MDMA
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July 9, 2018

Via Electronic Transmission

The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop: Patent

Attention: Vice Chief Administrative Patent Judges Michael Tierney & Jacqueline Wright Bonilla

Re: Proposed rule to change the claim construction standard for interpreting claims in inter partes review, post-grant review, and the transitional program for covered business method patents proceedings before the Patent Trial and Appeal Board (PTO-P-2018-0036)

Dear Under Secretary Iancu,

On behalf of the Medical Device Manufacturers Association (MDMA) and the hundreds of innovative medical technology companies we represent, I am writing to express MDMA's strong support of the United States Patent and Trademark Office (USPTO) proposal to adopt the Phillips standard for claim construction at proceedings before the Patent Trial and Appeals Board (PTAB). Aligning the claim construction at PTAB with the standard used in federal court is an important step to restore balance to PTAB proceedings and slow the decline in patent rights in the United States.

MDMA's members, the majority of which are small, venture-backed, start-ups, are inventing cures to help treat the most complex medical conditions and diseases. Advancements in exoskeletons are helping the paralyzed walk, new optic nerve stimulators are restoring sight to the blind, and continuous glucose monitors are helping diabetics more effectively manage their insulin. Soon robotic surgery systems using artificial intelligence will allow doctors to perform extremely precise surgeries remotely on patients half way around the world.

The companies developing these medical break throughs, and thousands of others like them, rely on strong intellectual property protections to attract capital to develop their technologies. When patent rights are weakened and unreliable, fewer inventors and investors will devote the many years, sometimes a decade or more, and tens of millions of dollars to secure regulatory approval and

reimbursement to bring new medical devices to market. While strong patent rights are important for many industries and for economic growth broadly, policy makers have a responsibility to patients to keep robust IP protections in place that promote innovation in the life sciences to improve health outcomes and alleviate suffering.

Since the implementation of the America Invents Act (AIA) in 2012, patents can now be challenged through the PTAB in addition to the federal courts. Congress envisioned AIA trials as a cheaper and timelier alternative to the courts to invalidate "bad" patents. However, AIA trials employ different standards than the courts and strongly favor challengers. These disparities have created an environment where 80% of the patent claims instituted by the PTAB are invalidated (versus just 40% in the courts), and even patents upheld by a court are subjected to serial challenges at the PTAB where many are subsequently invalidated.

MDMA applauds the USPTO for reviewing PTAB proceedings and proposing reforms to ensure that patent owners receive fairer treatment at AIA trials. Specifically, the USPTO's recommendation to harmonize claims construction with the Phillips standard used in federal court will ensure that patent claims receive uniform treatment across forums. The Phillips standard, unlike the broadest reasonable interpretation (BRI) standard currently used at PTAB, relies on discovering the actual meaning of the claim, instead of its most expansive meaning. BRI allows challengers to introduce more prior art and make far more expansive arguments at the PTAB to challenge the validity of patents, and the current differences in claims construction standards encourage challengers and infringers to attack patents in both venues; availing themselves of the benefits of broader claims construction at the PTAB while also pursuing action in the courts.

In closing, MDMA appreciates this opportunity to comment on the proposed rule and urges the USPTO to implement the Phillips standard for claims construction at the PTAB. This change restores consistency in patent review and improves confidence in our IP system which is so fundamental for innovation in medical technology. As always, MDMA looks forward to working with the USPTO in the future to improve the environment for medical innovation in the U.S.

Sincerely,

Mark Leahy
President & CEO, MDMA