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Client Alert

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Drug Manufacturers Gain More Control Over Market Exclusivity for Generics

A recent court decision strengthened the trend that a drug manufacturer can freely delist patents from the Orange Book so long as no Abbreviated New Drug Application (ANDA) containing a paragraph IV certification has been filed. Whether a patent is listed or delisted is up to the drug manufacturer; the Food and Drug Administration (FDA) continues to play only a ministerial role in the listing and delisting of patents.

The case, Teva Pharmaceuticals v. Leavitt, involved Janssen Pharmaceuticals' anti-psychotic drug Risperdal and an ANDA filing on Risperdal by Teva Pharmaceuticals. Janssen Pharmaceuticals got FDA approval to market Risperdal in 1993 and submitted information for two related patents to the FDA. The FDA listed both patents in its directory of *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the Orange Book). Teva filed an ANDA, but not before Janssen had requested delisting of one of its patents and the FDA had approved the delisting. However, Teva did file its ANDA before the FDA removed the patent from the printed editions of the Orange Book. The question in the case was whether Teva could maintain its ANDA with the paragraph IV certification on the basis that the FDA had not delisted the patent at the time Teva filed its ANDA. The Court of Appeals for the District of Columbia Circuit held that the Janssen patent was delisted effective on the day that Janssen filed its request for delisting. Based on this, the court held that the FDA properly refused to accept Teva's ANDA containing a paragraph IV certification for the delisted patent.

ANDAs and Orange Book listings of patents are part of the Hatch-Waxman framework. The Hatch-Waxman Amendments help to expedite the marketing of generic drugs. Getting a new "branded" drug to market is a time-consuming process. The manufacturer must file a New Drug Application (NDA) with the FDA, showing the new drug is safe and effective and identifying the number and expiration date of any patent or patents applicable to the drug. The FDA has to publish this information, which it does in the Orange Book. A manufacturer preparing to market a generic bioequivalent of a branded drug can take a short-cut: filing an ANDA that piggybacks on the original manufacturer's evidence of safety and efficacy. To start the process, the ANDA applicant must certify—for each patent claiming a drug for which the applicant is seeking approval—under one of four paragraphs that (I) patent information has not been filed; (II) the patent has expired; (III) the patent will expire on a specified date; or (IV) the patent is invalid or will not be infringed by the man-

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ufacture, use, or sale of the new drug for which the application is submitted. The first drug manufacturer to file an approved ANDA containing a paragraph IV certification is rewarded with a 180-day period of marketing exclusivity for the manufacturer's generic version of the drug. Marketing exclusivity is valuable, and is designed to compensate manufacturers for research and development costs as well as the risk of litigation from patent holders.

Although this case focused on the timing and effect of the FDA's actions after the manufacturer of an approved drug requested delisting of a patent, the reasoning of the court and its interpretation of the statute made clear that drug manufacturers have significant influence on the ANDA process. Manufacturers with approved new drug applications are supposed to list any patents that cover the approved drug. However, there is no mechanism for compelling a manufacturer to list a patent. The FDA has adopted only a ministerial role in listing and delisting patents. For example, the FDA makes no assessment of whether a patent does or does not cover the drug for which it is listed. The decision in Teva Pharmaceuticals v. Leavitt found this ministerial approach is consistent with the Hatch-Waxman Amendments. In fact, the court noted that Janssen's notification to the FDA to delist the patent was sufficient for the FDA to consider the patent withdrawn. The court also noted that whether a patent that claims the listed drug is available for paragraph IV certification depends solely on whether the manufacturer with the approved drug identifies such a patent for listing in the Orange Book. The FDA has taken the position that the manufacturer determines whether a patent claims the approved drug, and the court approved this ministerial view of the FDA.

There is a limit to delisting by manufacturers of approved drugs. In the earlier case Ranbaxy Laboratories v. Leavitt the Court of Appeals for the District of Columbia Circuit held that a manufacturer and the FDA could not delist a patent once an ANDA with a paragraph IV certification on the patent had been filed. The Ranbaxy case is distinguished from the Teva case discussed here because the court in the Ranbaxy case determined that an ANDA filer's right to the period of market exclusivity cannot be denied once a proper ANDA had been filed. In the Teva case the court held that the ANDA with the paragraph IV certification was not a proper ANDA at the time it was filed because the patent involved was no longer listed at the time the ANDA was filed.

Manufacturers of approved drugs continue to have significant control of the ANDA process. As this case shows, manufactures are free to list or delist patents, which allows the manufactures to control ANDA filings with paragraph IV certifications. Authorized generics allow manufacturers to influence the value of ANDA approvals and market exclusivity to generic manufacturers.