From: [redacted] betty ryberg[redacted]
Sent: Friday, November 19, 2010 3:48 PM
To: HumanitarianProgram
Subject: Comments - Incentivize Humanitarian Technologies

Dear Sir or Madam:

Attached please find comments from Novartis Corporation in response to the USPTO's Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System.

Best regards,

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VIA Electronic Mail

November 19, 2010

Mail Stop Comments – Patents,
Commissioner for Patents
Attn: Joni Y. Chang
P.O. Box 1450
Alexandria, VA 22313-1450

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

Dear Sir or Madam:

Novartis Corporation through its wholly-owned subsidiaries (Novartis) respectfully requests that the United States Patent and Trademark Office (USPTO) consider the following comments in response to its Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System (Request). Novartis believes that the USPTO's proposal is a meritorious and worthwhile endeavor, and wishes to assist the USPTO in the development of this program. We have not, at this time, developed a test to apply the humanitarian principles set forth by the USPTO in the Request, but submit these initial comments, with the hope that a robust conversation between the healthcare industry and the USPTO will ensue to establish specific parameters to further define this new initiative:

1. In response to Question 11 of the Request, Novartis believes that the incentives from the USPTO need not be limited to vouchers for fast tracking an Ex Parte Reexamination of choice by a Patent Holder who has satisfied the Humanitarian Program (PHHP), but should include other types of vouchers, such as

- a voucher that accelerates normal examination of a patent application or an entire family of related applications (we note that the USPTO already allows fast tracking of certain applications via accelerated examination, petitions to make special and the patent prosecution highway);
- a voucher allowing a Request for Continued Examination (RCE) filing to be placed on an Examiner's normal docket (rather than an Examiner's special docket);
- a voucher for the waiver of maintenance fees and extension fees;
- a voucher accelerating other relatively slow types of examinations or proceedings, such as reissue proceedings, interference proceedings, *Inter Partes* Reexaminations, decisions on petitions, appeals to the Board of Patent Appeals and Interferences; and
- a voucher accelerating oppositions in the event oppositions are instituted.

2. Any patent issued quickly due to a voucher granted through the PHHP program should be entitled to the same presumption of validity that attaches to any issued patent. While this may seem obvious, there are concerns that a patent challenger may argue that a fast-tracked patent has not been fully considered. Thus, any fast-tracked application (or reexamination) should be accompanied by stringent assurances of quality examination by the USPTO.

3. Any fast tracking should be concurrently linked with a different Patent Term Adjustment (PTA) standard under 35 U.S.C. § 154(b)(1)(B), which would further incentivize humanitarian technologies. Specifically, 35 U.S.C. § 154(b)(1)(B) provides for PTA accumulation beginning on the date that is 3 years after the filing date of a given application. However, in the event of accelerated examination for a PHHP, we submit that a new guarantee, e.g., PTA accumulation beginning on the date that is 1.5 – 2 years after the filing date, should be considered as triggering the accumulation of PTA under 35 U.S.C. § 154(b)(1)(B). Novartis recognizes that this would need to be addressed legislatively, but respectfully request that the USPTO support a legislative proposal that would provide for this.

4. In response to Question 2 of the Request, any incentives granted by the USPTO, be they vouchers or other, should be freely transferrable intercompany and intracompany. Allowing the transfer of such vouchers on the open market is highly desirable, and will further the USPTO goal of incentivizing humanitarian technology.

5. The USPTO proposal seeks to develop workable tests to define "humanitarian research" (significance and access) and "humanitarian use" (subject matter, effectiveness, availability and access). The comments in this portion are solely intended to address the Proposal to Incentivize Humanitarian Technologies and Licensing as it relates to the healthcare industry, and not other industries (e.g., those involved in water purification, sanitization, food use and distribution, land use, housing, etc.). We believe that an abuse-resistant metric for a patentee in the healthcare industry to establish that an invention is related to humanitarian research or use should be adopted. Novartis urges the USPTO to adopt a metric tied to research or use *in humans*, e.g. whether the patented compound or vaccine has been introduced into humans, the patented medical method is used on or in humans, the patented diagnostic test or method is used on or in humans, or the patented medical device is used on or in humans. There are myriad routes by which this may be achieved. Examples of such routes include funding external research, internal development, manufacture and delivery of compounds for clinical trials, commitment to manufacture for commercial purposes, providing scientific or technical advice or expertise, transfer of trade secrets and work product, licensing and partnering (including joint ventures), and sharing and pooling resources. By requiring that the patented technology be used or tested on humans, there is a clearly defined end-point that is substantially resistant to abuse.

6. Humanitarian issues should include more than the categories mentioned by the USPTO in Question 3 of the Request. Humanitarian issues should encompass all technologies that help impoverished or disadvantaged populations improve the quality of basic human needs, such as food, water, and health. This should include technologies used to address orphan diseases (e.g., hypophosphatasia) and diseases that are neither orphan nor neglected, but which, due to patient

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impoverishment in a particular geographic area, remain substantially untreated (e.g., treating hypertension among impoverished Americans in the Southeast United States). Humanitarian issues should also include acts that facilitate access to humanitarian technologies by particular populations, such as providing free or reduced-cost medication to impoverished patients and donations of medications. The goal of the USPTO's proposed program is to incentivize companies to invest in technology serving humanitarian purposes. Thus, expanding humanitarian issues to include geographic sensitivity, as well as orphan disorders, furthers that objective.

Novartis Corporation

Betty Ryberg

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