



July 15, 2015

Chairman Chuck Grassley
Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, DC 20510

Ranking Member Patrick Leahy
Senate Judiciary Committee
224 Dirksen Senate Office Building
Washington, DC 20510

Chairman Robert Goodlatte
House Judiciary Committee
B351 Rayburn House Office Building
Washington, DC 20515

Ranking Member John Conyers
House Judiciary Committee
2138 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Grassley, Ranking Member Leahy, Chairman Goodlatte, and Ranking Member Conyers –

We write to express our support for changes to H.R. 9, the Innovation Act, and S. 1137, the PATENT Act, to preserve the integrity of the Drug Price Competition and Patent Term Restoration Act (commonly referred to as Hatch-Waxman) and the Biologics Price Competition and Innovation Act (BPCIA) by exempting certain biopharmaceutical patents on approved medicines from the *inter partes review* (IPR) process at the Patent and Trademark Office (PTO), and to rebut several erroneous statements that have been made about these proposals. Unfortunately, these statements disregard the intent behind both the America Invents Act (AIA) and the patent resolution frameworks established under Hatch-Waxman and BPCIA, and contain a number of false statements about the impact of failing to correct this unintended consequence of the AIA. We are writing to set the record straight.

Hatch-Waxman and BPCIA were established by Congress as separate patent resolution frameworks for biopharmaceutical patents in order to achieve two key objectives: 1) to increase the ability of generic and biosimilar manufacturers to offer consumers lower cost versions of off-patent medicines, and 2) to preserve incentives for the discovery and development of new, innovative medicines. In fact, as the Supreme Court has stressed, one of the “key features” of the Hatch-Waxman Act was the establishment of “special procedures for identifying, and resolving, related patent disputes” including the paragraph IV

pathway for provoking and resolving patent litigation.¹ These specialized and carefully balanced systems have worked. Currently, 88 percent of prescriptions filled in the United States are for generics, up from just 19 percent in 1984 (when Hatch-Waxman was enacted). In fact, the existing frameworks and the use of generics have generated nearly \$1.5 trillion in savings to the U.S. health care system between 2004 and 2013 alone. At the same time, since 1995, R&D investment by the biopharmaceutical industry has grown by nearly 240 percent, reaching over \$51 billion in 2014.

Unfortunately, the tremendous uncertainty caused by IPR challenges to patents on FDA-approved products threatens to undermine this delicate balance. Rather than working in harmony with the goals of Hatch-Waxman and BPCIA, as some have argued, the IPR process threatens to disrupt the careful balance that Congress achieved over 30 years ago, by increasing business uncertainty for innovative biopharmaceutical companies having to defend their patents in multiple venues and under differing standards and procedures, ultimately diverting finite resources away from the research and development of new cures and treatments, to the detriment of patients. Indeed, more than 90 patient organizations recently wrote to Congress to express their concerns about the undermining of IP protection that drives innovation in medicine.

In addition, there is no evidence that Congress intended the IPR process to be used by generic and biosimilar companies to challenge biopharmaceutical patents outside of Hatch-Waxman and BPCIA. Indeed, at no point during the debate of the AIA was there contemplation that the IPR procedure would be an alternative to the Hatch-Waxman and BPCIA patent challenge procedures.

We appreciate that provisions were included in H.R. 9 that were intended to address abusive IPR filings by unscrupulous hedge funds and other questionable entities. Unfortunately, while well intentioned, these provisions contain numerous loopholes that will allow such entities to continue to abuse IPRs for their own financial gain. Furthermore, these provisions fail to address the larger challenge – which is the use of IPR outside of the Hatch-Waxman and BPCIA schemes that threatens to fundamentally undermine the delicate balance struck by Congress when enacting these biopharmaceutical patent dispute resolution systems. Among other relevant aspects of these schemes is the bar on innovators suing generic or biosimilar developments for infringement prior to their filing of an FDA application – known as the “infringement safe harbor.” This makes it particularly unfair to permit those competitors to be able to both freely infringe the innovator’s patent and challenge them in an IPR at the same time.

It is important to point out that PhRMA and BIO’s members are not seeking to be shielded from all challenges at the PTO. The language we have proposed would apply only to IPRs filed against certain patents on FDA-approved products – those covering the product, its use or manufacture, and only after the date of FDA approval. All other pharmaceutical-related patents, including those same patents prior to approval, would remain subject to challenge at the PTO. In this way, the language is similar to the underlying House and Senate patent bills, both of which exempt litigation under Hatch-Waxman and BPCIA from several of the proposed general patent litigation reforms. These exemptions recognize that, unlike companies in other sectors, biopharmaceutical companies are not able to immediately capitalize

¹ *FTC v. Actavis Inc.*, 133 S. Ct. 2228 (2013).

on the value of their patents. Instead, they must spend 10 to 15 years and an average of \$2.6 billion to research and develop a new medicine, including clinical trials often involving thousands of patients, before they can receive approval from FDA to bring that new cure or therapy to market. Such a significant investment of time, money, and resources merits respecting the specialized procedures Congress has established for resolving these patent disputes, and those tailored procedures should not be disrupted by the IPR process.

We also note that there is no evidence that IPRs will allow generic and biosimilar companies to bring products to market more quickly. Overall, IPRs have not been shown to be an effective method to allow generics or biosimilars to enter the market. Simply put, no generic or biosimilar has come to the market as a result of an IPR. The IPR process provides only a limited means for challenging a patent claim – a challenge to a patent in an IPR can only be made on the basis of prior art consisting of patents or printed publications – and cannot be based on an assertion of non-infringement. Accordingly, it is highly unlikely that IPR can or will be used to invalidate all of the patents covering a particular FDA-approved drug or biologic, limiting the ability of IPRs to be used to speed generic and biosimilar approval. Nevertheless, the risks and uncertainties associated with having to defend patents in multiple venues is already impacting investment considerations by innovator biopharmaceutical companies and potential investors.

Hatch-Waxman and the BPCIA already allow for generic and biosimilar companies to effectively challenge patents that are perceived as overly broad or invalid. Key provisions in Hatch-Waxman are designed to encourage generic companies to bring patent challenges, and recent data demonstrates that this is exactly what generic companies are doing – in 2012, more than 80 percent of innovator drugs experienced at least one patent challenge before generic entry, up from just 14 percent in 1996.

Nor is the IPR process needed to protect against the purported practice of “evergreening,” where new patents are asserted to have been claimed on existing innovator medicines. New patents cover their subject matter, and not previous patented matter. To the extent there is a concern with respect to new patents relating to innovator medicines, those patents will remain subject to challenge under the post-grant review process at the PTO, as the proposed exemption only covers IPR proceedings. And to the extent that those new patents do not cover meaningful improvements to existing products, generic companies simply can make and sell copies of the older versions.

Finally, it has been argued that the IPR process is needed so that companies can obtain patent information on biologic drugs, since there is no Orange Book-type listing for such patents. However, Congress established the process to challenge patents on biologic drugs in BPCIA. Under the BPCIA, biosimilar manufacturers, as early as four years after approval of the reference biologic, can seek FDA approval for the biosimilar application and utilize the BPCIA procedures to gain information about relevant patents, challenge patents, and resolve patent issues. Biosimilar manufacturers do not need an additional mechanism to challenge patents outside of the process Congress created in order to effectively bring biosimilars to market.

PhRMA and BIO appreciate your work fighting abusive behavior in patent litigation, and believe it must extend not just to those who abuse patent rights, but also those reverse trolls who are abusing the systems for patent challenge. Failing to exempt biopharmaceutical patents on approved medicines could disrupt the delicate balance Congress struck under Hatch-Waxman and BPCIA and harm the discovery and development of new cures and treatments for patients across the country. We thank you for your attention to this matter and we look forward to working with you to move this legislation forward with our full support.

Sincerely,



James C. Greenwood
President & CEO
BIO



John J. Castellani
President & CEO
PhRMA

cc: Members of House and Senate Judiciary Committees

The Honorable John Boehner, Speaker of the House of Representatives
The Honorable Kevin McCarthy, Majority Leader, House of Representatives
The Honorable Steve Scalise, Majority Whip, House of Representatives
The Honorable Nancy Pelosi, Democrat Leader, House of Representatives
The Honorable Steny Hoyer, Minority Whip, House of Representatives
The Honorable Fred Upton, Chairman, House Energy and Commerce Committee
The Honorable Frank Pallone, Ranking Member, House Energy and Commerce Committee
The Honorable Mitch McConnell, Senate Majority Leader
The Honorable Harry Reid, Senate Minority Leader
The Honorable John Cornyn, Senate Majority Whip
The Honorable Charles E. Schumer, Chair, Democratic Policy and Communications Committee
The Honorable Lamar Alexander, Chairman, Senate Health, Education, Labor and Pensions Committee
The Honorable Patty Murray, Ranking Member, Senate Health, Education, Labor and Pensions Committee