

April 14, 2015

The Honorable Bob Goodlatte Chairman
House Committee on the Judiciary
Washington, DC 20515

The Honorable John Conyers Ranking Member
House Committee on the Judiciary
Washington, DC 20515

Dear Chairman Goodlatte and Ranking Member Conyers,

On behalf of the Medical Device Manufacturers Association (MDMA) and the hundreds of innovative and entrepreneurial medical technology companies we represent, I am writing to share our concerns with H.R. 9, The Innovation Act. Our members, the majority of which are small, venture-backed, start-ups, rely upon a strong patent system to attract the capital needed to invest in and develop new life-saving technologies. Changes to the patent system that would devalue property rights or the ability to protect intellectual property will have a chilling effect on developing the medical cures and treatments of tomorrow.

The issue of “patent trolls” is an emerging one in medical technology, and MDMA supports balanced efforts to improve the U.S. patent system and agrees that targeted steps can be taken to curb abusive patent litigation. However, the provisions in H.R. 9 that purport to target only abusive patent practices are so broadly drafted that they would make the defense of legitimate intellectual property from infringement more costly and burdensome, and discriminate against innovation models such as those who develop technologies and license them to larger players for distribution purposes. The patent is the lifeblood of the medical technology industry and serves as the bedrock on which risk-taking entrepreneurs are able to create new markets and new jobs, and most importantly, deliver break-through technologies to patients who need them.

MDMA respectfully requests that the Committee reconsider the far-reaching approach to patent legislation under H.R. 9 and address the issues below before moving patent legislation that could jeopardize our fragile innovation ecosystem:

Establish a balanced fee shifting threshold

Fee shifting is warranted in cases where a party acted in bad faith or was unreasonable. The courts have the authority to impose fees on a party that asserts a patent in bad faith, and the Supreme Court’s recent rulings in *Octane* and *Highmark* have further relaxed the standard for recovering attorney’s fees. Moving to a loser pays system that removes this discretion from the court is an unnecessary weakening of judicial authority and will discourage smaller patent holders from legitimately defending their patents against dominant incumbent companies who could bankrupt them in court. Faced with the prospect of having to cover the legal expenses of

larger companies, start-up companies with limited capital either will not bring otherwise meritorious cases against infringers of their patents or will be forced into early settlements when defending against alleged infringement. The perverse incentives created by this provision would encourage infringement by large incumbent players who could easily handle the expense of covering the legal expenses of the prevailing party in cases they lose and cripple the ability of small inventors to defend their intellectual property.

We are also concerned that the joinder language would drive venture capitalists and other investors out of patent intensive industries like the medical device industry. It takes years, sometimes a decade or more, and tens of millions of dollars to secure regulatory approval and reimbursement for new medical devices. Because the industry is so highly regulated, investment in early-stage medical device companies is a very risky proposition. Exposing investors to the significant financial liabilities created by the joinder provision would further discourage investment in the breakthrough medical technologies of tomorrow.

Significantly narrow or eliminate the customer stay language

All parties support indemnification for the true end user. In fact, in the medical technology space, end users (doctors and patients) are already shielded from patent liability. However, the current customer stay provision is so broad that it could protect direct infringers and should be modified so that it does not indemnify parties in the chain of commerce that have a clear commercial interest in infringement.

Require balance in any heightened pleadings requirements and discovery limits

The proposed heightened pleadings requirements and discovery limits prior to claim construction will create an imbalance and burden for smaller patent holders seeking to assert their patent rights.

The fact that certain elements or facts are not known or included in the initial pleadings, should not limit a petitioners ability to gain access to those facts and amend pleadings. The combination of heightened pleadings and limited discovery is a “double jeopardy” of sorts that requires a petitioner to guess at detailed facts that may not be in their possession (e.g. how a product is manufactured), and then be penalized by not being able to obtain the facts, even those that may establish clear infringement. While there is variability in local practice, certain jurisdictions, like the Northern District of California, do a very good job ensuring specificity at the appropriate times. Standardizing that practice instead of creating yet another approach that creates barriers to legitimate challenges seems the prudent course.

Furthermore, the Judicial Conference of the United States has already adopted changes to the Federal Rules of Civil Procedure that direct courts to limit excessive and abusive discovery requests and ensure adequately described pleadings in patent cases. These reforms are expected to be fully implemented this year.

Maintain strong estoppel for the newly created post-grant review (PGR) process

PGR was established as a mechanism to provide an administrative option that would reduce litigation in the courts. To achieve this objective, strong estoppel is required. Reducing the estoppel threshold would result in serial challenges that would be abusive to patent holders, particularly start-up companies and entrepreneurs. Post-Grant Review is a litigation-like proceeding that requires a patentee to undergo significant costs and distraction to defend their patent. Parties challenging a patent should not be given multiple bites at the apple. “Could have raised” estoppel prevents a challenger from withholding certain arguments so the challenger can raise them in another later challenge. Eliminating such estoppel would burden the patent system, increase litigation, and require significant resources to be spent by smaller patent holders to defend themselves in multiple settings. If “could have reasonably raised” is considered overly burdensome given the 9-month window, we recommend amending the provision to read “or reasonably could have raised based on the information actually known or in possession of the petitioner [sufficient to support a challenge at the time of the initial filing].” This would put to rest any concerns that the estoppel might apply to information not actually known to the petitioner or that is findable only by performing a search.

Permanently end the diversion of patent fees from the US Patent and Trademark Office (USPTO)

Over the past 20 years, the practice of fee diversion has resulted in over \$1 billion in diverted fees which have produced more than 600,000 unexamined patent applications during that same timeframe. All parties agree that a key element to a fair and effective patent system begins with the issuance of strong, valid patents. Many of the complaints about patent trolls include allegations that these entities are asserting “bad patents” that should never have been granted. The most effective action that can be taken to improve patent quality is to allow the USPTO to retain its revenues to allow it to improve the examination process, hire more and better-qualified examiners, increase examiner training, and upgrade the USPTO’s IT infrastructure. This should be a core element of any legislation aimed at addressing the “troll” problem. The continual diversion of hundreds of millions of dollars from USPTO to the US Treasury is a tax on innovation and must end.

We appreciate the efforts of the Judiciary Committee to address abusive practices in the patent system, but respectfully request that enhancements to the bill raised in this letter are made before the legislation is brought to the floor for a vote. It's critical that legislation impacting such a broad cross-section of the economy and constitutionally protected property rights is narrowly focused to address the abuses of patent trolls while protecting the patent system for all stakeholders. Failure to deliberate thoughtfully and make the necessary changes to mitigate these unintended consequences will undermine our country's leadership position in innovation and America's future economic growth and competitiveness.

Thank you for your consideration of our views and concerns.

Sincerely

A handwritten signature in black ink, reading "Mark B. Leahey", is positioned to the left of a vertical line that separates the signature from the typed name below.

Mark B. Leahey
President & CEO, MDMA