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Recent Supreme Court Decisions On Inter Partes Review — What Biosimilar Developers Need To Know

By Limin Zheng, Ph.D., GCA Law Partners LLP

The U.S. Supreme Court recently issued two decisions related to inter partes review (IPR). This article will briefly introduce IPR, discuss the Supreme Court's decisions, explain how these decisions may impact IPR and biosimilar companies, and suggest how biosimilar companies should respond.

An Introduction To IPR

IPR is an adversarial administrative patent review proceeding before the Patient Trial and Appeal Board (PTAB) where a third party challenges the validity (specifically, novelty or non-obviousness) of one or more claims of an issued patent based on prior patents or printed publications. A challenger initiates the IPR by filing a petition against one or more claims in a patent, and, for each claim, on one or more grounds (such as different prior art references or combinations). A review may be instituted only if the PTAB finds there is a reasonable likelihood the petitioner will prevail on at least one of the claims challenged. The PTAB is required to issue a final written decision within one year of the institution, unless there is good cause to extend the deadline. Introduced by the Leahy-Smith America Invents Act, IPR took effect on September 16, 2012, and has quickly become popular among companies—including biosimilar companies—facing actual or potential threats of patent infringement actions.

Supreme Court Releases New Rulings On IPR

On April 24, the Supreme Court issued its long-awaited decision in Oil States Energy Services, LLC v. Greene's Energy Group, LLC, affirming the constitutionality of IPR. The Court ruled 7-2 that neither Article III nor the Seventh Amendment of the U.S. Constitution requires that a federal court or jury conduct the type of patent review in an IPR. The majority reasoned Congress has significant

latitude to assign adjudication of public rights to agencies, and IPR is simply a reconsideration of the Patent and Trademark Office's (PTO's) decision to grant a patent, a matter involving public rights. (The Court, however, left the door open for future constitutional challenges on other grounds, including the retroactive application of IPR and whether IPR violates the Due Process Clause or the Takings Clause of the Constitution.)

On the same day, the Supreme Court held, 5-4, in SAS Institute Inc. v. Iancu that should the PTAB institute review, it must decide the validity of each and every claim challenged by the petitioner. Under the statute, if an IPR is instituted, the PTAB must "issue a final written decision with respect to the patentability of *any* patent claim challenged by the petitioner" (emphasis added). According to the majority, "any" in this context means "every." Rejecting a PTO regulation that allowed the PTAB to institute review "on all or some of the challenged claims and on all or some or the grounds of unpatentability asserted for each claim," the majority dismissed the PTO's policy argument about efficiency as properly addressed only to Congress and held that the PTAB has no such power to pick and choose which claims to reconsider once a review is instituted.

The Benefits (And Potential Perils) Of IPR

So for now, IPR is here to stay. This is good news for biosimilar developers, who have found IPR to be an easy and cost-effective way to combat patents that should not have been granted in the first place.

The speed and cost-savings of IPR are considerable when compared to court patent litigations. While on average it takes about two and a half years to reach trial in a district court patent case, IPR typically takes about 18 months from start to finish—six months from filing the petition to a decision on institution and 12 months from institution to a final decision. Although the PTAB has at times used procedural maneuvers (such as joining a later-filed related IPR with an earlier one) to get around the one-year deadline, it has for the most part adhered to the deadline.

The streamlined process of IPR, especially the limitations on discovery and motion practice and its narrow focus on discrete validity issues, translates to lower costs. According to the AIPLA 2015 Report of the Economic Survey, the median cost of patent infringement litigation through trial for a $10 million to $25 million case is $3.5 million ($2 million when $1 million to $10 million is at stake, and $5 million when more than $25 million is at stake), whereas the median cost for IPR through oral hearing is $275,000. (The increase of the basic filing fee for an IPR in January from $9,000 to $15,500, while not insignificant, is nothing compared to the cost of court litigations.)

In addition, the bar for proving patent invalidity in IPR is, at least in theory, significantly lower than in district courts, with a lower burden of proof ("preponderance of the evidence" rather than "clear and convincing evidence") and under a broader claim interpretation standard ("broadest reasonable interpretation" rather than "ordinary and customary meaning"). (Earlier this month, the PTO proposed to replace the current claim construction standard applied in IPR—the same standard used by a patent examiner when deciding whether to grant a patent—with the standard applied in court

proceedings. Setting aside whether the rule change will in practice have any actual impact on outcomes, it likely will have implications on the constitutionality of IPR, as the change of standard means IPR would no longer be "simply a reconsideration of" the PTO's decision to grant a patent, as the majority in Oil States found.) Moreover, rather than presenting technical arguments to a lay judge or jury, in IPR, such arguments are presented to administrative patent judges, who are usually more technically savvy and may be less inclined to defer to the judgments of patent examiners who allowed the claims to be issued.

However, there is a catch. Should the petitioner fail, "estoppel" attaches once the PTAB issues a final written decision—meaning the petitioner (or its privy) cannot assert in another administrative or court proceeding that the challenged claim is invalid "on any ground that the petitioner raised or reasonably could have raised during" the IPR. The case law on what constitutes "reasonably could have raised during" the IPR is still developing, and the lower courts are split on a number of related issues. Regardless, however, the Federal Circuit has held that petitioned but non-instituted grounds are deemed "not raised and could not have been raised during" the IPR, and thus not subject to estoppel.

Biosimilar Companies Find Success Via IPR

Since its introduction, and fueled by the PTAB's initial high rate of institution (over 80 percent, which has since dropped to the low 60s), IPR has quickly become a popular tool for challenging the validity of patents. As of March 31, 2018, 7,686 IPR petitions were filed. The number of biologics-related IPR filings by biosimilar developers has increased from one (by Hospira) in 2013 to over 100 by the end of 2017, covering patents relating to 10 commercial biologics or general tools for making them. (The number of filings dropped sharply in the first four months of 2018, which could be due to a combination of the increase in IPR filing fee and the uncertainty of the Supreme Court's then-pending decision in Oil States.)

Leading the charge is Pfizer, which has filed 24 IPRs against patents relating to Rituxan, Herceptin, and more recently Avastin, in addition to the seven IPRs filed by Hospira (acquired by Pfizer in September 2015) between 2016 and 2017. Smaller companies have also used IPR to try to clear some of the patents ahead of regulatory submissions. Coherus, for example, has filed 12 IPRs against patents relating to Humira and Enbrel.

Biosimilar developers have so far been largely successful in IPR proceedings. As of the end of April, the institution rate for biologics IPRs filed by biosimilar developers was about 54 percent. The institution rate was lower for claims directed to formulations (9 percent), cell culture (zero out of two), or pharmacokinetic/pharmacodynamic (zero out of one), but much higher for claims directed to antibody or protein compositions (83 percent) or protein purification or preparation (86 percent). The institution rate for method-of-treatment claims was about 53 percent, similar to the overall rate.

About 33 percent of the instituted biologics IPRs filed by biosimilar developers were terminated post-institution without a final decision due to settlement. Of the instituted IPRs that resulted in a final written decision, the overall "win" (i.e., the PTAB finding all or a majority of the challenged claims invalid) rate for biosimilar developers was about 67 percent. Among these, IPRs against method-of-treatment claims had the highest win rate (six out of eight), compared to those against protein purification/preparation claims (two out of three) or formulation claims (zero out of one). (Despite the high institution rate, the fate of IPRs challenging claims directed to antibody or protein compositions remains to be seen, as there is no final written decision yet on these instituted IPRs.)

Potential Impact Of SAS On Future IPR Cases

The Supreme Court's decision in SAS, however, may change the odds and the risk-benefit analysis of IPR in a number of ways. First, before SAS, for efficiency, the PTAB would generally only institute review on claims for which the petitioner had established a reasonable likelihood of prevailing. Under SAS, however, if an IPR is instituted, the PTAB must review the patentability of each and every claim challenged. This would increase the PTAB's workload considerably and add to the strain on the PTAB's ability to meet the one-year statutory deadline from institution to final written decision. To alleviate the burden, the PTAB could either extend the deadline for cause, thereby causing delays and diminishing one of the advantages of IPR, or decline to institute review altogether—a decision within the PTAB's complete discretion and not subject to judicial review.

Indeed, two days after the SAS decision, the PTAB announced it "will institute as to all claims or none. At this time, if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition." (Emphasis added.) For pending trials instituted before SAS, the PTAB "may issue an order supplementing the institution decision to institute on all challenges raised in the petition," and, if so, "the panel may take further action to manage the trial proceeding, including, for example, permitting additional time, briefing, discovery, and/or oral argument, depending on various circumstances and the stage of the proceeding."

While the PTAB may be intentionally vague here, "all challenges" appears to refer not only to all the claims but also all the grounds raised in the petition. Pre-SAS, the PTAB routinely denied institution on grounds it deemed redundant. SAS does not address the issue of whether the PTAB has discretion to institute review on only some but not all the *grounds* raised (and the statute only requires that the PTAB issue a final written decision "with respect to the patentability of any patent claim challenged by the petitioner"). However, the PTAB has, at least for now, self-imposed a broader all-or-nothing requirement than mandated by SAS, which may lead to a lower institution rate, make the proceeding less speedy and more expensive, or both.

Moreover, for claims that would not have been instituted for review but for SAS, the likelihood of the PTAB finding them invalid is low. Should the PTAB uphold their validity in the final written decision, estoppel attaches against the petitioner with respect to all the grounds that were or could have been raised concerning these claims; whereas if they were not instituted, the general view is that under the Federal Circuit precedent, estoppel would not attach to these claims.

Conclusion

Thus, while Oil States keeps IPR alive, SAS disrupts the playbook. The real impact of SAS on the PTAB's decision making and IPR remains to be seen. Biosimilar developers considering filing an IPR should carefully balance the need or desire to challenge all the claims for which infringement could potentially be asserted against the risks of long delays, non-institution, or estoppel effects.

About the Author:

Limin Zheng is a partner at GCA Law Partners LLP. Her practice emphasizes patent and other complex technology litigation and spans a broad range of technologies, with a focus on biotechnology, biotherapeutics, and medical devices. She can be reached at lzheng@gcalaw.com.