

Inter partes review: to appeal or not to appeal?

The US Federal Circuit has imposed restrictions on who can appeal against an *inter partes* review decision, making life difficult for some petitioners. However, there are some practical tips to consider, as **Rose Cordero Prey** and **Eric Ding** of **Greenberg Traurig** explain

In 2011, Congress passed the America Invents Act (AIA), which created the popular *inter partes* review (IPR) proceeding. The IPR is used to challenge patent validity outside of federal district court litigation in the US. Although Congress specifically legislated a right to appeal for parties dissatisfied with the outcome of an IPR, the Federal Circuit has rejected that authority and imposed Article III standing requirements on appellants restricting who is able to appeal validity determinations of the Patent Trial and Appeal Board (PTAB). In doing so, the Federal Circuit has prevented a group of IPR petitioners who have made a business decision around another's patent rights and expended the necessary fees for the IPR process from verifying the correctness of the PTAB's decision on appeal. Presently, not every IPR petitioner has standing to appeal an unfavourable decision, and the Supreme Court is considering whether to take up this issue on *certiorari*.

The standing issue in IPR appeals

The IPR provisions of the AIA, codified in 35 USC §§ 311–319, gave the director of the USPTO the power to cancel patent claims when unpatentability has been shown. Any party who is not the patent owner can file an IPR petition challenging an issued US patent based on published prior art. The petitioner does not need to have a pending litigation against it involving the patent or conduct a business that is contingent upon the patent's validity. In sum, there is no requirement that the IPR petitioner have Article III standing to initiate proceedings before the USPTO. However, there are constitutional requirements for appeals to the Federal Circuit.

1 MINUTE READ

The conflict between the America Invents Act's provisions for the *inter partes* review (IPR) and the standing requirements for appellants presents a number of problems. It denies the IPR petitioner a full and fair opportunity to achieve the correct result and limits the checks and balances on the USPTO, undermines the petitioner's litigation position in light of the estoppel provision, discourages utilisation of IPR proceedings and can decrease economic activity. Practitioners will be looking to the Supreme Court for a resolution of these issues. In the meantime, there are some practical tips that petitioners can consider, including developing evidence that clearly identifies features of any product at issue and memorialising communications with the patent owner regarding licensing of the challenged patent.

Article III of the Constitution only allows federal courts to adjudicate “cases” and “controversies”. This has been interpreted as limiting federal court jurisdiction to disputes seeking to “redress or prevent actual or imminently threatened injury to persons” caused by a violation of law. *Consumer Watchdog v Wisconsin Alumni Research Foundation*, 753 F.3d 1258, 1260 (2014). Standing under Article III for an appeal to the Federal Circuit has three requirements. The appellant must show (1) it has suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the opposing party, and (3) that is likely to be redressed by a favourable judicial decision. *El du Pont de Nemours v Synvina*, 904 F.3d 996, 1004 (2018).

For parties who take advantage of the IPR process, there are estoppel provisions in the patent statute that apply to ensure that the petitioner cannot again challenge a patent’s validity on any ground that the petitioner raised or reasonably could have raised during the IPR. 35 USC § 315(e). In addition, Congress specifically provided a provision in the AIA that a party dissatisfied with the final written decision of the PTAB in an IPR has the right to appeal that decision. 35 USC § 319. However, according to the Federal Circuit, even if you went through the IPR proceedings and are dissatisfied with the results, you are not entitled to an appeal of the PTAB’s final written decision unless you can show a patent-infringed injury because Congress cannot legislate around constitutional requirements. *Consumer Watchdog*, 753 F.3d at 1262. As a matter of constitutional law, the appellant must demonstrate that it has Article III standing, not just a procedural right to appeal.

Shaping the restrictive view

There have been a number of recent decisions by the Federal Circuit dismissing appeals from the PTAB in IPR cases based on a lack of standing.

In *JTEKT v GKN*, the Federal Circuit dismissed an appeal from an unsuccessful IPR challenge of GKN’s patent directed to a drivetrain for a four wheel drive vehicle where petitioner JTEKT, a competitor, only had a product in the design stages. JTEKT had not developed a final product, and no infringement had been alleged by GKN. The Federal Circuit noted that IPR petitioners need not concede infringement to establish standing to appeal, but a concrete and substantial risk of infringement or likely claim of infringement must be shown. 898 F.3d 1217, 1221 (Fed. Cir. 2018). JTEKT failed to meet that burden with the declarations its engineers submitted because they could not definitely say whether or not the planned product could infringe because of the continuous evolving nature of the product design. *Id.*

JTEKT also tried to rely on the IPR’s estoppel provision as its injury in fact, but the Federal Circuit dispositively stated that the estoppel provision did not create a sufficient injury because JTEKT was not engaged in any activity that would give rise to a possible infringement suit. *Id.* In reaching this conclusion, the Federal Circuit relied on its decision in *Consumer Watchdog*, one of the first cases addressing the issue of estoppel as an injury in fact. In that case, the Federal Circuit reasoned that the estoppel created by virtue of the petitioner’s participation in an *inter partes* reexamination did not create a patent related injury because the petitioner, a nonprofit public charity, did not provide any indication that it was conduct-

ing stem cell research or related commercial activities that could subject it to infringement allegations or was an actual or prospective competitor of the patent owner. *Consumer Watchdog*, 753 F.3d at 1262. There was no harm to be imposed in that case by the estoppel provision in the foreseeable future.

While IPR estoppel has not been found to be an injury in fact *per se*, the Federal Circuit has left the question open-ended for “future panels to decide whether, under other circumstances, the preclusive effect of the estoppel provisions could constitute an injury in fact”. *Id.* at 1263.

Economic injury has also been alleged as an injury in fact, but the Federal Circuit requires that there be a high likelihood of retaining the economic benefit but for the challenged patent. In *Phigenix v ImmunoGen*, the IPR petitioner argued on appeal that its licensing revenue was affected by the validity of ImmunoGen’s patent directed to antibody conjugates used for cancer treatment. Phigenix did not contend that there was a risk of infringement based on its current or planned actions, and it did not contend it would be a licensee of the patent at issue. Instead, Phigenix argued that if the patent in question was valid, Phigenix would have a harder time licensing its own patent. This rationale was not rejected by the Federal Circuit, but Phigenix’s appeal of the PTAB’s decision in its IPR was dismissed for lack of standing because Phigenix did not provide enough evidence to support its claimed injury in fact. 845 F.3d 1168, 1174 (Fed. Cir. 2017). Phigenix had never licensed its patent and there was no evidence to suggest that Phigenix would license it to the same parties to whom ImmunoGen also would be licensing the challenged patent. The Federal Circuit found that Phigenix’s proposed licensing revenue was hypothetical, and there was insufficient evidence of an injury in fact to establish standing for appeal.

While the Federal Circuit may tolerate a wide range of possible injury in fact, it requires the appellant to demonstrate that injury beyond mere allegations. In *RPX Corporation v Chanbond*, the alleged injury for standing purposes on appeal was reputational. RPX, a patent risk management provider, argued that the PTAB’s decision in its IPR upholding the validity of the challenged patent tarnished RPX’s reputational goodwill generated by successful IPR challenges. However, RPX was “unable to quantify the reputational and economic harm”. 2018 U.S. App. LEXIS 36921, 7 (Fed. Cir. 2018). Given this, the Federal Circuit found no evidence of a concrete injury and dismissed RPX’s case for lack of standing.

Furthermore, the Federal Circuit will dismiss a case for mootness when the IPR petitioner appealing the PTAB’s decision no longer suffers an injury in fact. In *Momenta v Bristol-Myers Squibb*, significant resources were invested by Momenta in developing a biosimilar that potentially could have infringed on a patent held by BMS for an immunosuppressive agent used in treating disorders such as rheumatoid arthritis. Momenta challenged BMS’s patent in an IPR, and its validity was confirmed. Momenta appealed, and BMS moved to dismiss for lack of standing because Momenta’s product failed its Phase 1 clinical trials, and Momenta announced that it would exit from the product’s development. While Momenta insisted that it did not abandon its intention to develop another similar product, the Federal Circuit ruled that all potentially infringing activity had terminated and dismissed the appeal for absence of standing and for mootness. 2019 U.S. App. LEXIS 3786, *12 (Fed. Cir. Feb. 7, 2019).

Federal Circuit precedent

While it appears to be a difficult burden for some IPR petitioners to meet the Article III standing requirement on appeal, the Federal Circuit has found sufficient injury in fact to support an IPR petitioner's appeal in certain circumstances.

The Federal Circuit has recognised the timing of entering into the market as a proxy for showing economic harm sufficient to establish an injury in fact under Article III. In *Amerigen v UCB*, Amerigen was found to have suffered an injury in fact because it potentially could have brought its new drug to market three years sooner if the challenged patent was invalidated. Amerigen's drug in development had already received the FDA's tentative approval, and the validity of the challenged patent prevented the drug from receiving the FDA's final approval. The Federal Circuit did not require Amerigen to specify a dollar amount to show actual injury, and it treated the market entry delay as a form of economic injury because Amerigen had a finalised product and quantified its injury (in number of years of delay). 2019 U.S. App. LEXIS 997, *15 (Fed. Cir. Jan. 11, 2019).

The Federal Circuit also has recognised litigation history as a factor when analysing the risk of infringement sufficient for an injury in fact. In *Google v Conversant Wireless Licensing*, although there was no current litigation against the IPR petitioners on the challenged patent, the Federal Circuit found a substantial risk of infringement based on the patent owner's litigation history and infringement allegations that implicated Google's products. 2018 U.S. App. LEXIS 32772, *11 (Fed. Cir. 2018) (non-precedential). The patent owner had sued one of the IPR petitioners and alleged that an application on its devices performed the claimed method. Even though the patent owner dismissed the allegations in the lawsuit, it did so without prejudice. The patent owner specifically reserved its right to assert the claims of the challenged patent, and it refused to grant a covenant not to sue to the IPR petitioners. Given the litigation history, the patent owner's refusal to grant a covenant not to sue, and the fact that both IPR petitioners market and sell the accused products, the risk of infringement was concrete and substantial to satisfy the standing requirement on appeal.

In addition to the patent owner's litigation behaviour, the Federal Circuit also has recognised an IPR petitioner's status as a competitor and capability to infringe as factors evidencing a risk of infringement for standing. In *El du Pont de Nemours*, as a competitor of the patent owner, DuPont built and operated a plant that was capable of infringing the challenged patent. While DuPont had not been sued, the patent owner had alleged that DuPont's processes were "embraced" by its claims and refused to grant a covenant not to sue. The Federal Circuit found that DuPont had a substantial risk of future infringement sufficient to satisfy the injury in fact requirement and standing for the appeal was confirmed. 904 F.3d 996, 1005 (Fed. Cir. 2017).

The issue to be resolved

The Supreme Court has been presented with writs for certiorari in both *JTEKT* and *RPX* addressing the standing issue found at the intersection of the AIA provisions and Article III standing re-

quirements for appeals to the Federal Circuit. The legal question to be decided is whether the Federal Circuit can refuse to hear an appeal by a petitioner from an adverse final decision in an IPR on the basis of a lack of patent inflicted injury in fact where Congress has (i) statutorily created the right to have the director of the USPTO cancel patent claims when the petition has met its burden to show unpatentability, (ii) statutorily created the right for parties dissatisfied with a final decision of the USPTO to appeal the Federal Circuit, and (iii) statutorily created an estoppel prohibiting the petitioner from re-challenging the patent claims on the basis of published prior art. *JTEKT*, 2018 U.S. Ct. Briefs LEXIS 4751.

Establishing a patent injury

Given the interplay between the AIA provisions and the Article III standing requirements, and based on the current state of the law, IPR petitioners looking to invalidate allegedly improperly granted patent claims must be successful at the USPTO or be prepared to make a case for patent inflicted injury in order to proceed with an appeal. The injury to be established is beyond the estoppel that is created upon completion of the IPR proceeding because there must also be a substantial risk of infringement or likely claim of infringement. Whether the IPR petitioner is a competitor to the patent owner looking to gain freedom to operate, seeking to remove a competitive harm, or simply decrease an economic injury, it must show a particular, concrete interest in the patentability of the challenged patent claims.

The standing issue is typically raised by the patent owner in a motion to dismiss the IPR petitioner's appeal. When it is necessary for an IPR petitioner to explain and substantiate its entitlement to judicial review, declarations or affidavits and other evidence should be submitted to demonstrate a patent inflicted injury. Keeping in mind that the requisite injury must be actual or imminent, and not merely conjectural or hypothetical, here are some practical approaches for IPR petitioners to confirm standing on appeal:

- Develop evidence clearly identifying features of any product at issue. While the product does not necessarily need to be finalised or already on the market, it will be important to distinguish whether it is ready for marketing or simply in the nascent stages of development. Specifying what current or planned actions exist can support an argument that there could be claims of infringement even if the design subsequently continues to evolve.
- Memorialise communications with the patent owner regarding licensing of the challenged patent. If there is a demonstrated need for a licence, then without that licence there may be unauthorised use and a risk of infringement. Showing that the IPR petitioner should be an actual or prospective licensee of the challenged patent supports a showing of a patent-related injury.
- Highlight communications around litigation. If there are infringement allegations made directly to the IPR petitioner or indirectly, such as in a litigation involving a supplier or distributor, then clearly there is concrete interest in the patentability of the challenged patent claims because of the possibility of an infringement suit.

- Seek a covenant not to sue from the patent owner. A request for a covenant not to sue requires the patent owner to assess the strength of its patent and arguments in the IPR against the potential infringements it could go after in the future. If a covenant not to sue is granted, then the IPR result is moot. But if the patent owner refuses to provide a covenant not to sue, then this is evidence of an infringement risk.
- Quantify any economic harm. After an economic injury to the IPR petitioner from the challenged patent has been identified, it must be quantified in some form to present it as more than mere conjecture. The more tangible the evidence of the economic harm is, the stronger it will be as evidence of an actual injury.
- Substantiate the petitioner’s reasoning for pursuing an IPR. There are always business considerations weighed in the decision to challenge a patent’s validity in an IPR given the costs associated the process. Identifying the risks the IPR petition seeks to mitigate and how the outcome could affect the business can be used as evidence of injury in fact.
- Maintain the patent-related injury throughout the appeal. It is important to keep the issue of mootness in mind because even after establishing an injury in fact, the IPR petitioner’s appeal can be dismissed for lack of standing if that injury disappears before appeals are exhausted.

Proving a patent-related injury could potentially serve to

enhance future litigation by providing details that the patent owner might not have or be aware of. This could lay the foundation for a patent infringement case or even bolster wilfulness arguments made by the patent owner. If unsuccessful on appeal, the downside is theoretically the same as having lost the IPR because the challenger will be estopped from subsequently challenging the patent in any defensive case. However, the upside reward of overcoming the PTAB’s decision and invalidating the patent far outweighs the downside.

The conflict between the AIA provisions and Article III standing requirements presents a number of problems. It denies the petitioner a full and fair opportunity to achieve the correct result and limits the checks and balances on the USPTO, undermines the petitioner’s litigation position in light of the estoppel provision, discourages utilisation of IPR proceedings and can decrease economic activity. Practitioners will be looking to the Supreme Court for a resolution of these issues.



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