MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

1333 H Street, NW
Suite 400
Washington, DC 20005
P: (202) 354-7171

April 10, 2012

Via Electronic Submission

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

Re: [Docket No. PTO-P-2011-0084]

Dear Director Kappos,

The Medical Device Manufacturers Association ("MDMA") appreciates the opportunity to provide comments on the proposed regulation, *"Changes to Implement Post-Grant Review Proceedings"* (Docket No. PTO-P-2011-0084). MDMA represents hundreds of innovative and entrepreneurial medical technology companies which produce life-saving medical therapies for patients.

The medical device industry is comprised primarily of small companies with 50 employees or less. In fact, most companies in our industry are true "start-up" companies, often comprised of only a few employees in total. These companies are, in most cases, supported by various sources of venture capital or other financing. To this end, one of the greatest assets for these companies is an efficient and predictable patent office to ensure that intellectual property is protected and that the patent filing process is predictable. Both innovators and investors rate these factors of highest importance.

MDMA commends the United State Patent and Trade Office ("USPTO") for its work in implementing the Leahy-Smith America Invents Act ("AIA"). We believe that the proposed rules for implementation, in general, as well as this rule, represent a balanced approach to implementing the Act. The AIA, while not perfect, should adequately provide the predictability and expediency needed by America's innovators.

While MDMA believes that the rules present an overall balanced approach to implementation, we are concerned with one provision in particular in the *Changes to Implement Post-Grant Review Proceedings* (Docket No. PTO-P-2011-0084) proposed rule. Specifically, we urge the USPTO to utilize caution in implementing section 42.224 of the proposed rule which states:

> 42.224 would provide that additional discovery in a post-grant review is limited to evidence directly related to factual assertions advanced by a party to the proceeding and that the standard for additional discovery is good cause.[1]

[1] 77 Fed. Reg 28 (February 10, 2012) at 7066

As the AIA was debated in Congress, MDMA opposed the creation of a new system for post-grant review proceedings. Specifically, we believe the post-grant opposition proceeding will create uncertainty, and prohibitive costs for start-up companies, and provide an effective vehicle for larger companies to cause smaller companies to spend resources that are best used developing the innovative technology. Similarly, we believe that the use of the good cause standard in the post-grant review proceedings for granting additional discovery will have a similar effect. To avoid this impact, MDMA believes that the higher interests-of-justice standard should be used in post-grant review proceedings. This standard will likely deter potential abusive use of additional discovery by a larger party challenging a smaller party patent owner.

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MDMA appreciates the opportunity to provide comments on the proposed regulation, *Changes to Implement Post-Grant Review Proceedings*. We believe that this rule and the proposed rules in general represent a balanced approach to implementation of the AIA. We look forward to working with the USPTO to ensure that medical device innovators have a predictable patent process that ensures both fairness and efficiency.

Sincerely,

Thomas C. Novelli
Vice President of Government Relations
Medical Device Manufacturers Association