

**From:** Serena.Farquharson-Torres [redacted]  
**Sent:** Friday, November 19, 2010 5:37 PM  
**To:** HumanitarianProgram  
**Cc:** [redacted]  
**Subject:** sanofi-aventis comment on PTO humanitarian incentives

Dear Joni Chang,

Attached please find the comment requested by the PTO on incentives for humanitarian technology sent on behalf of the U.S. patent group of sanofi-aventis.

Best regards,

***Best regards / Cordialement / Mit freundlichen Grüßen***

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## U.S. Patent Operations

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HumanitarianProgram@uspto.gov

19 November 2010

Re: **Comments of sanofi-aventis U.S. Inc. in Response to the PTO's Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System**

Attention: Joni Y. Chang,

The U.S. patent department of sanofi-aventis welcomes the opportunity to submit comments in connection with the United States Patent and Trademark Office (PTO) "Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System," as published in Federal Register Notice: Vol. 75, No. 181, Monday, September 20, 2010; pp. 57261 – 57262. Sanofi-aventis is a global healthcare company engaged in the research, development, manufacture and marketing of healthcare products. Our business is diversified and includes pharmaceuticals comprising Rx (prescription) drugs, consumer healthcare business, over-the-counter (OTC) / combined OTC and Rx drugs, generics, biomedical devices, vaccines and animal health. The Humanitarian Sponsorship Department of sanofi-aventis coordinates some fifty programs in over 50 countries. Sanofi-aventis has on-going global programs under way around the world that not only cover prevention of disease, education, health and access to care and support for the disabled, but we also have a commitment to research and development for the treatment of neglected diseases. These commitments form part of a long term agenda, aimed at providing sustainable support to the world's most vulnerable populations.

### **PTO's proposed voucher program:**

We are pleased that the PTO has opened a discussion regarding ways for the PTO to incentivize technology based companies to engage in humanitarian efforts. It is our intention to provide the PTO with the benefit of our thoughts about possible incentives, including alternatives to the PTO's idea of awarding a fast-track ex parte reexamination voucher to companies engaging in humanitarian efforts. Although, such a voucher could be valuable under the right circumstances, we believe that alternatives to the fast-track ex parte reexamination voucher could provide greater incentives and thereby better incent humanitarian efforts and would help us justify continuing and increasing our humanitarian efforts in the face of the disparate needs of the company's stakeholders.

### **A voucher with added value:**

We encourage the PTO to consider offering a qualifying company a choice of vouchers. The choices would include:

**1) Expedited Examination of any patent application of the voucher holder's choosing.** This voucher would entitle the holder to expedited examination from the beginning to end of prosecution of a given application. The patent application could be selected from any one of the company's pending applications. Strict deadlines for first and subsequent office actions and, where patentable subject matter is found, issuance and publication of the granted patent should be included as part of such a voucher.

**2) Expedited Ex parte Reexamination of any patent of the patent holder's choosing.** As suggested by the PTO, this voucher would remain an option and could be used to expedite ex parte reexamination of the voucher holder's own request to reexamine one of its patents. Optionally, the PTO should consider whether the voucher could be used to expedite ex parte reexamination where reexamination is requested of one of the voucher holder's patents by a third party.

**3) Expedited Appeal of an examination or reexamination decisions within the PTO.** In addition, we invite the PTO to consider allowing a qualifying company to select a voucher that would entitle the holder to obtain an expedited hearing date and decision from the BPAI in either a reexamination proceeding or in an appeal from an examiner's final rejection of claims in a pending application.

The multiple choice nature of such a voucher system will increase the value of the voucher because the company would choose from among the options, a voucher that is best suited to its business needs. The value of the voucher will thereby be enhanced and consequently be given extra weight in the consideration and reevaluation of humanitarian projects in this difficult economy where cost cutting puts such programs at risk. It is the combination of various incentives such as tax incentives, FDA priority review vouchers, goodwill, and the impact on human life around the world that helps justify continuing to provide humanitarian technology to the developing world. Thus, the PTO's voucher based program could provide additional support and justification for the stakeholders to continue humanitarian efforts.

It is important to note that the time savings achieved in the 3 proposed options above, will be accomplished through procedural modifications and not due to preferential treatment during the PTO's substantive review. Furthermore, the company's humanitarian efforts are not to influence the PTO's findings during examination or appeal.

Surely there will be healthy and constructive debate over implementing such a voucher based incentive program. Important questions such as which activities qualify as humanitarian, how much humanitarian activity justifies receiving the voucher, how many vouchers would be awarded as well as their term, are all topics to be addressed. And while we have not offered a complete analysis of these additional questions, we nevertheless hope that the PTO gives due consideration to our comments, all of which are directed to help the PTO identify incentives that will increase humanitarian involvement by the industry.

**Conclusion:**

The U.S. patent department of sanofi-aventis appreciates the opportunity to respond to the PTO's request for ideas on ways intellectual property related incentives can be used to encourage humanitarian technology participation. We also encourage the PTO to continue to promote discussions with the aim of improving the intellectual property system.