

FDA's "Holding On The Merits" Test

Friday, April 21, 2006 --- In the latest development relating to the triggering of the 180-day generic marketing exclusivity period, the U.S. District Court for the District of Columbia upheld the Food & Drug Administration's ("FDA") April 11, 2006 letter ruling, in which FDA adopted a new "holding on the merits" test. In its letter ruling, FDA determined that only a decision on the merits holding the brand company's patent invalid, unenforceable or not infringed, will trigger the running of the 180-day generic exclusivity period. FDA rejected the argument that a dismissal of a declaratory judgment action relating to the patent triggers the running of the exclusivity period. On April 19, the D.C. District Court upheld FDA's decision, finding FDA's approach to be permissible under the statute. Pharmaceutical companies and their counsel will need to stay tuned, however, because the U.S. Court of Appeals for the D.C. Circuit will ultimately decide this important issue.

* Hatch-Waxman Regime *

Before marketing a new drug in the United States, the Federal Food, Drug and Cosmetics Act ("FDCA") requires that a drug company submit to FDA a New Drug Application ("NDA"), demonstrating that the drug is safe and effective for its proposed use. Once approved by FDA, a new drug is generally referred to as a "branded" drug because NDA holders usually market such drugs under brand-name trademarks. Along with clinical studies and other data submitted to FDA, an NDA applicant is required to provide to FDA the patent number and expiration date of any patent covering the drug product or method of using such drug product. FDA lists this patent information in a publication commonly referred to as the "Orange Book."

Under the 1984 Hatch-Waxman Amendments to the FDCA, the manufacturer of a generic drug may file an Abbreviated New Drug Application ("ANDA"), relying on the safety and efficacy data submitted by the NDA holder, if the ANDA applicant can demonstrate that the proposed generic product is bioequivalent to the approved drug. An ANDA applicant must file, in addition to its proof of bioequivalence, a certification with respect to any patent covering the proposed generic product or a method of using such product. The applicant must certify one of the following: (I) that patent information has not been filed for the approved drug; (II) that the listed patent has expired; (III) that the listed patent will expire on a particular date (and that the ANDA applicant is not seeking to market its generic product until the patent expires); or (IV) that the listed patent is invalid, unenforceable or would not be infringed by the manufacture, use or sale of the proposed generic product (a "Paragraph IV certification"). With respect to a method-of-use patent, the ANDA applicant alternatively may file a statement that the listed patent does not claim any use for which the applicant is seeking approval.

To encourage patent challenges, Congress provided that the first applicant to file an ANDA with a Paragraph IV certification with respect to a particular branded drug (the “First Filer”) is, under certain circumstances, entitled to a 180-day exclusivity period during which the First Filer is the only ANDA applicant allowed to market a generic version of the branded product. If the First Filer challenged a patent listed in the Orange Book (through a Paragraph IV certification) prior to Dec. 8, 2003 (the date of enactment of the 2003 Medicare Modernization Act (the “MMA”)), the 180-day exclusivity period begins to run on the earlier of: (1) the date of the first commercial marketing by the First Filer; or (2) the date of a decision by a court holding the listed patent invalid, unenforceable or not infringed (the “court decision trigger”). Under the MMA, the 180-day exclusivity period relating to a product for which the first Paragraph IV certification was filed after Dec. 8, 2003, is triggered only by the first commercial marketing. The exclusivity period is, however, now subject to numerous forfeiture events, including the failure to commence marketing within 75 days of a favorable court decision, which expressly includes a court-authorized consent decree finding that the patent is invalid or not infringed. Although the MMA has been in force for more than two years, numerous ANDAs for generic drugs that have not yet been marketed are still subject to the pre-MMA legal regime.

The 180-day exclusivity period awarded to the First Filer is extremely valuable. Most of the profits earned on a “new” generic drug are generated in those first six months. The period can also provide first-mover advantages in the form of market share and contracts that can benefit the First Filer for years to come. Shortly after the expiration of the exclusivity period, many generics may enter the market, and prices can fall by 80% or more.

In order to obtain earlier market entry, some ANDA applicants whose entry into the market will be delayed by the First Filer’s exclusivity period have attempted to trigger the running of the exclusivity period by filing declaratory judgment actions seeking rulings that the listed patents are invalid, unenforceable and/or not infringed. In this kind of action, the patent holder typically seeks a dismissal, arguing that there is no subject matter jurisdiction because the plaintiff has no reasonable apprehension of suit. Often, this kind of action is dismissed by the court on the defendant’s motion or by stipulation of the parties. Some ANDA holders have argued to FDA that such a dismissal should act as a court decision trigger of the running of the First Filer’s exclusivity period.

* FDA’s Changing Approach *

When FDA first addressed this issue in relation to the drug ticlopidine, it determined that a dismissal of a declaratory judgment action for lack of subject matter jurisdiction was not a court decision trigger because it was not a “decision of a court” or a “holding” addressing the patent issues. The D.C. Circuit, however, twice rejected FDA’s approach, finding that FDA’s decision was arbitrary and capricious and lacked “reasoned decision-making.” *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999) (“Teva I”); *Teva*

Pharms., USA, Inc. v. FDA, 2000 U.S. App. LEXIS 38667, Dkt. No. 99-5287 (D.C. Cir. Nov. 15, 2000) (“Teva II”).

In December 2000, Teva Pharmaceuticals (“Teva”) was the First Filer with respect to certain patents listed in the Orange Book for Bristol-Myers Squibb’s (“BMS”) Pravachol® (pravastatin sodium) product. In October 2003, a subsequent ANDA filer, Apotex, Inc. (“Apotex”), brought a declaratory judgment action against BMS, attacking three of the patents listed in the Orange Book for Pravachol®. This action was dismissed by stipulation and order on July 23, 2004, in which the parties agreed that BMS had “no intention to bring suit against Apotex” on the relevant patents. In September 2004, Apotex requested that FDA determine that the dismissal was a court decision that triggered the running of Teva’s generic exclusivity period. Believing it was bound by Teva I and Teva II, FDA issued a letter in June 2005, finding that the dismissal of the BMS/Apotex lawsuit triggered the running of Teva’s exclusivity period.

Teva challenged this decision in court. After the district court reversed FDA’s decision, the D.C. Circuit vacated with instructions to remand the case to FDA for further consideration. *Teva Pharms. USA, Inc. v. FDA*, 441 F.3d 1 (D.C. Cir. March 16, 2006). Specifically, the Court of Appeals held that Teva I and Teva II were not binding decisions on the substantive issue but were, rather, rejections of FDA’s previous approach because FDA had not engaged in adequately reasoned decision-making. The Court of Appeals instructed FDA to fully consider the substantive issues raised by Apotex.

In its April 11 letter ruling, FDA attempted to address various issues under the statutes and the regulations, including the policy goals underlying the exclusivity period and the issues raised by the D.C. Circuit in Teva I and Teva II. Central to FDA’s decision is the following excerpt:

“FDA interprets the language of the court decision trigger provision, “the date of a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed,” to require a court decision with an actual “holding” on the merits that the patent is invalid, not infringed, or unenforceable. The holding must be evidenced by language on the face of the court’s decision showing that the determination of invalidity, noninfringement, or unenforceability has been made by the court.”

Importantly, FDA’s letter ruling rejected the notion that a dismissal for lack of subject matter jurisdiction constitutes a court decision trigger. Instead, FDA required that a court decision address validity, enforceability and/or infringement on the merits (and find against the patent holder) in order to trigger the 180-day exclusivity period.

Apotex challenged this decision in the U.S. District Court for the District of Columbia. In its April 19 order, the district court denied Apotex’s motions for a temporary restraining order and preliminary injunction, upholding FDA’s letter ruling. Specifically, the court determined that “the holding-on-the-merits approach adopted by the FDA is more faithful to the statutory language, preferable from a policy standpoint and facilitates consistency and industry

certainty—all things that amount to a ‘faithful application of the law.’” *Apotex, Inc. v. FDA*, Dkt. No. 06-0627, at 35, n. 12 (D.D.C. April 19, 2006).

* Stay Tuned *

Although the district court’s action in upholding FDA’s April 11 letter ruling is the latest development in this nearly decade-long saga, Apotex has already appealed the decision. As a result, the D.C. Circuit will ultimately decide this issue.

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