Inter Partes Review (IPR) Is Necessary to Lower Drug Prices by Ensuring that PTO Only Grants Patents that Reflect True Innovation

What is "Inter Partes Review" (IPR)?

Congress established today's Inter Partes Review (IPR) process within the U.S. Patent and Trade Office (PTO) as part of the America Invents Act signed into law in 2011. Under IPR, the Patent Trial and Appeal Board (PTAB) at the PTO takes a "second look" at its earlier decision to grant a patent but this time allows third parties to bring evidence about the appropriateness of that decision.[1] The goal of these processes was "to ensure that the poor-quality patents can be weeded out through administrative review rather than costly litigation" and "to improve patent quality and limit unnecessary and counterproductive litigation costs."[2]

The IPR process as we know it today has existed at the PTO in one form or another for nearly 40 years.[3] Throughout this time, the PTO's ability to reconsider and cancel patents that never should have issued has been an important part of the patent system.

It is important to note that the IPR process equally applies to all industries – including the pharmaceutical industry.

Why is IPR necessary?

IPR and patent litigation in federal district courts serve two different but equally vital functions, and Congress intended to make both systems available.

It is widely known that the PTO frequently issues invalid patents. The examiners making patent grant decisions have heavy caseloads: In 2016, fewer than 9,000 patent examiners were tasked with reviewing more than 650,000 patent applications. Congress established the IPR process to remedy those mistakes. According to PTO statistics, a patent examiner spends, on average, only 19 hours reviewing the extraordinarily technical features of a patent application. Unfortunately, this means that PTO grants a very high percentage of patents that do not represent patentable innovation. Left unchecked, this allows brand-name pharmaceutical companies to keep drug prices high when there should be generic or biosimilar competition that drives down prices.

The IPR process contains a number of cost- and time-saving features designed to allow the PTO to identify improvidently granted patents—and correct its own mistakes—quickly and efficiently—and to eliminate bad patents, before they are ever litigated in court. While a court can also decide whether a patent is invalid, the court process looks at other issues as well, including whether a party has "infringed" the patent. As a result, that court process generally takes much longer than an IPR proceeding and costs much more. In the IPR process, there is an 18-month time limit, while in patent litigation, Congress has approximated that a pharmaceutical patent case will take 30 months to resolve in district court, and sometimes many take longer. The discovery process, especially expert discovery, in litigation is much more costly than in the IPR process because the scope of issues that the court looks at is more in depth.

Is the IPR process working?

The IPR process is working as Congress intended.

According to the PTAB's own data, as of January 31, 2018, approximately 62 percent (369 of 597) petitions on biotechnology/pharma patents have been instituted—which means that, in the 62 percent of petitions instituted, the PTAB found a "reasonable likelihood" that the patents were invalid and therefore allowed the case to move forward. From the IPR program's inception through March 31, 2017, approximately 36 percent resulted in a final written decision finding claims unpatentable, and approximately 7 percent had claims cancelled by the patent owner. Thus, unlike what some critics have claimed, IPR is not a "death panel" for patents. Rather, it corrects mistakes and cures monopolies that were never warranted in the first place.

PTAB data also show that of all the business sectors, biopharmaceutical IPRs have the lowest rate of being instituted and the lowest rate of receiving an "unpatentable" decision.

- Through Jan. 31, 2018, a total of 7,437 IPRs have been filed with the PTAB since the process was introduced in September 2012 under the America Invents Act.
- Biopharmaceutical IPRs have the lowest rate of being instituted among the major sectors: since 2012, as noted above, 62 percent of biopharma IPRs have been instituted, compared to 69 percent in the hi-tech sector; 69 percent in the mechanical sector; and 66 percent in the chemical sector.
- Biopharmaceutical IPRs have the lowest rate of receiving an "unpatentable" decision among the major sectors: from 2012 thru March 31, 2017 (latest data available) only 36 percent of biopharma claims have been decided "unpatentable," compared to 62 percent of claims ruled unpatentable in the chemical sector; 55 percent unpatentable in hi-tech sector; and 47 percent unpatentable in the mechanical sector.
- IPR is also a less expensive and more efficient process than traditional patent litigation. Under IPR, resolution of the patents is usually achieved within 18 months (as opposed to litigating in the court system, which typically takes no less than 2 ½ years). The IPR process is also much less cumbersome in terms of discovery, which reduces the cost as opposed to litigation.

In other words, the IPR process is achieving all of Congress' goals: it is fair, efficient and cost-effective. Thanks to IPR, patients have access to the savings from generic and biosimilars sooner.

Why is the IPR process necessary to help lower skyrocketing prescription drug costs?

Eliminating invalid patents by brand-name drug companies is necessary to permit patient access to more affordable generic and biosimilar medicines.

Today, generic medicines represent 90 percent of all prescriptions dispensed. The U.S. has one of the highest generic market penetration rates in the world. These are facts of which the generic and biosimilar industry is proud. More generics and biosimilars mean more savings to patients and taxpayers. In the last decade, the availability of low-cost, FDA-approved generic medicines has saved the U.S. health care system $1.67 trillion.

Despite these successes, even more generics and biosimilars could be on the market and the savings could be even greater. Although they represent 90 percent of prescriptions, generics account for only 23 percent of the total spending on medicines in the U.S. That means that, although the brand industry comprises only 10 percent of the prescriptions dispensed, they make up 77 percent of the drug spending.

Clearly, then, a problem remains: patients are paying too much for brand-name drugs.

As the Supreme Court has noted, "Patent law strikes a delicate balance between creating incentives that lead to creation, invention, and discovery and impeding the flow of information that might permit, indeed spur, invention."[4] Especially in the pharmaceutical context, that balance can be upset by brand-name drug companies seeking invalid patents that do not reflect true innovation. Delay in removing improperly awarded patents can lead to substantially higher drug costs for patients, insurers and taxpayers.

Generic and biosimilar medicines are a proven solution to high drug prices and policies that continue to foster generic access are needed. Maintaining a strong and efficient IPR process is just one of those policies.

References

1. In the initial grant of the patent, it is only the party seeking the patent who provides that evidence.
2. 157 Cong. Rec. S5409 (Sept. 8, 2011) (Sen. Schumer); 157 Cong. Rec. S1348 (Mar. 8, 2011) (Sen. Leahy).
3. The initial administrative review processes created by Congress suffered from structural deficiencies that hampered its ability to weed out bad patents. As a result, numerous legislators, including Senators Sessions, Schumer, Leahy, and Whitehouse, expressed concerns that poor-quality patents were still escaping re-examination. Legislators recognized that simple but robust PTO review would enable inventors and their competition to spend their resources productively, on raising money, commercializing inventions and manufacturing products for patients, rather than spending millions of dollars per lawsuit litigating weak patents. It could also provide "additional access to the expertise of the Patent Office on questions of patentability"—something that was not possible in district court litigation. 157 Cong. Rec. S1352 (Mar. 8, 2011) (Udall).
4. Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013).