From: Chang, Terry
Sent: Monday, August 31, 2009 5:11 PM
To: AC6/Comments
Cc: Bahr, Robert
Subject: AdvaMed Comments on Deferred Examination for Patent Applications; 74 Fed. Reg. 28473

Dear Under Secretary Kappos:

Attached please find the comments of the Advanced Medical Technology Association on Deferred Examination for Patent Applications, which are submitted pursuant to the Office's Federal Register notice at 74 Fed. Reg. 28473.

Thank you for your time and consideration.

Respectfully submitted,

Terry Chang

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Via email to: AC6comments@uspto.gov

August 31, 2009

The Hon. David Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office

Mail Stop Comments-Patents
Commissioner for Patents
P.O. Box 1450,
Alexandria, VA 22313-1450

Re: **Docket No. PTO–P–2008–0063, Additional Period for Comments on Deferred Examination for Patent Applications**

Dear Under Secretary Kappos:

The Advanced Medical Technology Association (AdvaMed) thanks you for the opportunity to comment on the proposed Deferred Examination for Patent Applications. AdvaMed is the largest medical technology association in the world, representing more than 1,600 medical device, diagnostic, and health information system manufacturers and subsidiaries. AdvaMed's members produce nearly 90 percent of the health care technology products 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. More than 70 percent of our members have less than $30 million in domestic sales annually. Patent protection is important to protect our members' investment in new medical device technologies.

Generally, AdvaMed's members are in support of an examination-on-request with a longer multiple year delay, such as 5 to 7 years, because of the long innovation and regulatory approval cycle for medical devices. AdvaMed also believes that the delay would benefit the USPTO by reducing its backlog of pending patent applications. In particular, AdvaMed offers its support for the positions espoused in the Biotechnology Industry Organization (BIO) comments submitted on May 29, 2009. Because of our support of the BIO comments, we are only providing some supplementary highlights to illustrate the positive impact an examination-on-request procedure would bring to our members.

Different medical devices have different development cycles. Improvements to existing "predicate" devices have shorter timelines than biotechnology therapies, but usually longer timelines than traditional technologies with fewer regulatory hurdles. More innovative Premarket Approval (PMA) devices can take many years and millions of dollars to develop, similar to biotechnology therapies. Despite the effort required, improvements in

medical devices should be encouraged. Continual improvements in medical device technology provide patients access to the best diagnostics and treatments, and greatly benefit overall U.S. health.

The exclusivity afforded by filing a portfolio of patent applications covering the high-risk development of a medical device is needed to attract the funding from venture capital at small companies and from internal budgets in large companies. At the same time, early public disclosure of medical devices under development is needed to obtain U.S. and foreign regulatory approvals and development funding from venture capital firms. Therefore, medical device developers have to file a portfolio of patent applications early in the development cycle or risk being barred from obtaining patent protection. Unfortunately, this early stage is usually when funding for patent prosecution is at its lowest. An optional 5 to 7 year delay would allow our members to selectively defer prosecution efforts and costs until a time when funding is more easily secured.

In addition, the final design of a medical device is much more certain nearer to the end of its development process. Ordinarily, the applicant would have to file multiple serial continuations to ensure pendency of a family member as the device approaches market entry. However, a delay before examination allows the applicant to more closely tailor prosecution of the claims in the application to the final design of the medical device. Without a delay, the medical device company is forced in the original and intervening applications to speculate on the final design with limited information. The original and intervening patent applications, therefore, often need to have large numbers of claims that may not cover the final design of the medical device. Thus, a 5 to 7 year delay would reduce the backlog at the USPTO by reducing the number of continuation applications filed and the amount of prosecution on embodiments that don't reflect the final design of the medical device.

As noted in the BIO comments of May 29, 2009, a 5 to 7 year delay is supported by similar examination-on-request procedures in foreign countries such as Canada and Germany. For our members, these longer delays are an especially good match for the delays encountered by the more innovative PMA devices which have multiple-year approval timelines. For shorter regulatory timelines, such as those encountered in 510K devices, our members would most likely opt for immediate examination.

AdvaMed appreciates the opportunity to submit these comments, and thanks you for your time and consideration.

Respectfully submitted,

Chris L White

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