

Fourth Circuit Rejects Another Authorized Generics Challenge

Wednesday, July 19, 2006 --- Following the lead of the Court of Appeals for the D.C. Circuit, the Fourth Circuit Court of Appeals has rejected the latest court challenge to the practice of authorized generics, in which a brand pharmaceutical company, after the first generic version of its brand-name product hits the market, licenses a second company to market a generic version of the brand product.

In its July 5, 2006 decision, the Fourth Circuit upheld the Food & Drug Administration's July 2004 decision in which FDA determined that it lacks authority to prohibit authorized generics, even when such products are launched during the first generic challenger's 180-day generic exclusivity period.

With this latest decision, opponents to authorized generics may be left with little recourse in the courts, enhancing the importance of Congressional lobbying and other efforts aimed at obtaining legislative relief.

* Hatch-Waxman Regime *

Before marketing a new drug in the United States, the Federal Food, Drug and Cosmetics Act requires that a drug company submit to FDA a New Drug Application, 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, 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 in question; (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.

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.

* Authorized Generics *

A brand company might launch an unbranded, or generic, version of its brand product either by licensing a third party or by selling the product itself, typically through a subsidiary. In either case, the authorized generic product is usually launched when market entry by the first generic competitor is imminent or has occurred.

Critically, the authorized generic is marketed and sold during the 180-day exclusivity period, and, as a result, the First Filer might see its profit during the exclusivity period cut in half.

Although the concept and legality of authorized generics and the question as to whether they are good or bad for consumers have been hotly debated for quite some time, brand companies only began to launch authorized generics in a systematic manner in the last few years. During that period of time, most of the prominent brand companies have adopted this practice, including GlaxoSmithKline, Johnson & Johnson, Pfizer, Bristol-Myers Squibb and Procter & Gamble.

This practice has led to an outcry from many in the generic drug industry, consumer groups and certain members of Congress, who have claimed that this practice will decrease the incentives offered to generic companies to challenge Orange Book patents and, consequently, will ultimately reduce generic alternatives. In response to a request from Congress, the Federal

Trade Commission has agreed to study the competitive impacts of authorized generics.

* The Courts' Rejection of Authorized Generic Challenges *

Mylan Pharmaceuticals Inc. and Teva Pharmaceuticals USA Inc., two of the largest generic companies, submitted citizen petitions to FDA in 2004, requesting that FDA prohibit the marketing and distribution of authorized generics until after the expiration of the 180-day exclusivity period. The petitioners argued, among other things, that the practice violates the incentive structure created by the Hatch-Waxman Amendments to encourage prompt, widespread generic drug entry.

In a July 2, 2004 letter, FDA denied both petitions, responding that, unless any related manufacturing changes pose safety or efficacy concerns, the FDCA does not "prohibit an ANDA or NDA holder's use of alternative marketing practices for its own approved new drug." Nor is a separate approval required as a general matter for third-party distribution of an approved drug.

Teva and Mylan filed separate suits to challenge FDA's denial of their citizen petitions. In December 2004, the U.S. District Court for the District of Columbia rejected Teva's challenge. That decision was upheld by the U.S. Court of Appeals for the D.C. Circuit on May 9, 2005. *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005).

After the decision was rendered in *Teva*, the U.S. District Court for the Northern District of West Virginia rejected Mylan's challenge by granting a motion to dismiss filed by FDA. Mylan appealed that decision to the Fourth Circuit.

On July 5, 2006, following the lead of the D.C. Circuit, the Fourth Circuit affirmed the district court and similarly upheld FDA's decision. In particular, the court found that the plain meaning of the Hatch-Waxman Amendments (and 21 U.S.C. § 355(j)(5)(B)(iv) in particular) does not prohibit authorized generics.

The Fourth Circuit explained, "Because the exclusivity is described from the perspective of the later-filing paragraph IV ANDA applicant, the FDA could only read the statute to cover drugs under approved NDAs by completely redefining the language describing paragraph IV ANDAs to also include NDAs. Interpretation of this kind would amount to rewriting rather than reading. It would dramatically depart from the statute's language and would be tantamount to an agency effort to exercise authority never delegated by Congress."

In view of the plain statutory meaning, the Fourth Circuit rejected Mylan's policy arguments.

* Where does this leave us? *

With this latest rejection by yet another appellate court, it appears that the courts are not going to be a fruitful avenue for challenging authorized generics. Instead, critics of authorized generics are probably going to increasingly focus their efforts on persuading policymakers that changes to the Hatch-Waxman Amendments are necessary.

--By Chad A. Landmon

Chad A. Landmon is an associate at Axinn, Veltrop & Harkrider LLP, practicing in the field of patent and other intellectual property litigation and counseling, including FDA and antitrust aspects thereof. He can be reached at (860) 275-8100 or at cal@avhlaw.com.

Axinn, Veltrop & Harkrider offers its clients an unparalleled range of counseling and litigation services in critical areas directly affecting the quality, security and scope of their businesses, including intellectual property, antitrust and trade regulation and complex litigation. Utilizing the firm's extensive experience in patent and antitrust law, Axinn, Veltrop & Harkrider has an active pharmaceuticals practice group, which focuses on numerous facets of the development and marketing of drug products and which provides in-depth counseling and litigation services to clients in the pharmaceutical industry relating to patent, FDA and antitrust issues.