please find enclosed AVAC's comments on the USPTO's proposed fast track re-examination voucher for humanitarian uses. We hope that it is not too late to submit comments.

Best regards
Kevin Fisher

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November 19, 2010

HumanitarianProgram@uspto.gov
Mail Stop Comments
Patents, Commissioner for Patents
US Patent and Trademark Office (USPTO)
P.O. Box 1450, Alexandria, VA 22313–1450
Attention: Joni Y. Chang.

RE: Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System 75 Fed. Reg. 57261, September 20, 2010

To the USPTO:

AVAC, a non-governmental public health organization, appreciates this opportunity to submit comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property (IP) System (USPTO Notice). AVAC uses education, policy analysis, advocacy, and community mobilization to accelerate the ethical development and eventual global delivery of AIDS vaccines and other new HIV prevention options as part of a comprehensive response to the pandemic.

HIV biomedical prevention is under study for a range of products including yet unproven complex vaccine biologics in early stage basic and clinical research and small molecule drugs in microbicides, oral formulations or other forms in advanced clinical trials. (Some of the incorporated small molecule compounds are already FDA approved with patented claims made for therapeutic use to treat HIV.)

The invention of a successful HIV vaccine has been called one of the most difficult challenges confronting biomedical research today. [1] Although we hope for rapid advances, a successful vaccine candidate has been an elusive goal for over 25 years.

[1] The Global HIV/AIDS Vaccine Enterprise: Scientific Strategic Plan, Coordinating Committee of the Global HIV/AIDS Vaccine Enterprise 2005 The Global HIV/AIDS Vaccine Enterprise: Scientific Strategic Plan. PLoS Med 2(2): e25. doi:10.1371/journal.pmed.0020025

An array of inventions for diagnostics, complimentary research tools, laboratory assays and methods of analyzing large data sets support this enterprise of research and discovery. In contrast, other biomedical HIV prevention products may have shorter R&D timeframes and/or depend on successful demonstrations of combining active compounds with novel delivery methods or devices.

AVAC has advocated for responsible IP practice and policy in the service of facilitating HIV prevention biomedical research and development for a number of years. In 2005 and in 2010, AVAC published results of its IP evaluations and policy recommendations affecting large molecule HIV vaccine biologics. [2] We assembled the first significant database of the underlying HIV vaccine patent landscape – a field characterized by issues of a patent thicket, uncertainty with regard to research tools, and complexity in sharing voluminous data sets and biological samples that are necessary for discovery and which underpin the application for many new patents. Copies of these reports are cited here with request that USPTO focus its development of humanitarian purposes policies on the AVAC recommended principles for collaboration, sharing and harmonization directed at the public good.

With this historical background, AVAC responds to the USPTO's proposal for "incentivizing the development and widespread distribution of technologies that address humanitarian needs." The principal way that the USPTO believes its proposal may have an incentivizing effect is either by: 1) providing a financial reward upon sale of a right to expedited re-examination to developers of products for humanitarian use; or 2) a benefit to those product developers pursuing humanitarian products while also marketing products under patent protection which require re-examination. The focus of our comments is on how these incentives may encourage and stimulate research for HIV prevention when the approval time horizon may be far off, discovery progress uncertain, new IP is continually being generated (both patents and underlying trade secrets and know-how) and/or when the majority of research funding is likely to come from government or nonprofit sources and not the private sector.

AVAC REACTIONS TO USPTO'S NOTICE AND PRELIMINARY QUESTIONS

AVAC is gratified that USPTO has turned its attention these issues but has some concerns with the initial directions or proposals to accomplish humanitarian aims. The USPTO Notice states that alternative incentive proposals will be considered where appropriate, so that this letter includes some suggestions which do not rely upon fast track re-examination.:

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[2] AVAC Report 2005: AIDS Vaccines at the Crossroads "Intellectual property at the crossroads" at http://www.avac.org/ht/a/GetDocumentAction/i/2504
AVAC Report 2010: Turning the Page, Data and Materials
A "to do" list for the future at ***http://www.avac.org/ht/a/GetDocumentAction/i/28317***

1. **<u>Uncertainty that a reexamination voucher program would have a material effect or include a sufficient range of "humanitarian purposes."</u>** The number of all patents subject to reexamination, in circumstances where expedited re-examination would have significant value, may be relatively confined. [3] Since patent rights exist until altered by re-examination, and because a majority of patents are either changed or found invalid, use of expedited re-examination might not be attractive to many patent holders. The preliminary estimates of value for the voucher - US$500,000 to US$1,000,000 are unlikely to incentivize investment in humanitarian research, but will rather be more likely to reward past actions. This starting point suggests that alternative actions by the USPTO should be evaluated, as we suggest below, to accelerate purposeful research and development.

2. **<u>Definition of "humanitarian research"</u>** - The USPTO asks for comment on its definition for humanitarian research with some proposed criteria and examples. USPTO Notice states:

> ''Humanitarian research'' would comprise two principles: significance and access. Significance requires that the patented technology make a significant contribution to research on a problem that predominantly affects an impoverished population, such as the tropical diseases identified by the FDA in its priority review voucher scheme. Access determines that the patented technology was made available to researchers on generous terms….
>
> "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?"

Increasingly, the needs for biomedical inventions for impoverished populations or to address diseases in developing countries cross borders or react to domestic US "humanitarian" purposes as well. They may be difficult to isolate humanitarian research which is predominately developing world. For example, WHO notes that over 80% of cardiovascular disease deaths, a serious domestic priority, take place in low and middle income countries. [4] HIV disproportionately affects large populations internationally but impoverished and marginalized populations in the U.S. also experience great disparities in access to prevention methods and treatment. [5]

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[3] http://www.uspto.gov/patents/stats/Reexam_Operations_from_2007_to_2010.pdf
[4] http://www.who.int/cardiovascular_diseases/en/
[5] http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf

These circumstances suggest that the administrative efficiency gained by circumscribing a measurable but broad "humanitarian" benefit may not achieve the goals of the program. A USPTO program directed at focusing the targeted purposes would benefit first from agreement or discussion with international partners such as WIPO, WHO, patient groups or other organizations to determine the ways in which incentives or other means will be applied or accepted in multiple jurisdictions.

3. **Support for all relevant sponsors and innovators.** AVAC strongly supports means to encourage greater participation in HIV prevention R&D by the private sector consistent with the USPTO's proposed "business" oriented approach. However, the overwhelming source of these humanitarian research funds come from public and philanthropic entities for basic science, clinical trials and product development. Less than 3% of HIV vaccine research funds and less than 1% of HIV microbicide research funds came from private sources in 2009. [6] Accelerating humanitarian research using the patent system would benefit from means also applicable to the ways in which publicly funded private sector innovators operate. In the field of HIV vaccines, a large number of vaccine related patents -including assays- are held by the US government who then may license to others or they may assign the patent. It is unclear how the USPTO proposal might incentivize product development in fields where the government fund research and often develops and owns the patents.

4. **Ethical concerns with transfers or swaps.** AVAC is also concerned with adverse shifting of costs and burdens that may arise when patent life periods are traded or swapped, a circumstance that may result from the USPTO proposal. As you are aware, a patent can allow a type of monopoly control for a period of time even if it is not an absolute monopoly in the classic or antitrust sense. Trading or swapping between rights for different potential disease uses means one particular patient population may bear higher costs from delayed availability of generics, for example, than it otherwise would even if another patient group benefits from the trade. Patients should not be seen to be placed in competition with each other. A possible example of how this could occur would be if the patent on an HIV treatment drug subject to challenge might, for example, be more rapidly affirmed under a voucher received for developing a drug for Chagas disease. The USPTO notice is silent on the question of whether the voucher can be used offensively by a third party wishing to invalidate a patent through expedited re-examination. The right to use the voucher in such a way might be one way to mitigate the appearance of patient and disease competition.

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[6] HIV Vaccines and Microbicides Resource Tracking Working Group, *Advancing the Science in a Time of Fiscal Constraint: Funding For HIV Prevention Technologies in 2009*, available at http://www.hivresourcetracking.org/

5. **Transferability.** The USPTO notice asks whether the voucher "transferable on the open market ." If the voucher is not transferable, then only companies with broad portfolios of products will benefit. The application of the USPTO proposal will have limited applicability as a result.

ALTERNATIVE SUGGESTIONS FOR USPTO ACTIONS

AVAC suggests some modest alternative efforts which are simply administered, broadly available and responsive to the ways in which research is carried out to accomplish the goals of the USPTO's humanitarian research efforts:

1. **Support and encourage non-profit consortia arrangements based on sharing of rights, data and materials.** Difficult, long term biomedical research for HIV prevention depends on amassing and sharing large volumes of data and biological sample materials. Projects such as the publicly funded Center for HIV-AIDS Vaccine Immunology, organizing collaboration among over 93 investigators in 43 institutions and 9 countries, are examples of collaborative research in which rights, data and materials are shared for a humanitarian purpose. [7] This consortium allows members freedom to operate with a variety of inventions and to pursue new research goals based on data generated by other members.

   Another model of an IP policy suitable to define supportable humanitarian collaborations with a variety of incentives is found in the regulatory scheme adopted by the California Institute for Regenerative Medicine rules to share patents, materials and data and to provide patient access for drugs developed with CIRM research funds. [8]

   USPTO could support these innovators, for example, by accelerated initial examination and by reducing or eliminating patent fees[9] for consortia members who commit to arrangements for open data and materials sharing, royalty free non-exclusive use of inventions to specifically dedicated research projects or field of use, sharing of research tools, reasonable or low cost pricing for final products to impoverished populations or other efforts to expand freedom to operate in the humanitarian field.

   A USPTO program or guidance which rewards this collaboration could have a significant impact.

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[7] https://chavi.org/

[8] http://www.cirm.ca.gov/reg/pdf/Reg100407_IP_RevShare_Profit_Org.pdf

[9] Fees may be reduced or eliminated even further than discounts now provided for small entities.

2. **Prizes.** AVAC agrees with USPTO that prizes may help spur investment, research and awareness. Prize winners may also be able to leverage other funding because of the recognition. Although USPTO may be limited in offering monetary prizes, it has a history of co-sponsorship for monetary awards.[10]

   Prizes in complex biomedical research are most likely to be effective for clear time-line achievable milestone discoveries or for inventions such as diagnostics or devices that may require relatively shorter time periods to develop. [11]

3. **Definition of Humanitarian Research.** USPTO has asked for comment on criteria to identify targeted humanitarian research. AVAC supports reference to criteria such as the example of reference to the U.S. neglected disease program but does not limit its support based only on these statutory lists. Other criteria to identify humanitarian biomedical research should also be used. We recommend identifying purposeful work to include research on diseases for which global investment has been shown to be substantially provided only by public and philanthropic funders as documented for example for both HIV prevention and tuberculosis. [12] These are areas where incentives for private investment would be most valuable. Additional criteria may include research on high prevalence serious or life threatening diseases conducted by non-profit consortia based efforts committed to shared work efforts.

4. **International and Federal Consultation.** AVAC requests that USPTO engage in international consultations to develop IP incentives that can be applied and accepted in multiple jurisdictions. We also encourage cooperation between the USPTO and federal family efforts such as the National Academy of Sciences Board on Research Data and Information to develop systems for shared use of publicly funded data.[13]

   Although the USPTO proposal focuses on patent protection issues, copyrights also affect the ability of humanitarian purpose innovators and other

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[10] Collegiate Inventors Competition
http://www.invent.org/collegiate/CIC2007Winners.pdf
[11] Report of the World Health Organization Expert Working Group on Research and Development Financing, January, 2010
http://www.who.int/phi/documents/ewg_report/en/index.html
[12] http://www.treatmentactiongroup.org/TB_RD_2009.aspx and
http://www.treatmentactiongroup.org/TB_RD_2009.aspx
[13] Designing the Microbial Research Commons: An International Symposium
http://sites.nationalacademies.org/PGA/brdi/PGA_050857
The Value of Shared Access and Re-use of Publicly Funded Scientific Data
http://sites.nationalacademies.org/PGA/brdi/PGA_059258

stakeholders to accelerate research. We request that USPTO support efforts to allow open access to publicly funded research results in publications or in other systems.

Thank you for considering these comments. The suggestions for USPTO actions included in this letter could be adopted either in addition to or in lieu of the plans described in USPTO's notice.

Please contact Kevin Fisher, AVAC's Director of Policy (212-367-1051; Kevin@avac.org) or Robert Reinhard, consultant (415-570-1010; rjreinhard@gmail.com) if you have any questions. We look forward to working with you to develop these programs further.

Sincerely,

Mitchell Warren
Executive Director