From: Cristin Lis [redacted]
Sent: Friday, November 19, 2010 4:24 PM
To: HumanitarianProgram
Subject: Comments on "Incentivizing Humanitarian Technologies"

Dear Joni Chang,

On behalf of Gilead Sciences, Inc., I am submitting the attached comments on the Department of Commerce and USPTO's proposal on "Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System". Thank you for the opportunity to weigh in on this important proposal.

Regards,
Cristin Lis

Cristin Lis
Senior Director, Government Affairs
Gilead Sciences, Inc.
333 Lakeside Drive, Foster City, CA 94404
Tel: 650-522-5046
Fax: 650-522-5314
[redacted]

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November 19, 2010

Joni Y. Chang

Humanitarian Program

United States Patent and Trademark Office

U.S. Department of Commerce

14th Street and Constitution Ave., NW

Washington, DC, 20230

Dear Joni Chang:

Gilead Sciences, Inc. submits the following statement in response to the Department's September 20, 2010 Federal Register notice seeking comments addressing the fast-track *ex parte* reexamination voucher pilot program as an incentive to stimulate technology creation or licensing that addresses humanitarian needs.

Gilead is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet need. With each new discovery and experimental drug candidate, we seek to improve the care of patients suffering from life-threatening diseases.

Our portfolio of 13 marketed products includes a number of category firsts and market leaders, including Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate) – the first complete single-tablet regimen for HIV infection – and Viread® (tenofovir disoproxil fumarate, or TDF) – the company's first agent approved for HIV infection, which was also approved in 2008 for the treatment of chronic hepatitis B.

Gilead: Commitment to Responsible Stewardship of Intellectual Property

Gilead is the market leader in therapeutics for the treatment of HIV/AIDS. Viread was developed by Gilead and is the most widely prescribed molecule for the treatment of HIV in the developed world. Truvada® (emtricitabine and tenofovir disoproxil fumarate), a fixed-dose combination of Gilead's two anti-HIV therapies (Viread and Emtriva®, or emtricitabine), is used in combination with a third antiretroviral molecule for the treatment of HIV and is considered the backbone of the standard of care for HIV-infected individuals.

An estimated 33 million people worldwide are living with HIV, of which 95 percent live in the developing world. In low-income countries where HIV has hit hardest, millions of HIV-infected individuals either go without treatment or only have access to older regimens that are often associated with serious side effects and can lead to the development of drug resistance and subsequent treatment failure.

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA
phone 650 574 3000 facsimile 650 578 9264
www.gilead.com

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Gilead believes in a system of strong intellectual property protection. Gilead also believes that along with intellectual property comes responsibility, particularly to vulnerable populations. This responsibility is particularly present in relationship to therapies addressing life-threatening diseases like HIV.

With this responsibility in mind, Gilead has developed a first-of-its-kind comprehensive program designed to enhance access to these lifesaving medications. The first component is a tiered pricing system which was launched in 2005, and is objectively based on a country's economic condition and HIV prevalence. For the least-developed countries in the lowest pricing tier, Gilead has a no-profit policy for the company's branded medications. Gilead uses this transparent methodology to provide lifesaving treatments at a fair price to those countries that need them the most. This transparent, systematic pricing method, based on objective criteria – an individual country's GDP per capita, cross-referenced with national HIV prevalence – has resulted in a greater capacity to provide access to our lifesaving medications.

In addition, Gilead has pursued a technology transfer and licensing partnership with the Indian pharmaceutical industry in order to create a sustainable, market-based model that would make Viread and Truvada, and their generic versions, more affordable and accessible in low-income countries. This partnership, centered around open, voluntary license agreements with eleven India-based pharmaceutical companies, has rapidly expanded access to TDF medications. By the end of 2006, when the first license agreements were signed, only 30,000 patients in low-income countries had access to TDF. Today, 60 percent of the 900,000 HIV patients in these countries who receive either branded or generic versions of Gilead's antiretrovirals, receive generic TDF distributed by our Indian licensing partners. The licensees now offer the lowest available price for TDF in India and many other countries covered by the licensing agreements. Under the licensing model, licensees offer generic Viread at $7.25 per month. By contrast, Gilead offers branded Viread to these same countries for $17.00 per month (this is a no-profit price that represents manufacturing cost to Gilead).

The license agreements are non-exclusive and the model thereby encourages competition in the marketplace. Under the terms of the agreements, partners establish their own pricing for their products and can sell their generic products in 95 low-income countries, including India and Thailand. Gilead receives a five percent royalty on sales of finished product sold. The vast majority of people with HIV worldwide live within these licensed territories. According to the Clinton Health Access Initiative (CHAI), 3.47 million of the 4 million patients in low-income countries who are currently on HIV treatment are included under the Gilead licensing model and live in countries that are included in the Indian license agreements.

All licensees receive a complete technology transfer for the Viread manufacturing process, so the Indian companies are able to quickly produce and distribute generic versions of Gilead's medications. The complete technology transfer package includes more than 400 pages of detail on the manufacturing process, quantitative composition, quality attributes and analytical characterization and testing for both the active pharmaceutical ingredient and finished product. The technology transfer component of the licensing model has measurably improved the ability of Gilead's partners to manufacture quality medicines, secure tentative FDA approval for their TDF products and enter the marketplace.

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In one instance, the partnership with an Indian licensee is evolving into a clinical and regulatory collaboration on a novel pediatric formulation of TDF. This product could potentially address a severe unmet medical need in this patient population, particularly in resource-limited regions.

Overview of Gilead's Position on the Fast-Track *Ex Parte* Reexamination

Gilead strongly supports the creation of a fast-track *ex parte* reexamination voucher pilot program to incentivize technology creation or licensing to address humanitarian needs. From a policy perspective, this program establishes a link between strong intellectual property protection and responsible use of innovative technology. By recognizing patent holders that use their technology in a responsible manner, a significant new method of protecting intellectual property is created.

In addition, we endorse this program because it strengthens the diplomatic hand of the United States Government. This program provides the United States with strengthened credibility in the developing world to show that the intellectual property policies of the United States encourage responsible use of intellectual property rather than merely protecting the monopoly of patent holders having no regard to broader humanitarian implications. Importantly, a commitment to humanitarian use helps to protect that underlying innovation.

Response to the Department's Questions

- 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 priority review program for neglected tropical diseases (NTD) is an important step in providing an incentive for the development of treatments for these diseases. However, the receipt of such a voucher does not necessarily indicate that the applicant is responsibly using the intellectual property to achieve the underlying humanitarian goals of the proposed program. The goal of USPTO's program is to ensure broad access of intellectual property that achieves the humanitarian results of improving and saving human lives. The development of the product alone does not by itself justify the granting of the voucher – it is the question of how this intellectual property is used that should be determinative of the granting of the voucher.

In the description of a potential pilot of this program in the Federal Register, four criteria are identified to determine humanitarian use: subject matter, effectiveness, availability and access. According to the Federal Register, subject matter evaluates whether the patented technology addresses a recognized humanitarian problem; effectiveness assesses whether the technology is being used to address the problem; availability looks at whether the technology is available to the impoverished population; and access looks to the effort the patent holder makes to increase the population's access to the technology.

Gilead endorses this four-step approach, and believes it should apply evenly across disease states, including NTDs. As an example, if a patent holder is making no effort to ensure access

to the product, then it seems that the humanitarian goals of the program are not being accomplished.

- 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?

Yes, we recommend that the USPTO fast-track vouchers be transferable on the open market. For many of the humanitarian issues contemplated by this program, there are few incentives for patent holders to develop the technology required to address the problems presented. Therefore, the stronger the incentives in the voucher program, the more likely the Department will see broad-based participation in the program. Transferability is one way to strengthen the incentives for participation in the program.

- What humanitarian issues should qualify for the voucher programs? 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 have two recommendations in response to this question. The first is the specific recommendation that "life threatening health conditions" be added to the list of therapies that that qualify for the voucher program. Perhaps the most important humanitarian impact is saving human life. Further, we believe HIV therapies and therapies to treat other diseases that also disproportionately impact resource-limited regions would fit under these criteria. Given the magnitude of the HIV epidemic and its impact in the developing world, we believe that encouraging further access of HIV therapies is paramount to the ultimate success of this program.

Second, we recommend that rather than defining humanitarian issues by reference to existing humanitarian aid organizations, the USPTO develop a comprehensive review for determining which areas are eligible for the voucher program. Ultimately, the USPTO should be the decision maker. To advise the USPTO, we recommend establishing a council of federal government agencies that would provide counsel the USPTO. The Council may include the Director of the National Institute for Allergy and Infectious Disease (NIAID), Director of the Centers for Disease Control (CDC), Director of President's Emergency Plan for AIDS Relief (PEPFAR) and the Director of United States Agency for International Development (USAID).

Further, the agency may create a comment process where all stakeholders, including humanitarian aid organization representatives, could provide comment. We believe this approach permits for broad-based input from a variety of stakeholders rather than limiting the decision to only certain organizations. This approach also affords the agency the flexibility to adapt to new situations as they present themselves in the future.

Such a comprehensive approach takes under advisement the opinions of various involved parties but leaves the ultimate decision in the hands of the United States Government. We believe this is the approach that will best serve the goals of the voucher program.

- 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?

First, we believe that actual practice is the most significant factor for the USPTO to consider. There is no better demonstration of humanitarian commitment than actual practice. To the extent that actual practice is not available, then the USPTO may require that patent owners develop and submit a detailed plan establishing how their technology satisfies the four criteria of the program.

- 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?

The open comment period described above is a sufficient and constructive forum for third parties to provide comment and help establish the program's eligibility standards. Through this process, all stakeholders, including humanitarian organizations can participate and provide comments on eligible categories and definitions of technologies, including the four criteria test.

- 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?

We believe that the participation of government agencies is critical to the success of the program. These and other agencies can have a formal advisory role in the process of creating the voucher program, including providing definitions to facilitate the expeditious implementation of the pilot program. This refers to the comment above that all stakeholders be allowed to comment as the general definitions for "qualifying humanitarian criteria" are established.

- 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 determining whether a patent holder has made significant efforts to increase access to a patented technology, we recommend that the USPTO require companies to submit a description of their efforts to increase access to the patented technology. The USPTO could also provide a list of best practices that if employed by a patent holder would give significant indication of meeting the humanitarian requirements. As an example, the creation of a tiered-pricing program, that is transparent and has objective criteria, could be one-such best practice. Additionally, technology transfer and licensing agreements with generic companies could also be another example of a best practice. By providing a list of best practices, USPTO could let stakeholders know what it is looking for, and also ease the burden of review of the individual programs.

- 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?

We recommend that significance of an intervention be evaluated on the basis of measurable impacts on the communities or populations the research project is designed to address. What's more, in establishing the voucher program, the Department can delineate the time frame over which significant impacts are expected to be made and set out for the program certain criteria by which significance will be judged. These criteria will likely depend on the type of intervention at issue. For example, in the context of HIV/AIDS and other infectious diseases, significance might include numbers of patients who are on therapy, reducing transmission, increasing early diagnoses or improving patient and public health outcomes.

- 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 of the results of the humanitarian research?

We would encourage looking at a wide range of factors, beyond cost, to determine whether the terms of use are generous. In addition, we encourage taking into consideration how a patent holder's terms of use expand access to treatments or interventions among impoverished and vulnerable populations. Availability of education or other resources in relation to the humanitarian research project could be another useful factor for evaluating whether the terms of use are generous.

- 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?

Gilead's tiered pricing program recognizes that there are levels of development. There are nuances beyond simple definitions of "developed world" and "developing world." For more developed countries which still have significant access issues, we have found that a tiered pricing system based on objective criteria – and individual country's ability to pay and the prevalence of disease – can have a material impact on increasing accessibility to populations in middle-tier countries.

- 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?

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Vouchers intended to accelerate initial examination can certainly be considered as USPTO develops the scope of this program. But we recommend that a comprehensive description of the innovator's plan to make such a technology accessible is provided to USPTO for consideration. When relevant, we also recommend that a description of the company's practical application of similar efforts – or established track record of increasing access to technology – is provided to USPTO for consideration.

- 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?

A stand alone non-monetary incentive is not likely to impact the decisions made by companies to invest in certain fields of research. However, if taken into consideration with other proposals and existing programs such as direct grants, tax credits, data exclusivity and other incentives, we believe that non-monetary prizes or awards have the potential to encourage greater investment in this important arena. For certain humanitarian conditions, due to the characteristics of the issue, technological developments in certain areas are often not profitable for patent holders. In these situations, non-monetary awards combined with other incentives can serve as motivators to make progress on these issues.

In selecting recipients, the Department may look at the seriousness of the humanitarian issue that is sought to be addressed by the technology; the extent to which the patent holder's efforts alleviate or lessen the burden of the disease or other issue; the innovativeness of the approach taken; and other efforts by the patent holder in other countries to alleviate the same disease or issue. Finally, award recipients would ideally be those innovators that make strides in reducing the prevalence of a disease or reducing the impact of diseases.

Thank you for the opportunity to submit comments on this important proposal.

Sincerely,

Gregg Alton

Executive Vice President, Corporate and Medical Affairs