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PERSPECTIVES

Let PTAB Decide

Federal courts are increasingly deferring to the Patent Trial and Appeals Board.

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In February, the U.S. Court of Appeals for the Federal Circuit issued an opinion in *In re Cuozzo Speed Techs.*, affirming the Patent Trial and Appeals Board (PTAB) on a number of issues and effectively endorsing the current PTAB rules and regulations. The Federal Circuit's decision reinforces what many practitioners already suspected: The Federal Circuit may give significant deference to PTAB decisions, making PTAB proceedings power tools to invalidate patents.

Indeed, in other recent cases, *Softview v. Kyocera* and *University of Illinois v. Micron.*, the Federal Circuit deferred to the PTAB's decisions to invalidate by issuing one-line affirmances. As PTAB proceedings have become commonplace, the potential intersections between PTAB proceedings, new drug application and biologics litigation under the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act present new strategic considerations for both brand-name and generic drug companies.

The Hatch-Waxman Act was enacted in 1984 to balance patent protection for innovative brand-name drugs with the goal of promoting the timely introduction of generics. Under the act, a generic company need not conduct costly and time-consuming clinical trials to establish a generic drug's safety and efficacy, as is required for new drugs. Instead, a generic company may shorten the normal Food and Drug Administration approval time by filing an Abbreviated New Drug Application (ANDA) that shows the proposed generic drug is bioequivalent to the FDA-approved drug and is entitled to claim the benefit of its clinical testing.

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In addition, under the act, a generic company may file a "Paragraph IV certification"—and serve a corresponding notice letter to the brand-name company—alleging that one or more patents listed in the Orange Book as covering the brand-name drug are invalid or not infringed. Filing a Paragraph IV certification is, by statute, an act of infringement, and the patent holder is permitted to bring suit against the ANDA applicant in district court. Assuming that such a lawsuit is timely filed, approval of the ANDA is typically stayed for the shorter of 30 months or until a district court finds the brand-name company's patents invalid, unenforceable or not infringed. If the branded company prevails in litigation, approval of the ANDA is postponed until expiration of the relevant patents. Even under the specialized statutory rules governing generic drug litigation, these suits are costly and typically last up to three years through resolution of an appeal.

For a generic ANDA filer, PTAB proceedings provide potential advantages over traditional district court patent litigation. For example, the challenger need only show that the patent is invalid by a preponderance of the evidence, as opposed to the higher "clear and convincing" standard in district court, which may increase the likelihood of invalidating the patent at the PTAB. In addition, PTAB proceedings are, on average, six to 18 months faster than Hatch-Waxman district court litigation. Finally, to date, the PTAB has instituted over 75 percent of petitions for inter partes review ("IPR") and, in turn, invalidated all challenged claims in over 75 percent of instituted cases.

Unsurprisingly, generic companies have begun using PTAB proceedings as an

additional venue for challenging patents associated with marketed drug products. The use of such proceedings presumably reflects the hopes of those challengers that use of PTAB proceedings to invalidate drug patents listed in the FDA's Orange Book has the potential to accelerate market entry. While ANDA litigation in a district court typically takes roughly three years, PTAB challengers will generally receive a final written decision within 18 months, which could provide petitioners with additional evidence of invalidity in related district court litigation. And if the Federal Circuit continues to give strong deference to PTAB decisions, generic companies may become tempted to risk launching their products "at risk" after obtaining a favorable decision at the PTAB but before infringement and validity are fully resolved by the district court.

PTAB proceedings can also affect the prospects of settlement for companies involved in Hatch-Waxman litigation. For example, in *Alcon v. Teva Pharms.* USA, a district court found brand-name drug company Alcon's patents valid, thereby preserving Alcon's market exclusivity. Years later, after enactment of the AIA, Apotex, a different generic company, successfully petitioned for IPR of Alcon's patents using the same prior art previously rejected by the district court in *Apotex v. Alcon Pharmaceuticals*. After institution, the parties to that proceeding settled.

Despite their potential advantages, PTAB proceedings have resulted in outcomes unfavorable to generic companies on several occasions. Last December, in the first three final written decisions involving generic companies, the PTAB upheld all of the patents covering the brand-name drug Oracea after IPR in *Amneal Pharmaceutical v. Supernus Pharmaceuticals*. Then, in January, the PTAB denied covered business method review for four Orange Book-listed patents, based on its interpretation of what patents qualify CBM review. *Par Pharm. v. Jazz Pharms*. Brand-name companies presumably can learn from these cases and begin fortifying early against potential PTAB challenges. By identifying potential target patent applications and patents, and then strengthening them against invalidity challenges at the PTAB, brand-name companies can effectively prepare to oppose IPR petitions.

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The landscape for biologics litigation under the Biologics Price Competition and Innovation Act—a Hatch-Waxman-like Act enacted on March 23, 2010, and designed to streamline approval of large biologic molecules as opposed to simple chemical compounds—is also emerging. While the Hatch-Waxman Act requires brand-name companies to publicly list their patents in the Orange Book and provides for an automatic 30-month stay of FDA approval, the Biosimilars Act imposes no such obligations. Instead, after the biosimilar applicant provides the brand-name company with access to its application for FDA approval and related manufacturing process, the parties must agree on a list of patents to litigate in a first round, with the brand-name company having a second chance to seek injunctive relief based on additional patents 180 days before launch of the biosimilar product.

Despite the difference in the regulatory scheme, many of the same considerations arise in biosimilars litigation as in the Hatch-Waxman space. In addition, biosimilar companies may seek to initiate PTAB proceedings early rather than wait for anticipated patent litigation.

PTAB proceedings give generic and biosimilar companies another proceeding to consider in addition to ANDA and biologics litigation. Given the high cost of pharmaceutical research and development and the tremendous commercial impact, it is critical that companies—brand-name and generic alike—carefully consider the implications of PTAB proceedings to protect against other market entrants or to get into the market early.

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