The Metropolitan Corporate Counsel®

www.metrocorpcounsel.com

Volume 16, No. 6 June 2008

Civil Actions To Obtain Patent Certainty: Controversy At The Federal Circuit

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Introduction

There is a long-standing controversy over the proper role for the courts in resolving business disputes affecting generic drug competition. The disputes are grounded in some interesting, albeit perplexing, discussions of basic issues involving jurisdiction.

Limitations are imposed upon the federal judicial system by Article III of the United States Constitution and by the Congress. Traditionally, the federal courts have declined subject matter jurisdiction over cases in which the litigants were not truly adverse. Recent legislation and case law seems to be creating a precedent for overriding some basic notions as to the subject matter that courts ought to be resolving.

Background

The Hatch-Waxman Act, originally passed in 1984, amended certain provisions of the Federal Food Drug and Cosmetics Act ("FFDCA") to speed up U.S. Food and Drug Administration ("FDA") approval of generic drugs. The Act also amended the Patent Laws of the United States to simultaneously create a new and highly artificial act of patent infringement that created federal subject matter jurisdiction over certain types of cases affecting the generic drug approval process.

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In general terms, the Act provides that innovator drug companies must submit certain types of patent information to the FDA. The statute actually mandates this submission as part of the drug approval application submitted by the innovator. The FDA publicly lists the patent information, but does not review it. One who wishes to market a generic copy of the innovator's drug must inform the FDA whether they wish to receive marketing approval before the listed patent has expired. When they do so, the patent owner may sue for patent infringement and, if successful in the infringement suit, may obtain an order from the Court that the generic drug approval be withheld until the patent does expire.

To encourage and reward the early filing of a generic drug application (called an Abbreviated New Drug Application or "ANDA"), Congress created a mechanism for ensuring that the first generic would enjoy a period of exclusivity during which other later-filed ANDAs could not receive FDA approval. As simple as that may appear, there has been an inordinate amount of litigation brought against the FDA over how that exclusivity is to be administered.

Over the years since the Act was passed, there have been several attempts by Congress to tinker with the generic exclusivity scheme. What happens when a first-to-file generic ANDA applicant has not begun to market its generic product and a later ANDA application remains blocked by the exclusivity held by the first-to-file applicant? Anyone who has played the board game Parcheesi is familiar with the concept of a blockade – although this one is regulatory in nature.

In this last scenario, who is the later ANDA applicant actually adverse to? Is it the patent owner, the first-to-file generic applicant or the FDA? And, do the courts have jurisdiction to resolve the statutory and regulatory blockade?

Discussion

A threshold issue in commencing litigation is to choose a court that will have

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jurisdiction over the subject matter. The jurisdiction of federal courts to hear patent cases arises under Article III of the United States Constitution and by Act of Congress. The Declaratory Judgment Act ("DJA"), 28 U.S.C. §§ 2201, 2202, provides that "[i]n a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." Courts have consistently held that the Declaratory Judgment Act "enlarged the range of remedies available in the federal courts but did not extend their jurisdiction." *Skelly Oil v. Phillips Petroleum Co*., 339 U.S. 667, 671 (1950).

In 2003, Congress amended the FFDCA and the Patent Laws to create a new type of declaratory judgment action called a "Civil Action to Obtain Patent Certainty." This became codified in the FFDCA at 21 USC §355(j)(5)(C) and in the Patent Laws at 35 USC §271(e)(5), but with one important distinction. As codified in §271(e)(5), Congress included the following language: "… the courts of the United States shall, *to the extent consistent with the Constitution, have subject matter jurisdiction* in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed." (Emphasis added).

The Supreme Court has dealt with such issues throughout its history and consistently held that the federal courts lack jurisdiction over suits where there is no case or controversy between the litigants themselves. When Congress added the above-quoted language to §271(e)(5), it was recognizing this long-held view of the Supreme Court that Congress could not create jurisdiction that extended beyond the bounds of the powers granted to the judiciary under the Constitution.

The Hatch-Waxman Scheme:

Under the Hatch-Waxman scheme, as interpreted prior to the 2003 amendments, a first generic applicant could have its exclusivity triggered once there was a court decision on the listed patent. So, for example, a second generic could theoretically litigate the same patent and win its suit thereby triggering the running of first applicant's exclusivity period. This scheme was preserved to some extent in the 2003 amendments but is now incorporated in a much more complex set of forfeiture provisions.

In either case, a second applicant still can theoretically overcome the first generic applicant's blockade by obtaining a favorable court decision on the listed patent. But, who is the adverse party in that scenario?

Controversy over Jurisdiction:

Patent owners seeking to avoid litigation typically will give a covenant not to sue to the second generic applicant. Notwithstanding the Supreme Court's *Medimmune* decision last year (which abrogated part of the test for declaratory judgment jurisdiction formerly used by the court), the Federal Circuit post-*Medimmune* continued to hold that a covenant not to sue divests the district court of subject matter jurisdiction. *Benitec Australia, Ltd. v. Nucleonics, Inc*., __ F.3d ._____,2007 WL 2069646, *5 (Fed. Cir. 2007).

Thus, when that second applicant persists in its desire to continue the litigation, notwithstanding the grant of a covenant not to sue, the sole purpose of the suit is to aid the second generic in overcoming the blockade at the FDA caused by the statutory scheme itself. But, is this dispute one over which an Article III federal court has subject matter jurisdiction?

The Federal Circuit recently held that the courts do in fact have subject matter jurisdiction in such cases. *Caraco Pharmaceutical Labs., Ltd. v. Forest Labs., Inc*., et al., No. 2007-1404 (Fed. Cir., April 1, 2008). The *Caraco* decision thus abrogates a long line of precedent in the Federal Circuit holding that a covenant not to sue divests the courts of jurisdiction for lack of a case or controversy. Forest has moved for rehearing en banc. Numerous amicus briefs have also been filed and a decision on the motion is still pending.

Rationale for Denying Jurisdiction:

Judge Friedman filed a dissenting opinion in the *Caraco* case. He criticized the majority's rationale, that a denial of jurisdiction based on a covenant not to sue would allegedly defeat the objectives of Congress, stating: "To the extent that Congress may conclude that particular judicial interpretations of the Act thwart the purposes of the legislation, it is for Congress, not for this court, to make whatever changes in the Act it deems appropriate." Dissent at 5.

In a case similar to *Caraco* and also now pending at the Federal Circuit, Apotex, Inc. is appealing from dismissal of its declaratory judgment claims in *Merck & Co., Inc., v. Apotex, Inc*., Civ. No. 06-230, Memorandum Opinion (D. Del., May 21, 2007). The Delaware court recognized the long line of precedent in the Federal Circuit which held that a patent owner's grant of a covenant not to sue under the patent divests the district court of subject matter jurisdiction over a declaratory judgment counterclaim (or stand-alone action) brought to establish patent invalidity or noninfringement.

Responding to the generic's arguments concerning the Hatch-Waxman statutory scheme, the court bristled at the notion of enmeshing courts "in unnecessary, and in this court's opinion, improper involvement in business competition." In fact, the Delaware court held that the Hatch-Waxman amendments expressly sanctioned the patent owner's grant of a covenant not to sue. The court also determined that dismissal of the declaratory judgment claims brought by Apotex was consistent with the legislative history of the MMA, citing Sen. Kennedy, who had specifically remarked that the civil action to obtain patent certainty was not intended to apply in those "rare" instances wherein the patent owner grants an unconditional covenant not to sue. 149 Cong. Rec. S15885 (Nov. 25, 2003).

In holding that the consequences to Apotex of delayed market entry are "specific products of the statute," the District of Delaware further observed that "ANDA litigation reaches the federal courts through specialized legislation enacted by Congress, perhaps without prescience of the maze it would be creating, and the ingenuity of motivated business persons and lawyers to capitalize on its imperfections."

Conclusion

Declaratory judgments for a "civil action to obtain patent certainty" are a creature of the Hatch-Waxman Act. They may offer a means to an end for some generic applicants. The courts have not been uniform in their assessment of whether such actions are consistent with the statutory scheme or are merely attempts to thwart it. Cases now on appeal to the Federal Circuit will hopefully clarify the issue.