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Federal Circuit Clarifies Delaware Rulings on Personal Jurisdiction in Hatch-Waxman Paragraph IV Orange Book Patent Litigations in Mylan Cases

On March 18, 2016, the Court of Appeals for the Federal Circuit ("CAFC") held that the U.S. District Court for the District of Delaware had personal jurisdiction to hear Acorda's patent infringement suit against Mylan asserting patents covering the MS drug Ampyra.

Mylan had argued that the Delaware District Court did not have personal jurisdiction over Mylan because: (i) Mylan is based in West Virginia; and (ii) Mylan filed the ANDAs at issue with the FDA in Maryland. In a separate suit pending before the Delaware District Court, Mylan also made the same argument in AstraZeneca's lawsuit based upon Mylan's ANDAs seeking to market a generic version of the type II diabetes drugs Onglyza and Kombiglyze.

In both cases, the Delaware District Court held that it had personal jurisdiction, although the respective judges relied on different rationales. Thereafter, the CAFC affirmed the Delaware District Court decisions in an opinion authored by Judge Richard G. Taranto relying solely on the grounds of specific personal jurisdiction.

"Specific personal jurisdiction" refers to jurisdiction based on a company's minimum contacts with the forum state when the claim arises out of, or is related to, those specific contacts; whereas "general personal jurisdiction" refers to a situation where a court in a given state may assert personal jurisdiction over a defendant irrespective of the nature of the claim by virtue of that defendant's continuous actions and relations with the state.

According to the CAFC's decision, Acorda markets Ampyra, under the authority of a new drug application or NDA to help individuals with multiple sclerosis, and in seeking approval for Ampyra, Acorda identified five patents for listing in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication—the "Orange Book."

In January 2014, Mylan submitted its ANDA to the FDA seeking approval to market generic versions of Ampyra, and certifying that Acorda's Orange Book patents for Ampyra were invalid and/or not infringed. Mylan also submitted ANDAs seeking approval to market generic versions of Onglyza and Kombiglyze making the same type of certification.

Acorda, Alkermes and AstraZeneca each filed separate suits against Mylan in the District of Delaware for patent infringement under the Hatch-

Waxman artificial infringement provision of 35 U.S.C. § 271 (e)(2) (A).

Faced with Mylan's arguments, Chief Judge Leonard P. Stark in the Acorda case and Judge Gregory M. Sleet in the AstraZeneca case denied Mylan's respective motions to dismiss. The judges, however, disagreed on the grounds. Judge Stark's ruling relied upon a general personal jurisdiction theory finding that Mylan had consented to such jurisdiction by registering to do business in Delaware; and Judge Sleet relied upon a specific jurisdiction theory.

On appeal, the CAFC found that the minimum-contacts standard is satisfied by the particular actions Mylan had already taken—its ANDA filings—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in Delaware. "[Mylan's] ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Delaware is undisputedly a State where Mylan will engage in that marketing if the ANDAs are approved."

The CAFC also opined that the magnitude and costs of the work required before the ANDA is filed soundly link the ANDA filing to the filer's entry into the market to compete with the brand-name manufacturer if approval is obtained and that it had emphasized the link in its decisions in *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1386 (Fed. Cir. 2015) and *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008).

The CAFC further wrote that although Mylan did not meaningfully develop an argument that a rigid past/future dividing line governs the minimum-contacts standard, "Mylan does not show that a State is forbidden to exercise its judicial power to prevent a defendant's planned future conduct in the State, but must wait until the conduct occurs. Such a rule would run counter to the legal tradition of injunctive actions to prevent a defendant's planned, non-speculative harmful conduct before it occurs."

In her concurrence, Judge O'Malley agreed with Stark that the Delaware District Court could have exercised general personal jurisdiction over Mylan in the case, citing for example the Supreme Court's decision in *Pennsylvania Fire Insurance Co. of Philadelphia v. Gold Issue Mining & Milling Co.*, 243 U.S. 93 (1917).

According to prognosticators, "It's a good decision for brand manufacturing companies because it allows personal jurisdiction over a generic manufacturer in a Hatch-Waxman case anywhere in the country." That is, "Under the decision, specific jurisdiction is established because an ANDA filed with the Food and Drug administration shows a plan that leads to the deliberate making of sales and potentially real word of infringement that harm brand name manufacturers."

Federal Circuit Rules that While the Patent Trial and Appeal Board has the Authority to Eliminate "Redundant" Arguments in a Patent Challenge, Estoppel Does Not Apply to Those "Eliminated" Arguments

The CAFC recently ruled that Patent Trial and Appeal Board ("PTAB") has

the authority to eliminate "redundant" arguments in a patent challenge, but that those “eliminated” arguments are not subject to estoppel and may be made later in a District Court proceeding. The CAFC also reiterated that the AIA leaves it with little ability to review "trial institution" decisions. At issue here, the PTAB eliminated a Shaw Industries Group argument for why Automated Creel Systems’ (“ACS”) carpet manufacturing patent was invalid.

The CAFC held that the AIA defined an IPR challenge to begin when trial is instituted, not when an IPR petition is filed, and while the PTAB ultimately ruled that the patent was not invalid, the CAFC held that Shaw did not lose based upon the eliminated argument since the PTAB never considered it. The CAFC also ruled that, on the merits, the PTAB’s final decision of patent validity in this case was so ambiguous that it required additional clarification and remanded.

By way of background, ACS asserted infringement, in the U.S. District Court for the Northern District of Georgia, of U.S. Patent No. 7,806,360 directed to "creels" for supplying yarn and other stranded materials to a manufacturing process. Shaw thereafter filed an IPR petition challenging the ‘360 patent on both anticipation and obviousness grounds. Two of those grounds relied on a patent issued in 1985 to William Payne. While the PTAB instituted an IPR, the PTAB denied the Payne-based invalidity as redundant; the CAFC noted that the PTAB’s final written decision does not mention the Payne reference.

The CAFC then rejected Shaw’s attempts, *i.e*., appeal and petition for writ of mandamus, seeking appellate review of the PTAB’s "redundancy doctrine." Shaw characterized the doctrine as where "the Board arbitrarily and capriciously denies some grounds but not others," but acknowledged that its main concern was the fear that they would be barred from relying on the Payne reference at a future PTAB or pending district court proceeding.

In addressing the eliminated Payne reference, the CAFC said that Shaw would only be barred from asserting invalidity grounds that were raised or could have been raised during the IPR, and because Shaw was precluded from raising its Payne-based invalidity arguments during IPR, the estoppel provisions did not apply to those grounds.

Judge Jimmie V. Reyna wrote a concurrence heavily criticizing the PTAB for its redundancy doctrine and rejecting the USPTO’s argument that no such doctrine exists. He also mocked the USPTO for claiming it has "complete discretion" to institute trial. "The PTO’s claim to unchecked discretionary authority is unprecedented," he said.

The U.S. Supreme Court heard oral arguments April 25 on appellate authority to review the PTAB’s trial institution decisions in *Cuozzo Speed Techs., LLC v. Lee*, No-15-446 (Jan. 15, 2016).