

Will The Pendulum Swing Back In IPR Proceedings?

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Last month, the U.S. Patent and Trademark Office's Patent Trial and Appeal Board issued three decisions invalidating patents that protect Genzyme Corp.'s drug Myozyme for Pompe disease in inter partes review proceedings initiated by competitor BioMarin Pharmaceutical Inc. — a first for a biologic. Indeed, IPR is being increasingly used by competitors in the pharmaceutical industry to knock out commercially significant patents that protect drug products. In 2014, more than 30 IPRs were filed on patents at issue in Hatch-Waxman litigations compared to seven in 2013. Recently, even hedge funds are utilizing IPR as a tool to attack key drug patents of the pharmaceutical industry to shake up financial markets. Many fear that Judge Randall Rader's "death squad, killing property rights" prediction is becoming a reality.

Whether or not IPRs live up to the death squad moniker, IPR proceedings undeniably have proven to be petitioner friendly. The PTAB has granted institution of close to 80 percent of petitions filed since these new IPR proceedings went into effect in September 2012, under the America Invents Act. Also, overall, more than 73 percent of claims that were challenged did not survive review in IPR proceedings.

Many have argued that these staggering win rates experienced by petitioners are a natural outcome of a system that is stacked in their favor. At its base, the statutory framework tends to favor petitioners — the presumption of patent validity is removed, the ability to offer evidence in the initial phase is limited and the standard of proof is lowered. Building onto this framework, the PTAB has promulgated rules that tip the scales further in favor of petitioners. For example, by applying the broadest reasonable interpretation for claim construction versus the presumptively more narrow Phillips standard, the PTAB has made it easier to establish unpatentability by opening the claims up to challenge by additional prior art. This approach typically makes the prior art more difficult to avoid. Further compounding the challenge for patent owners, the requirements for amending claims are so stringent that only three motions to amend have been granted since IPR proceedings commenced.

Will Balance Be Restored?

There is an increasing effort to restore the balance in the IPR proceedings. New legislation has been



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introduced in both the House of Representatives and Senate to make significant modifications to IPR and other post-grant review proceedings to make it harder to invalidate patents. However, many commentators question whether such bills will survive the legislative process. Recently, the USPTO also announced it will unveil proposed new rules for AIA proceedings in the next several months, which would include potential changes that would lower requirements for patent owners to amend claims during IPR.

With the numbers against them in the PTAB, patent owners necessarily have been turning to the Federal Circuit for relief. Of the 118 notices of appeal filed from IPR proceedings, approximately 71 percent are filed by patent owners. Patent owners hoped that the Federal Circuit would not endorse the PTAB's petitioner-friendly approach. However, in its first eight decisions on IPR appeals, the Federal Circuit has sided with the PTAB on key issues.

For example, in its first and most widely anticipated opinion, *In re Cuozzo Speed Technologies LLC* (Appeal No. 14-1301), the Federal Circuit held that the "broadest reasonable interpretation" standard used by the PTAB for construing unexpired claims is the correct standard. The Federal Circuit also agreed that the decision of the PTAB to institute IPR is not appealable, even after a final written decision has been issued in the proceeding. While the decision in *Cuozzo* was split (with Judge Pauline Newman authoring the dissent), the decision signals the Federal Circuit is willing to give deference to the PTAB. Likewise in six other cases, the Federal Circuit issued Rule 36 judgments affirming PTAB.

Don't Panic ... Yet

It is, however, too early for patent owners to panic. The Federal Circuit has yet to decide a series of appeals that could significantly impact IPR proceedings. Among them, the following appeals are likely to be decided in the near future and should be watched closely.

CBS Interactive Inc., et al. v. Helferich Patent Licensing, et al.

At the heart of the dispute are two issues. First, the Federal Circuit must resolve the apparent conflict that arises in the context of motions to amend between 35 USC § 316(e), which mandates that the petitioner in an IPR has the burden to establish unpatentability, and 37 CFR 42.102(c), which provides that a moving party has the burden to demonstrate it is entitled to the requested relief.

Second, the Federal Circuit must determine how 37 CFR § 42.121 sets forth the totality of the requirements for a motion to amend. In other words, is it sufficient that an amendment pursued by a motion to amend: (1) be responsive to a ground of unpatentability involved in the trial, (2) not enlarge the scope of the claim and (3) be supported by the original disclosure and any earlier disclosure for which the claim relies on for priority?

The Federal Circuit's decision in this case may potentially make it easier for patent owners to amend and clarify the claims to avoid prior art during IPR. Oral arguments in this case are scheduled for early April 2015.

Synopsis v. Mentor Graphics

Like in *CBS*, this case raises the question of whether the procedural constraints imposed by the PTAB for amending claims during IPR are unreasonable. In particular, the patent owner, *Mentor Graphic*, asked the Federal Circuit to specifically address if such procedural constraints: (1) improperly shift burden to

patent owners and (2) improperly require patent owners to show general patentability over the prior art.

This case also addresses privity (privity/real-parties-in-interest) in the context of instituting IPR. In this case, the petitioner Synopsis acquired an entity that had been served with an infringement complaint in district court more than one year prior to the filing of the petition for IPR. The patent owner, Mentor Graphic, argued that the petition should be barred under 35 USC 315(b). The PTAB disagreed and instituted the IPR.

The appeal raised two questions: (1) what factors should be considered in determining whether parties are in privity, and in particular if all of the factors outlined by the U.S. Supreme Court in *Taylor v. Sturgell* should be considered; and (2) when do the parties need to be in privity — date of service of complaint, date petition is filed or any time during the IPR?

The Federal Circuit's decision in this case could bring the PTAB jurisprudence in line with privity law and eliminate those IPRs filed outside the statutory limitation set forth under 35 USC 315(b). Appellant and cross-appellant briefs have been filed in this case. The USPTO filed an intervenor brief on Feb. 25, 2015. Oral argument has not yet been scheduled.

Gnosis SPA v. South Alabama Medical Science Foundation

In these cases, the patent owner South Alabama Medical Science Foundation asked the Federal Circuit to review whether the PTAB properly weighed "compelling" secondary considerations in assessing obviousness under 35 USC 103. Specifically, the patent owner argued the PTAB did not give proper weight to the secondary considerations because the board: (1) determined that the evidence of nonobviousness needed to be directed to a novel claim element, (2) determined the secondary consideration were not commensurate with the scope of the claims and (3) disregarded other forms of secondary evidence.

According to a recent report, there is a particularly big difference in the rates of invalidation for obviousness in the PTAB as compared to the results in district court litigation. Specifically, the PTAB found 57.6 percent of the challenged claims unpatentable for obviousness as compared to only 27.8 percent in district courts. The more stringent standard typically applied by the PTAB in evaluating secondary considerations may be a material factor underlying this discrepancy.

The Federal Circuit's decision in these cases could potentially bring the obviousness standard used in the IPR proceedings more in line with that used in the traditional court system. Oral arguments in the *Gnosis* cases are scheduled for April 7, 2015.

Can patent owners expect to see more balance in future IPR proceedings? Upcoming Federal Circuit likely will tell us. While the early signs indicate that the Federal Circuit will give much deference to the PTAB in certain circumstances, time will tell if the pendulum begins to swing back in favor of beleaguered patent owners.

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