Legal Backgrounder

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STATE ANTITRUST LAWSUITS: A GOOD WAY TO BALANCE COSTS AND INCENTIVES FOR PATENTED DRUGS?

by

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A recent lawsuit filed by twenty-five states and the District of Columbia against drug maker Abbott Laboratories and its French partner Fournier highlights a growing trend of state enforcers using the antitrust laws to interject themselves into the federal domain of regulating pharmaceuticals.[1] The states argue that branded drug makers tried unlawfully to extend the life of their patented drug and the resulting monopoly profits. The drug companies argue they are following lawful federal procedures under the Hatch-Waxman Act to protect the fruit of their capital-intensive labors. The court's decision will likely help resolve nagging questions about the inherent conflicts between the patent and antitrust laws, and will have far reaching implications for the drug industry.

The states' motivation apparently is to speed the entry of cheaper generic drugs to the marketplace as a counterweight to increased health care costs. Even though states face considerable political pressure to reduce health care spending, this lawsuit and others like it could have serious negative repercussions for the health care industry and consumers. The states effectively ask the court to second-guess the Food and Drug Administration (FDA) new drug approval process and cast doubt on the rigorous intellectual property protections designed to encourage innovation and to reward risk-taking within the marketplace. For these reasons, it is important to consider whether the present action actually does more harm than good to the drug approval process.

The Hatch-Waxman Act and Federal Drug Approval Process. The federal process at the center of the debate – the Hatch-Waxman Act – was passed by Congress in 1984 with the intent to encourage the entry of generic drugs and to facilitate price competition with branded drugs. The Act allows generic drug manufacturers to apply for FDA approval for generic drugs without replicating costly and time-consuming clinical trials. Hatch-Waxman created the abbreviated new drug application (ANDA) approval process to fast track the market release of lower-priced generic versions of previously-approved innovator drugs. This requires that an ANDA demonstrate the generic drug has key characteristics identical to the original drug. The generic must have the same active ingredients and labeling as the previously-approved drug and must be pharmaceutically equivalent and bioequivalent to the original drug.

[1] *Florida et al. v. Abbott Labs. et al.*, No. 1:08-CV-00155-UNA, (D. Del., filed Mar. 18, 2008)

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The FDA publishes a list of all approved drugs and therapeutic equivalents in the "Orange Book." The Orange Book also lists all patents, if any, covering an approved drug. If the ANDA applicant seeks approval to market a drug before the expiration date of one or more of the patents listed in the Orange Book, the ANDA applicant must certify that each patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[2] This is known as Paragraph IV certification. A Paragraph IV certification notice must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved new drug application (NDA) to which the ANDA refers. If the original patent holder brings an infringement action within 45 days, the ANDA approval is automatically stayed for 30 months.

The Current Lawsuit. The current lawsuit comes on the heels of an investigation led by the Florida Attorney General's Office. The states allege that Abbott and Fournier have thwarted the Sherman Act, various state anti-competition laws, and state consumer protection laws, by engaging in a strategy to block generic drug competition for the drug TriCor, a cholesterol-lowering drug. They allege that defendants feared that competition from lower-priced generics would significantly decrease prices for TriCor.

At the center of the states' allegations is an agreement employed by Abbott and Fournier to use the Hatch-Waxman Act process to forestall competition from generic drug manufacturers. The states claim that Abbott and Fournier had a strategy to delay generic entry and foreclose competition in the market by obtaining multiple patents through inequitable conduct, listing the patents with the FDA knowing they were obtained improperly, and then filing sham patent litigation without a reasonable basis to believe the patents were enforceable and/or were infringed. According to the complaint, the strategy also included enforcing multiple patents with knowledge that they were not infringed in order to buy time to introduce a reformulated TriCor, thereby keeping one-step ahead of the generic manufacturers.

Initially, the companies faced generic competition from two companies: Teva Pharmaceuticals and Impax Laboratories. Upon receipt of Paragraph IV notices from Teva and Impax, Abbott and Fournier allegedly filed suits against them arguing that the generics would infringe a valid and enforceable TriCor patent. Because Abbott and Fournier brought their actions within 45 days of receipt of Paragraph IV notices, the FDA was precluded from granting final approval to the generic manufacturers for 30 months.[3]

The states allege that the companies used the 30-month stay to ensure they had sufficient time to launch the new formulation, to force the market to convert to it, and to withdraw the prior formulations. The states allege that the companies forced the market to convert to new formulations of TriCor before generic entry by (a) reformulating TriCor with only minor changes; (b) creating an artificial product differentiation used as a marketing tool with physicians; (c) stopping promotion and sales of the previous TriCor formulation upon the introduction of the new formulation; (d) removing the old TriCor formulation from the market; and (e) interfering with distribution channels.

According to the complaint, the companies repeated this strategy every few years near the end of the 30-month stay, thereby stymieing competition from generic manufacturers.

Recent Drug Patent Antitrust Decisions. The action against Abbott and Fournier turns the spotlight on the steps pharmaceutical companies take to protect their patents in light of Hatch-Waxman and the rise of generic drug competition. Not surprisingly, courts are divided as to the steps a drug manufacturer may take lawfully to protect its patents. Courts have considered the issue primarily in the context of the highly-publicized "exclusionary payment" or "reverse payment" cases of the past few years. Those cases involved patent holders settling infringement suits with generic manufacturers by paying the generics to refrain from making drugs during

[2]21 U.S.C. 9355 (b)(2)(A)(iv). Both Teva and Impax provided notice to the company stating that their generic formulation did not infringe upon the TriCor patent.

[3]Once an action is brought within 45 days of the Paragraph IV notice, the FDA cannot grant final approval to the generic manufacturer until, generally, 30 months from the receipt of the Paragraph IV notice. If the patent holder or NDA holder does not file a patent infringement action within the 45-day period, the FDA may grant final approval of the ANDA, if the FDA's other regulatory requirements are satisfied.

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the remaining life of the patent.

The Sixth Circuit, in the 2003 *In re Cardizem CD Antitrust Litigation*,[4] concluded reverse payment settlements were per se unlawful market allocation agreements. The court relied primarily on three facts in reaching its decision: that the parties were potential competitors, that the patent holder paid the generic manufacturer to stay out of the market, and that by delaying its entry into the market, the generic maker was indefinitely postponing the commencement of its 180-day exclusivity period (as the first to market) and blocking other generics from entering the market.[5]

The Eleventh Circuit in *Valley Drug Co. v. Geneva Pharmaceuticals*[6] disagreed with the Sixth Circuit's approach, insisting that the analysis must be different where one of the two parties has a lawful monopoly through a patent. "If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market," the Eleventh Circuit would agree with the Sixth Circuit's more traditional antitrust approach.[7] However, because of the patent the Eleventh Circuit concluded that the appropriate analysis is whether the agreement or challenged conduct would create any adverse antitrust effects outside the lawful exclusionary scope of the patent.[8] The Eleventh Circuit confirmed its position in *Schering-Plough Corp. v. FTC*, a case in which the FTC and Solicitor General disagreed over the petition for certiorari as to the viability of the Eleventh Circuit's analysis and the existence of a circuit court split.[9] The Supreme Court denied review, leaving the issue open.

Most examining courts have applied the Eleventh Circuit's approach and its rationale that "any adverse effects [to competition] within the scope of a patent cannot be redressed by antitrust law."[10] The courts agreed that they would not consider the validity of a patent in evaluating an antitrust challenge absent allegations of fraud on the Patent and Trademark Office or the assertion by defendant of a patent known to be invalid (circumstances giving rise to an allegation of *Walker Process* fraud or sham litigation).[11] This limits the force of a frontal antitrust attack on patent holders' efforts to protect their branded drugs from generics.

Possibly seeing this limitation, government agencies and private plaintiffs are now directly attacking the validity of the patents and the FDA approval process in an effort to open the markets to generics more rapidly.[12] For example, in *Abbott Laboratories v. Teva Pharmacueticals*,[13] the private plaintiff corollary to the recent complaint filed by the state attorneys' general, Teva has accused Abbott of reformulating TriCor and pulling the old formulation off shelves to stymie the entry of generics.[14] Similarly, the FTC reached a consent order with Biovail in 2002 after alleging that Biovail obtained an exclusive patent license for a drug (Tiazic) unlawfully,

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[4]332 F.3d 896 (6th Cir. 2003).

[5]*Id.* at 907.

[6]344 F.3d 1294 (11th Cir. 2003).

[7]*Id.* at 1304.

[8]*Id.* at 1306.

[9]402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

[10]*In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 524 (E.D.N.Y. 2005); *see also In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005); *Asahi Glass Co. v. Pentech Pharm.*, Inc. 289 F. Supp. 2d 986 (N.D. Ill. 2003).

[11]*See, e.g., Valley Drug*, 344 F.3d at 1312. Defendant drug manufacturers have argued that the *Noerr-Pennington* doctrine protects their infringement actions as lawful First Amendment expression. This strategy has met with mixed success. *Compare Andrx Pharm., Inc. v. Elan Corp.*, 421 F.3 1227 (11th Cir. 2005) cert. *denied*, 126 S. Ct. 2929 (2006) (allowing *Noerr* argument) *with In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349 (D. Mass. 2004) (rejecting *Noerr* argument); *see generally Eastern Railroad Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961).

[12]Short of attacking the validity of the patents and the FDA approval process, Congress included a provision within The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that now requires that brand-name drug manufacturers and generic drug applicants file pharmaceutical patent settlement agreements with the FTC and the Department of Justice. Since 2004, the FTC has issued three annual reports summarizing these filings, available at: http://www.ftc.gov/bc/healthcare/drug/index.htm.

[13]432 F. Supp. 2d 408 (D. Del. 2006) (denying motion to dismiss).

[14]*Id.*

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wrongfully listed it in the Orange Book, and made misrepresentations to the FDA.[15] The consent order required Biovail to sell part of the license, prohibited Biovail from taking additional steps to stay approval of a generic form of Tiazic, and prohibited Biovail from abusing the Orange Book listing process.[16] Thus rather than pursuing a claim against solely post-patent conduct, plaintiffs are instead raising allegations of fraud in obtaining the patent or in obtaining drug approval from the FDA.

Implications of Aggressive Antitrust Enforcement Favoring Generics. This aggressive enforcement approach creates several problems both for plaintiffs and for the process of drug approval. First, the states and private plaintiffs have asked courts to substitute their own judgment on the value of a drug approval over that of the FDA—the agency tasked with examining new drug applications and weeding out unnecessary or unhelpful drug reformulations. This thwarts the FDA's mandate and undermines the reliability of the entire drug approval process. It also allows individual states to interfere with nationwide drug approvals and drug sales, raising questions about the viability of these suits under many states' antitrust laws, which generally limit applicability to primarily intrastate conduct.

Second, this assault on drug patents circumscribes the patent holders' right to enforce a lawfully-obtained patent and reduces the value of the patent's lawful monopoly. In the short term, the state lawsuits, if successful, could drive the cost of existing drugs down as their generic alternatives come on the market more quickly. However the ultimate cost of this litigation effort will be borne by future generations that may not get the benefit of new life-saving drugs. Drug companies spend hundreds of millions of dollars to develop new drugs and bring them to market. By limiting the financial value of patents through this type of litigation, states are reducing the incentive for pharmaceutical companies to create new drugs and altering the financial calculus for continued investment in the development of new and reformulated drugs.

Third, plaintiffs raise doubts about the validity of a patent by claiming fraud on the PTO or sham litigation without offering specific facts to support their theories sufficient to plead fraud under the heightened requirements of Fed. R. Civ. P. 9(b).[17] Permitting this claim to persist beyond a motion to dismiss may encourage additional similar lawsuits that could further undermine the financial appeal of patent protection by levying additional litigation costs on drug manufacturers.

Conclusion. Although the cost to develop the next pharmaceutical wonder drug can be high, the existence of key drugs, like TriCor, has helped many millions of Americans live healthier lives. Maintaining a regulatory system that creates ample incentives for pharmaceutical companies to continue developing life-saving medicine is paramount. The states' attempt to use the antitrust laws to directly attack the federal processes for drug and patent approval could have serious negative repercussions on drug development. The states' action against Abbott and Fournier could end up harming consumers because it undermines the FDA drug approval process and reduces drug makers' financial incentives to invest in new and better medicines.

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[15] *In re Biovail Corp.*, 134 F.T.C. 407 (2002).

[16] *Id.; see also In re Bristol-Myers Squibb Co.*, 135 F.T.C. 444 (2003) (consent order) (involving similar allegations by the FTC as to abuses of the patent and drug approval processes.)

[17] *See, e.g., Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146 (D.D.C. 2008) (affirming defendants' motion to dismiss because plaintiffs failed to show that enjoying the benefits of patent protection violated the Sherman Act, failed to demonstrated any antitrust injury, and failed to identify any antitrust law requiring a product new on the market to be superior to existing products).

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