

INTELLECTUAL PROPERTY & LIFE SCIENCES

Top 5 PTAB Tips for Big Pharma

Eldora L. Ellison and Trey Powers

With more than 6,000 IPRs having been filed since Sept. 16, 2012, and roughly 9 percent of those being filed in the biotech or pharmaceutical fields, the PTAB (Patent Trial Appeal Board) has become an active venue for adversaries in the life sciences. Patents relating to both small and large molecules have been challenged, including patents on well-known drugs such as Humira, Herceptin, Restasis, Vigamox, Rituxan, etc. And the petitioners span the gamut, from ANDA filers, to biosimilar applicants, innovator competitors or non-practicing entities. Some examples are: Merck, Amgen, Mylan, Boehringer, Ingelheim, Hospira, the Coalition for Affordable Drugs and others. Below, we provide five PTAB tips for big pharma.

1. Be Prepared

Big pharma patents now can expect IPRs or PGRs. Prudent

Ellison is a director in the Biotech/Chemical and Litigation Practice Groups at Sterne, Kessler, Goldstein & Fox in Washington, D.C. Powers is a litigator at the firm.



PHOTO BY ISTOCK

patent owners thus prepare early on to defend their important patents. This includes fortifying the company's patent portfolio and creating a thicket of protection around core assets. This isn't just a numbers game. Rather, thoughtful patent owners seek to build their portfolios from every angle, e.g., taking into consideration clinical trial results, competitor's activities, manufacturing methods, etc. And, patent owners should not automatically recoil at the idea of robust prosecution. A prosecution file history that provides a compelling patentability story in the face of the most pertinent art, and which includes declarations and objective indicia evidence, may be the best shield

against a successful post-grant challenge. It's now more important than ever to draft applications carefully, providing clear definitions of important claim terms. Also, while patent owners involved in post-grant challenges at the PTAB may submit declarations to support their preliminary responses, such declarations have not generally been effective to avoid trial, underscoring the importance of strong prosecution. In the event of a post-grant challenge, patent owners should consider using Track 1 applications to expedite prosecution of related cases, before any patent owner's estoppel might arise. And because amending claims during an IPR or PGR is rarely successful, it is

wise to keep an application pending. Failing that, patent owners can consider reissue strategies.

Since petitioners largely control the timing of post-grant challenges, they typically have plenty of time to “get their ducks in a row,” and should use such time to gain a strong understanding of the state of the art from which the invention arose. And neither party should underestimate the challenge of retaining suitable expert witnesses. Often—especially in the pharmaceutical arena—qualified experts are already affiliated with a company or are unwilling to become embroiled in big pharma’s battles. Potential petitioners should not overlook the fact that PGRs are available for an increasing number of patents. Because the PGR window is open only for nine months, monitoring prosecution is key.

2. Marshal Your Evidence

PTAB proceedings tend to focus on documentary evidence, which is excluded infrequently. While the petitioner bears the ultimate burden of persuasion, the patent owner bears the burden of production on objective evidence of non-obviousness. Parties should understand that the PTAB adheres closely to the relevant legal standards in assessing such evidence. Often, objective evidence fails because the patent owner does not establish a nexus to the merits of the invention. Or, the patent owner overreaches and relies upon evidence that is not commensurate in scope with the claims. Obtaining patent claims of varying scopes may help ensure

that at least some claims will be commensurate in scope with the evidence. Patent owners should consider, early on, what objective evidence they may be able to rely upon, bearing in mind that any efforts to show that unexpected experimental results must compare the invention with the closest prior art. Too often, evidence fails in this regard. Moreover, parties should consider the qualifications of the witnesses, and refrain from pushing their primary technical expert witness to the edge of his or her comfort zone. Rather, it may be advantageous to employ an economist to address commercial success or a clinician to address long-felt, unmet need, for example.

3. Consider Who the Parties Are

Though the patent statute says that “a person who is not the owner of a patent may file” a petition for IPR or PGR, the evolving case law has further defined who can be involved in these proceedings. The patent statute makes IPRs available for some challengers who would be shut out of district court. For example, the doctrine of assignor estoppels, which blocks certain challenges in district court, is not applied at the PTAB. The PTAB has, however, recognized at least one limitation on the patents that can be challenged in an IPR, applying Eleventh Amendment sovereign immunity to dismiss a petition filed against an arm of a state. *Covidien v. Univ. Florida Research Foundation*, IPR 2016-01274. And Constitutional issues come into play when considering who may appeal a decision from

the PTAB. Though Article III standing is not needed at the PTAB, a party appealing to the Federal Circuit must show an actual or imminent injury-in-fact. *Phigenix v. ImmunoGen*, 845 F.3d 1168 (Fed. Cir. Jan. 9, 2017). Deprivation of appellate review may discourage or delay some potential petitioners.

4. Be Mindful of a Multi-venue Strategy

The advent of PTAB proceedings has opened up another front on the patent litigation battlefield. PTAB judges are generally much more comfortable down in the technical weeds than your average district court judge. In fact, PTAB judges often have graduate-level training in a technological area relevant to the cases they are assigned. For this reason, counsel must be much more than conversant in the patented subject matter. Ideally, your PTAB counsel should have a deep technical bench with a strong command of the science at issue. PTAB cases are often won or lost on minor scientific nuances. And a team that can discover and exploit such nuances is essential to success at the PTAB. Moreover, PTAB rules and customs are different than those in district court. Failure to adhere to the proper rules before the PTAB can increase cost and annoy judges. Choosing PTAB-experienced counsel can help prevent this.

Nowadays, patent owners should always go into district court with a clear PTAB strategy in place. Patent owners have only about three months from the time they are served with a petition until their preliminary response is due. Developing a strategy, lining

up experts, and drafting a response sufficient to maximize the chances of institution denial can take significant time. Patent owners are smart not to be caught flat-footed. Instead, well in advance, they should rigorously assess their patents' weaknesses and prepare to defend against the nearly inevitable post-grant attacks. Similarly, petitioners should prepare their PTAB strategy as early as possible in the litigation cycle.

Parties should also be mindful of possible district court stays pending resolution at the PTAB and coordinate their approach in the forums to maximize the possibility of their desired result. Generally, district court infringement actions are more likely to be stayed pending the outcome of PTAB trials if the district court proceeding is in its early stages. Defendants wishing to stay district court action in favor of resolution at the PTAB should bear such timing in mind when determining when to file a petition. Courts may take a dim view of petitioners who wait until the 11th hour to file a petition. *See, e.g., Realtime Data v. Actian Corp.*, No. 6:15-cv-463-RWS-JDL (E.D. Tx. June 14, 2016). And patent owners should be aware that their stance in the litigation can affect the likelihood of a stay. For example,

a patent owner's failure to seek a preliminary injunction may weigh in favor of granting a stay. *See, e.g., Acqis v. EMC Corp.*, 109 F. Supp. 3d 352, 357 (D. Mass. 2015).

5. Estoppels May Not Be as Sweeping as Once Thought

Petitioner estoppels might not have the bite many petitioners were once so concerned about. But the application of estoppels arising out of PTAB proceedings has not been fully settled. Initial concerns regarding estoppels have been tempered by the Federal Circuit's decision in *Shaw Industries v. Automated Creel Co.* (817 F.3d 1293 (Fed. Cir. 2016)). In *Shaw*, the court took a liberal view in interpreting 35 U.S.C. §315(e), finding estoppel only on grounds that were "raised or reasonably could have raised *during*" that IPR, reasoning that the IPR begins upon institution of trial. *Id.* at 1300. Therefore, under *Shaw's* logic, only the grounds actually instituted by the PTAB carry the risk of creating estoppel, but the petitioner would not be estopped based on other grounds not instituted by the PTAB. Although *Shaw* had a rather unique procedural posture, so far, district courts have not bucked against it.

Instead, several courts have applied estoppel only on the grounds that failed at the PTAB. *See e.g., Intellectual Ventures I v. Toshiba Corp.*, No. CV 13-453-SLR (D. Del. Jan. 11, 2017), and *Illumina v. Qiagen, N.V.*, No. C 16-02788 WHA (N.D. Cal. Sept. 9, 2016).

In contrast, estoppels arising from PGRs have not yet seen appellate review. In theory, PGRs would have a much larger estoppel footprint than IPRs because PGR petitions can be based on patent ineligibility, written description or enablement, as well as printed publications. However, the statutory language for PGRs mirrors that of IPRs. If PGR estoppels are viewed by courts the same way as IPR estoppels, then PGR estoppel may only attach to unpatentability grounds actually instituted by the PTAB, making PGRs more attractive to petitioners. Time will tell.

Finally, a patent owner's decision to cancel or amend challenged claims can create estoppels in other applications containing patentably indistinct claims. Patent owners should be wary of canceling or amending claims in response to a post-grant challenge and should be ready to argue that any claim they're pursuing is patentably distinct from those they canceled or amended. ■

