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Federal Court Rejects Teva's Challenge To Branded Generics

The United States District Court for the District of Columbia has rejected Teva Pharmaceuticals Industries, Ltd.'s bid to prevent Pfizer, Inc. and its subsidiary, Greenstone, from launching a branded generic version of Neurontin® (gabapentin) during Teva's 180-day exclusivity period on the drug. *Teva Pharmaceuticals, Industries, Ltd. v. FDA*, No. 04-1416 (D.D.C. Dec. 23, 2004).

Teva previously filed a citizen petition with FDA in which Teva asked FDA to declare that a brand drug manufacturer could not infringe the exclusivity period granted to ANDA first-filers. The FDA responded to the petition and concluded that FDA did not have authority under the Food, Drug and Cosmetics Act to prevent an NDA holder from introducing a branded generic during the 180-day exclusivity period granted to ANDA first filers. In the lawsuit, Teva claimed that the FDA's position was arbitrary, capricious and an abuse of discretion.

Teva argued that the FDA's decision allowing Pfizer and Greenstone to launch a branded Neurontin® (gabapentin) generic was contrary to Congress' intent in passing the exclusivity provision. According to Teva's submissions to the Court, branded generics remove several protections and incentives granted to ANDA filers by the Hatch-Waxman Act. By allowing branded generics, FDA artificially removes the commercial incentive for ANDA applicants to file paragraph IV certifications and creates added benefits for the NDA holder at the ANDA holder's expense. Teva also argued that branded generics should be subject to the same exclusivity rules as true generics, since FDA and the courts consider generics and branded generics to be equivalent.

The District Court entered summary judgment in favor of FDA, Pfizer and Greenstone. In reaching its decision, the Court focused on

the language of the statute, 21 U.S.C. 355(j)(5)(B)(iv)(2001). The Court held:

The statute, unambiguously on its face applies only to ANDA applications, not NDA applications. ... Accordingly, the statute only prohibits the FDA from approving subsequent ANDAs until after the 180-day exclusivity period has expired. Nothing in this statute provides any support for the argument that the FDA can prohibit NDA holders from entering the market with a branded generic drug during the exclusivity period.

Because the Court found that the language of the statute was unambiguous, the Court concluded that it was not required to go beyond the plain language of the statute and address Teva's arguments regarding the legislative purpose of the 180-day exclusivity period. The Court did express its view, however, that its interpretation of the statute did not lead to an "absurd result" as Teva argued:

Although it seems reasonable to assume that a plain reading of the statute will reduce the economic value of an ANDA holder's product during the generic exclusivity period and therefore diminish the incentive to file paragraph IV certifications, ... such a result does not rise to the level of absurdity, which would trigger this Court's obligation to look beyond the plain language of the statute.

The Court concluded that FDA's application of the statute was consistent with the plain meaning of the statute and, therefore, could not be arbitrary, capricious and an abuse of discretion as Teva claimed.

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Teva has filed a notice of appeal of this ruling.

Coincidentally, on the same day that the district court handed down the decision in *Teva v. FDA*, Andrx Pharmaceuticals filed a citizen petition with FDA asking FDA to revisit the issue of authorized generics. Andrx asserts that it intends to begin marketing methylphenidate hydrochloride (Concerta®) upon receiving FDA approval of Andrx's pending ANDA. According to Andrx, McNeil Specialty and Consumer Pharmaceuticals intends to launch an authorized generic version of Concerta® at or near the same time that a "true generic" is launched.

In its citizen petition, Andrx argues that authorized generics violate the Food, Drug and Cosmetics Act's labeling and misbranding provisions and harms competition. Andrx asserts:

Petitioner believes that labeling and marketing an NDA-approved drug as a "generic" product is fundamentally misleading and therefore unlawful under FDCA. In effect, the labeling, packaging, and pricing of such a product as something other than a branded product all convey that the product is a therapeutic and pharmaceutical equivalent of a name brand product, but from a different manufacturer, different imprinting and with the possibility of different inactive ingredients, when in fact it is nothing other than the name brand product.

As a result, Andrx claims, purchasers of the brand name drug from the NDA holder are deceived into paying more for an identical product and the "best price" calculations used in government prescription drug reimbursement programs may be affected. Andrx also argues that FDA has not addressed adequately the competitive issues raised by authorized generics.

Andrx requests that FDA:

1. Seek public comment, including formal written input from the Federal Trade

Commission's Bureau of Competition and Consumer Protection, and the Department of Justice's Antitrust Division, on the potential short- and long-term effects of the marketing of authorized generics on consumers, generic drug producers, and competition; and

2. Inform McNeil that, during the period of public comment and consultation requested by Andrx, any authorized generic version of Concerta® introduced before or during the initial product launch of the first ANDA-approved version will be regarded as misbranded and subject to regulatory action.

As is evident from the *Teva* case and Andrx petition to FDA, authorized or branded generics remain a hotly debated issue. Other generic drug manufacturers and consumer groups have challenged authorized or branded generics of Paxil® (*SmithKline Beecham v. Apotex; Congress of California Seniors v. GlaxoSmithKline*) and Macrobid® (*Mylan Pharmaceuticals v. Proctor & Gamble and Watson Pharmaceuticals*). There likely will be further developments in the law on authorized or branded generics as these cases continue.

ABOUT THE AUTHORS

Michael Gaertner, David Abramowitz and Kevin Nelson represent pharmaceutical industry companies in litigation, intellectual property and regulatory matters.

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