Biotechnology Industry Organization

James C. Greenwood
President & CEO

June 19, 2015

The Honorable John Conyers
Ranking Member, House Judiciary Committee
B-351 Rayburn House Office Building
Washington, D.C. 20515

Dear Representative Conyers:

The Biotechnology Industry Organization (BIO), whose members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, appreciates your active leadership in protecting patent rights. As you know, due to serious concerns with H.R. 9, we expressed our strong opposition to the bill. Per your staff's request, we summarize our principal concerns with the legislation below.

Inter Partes Review

In BIO's view, the growing, ongoing abuses of the U.S. Patent and Trademark Office's (PTO) *Inter Partes* Review (IPR) process pose a major threat to the biopharmaceutical industry, particularly to emerging companies engaged in the development of innovative therapies for unmet medical needs. IPR proceedings were designed to provide a quicker, cost-effective alternative to district court litigation, but have now become a process that is fundamentally skewed against patents and patent owners – leading to invalidation rates far in excess of what would be expected to occur in court, which in turn are undermining the reliability of patents as a basis upon which to invest and innovate.

BIO appreciates the IPR reforms in the bill, but we believe they are insufficient to address the fundamental problems and abuses within the IPR system. The bill does not resolve the main drivers of IPR abuse – the lower standard for invalidating a patent as compared to district court and the lack of any meaningful bar on repeated challenges to the same patent; nor does it contain, in the alternative, BIO-proposed language that would reduce IPR gamesmanship and preserve the integrity of existing Congressional schemes for challenging and litigating patents on FDA-approved drugs and biologics. And it does not require the PTO to fix the broken claim amendment process in IPR so that patent owners can narrow their claims to avoid total invalidation of otherwise valid patents.

The provision aimed at preventing stock manipulation through IPRs, while certainly welcome, is too narrowly drafted to be effective at preventing such

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abuse and the delayed effective date for the IPR reforms would permit such abuses to continue for too long.

Heightened Pleadings

In BIO's view, the new pleading requirements remain overly burdensome and will impede the ability of all patent owners to timely bring suit to protect against infringement. We believe that the new language regarding identification of claims is too ambiguous and does not provide sufficient guidance to parties or courts on what a sufficient complaint would require, creating too many opportunities for abusive motions by accused infringers challenging the sufficiency of complaints and delaying enforcement against them.

Joinder

While we trust that the joinder provision is a well-intended effort to combat shell companies and trolls, the language is too vague in critical respects and could potentially sweep in many legitimate patent owners and their assignees, licensees, and investors. This will chill investment in areas like biotechnology that require partnerships and collaborations among researchers, investors, and companies.

Venue

The new venue provision is complicated and raises important questions of access to the courts that require much more careful vetting than this process has allowed to date. We appreciate that the bill's proposed venue provisions seek no more than common sense reforms to alleviate the unusual current concentration of patent cases in certain districts. But we are concerned that, in pursuit of that goal, patent cases would be dispersed to district courts where venue would be just as illogical. For example, there is little common sense in barring infringement suits in districts where the infringement actually occurred and competitive harm accrued, or in districts where the aggrieved patentee resides or is incorporated. Overall, as currently drafted, the proposed venue provisions would not permit suit in reasonable locales important to patent owners, and could negatively impact the ability of courts to efficiently consolidate cases.

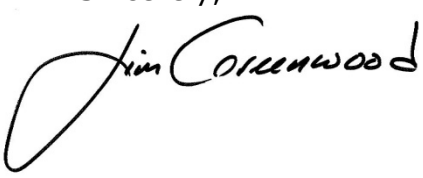
Discovery Stay

BIO greatly appreciates the significant improvements that the Manager's Amendment brought to H.R. 9 in this area, but we were disappointed that such progress was rolled back during the mark-up in committee, and we continue to have concerns regarding the competitive harm exception. That exception only covers companies with products already on the market, failing to protect the thousands of start-up companies on the cusp of commercial marketing from

being able to timely enforce their patents against infringers who are trying to destroy their businesses before they even make it to market.

We regret finding ourselves in a position of opposition to this bill—we worked hard with the bill's supporters to try to find a middle ground that would meet the proponent's needs without harming the intellectual property rights that are so vital to the life sciences industry. Unfortunately, as outlined in the above concerns, the legislation failed to reach that point. We remain hopeful that a more balanced approach to patent reform is still possible before the bill moves to the House floor, and BIO stands ready to work with anyone willing to achieve that goal.

Sincerely,



James C. Greenwood
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cc: The Honorable Bob Goodlatte