

From: Chang, Terry [redacted]

Sent: Friday, November 19, 2010 5:35 PM

To: HumanitarianProgram

Subject: AdvaMed Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System; 75 Fed. Reg. 57261

Attached please find the submission of the Advanced Medical Technology Association (AdvaMed) in response to the Office's Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System. 75 Fed. Reg. 57261 [Docket No. PTO-P-2010-0066]

Thank you for your time and consideration.

Respectfully submitted,

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Via email to: HumanitarianProgram@uspto.gov

November 19, 2010

The Honorable David Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Re: **Docket No. PTO-P-2010-0066**, Request for Comments on Incentivizing Humanitarian
Technologies and Licensing Through the Intellectual Property System

Dear Under Secretary Kappos:

This letter is submitted on behalf of the members of the Advanced Medical Technology Association (AdvaMed), in response to the U.S. Patent and Trademark Office's (USPTO) Request for Comments on Incentivizing Humanitarian Technologies and Licensing Through the Intellectual Property System [Docket No. PTO-P-2010-0066] published on September 20, 2010. 75 Fed. Reg. 57261.

AdvaMed is the largest medical technology trade association in the world, representing more than 1,900 medical device, diagnostic, and health information system manufacturers and subsidiaries. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. These technical devices require significant development expenditures and time. Many devices require clinical trials to obtain regulatory approval, which add to these costs and time. Medical devices undergo rapid innovation and typically have shortened product life cycles, which demand that our member companies recoup their investments in shorter time periods. This heightens the necessity to have a strong and predictable patent system.

AdvaMed's IP Working Group is very supportive of any effort by the U.S. Patent and Trademark Office (USPTO) to improve its administration of the U.S. patent system in a fair and efficient manner. However, AdvaMed cannot support the USPTO's proposed humanitarian voucher program. As discussed in more detail below, our position is that while the voucher program is a noble idea, it will not lead to any increase in humanitarian technology and could actually impede such technology along with other technologies by diverting scarce resources within the PTO from handling the normal application work load. If the USPTO believes that an

incentive for humanitarian technologies is important, then we suggest adding humanitarian technologies to the list of categories qualifying for a petition to make special.

The role of the USPTO, with regard to medical technology, is to determine the patentability of what is often a limited aspect of a medical device. Although obtaining patent protection directly impacts the ability to command investment capital to further a medical technology's development, the proposed voucher program's potential to consistently bring new medical technologies to patients sooner would be tenuous, as obtaining patent protection is an early step in developing a medical technology and bringing it to market. Accordingly, the proposed program would not directly benefit patients.

More importantly, AdvaMed is concerned that adding additional complexities and workload to an already-overburdened USPTO staff will have an adverse impact on all technologies. In particular, we are concerned that accelerating one subset of re-examination applications will divert resources from the remaining pending re-examination and first examination applications. The advance of technology as a whole improves the quality of life of all humanity, including third-world and other disadvantaged populations. Slowing such progress, even incrementally, can thus have a global impact. The value of a re-examination voucher will not support the million dollar fees needed to appreciably increase the USPTO's capacity to offset the demands of the USPTO voucher program.

If AdvaMed may be of any assistance moving forward, please do not hesitate to contact me. AdvaMed appreciates the opportunity to submit these comments, and thanks you for your time and consideration.

Very truly yours,



Christopher L. White
Executive Vice President, General Counsel and Assistant Secretary
AdvaMed