THE
NATIONAL LAW REVIEW

Orange Book Listing Creates Injury To Support Standing To Appeal IPR Decision

FOLEY & LARDNER LLP
Article By
Courtenay C. Brinckerhoff
Foley & Lardner LLP
PharmaPatents

- Intellectual Property
- Litigation / Trial Practice

- Federal Circuit / U.S. Court of Spec. Jurisdiction

Tuesday, January 15, 2019

Although “any person” except the owner can challenge a patent in an Inter Partes Review (IPR) proceeding, only those who satisfy the constitutional requirements for standing can appeal a decision of the USPTO Patent Trial and Appeal Board (PTAB) in a IPR proceeding. In *Amerigen Pharmaceuticals v. UCB Pharma GMBH*, the Federal Circuit held that a would-be generic competitor whose ANDA was tentatively approved but subject to a Paragraph III certification against the challenged patent had standing to appeal the PTAB decision upholding the patent. While Amerigen prevailed on that issue, the court affirmed the PTAB decision on the merits.

The Patent At Issue

The patent at issue was UCB’s U.S. Patent 6,858,650, which claims the active ingredient of Toviaz® (fesoterodine), an antimuscarinic drug used to treat urinary incontinence. Fesoterodine is a prodrug of 5-hydroxymethyl tolterodine (5-HMT), which itself is a metabolite of tolterodine, which is the active ingredient of Detrol®, an antimuscarinic drug used to treat overactive bladder.

Mylan filed the IPR petition, and Amerigen and two others joined after institution. At issue was whether it would have been obvious to modify 5-HMT to arrive at

fesoterodine. The PTAB held both that there was no motivation to modify HMT to improve its bioavailability, and that the specific modification required to arrive at fesoterodine was not obvious, and so upheld the challenged claims. Amerigen was the only party that appealed.

The Federal Circuit Decision

The Federal Circuit decision was authored by Judge Lourie and joined by Judges Chen and Stoll.

Orange Book Listing Creates Standing Injury

Amerigen asserted standing because invalidating the claims of the '650 patent would advance the launch of its product. As explained in the decision, the FDA had tentatively approved Amerigen's product, but, as a result of prior ANDA litigation, Amerigen's ANDA was subject to a Paragraph III certification that delayed approval until the patent expires.

UCB argued that Amerigen lacks standing because the FDA won't approve its ANDA until the patent expires. According to UCB, Amerigen is "foreclosed from infringing" the patent, and "without a possibility of infringement there can be no justiciable dispute" to support standing.

According to the Federal Circuit decision, the flaw in UCB's logic is that "if the patent is held unpatentable through reversal of the Board's decision," then the patent will no longer be a barrier to FDA approval. The court also noted that the patent at issue expires three years after the other Orange Book-listed patents for Toviaz®. Thus, "a conclusion … that the instituted claims of the '650 patent are unpatentable and the FDA's consequent delisting of the patent would enable Amerigen to launch its competing product substantially earlier than it otherwise could upon the patent's expiration."

As such, the Federal Circuit agreed with Amerigen:

Amerigen has a concrete, economic interest in the sales of its tentatively approved drug obstructed by the listing of the '650 patent, and has thereby demonstrated a controversy "of sufficient immediacy and "of sufficient immediacy and reality" for Article III standing.

In reaching its decision, the Federal Circuit rejected UCB's argument that Amerigen lacked standing because a "Paragraph IV certification is the fundamental, jurisdictional basis enabling parties to litigate Orange Book-listed patents in the Article III courts," because this case did not arise under the Hatch-Waxman Act. The Federal Circuit also rejected UCB's argument that "any delisting-based relief would be too speculative to support standing," noting that because "Amerigen has already been granted tentative approval … the only uncertainty is whether Amerigen would have to wait for another generic company's potential 180-day exclusivity period to expire," but even so "Amerigen's launch would be substantially advanced" if the patent was invalidated and delisted. The court also found that Amerigen's alleged injury was traceable to UCB, because "[t]he injury plainly is caused by UCB's listing

of the ’650 patent.”

> We agree with Amerigen that it has standing to appeal from the Board’s decision because the launch of its tentatively approved drug is blocked by the ’650 patent, and invalidation of the patent would advance its drug’s launch.

Although Amerigen prevailed on the standing issue, UCB prevailed on the merits. Because I found that aspect of the decision interesting in its own right, I will discuss it in more detail in another article.