

December 2, 2013

The Honorable John Boehner  
Speaker of the House  
United States House of Representatives

The Honorable Nancy Pelosi  
Minority Leader  
United States House of Representatives

Dear Speaker Boehner and Minority Leader Pelosi:

On behalf of the Medical Device Manufacturers Association (MDMA) and the hundreds of innovative and entrepreneurial medical technology companies among our membership, I am writing to share MDMA's views on H.R. 3309, The Innovation Act of 2013. Our members rely upon a strong and robust patent system to attract the capital needed to invest in new life-saving technologies. Any 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 treatments of tomorrow. Therefore, we urge the House to take the time necessary to seek feedback from all stakeholders before moving the bill to the floor for consideration.

MDMA supports balanced and reasonable efforts to improve the U.S. patent system and agrees that additional steps can be taken to curb abusive patent litigation. The issue of "patent trolls" is an emerging one in medical technology. However, any legislative effort must be carefully considered and not capture reputable innovation models such as those who develop technologies and license to larger players for distribution purposes. Furthermore, Congress should oppose changes to the patent law that make it more costly and burdensome for innovators to defend their intellectual property.

MDMA respectfully requests that Congress address the issues below before the House takes any action on the bill:

- Permanently end the diversion of patent fees from the USPTO. All parties agree that a key element to a strong patent system begins with the issuance of strong, valid patents. The continual diversion of hundreds of millions of dollars from USPTO to the US Treasury is a tax on innovation and must end. In addition, the user fees, paid by industry, should be exempt from any sequester cuts.
- 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 as included in H.R. 3309 would result in serial challenges that would be abusive to a patent holder. Parties challenging a patent should not be given multiple bites at the apple. It would burden the patent system 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 to “or reasonably could have raised based on the information known or in possession of the petitioner”. This would not require an obligation to perform a search.

- Modify the mandatory stay provision so that it does not indemnify parties in the commercial chain that have a commercial interest in infringement. Most parties recognize that innocent customers should have protections. However, the current language goes well beyond addressing this specific class.
- Strike the “covenants not to sue” provision in the fee shifting section.
- Support the limited discovery to initially claim interpretation. However, it must be clear that discovery can proceed on all other causes of action in the complaint beyond those relating to patents (i.e., trade secret, misappropriation, breach of confidentiality agreement, etc.).
- Support the use of District Court Construction in PGR and Inter Parties Reexamination.

In conclusion, the overwhelming majority of Congress has not had adequate time to review the specific provisions and understand the competing perspectives among stakeholders. Legislation this sweeping and impactful to innovation and our nation’s economy must not be rushed. Failure to deliberate thoughtfully and make the necessary changes to mitigate the unintended consequences will undermine our country’s leadership position in innovation and America’s future economic growth and competitiveness. We appreciate the efforts of the Judiciary Committee, but respectfully request that additional enhancements to the bill are made before the legislation is brought to the floor for a vote. Legislation impacting such a broad cross-section of the economy and constitutionally protected property rights should not be rushed. We urge you to continue to work toward a consensus position on the legislation which will address the abuses of patent trolls while protecting the patent system for all stakeholders.

Thank you for your consideration of our views and concerns.

Sincerely,



Mark B. Leahey  
President & CEO, MDMA