UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC., MYLAN SPECIALTY L.P., AND MYLAN INC.,	Civil Action No. 23-836-MRH

Statutes

Other Authorities

Regulations

automatic statutory bar on the FDA's ability to approve the competitor's drug for up to 30 months.

When triggered by an appropriately listed patent, this 30-month stay reflects Congress's intent to balance the interests of brand and generic drug manufacturers by facilitating the resolution of certain types of patent disputes before generic or other competing follow-on products are introduced. But when this stay is triggered by a patent that does not meet the statutory listing criteria, the stay merely delays consumer access to a competing product that might reduce prices, improve quality and access, or both. Given the high cost of many drugs, even a short delay in competition can have enormous consequences for consumers' access to cost-effective medications. The prospect of an automatic 30-month block on competition (and

cause substantial harm to competition and to consumers. And this harm can extend beyond the delay from the 30-month stay: improper listings can distort the competitive process by affecting the planning and incentives of potential competitors. Indeed, the prospect of a 30-month stay may deter rivals from developing lower-cost generic products, permanently depriving the market of competition and access to affordable medications. Improperly listing an ineligible patent, either on its own or alongside other anticompetitive conduct, may therefore constitute illegal monopolization.

INTEREST OF THE FTC

The FTC is an independent agency charged by Congress with enforcing competition and consumer protection laws.[4] It exercises primary responsibility for federal antitrust enforcement in the pharmaceutical industry.[5] The Commission has substantial experience evaluating pharmaceutical competition under the Hatch-Waxman Act and has brought numerous enforcement actions challenging anticompetitive abuses of the Hatch-Waxman framework.[6]

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should assume their veracity . . ."). Accordingly, the FTC's recitation of facts in this *amicus* brief are taken directly from Mylan's complaint and do not represent a view on what Mylan may ultimately prove.

[4] 15 U.S.C. §§ 41–58.

[5] For a summary of the FTC's actions in the pharmaceutical industry, see Fed. Trade Comm'n, Overview of FTC Actions in Pharmaceutical Products and Distribution (Oct. 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Overview-Pharma.pdf.

[6] *See, e.g. FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); *Impax Lab'ys., Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021); *FTC v. AbbVie Inc.*, 976 F.3d 327 (3d Cir. 2020); *FTC v. Shkreli*, 581 F. Supp. 3d 579 (S.D.N.Y. 2022); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015).

BACKGROUND

The Hatch-Waxman framework and Orange Book patent listings

Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act,[10] to "'speed the introduction of low-cost generic drugs to market' and promote competition." *FTC v. AbbVie, Inc.*, 976 F.3d 327, 339 (3d Cir. 2020) (quoting *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013)). The first company to seek approval for a novel drug must file a New Drug Application and go through the FDA's "full-length" application process, which requires extensive safety and efficacy data. *See AbbVie*, 976 F.3d at 338–39. The Act then allows subsequent companies to seek FDA approval for similar drugs through a streamlined process. This in turn allows them to get to market faster and offer their competing products at a lower cost. The net result is significant health care savings for consumers.

The Hatch-Waxman Act's streamlined application process offers two pathways. A company seeking to market an essentially identical generic version of a brand drug can file an Abbreviated New Drug Application (ANDA) under Section 505(j). *See id.* at 339. An ANDA applicant does not need to do its own safety or efficacy studies. Instead, the applicant can rely on the FDA's finding of safety and effectiveness for the brand drug so long as it demonstrates to the FDA that, among other requirements, the product has the same active ingredient, labeling, conditions of use (except those protected by patents or exclusivity), strength, dosage form, and route of administration and is bioequivalent to the brand drug (in very general terms, meaning that it is absorbed into the body in the same way). *See* 21 U.S.C. § 355(j)(2)(A).

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The patents that meet the Orange Book criteria of claiming the drug or method of using the drug are thus a narrower set than those that could be asserted in a patent infringement suit. Indeed, in another case involving one of the patents at issue in this litigation, the First Circuit held that a patent claiming part of a drug's delivery system was not properly listed in the Orange Book because it did not explicitly claim the drug. *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 8 (1st Cir. 2020).

Once a brand applicant has received NDA approval, the FDA publishes the patent numbers, expiration dates, and use codes submitted by the company "in a fat, brightly hued volume called the Orange Book." *Caraco*, 566 U.S. at 405–06. The FDA's role in this listing process is "purely ministerial." *Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 458–

statutory criteria, it receives an automatic 30-month stay during which the FDA cannot approve the competitor's application (unless the competitor prevails in litigation before then). 21 U.S.C. §§ 355(c)(3)(C), 355(j)(5)(B)(iii). This 30-month stay is not a "stay" in the traditional sense. It is not ordered or enforced by a court, but instead is an automatic hold on the FDA's ability to proceed with final approval of a generic application if paragraph IV patent litigation is initiated within the specified timeframe.

Sanofi, its Lantus products, and the patents listed in the Orange Book

According to the allegations in Mylan's complaint, Sanofi markets Lantus, which is the brand name for an insulin glargine injection used to treat diabetes. Compl. ¶¶ 88-89, 92. A predecessor company to Sanofi first received approval from the FDA in 2000 to market Lantus. Compl. ¶¶ 82, 86. Along with this application, the predecessor company submitted one patent, Patent No. 5,656,722 (the '722 patent) for listing in the Orange Book. Compl. ¶¶ 87, 90. In 2007, the FDA approved a supplement to the NDA for a disposable, pre-filled autoinjector pen device called the Lantus SoloSTAR. Compl. ¶ 96. The '722 patent, as extended 85³ 82pplh topoTd [(Alope /or ctenc

the Orange Book. In a separate antitrust case brought by a class of direct purchasers of insulin glargine, the First Circuit reinstated a complaint alleging that Sanofi had improperly listed one of the 2013 patents in the Orange Book. *Lantus*, 950 F.3d at 8. The Lantus SoloSTAR pen remains highly profitable today. In 2021, Lantus SoloSTAR sales totaled approximately $2.8 billion in sales to Medicare Part D patients alone.[12]

Mylan and Semglee

According to Mylan's complaint, in 2013, Mylan partnered with Biocon Limited ("Biocon"), an Indian company that had previously launched a biosimilar version of insulin glargine called Basolog in India. Compl. ¶ 124. Biocon had already started the process of obtaining regulatory approval for an insulin glargine product from the FDA when the companies formed their joint venture. *Id.* At that time, the only patent listed in the Orange Book was the '722 patent, which could only block generics until February 2015 when a period of pediatric exclusivity that attached to the patent was set to expire. *Id.* ¶ 126. In the same month that the joint venture was announced, Sanofi began to list the 2013 patents described above in the Orange Book. *Id.* ¶ 125.

Mylan claims that its application process was complicated by the likelihood that the FDA would at some point deem insulin glargine a biologic product and require an entirely different type of application pursuant to the Biologics Price Competition and Innovation Act ("BPCIA"). *Id.* ¶¶ 128-133. From 2013 to 2016, Mylan states that it sought regulatory guidance from the FDA concerning whether a traditional ANDA approach, 505(b)(2) application, or alternative pathway would be required. *Id.* ¶ 128. Mylan alleges that the prospect of a 30-month stay created

[12] *See* Centers for Medicare & Medicaid Services, Medicare Part D Spending by Drug, *available at* https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug/data.

significant risk that the FDA would change the regulatory status of insulin glargine before it could grant Mylan approval, thereby causing Mylan to switch to a different application process.

In April 2017, Mylan submitted a 505(b)(2) application for its injectable insulin glargine product, called Semglee. Sanofi promptly sued Mylan for infringement of its 2013 Orange Book patents, triggering the 30-month stay on FDA approval of its application. Compl. ¶ 129. The FDA ultimately approved Mylan's 505(b)(2) application in June 2020. Upon approval, by operation of the Public Health Services Act, Mylan's application was deemed an approved biologics license application. Compl. ¶ 136. Mylan then had to apply for Semglee to be considered an interchangeable biosimilar with Lantus. Compl. ¶¶ 136-139. In May 2023, Mylan brought this suit alleging that, as part of a course of anticompetitive conduct, Sanofi improperly listed a large number of patents in the Orange Book, which resulted in delays in FDA approval for Semglee.

ARGUMENT

Improper Orange Book listings raise serious competition concerns because they may illegally delay generic entry. Under the Hatch-Waxman framework, a brand pharmaceutical company can obtain a 30-month stay to block a competitor simply by listing a patent in the Orange Book and suing for infringement within a specified timeframe. Given the enormous profit margins of many brand drugs, even small delays in competition can be extremely lucrative to the brand company—but deny consumers access to affordable medications. The FTC takes no position on whether the Sanofi patents at issue were improperly listed. But, as a general matter, improper listings can cause significant harm to competition and consumers. As such, improperly

listing a patent in the Orange Book can constitute illegal monopolization or part of an illegal course of monopolistic conduct under Section 2 of the Sherman Act.[13]

The Hatch-Waxman scheme reflects a careful balance between encouraging innovation in drug development and accelerating the availability of lower-cost competing drugs.[14] The Orange Book listing process is part of this balance. As the Third Circuit has observed, "[t]he automatic, 30-month stay creates tension with the Hatch Waxman Act's procompetitive goals." *AbbVie*, 976 F.3d at 340. For this reason, Congress strictly limited the types of patents that can trigger the Hatch-Waxman litigation process and its automatic 30-month stay of FDA approval. This special treatment is afforded only to patents claiming "the drug for which the [brand] submitted the [NDA]" or "a method of using such drug." *See, e.g.*, 21 U.S.C. §§ 355(b)(1), (c)(2); *Caraco*, 566 U.S. at 405. And Congress confirmed this limitation in 2003 when it created a mechanism to remove any listed patent that does not claim either (a) the brand drug, or (b) "an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

Brand manufacturers, however, can evade th

deprive consumers of lower-priced competing drugs even long after any 30-month stay would expire.

As early as the late 1990s, "evidence mounted that some brands were exploiting this statutory scheme to prevent or delay the marketing of generic drugs." *Caraco*, 566 U.S. at 408.[19] Consumers suffer from this practice both because they are forced to continue paying non-

127. Mylan allegedly had not anticipated a potential 30-month stay of FDA approval because Sanofi's previously listed patents had expired or covered formulations that differed from Mylan's. Compl. ¶ 126. And Mylan further alleges that its planning was complicated by the prospect that the FDA would eventually deem insulin glargine a biologic product, thus changing its application process. Compl. ¶¶ 128-133. According to Mylan, the unexpected listing of Sanofi's additional patents "short-circuited" its plans, disturbing "the foundation of the timing decisions affecting Mylan's application[.]" Compl. ¶ 132. The complaint alleges that this led to significant delay in the approval of Mylan's product.

To the extent that Sanofi contends that Mylan could have avoided harm from an improper Orange Book listing by making different, more expedient business decisions, that is no defense. The antitrust laws did not require Mylan to foresee or preempt an anticompetitive scheme. *FTC v. Shkreli*, 581 F. Supp. 3d 579, 636-37 (S.D.N.Y. 2022) (describing how a pharmaceutical executive's actions were responsible for delays in approval despite arguments that generic competitors could have taken alternative actions to expedite the regulatory process). Generic drug companies "need not undertake herculean efforts to overcome significant anticompetitive barriers specifically erected to prevent their entry into a market." *Id.* at 637.

If Sanofi's actions harmed the competitive process, they may constitute illegal monopolization. Monopolization requires proof of "the willful acquisition or maintenance of [monopoly] power as distinguished from growth or development as a consequence of a superior wt23thres wth or de2fsiness deac5.2 4me. iticeacced n.2 4me-1.2 8."