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# Validity Challenges: District Court Vs. Patent Office

*Law360, New York (December 18, 2013, 12:15 PM ET)* -- In 2013, inter partes review and covered business method review — two new procedures created by the America Invents Act — fully joined ex parte re-examination as options for challenging validity in the U.S. Patent and Trademark Office. Each offers a profoundly different forum for adjudicating validity compared to U.S. district court. At the same time, many PTO-based challenges proceed in parallel with a related district court litigation, creating the possibility of inconsistent results — a possibility that was realized in two important 2013 decisions: Fresenius USA Inc. v. Baxter International Inc., __ F.3d __ (Fed. Cir. 2013) and Apotex Inc. v. Alcon Pharmaceuticals Ltd., IPR2013-00012 (PTAB Mar. 19, 2013). Both decisions illustrate the complexities that the availability of different tribunals has created, and the challenges that litigants face when executing an enforcement or defensive strategy.

The Fresenius case started as a declaratory judgment action by Fresenius that was followed two years later by three ex parte re-examinations to invalidate Baxter's patent claims. The litigation started with a jury invalidating the patents, the district court overturning the jury verdict and holding a trial that found $14 million in damages, the Federal Circuit mostly reversing the district court, and the district court on remand leaving the damage award in place and adding more than $9 million for continuing infringement.

In the meantime, the patent office was chugging away, dismissing two of the re-examinations as moot in light of the Federal Circuit ruling and rejected the claims in the third. Importantly, the patent office rejections got up to the Federal Circuit and were affirmed before the second litigation appeal. Baxter argued in that second appeal that the original damages judgment had been "final" first and was "binding" on the patent office, but the Federal Circuit rejected both points. Rather, because the re-examination was finally final (not even U.S. Supreme Court review was possible) before the litigation was finally final, the re-examinations trumped.

In Apotex Inc. v. Alcon Pharmaceuticals Ltd., IPR2013-00012 (PTAB Mar. 19, 2013), which involved Alcon's ophthalmic composition patent, Alcon initially sued Teva, the first abbreviated new drug application filer, in Delaware district court for infringing this patent. Teva challenged the validity of the patent and lost. Apotex, the second generic filer, later filed a petition for inter partes review of the patent.

In its petition, Apotex challenged validity on the very same art that Teva had unsuccessfully asserted in Delaware district court. However, the PTAB reached an entirely different conclusion, finding that Apotex established a reasonable likelihood that at least one of the claims of Alcon's patent was invalid, and granting Apotex's petition. The case ultimately settled without a final written decision on the merits. Nevertheless, it illustrates the different results that can occur when two different tribunals, applying

different standards, consider the same validity issue.

What does this mean for litigants? It potentially means a lot. These cases show that multiple, largely independent avenues are available for parties to get relief when they are threatened by patents of questionable validity. The choice of which forum to use, when to use it, and how to use it varies wildly depending on particular situations, but there are great opportunities for attorneys who understand all the dimensions of this problem and how they interact.

**Many Variables at Play**

One variable is timing. There are hard timing rules and soft timing rules. One hard timing rule is that a request for inter partes review must be filed within a year of a party being sued. Softer timing involves coordinating the filing of a request for review so that it is early enough to be effective (e.g., to win the "race" from Fresenius) but late enough to also be effective (e.g., after you've collected enough prior art).

Another variable is complexity. Certain technologies are simply too difficult to present effectively to a jury. Or certain assertions of obviousness, regardless of technical complexity, may be intuitive to a patent examiner but not to an average juror (or vice versa).

Yet another variable is the difference in legal standards between litigation and the patent office — the main two being the burden of proof (and the somewhat separate presumption by juries that the patent office is competent and does its job right) and the standard for claim construction. Sometimes these differences matter and sometimes they do not. For example, the "broadest reasonable interpretation" might not cover anything more, or anything more that is relevant, than a regular claim construction — so that patent office review would get a defendant nothing extra in this regard.

Other differences are more subtle. For example, inter partes review brings with it an estoppel against using "paper" prior art (e.g., patents and printed publications) in other procedings. That may be a showstopper in some situations. But in fields where lots of different goods are developed and sold, a defendant could present good paper art to the patent office and still have good nonpaper art for trial.

**Moving Forward in 2014**

As practitioners absorb the meaning of these decisions and try to work them into their own cases, we can expect a number of events to occur (and many are occurring already). First, we can expect ex parte re-examination filings in cases where such an approach may not have seemed worthwhile before Fresenius. Second, we can expect more inter partes reviews to be filed, and a higher percentage of them filed in strategic integration with litigation.The need for tight integration between litigation and IPR teams cannot be overstated — if possible, have them perform a mind-meld, but if that is not possible, find teams with a history of working seamlessly together. We can also expect to see additional wrangling relating to the relative timing of PTO proceedings and district court proceedings, as parties seek to get the upper hand toward locking in an estoppel.

And longer term, we can expect a flood of appeals to the Federal Circuit — perhaps increasing the court's overall argued case docket by 50 percent or more. That increase could lead to the court adopting coping mechanisms, such as more summary affirmances, fewer remands (because they lead to more appeals), and more affirmances overall. In such an environment, the winning party needs to get ahead of things and frame its post grant cases, from the beginning, to look good on appeal, whether the party

wins or loses at the patent office.

These and many other factors affect a party's best strategy when asserting patents and defending against patents, and they interact in very complex ways. This offers both challenges and opportunities for litigants. In particular, it requires a team with expertise in both district court litigation and patent office-based proceedings. Rarely will a single group of people have both qualifications. Consequently, there will be a need for separate teams that are fully integrated with each other, a need that will become even more acute as the number of patent office-based proceedings grows.

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*Fish & Richardson represented Fresenius USA in all of the litigation and ex parte re-examinations mentioned in this article.*