

October 12, 2017

Honorable Charles E. Grassley  
Chairman  
Committee on Judiciary  
SD-224 Dirksen Building  
Washington, DC 20510

Honorable Dianne Feinstein  
Ranking Member  
Committee on Judiciary  
SD-224 Dirksen Building  
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Feinstein:

I am writing on behalf of the Biotechnology Innovation Organization (“BIO”) with respect to a recent request by several Judiciary Committee members that the Committee investigate the recent patent licensing agreement between Allergan and the Saint Regis Mohawk Tribe. While BIO does not comment on specific business transactions of its members, BIO believes that any inquiry by the Judiciary Committee in this area must include a serious review of the numerous deficiencies of the U.S. Patent & Trademark Office (PTO) *inter partes* review system (“IPR”), and the extent to which its use by certain generic pharmaceutical manufacturers undermines longstanding and carefully-balanced procedures governing market entry and patent dispute resolution under the highly successful Hatch-Waxman Act.

BIO is the world’s largest biotechnology trade association. It represents over 1,100 companies, research institutions, technology incubators, and similar entities in the medical, agricultural, environmental and industrial biotechnology sectors, the vast majority of which are small, start-up companies that are engaged in the most cutting-edge and risky R&D and are heavily reliant on massive amounts of private investment. As such, BIO is focused on the critical and positive role that patents play in incentivizing biotechnology and pharmaceutical innovation and in generating millions of high-skill jobs in the United States. Given this focus, BIO is extremely concerned with the way in which the IPR system has failed to live up to Congress’s hopes for a limited, but faster and cheaper, *alternative* to certain types of patent litigation. Instead, IPR as it exists today, is undercutting the patent system’s intended incentives for innovation by serving as an open-ended and duplicative forum for a new class of “patent trolls” that is introducing significant business uncertainty and cost.<sup>1</sup>

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<sup>1</sup> BIO also recently submitted an *amicus curiae* brief in the *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*, No. 16-1712, which is currently before the United States



As you know, IPR has become highly controversial. There are persistent complaints that these proceedings lack finality and due process, use legal standards that are systematically unfavorable to patentees, and that the PTO has emphasized speed and efficiency over procedural fairness. IPR is too often used not as a substitute for, but together with, district court litigation for multi-pronged attacks on the same patents in different fora. There are instances of valuable patents being upheld after years of litigation by a federal court, only to be struck down on the same record through an IPR using a weaker legal standard. For patent challengers, IPR can be an effective form of answer-shopping. For patentees, they are a form of double – indeed seemingly endless – jeopardy.

Importantly, Congress never discussed or contemplated the potential impact on pharmaceutical patent litigation under the Hatch Waxman Act (HWA) when it created the IPR system.<sup>2</sup> And such use of IPR has introduced unexpected and unintended complications into the Hatch-Waxman system. The HWA, enacted in 1984, is the principal law governing approval and market entry of generic drugs. For 30 years, the HWA has successfully balanced its goals of drug innovation and cheaper access: more innovative new drugs have been developed in the United States than in the rest of the world combined, while at the same time, more than 90% of drug prescriptions in America today are for generic drugs – one of the highest generic market penetration rates in the industrialized world. In addition, U.S. consumers enjoy generic drug prices that are among the lowest among industrialized countries.

Generic drug companies already receive benefits under the HWA that exist in no other industry, including a safe harbor from infringement liability during drug development, the ability to issue patent challenges in FDA certifications, a lucrative 180-day generic exclusivity, and the ability to fully and fairly challenge patents in federal district court without risk of financial liability. Under this system, generic drug companies also get the benefit of the innovator company's prior demonstration of safety and efficacy for a given medicine, resulting in enormous reductions in both drug development costs and business risk. While continuing to reap these benefits, generic companies now use IPR to game the system in pursuit of further advantages – for example, by litigating the innovator company's patents for about a year in federal district court, and then using what they have learned to open a

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Supreme Court. It is BIO's position that the current IPR process is constitutionally infirm and requires significant reforms.

<sup>2</sup> See, e.g., Statement of Chairman Charles Grassley (R-IA), Executive Business Meeting, Senate Judiciary Committee, June 4, 2015 (“When the America Invents Act was considered, it’s my understanding that there was no debate over whether or how IPR would impact these important processes.”).



parallel challenge to the same patents in an IPR proceeding. If timed strategically, this parallel IPR proceeding can be used as a hedge against the results of the district court litigation. If the federal court determines the innovator's patent to be valid, the IPR may still produce the opposite result. And even if the court and the PTO both agree that the patent is valid, the generic company has not one but two chances to overturn the result on appeal. It is the quintessential double bite at the apple.

Through such gamesmanship, generic drug companies seek to secure for themselves the benefits of the Hatch-Waxman system without being bound by that system's results. In the process, they are undermining the carefully constructed policy balance of the HWA, by creating uncertainty, delay, and increased costs in the system for drug innovators and other generic competitors, without producing any offsetting benefits for patients or consumers. After five years of using IPRs in this way, generic companies cannot point to a single generic drug that entered the market sooner because the PTO ruled in their favor. Indeed, such gamesmanship by generic drug companies will serve only to harm patients in the long run by dampening investment in already risky biomedical innovation.

As you will recall, BIO has been raising concerns with the Senate Judiciary Committee about the impact of IPR on the HWA system for several years. And more than two years ago, members of this Committee began expressing their concern with these developments.<sup>3</sup> Since then, the problem has only become worse. It is time for this Committee to reassess whether IPR remains, in Senator Hatch's words, the "legitimate and cost-effective alternative to litigation" it was intended to be, while at the same time preventing misuse of "this administrative process to interfere with a litigation system that encourages the development of cheaper life-saving medicines."

Finally, let me emphasize that BIO takes no particular position with respect to Allergan's transaction with the Saint Regis Mohawk Tribe. We note, however, that sovereign immunity is nothing new in the patent system. State-owned patents have been part of the

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<sup>3</sup> See, e.g., Transcript of Executive Business Meeting, Senate Judiciary Committee, June 4, 2015 (Statement of Senator Charles Schumer (D-NY): "When we passed the AIA and set up the IPR process, no one anticipated it would be used as an end run around Hatch - Waxman....That pattern is troubling to me and many other sponsors and I see a strong justification for work to preserve the incentive structure as it existed for decades."); Statement of Senator John Cornyn (R-TX): "When we passed the America Invents Act, no one anticipated that IPR would impact [Hatch Waxman] in the way that it has and it is important we preserve incentives both for generics to come to market and to encourage future investments in developing new treatments for patients.").



Hatch-Waxman system for decades, and we are aware of no instance where sovereign immunity has ever interfered with or delayed resolution of innovator-generic patent disputes in federal court. It is the misuse of IPR, not the assertion of sovereign immunity, that has introduced imbalance into the HWA framework. We remain committed to restoring that balance through reasonable, but urgently-needed reforms of the IPR system.<sup>4</sup>

With Sincerest Regards,

A handwritten signature in black ink that reads "Jim Greenwood". The signature is written in a cursive style with a large, sweeping initial "J".

James C. Greenwood  
President and CEO

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<sup>4</sup> For a description of BIO's proposed reforms, see generally: testimony of Hans Sauer on behalf of BIO, United States Senate Committee on the Judiciary Hearing on "The Impact of Abusive Patent Litigation Practices on the American Economy" March 18, 2015. BIO also supports the PTAB reform concepts embedded in S. 1390, introduced 6/21/2017 by Senators Coons, Cotton, Durbin and Hirono.