MASSACHUSETTS Lawyers Weekly
MASSLAWYERSWEEKLY.COM
VOLUME 49 NUMBER 8 Part of the BridgeTower Media network FEBRUARY 24, 2020

Dismissal of Sanofi antitrust suit reversed

By Pat Murphy
pmurphy@lawyersweekly.com

Purchasers of a diabetes drug can pursue antitrust claims based on allegations that drug maker Sanofi-Aventis wrongfully extended its monopoly by improperly listing a patent in the U.S. Food & Drug Administration's "Orange Book," the 1st U.S. Circuit Court of Appeals has determined.

The "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, known in the pharmaceutical industry as the Orange Book, identifies drug products approved by the FDA and includes related patent and exclusivity information. The listing of a patent in the Orange Book enables the patent holder to later trigger an automatic 30-month suspension of the FDA's approval of competing products.

The plaintiffs in the case argued that Sanofi improperly listed in the Orange Book a patent for a pen injector used to administer Lantus to diabetes patients. According to the plaintiffs, the improper listing was designed to extend Sanofi's monopoly and thereby keep cheaper generic drugs off the market.

In reversing a dismissal by U.S. Magistrate Judge Judith Dein in Boston, the 1st Circuit concluded that the plaintiffs stated a plausible claim for antitrust liability.

"We … hold that the facts and reasonable inferences found in the complaint describe an improper submission of the '864 patent for listing in the Orange Book [and] that the defenses to antitrust liability as a result of such an improper submission include proving that the submission was the result of a reasonable, good-faith attempt to comply with the Hatch-Waxman [Amendments] scheme," Judge William J. Kayatta Jr. wrote for the unanimous 1st Circuit panel.

The 31-page decision is *In Re: Lantus Direct Purchaser Antitrust Litigation*, Lawyers Weekly No. 01-028-20. The full text of the ruling can be found at masslawyersweekly.com.

Two-prong test

One of the more notable aspects of the case was the court's recognition of a two-prong test that requires a showing of both reasonableness and good faith to determine whether a patent holder has established a defense to an allegation that the listing of a patent in the Orange Book was improper, according to Boston intellectual property attorney Howard J. Susser.

"At least in the 1st Circuit, it's a 'get out of jail free' card if it was an honest mistake and you did it in good faith," Susser said. "If someone's really being sneaky and intentionally trying to extend their monopoly by submitting a patent that doesn't belong in the Orange Book, then this case is saying there could be Section 2 antitrust liability."

Susser added that the ruling sends a message to companies to document decision-making regarding the listing of a patent in the Orange Book whenever there is any ambiguity regarding the appropriateness of the decision to do so.

"It becomes a compliance issue," Susser said.

Providence IP attorney C. Alexander Chiulli said he could envision the potential for abuse in Orange Book listings.

"There's a clear benefit to listing patents in the Orange Book and interpreting the definition of a drug [patent] claim fairly extensively because of the opportunities for a patent holder to place that 30-month stay over a competitor," he said.

Chiulli said he read the two-prong test for evaluating the appropriateness of an Orange Book listing as the court striking a balance between intellectual property rights and the public interest in allowing generic drugs to come to market.

Craig R. Smith said the case highlights some of the issues in deciding whether to list a patent in the Orange Book.

"One of the dilemmas companies face is deciding what is considered a patent for a 'drug' or 'drug product' relating to the drug you'd gotten your initial patent on," said Smith, an IP lawyer in Cambridge. "There's a question of how do you comply with the regulation."

Smith said that companies have asked the FDA for guidance on whether they should list a patent.

"They've never provided an answer that is clear enough for people to know for sure whether they should be filing or the approach they should take going forward," Smith said.

The plaintiffs are represented by Thomas M. Sobol. The Cambridge attorney was unavailable for comment. Defense attorney Laura Diss Gradel of Boston did not respond to a request for comment.

"If someone's really being sneaky and intentionally trying to extend their monopoly by submitting a patent that doesn't belong in the Orange Book, then this case is saying there could be Section 2 antitrust liability."

— Howard J. Susser, Boston

Extended monopoly

The FDA's Orange Book procedures are governed by the 1984 Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act.

Sanofi holds the patent for the drug insulin glargine, which it sells under the Lantus brand name. In 2000, the company obtained FDA approval to market Lantus for management of diabetes.

With its application for FDA approval, Sanofi also submitted its patent for drug insulin glargine for listing in the Orange Book. While the '722 patent for the drug expired in August 2014, its period of regulatory exclusivity did not expire until February 2015.

However, in 2006 Sanofi filed a supplemental new drug application for a disposable injector pen device for the self-injection of insulin called the Lantus SoloSTAR. In 2007, the FDA accepted Sanofi's application for the SoloSTAR, which it classified as a change to Lantus' labeling or container. Subsequently, in 2013 Sanofi submitted for listing in the Orange Book the patent for the drive mechanism used in the SoloSTAR drug delivery device. The '864 patent is set to expire in 2024.

In 2013, Eli Lilly unveiled plans to market a competing insulin glargine product, Basaglar, to be injected using the company's KwikPen device.

Sanofi responded by suing Lilly for patent infringement. In the lawsuit, Sanofi sought to bar Lilly from manufacturing or selling the Basaglar KwikPen until 2024 when the Lantus patents listed in the Orange Book expired.

Moreover, by operation of 21 U.S.C. §355(c)(3)(C), Sanofi's lawsuit triggered the 30-month stay of FDA approval for Basaglar. Sanofi similarly beat back attempts by Merck and Mylan to enter the insulin glargine product market.

The plaintiffs in the case before the 1st Circuit sued Sanofi in 2016. The plaintiffs seek to represent a class of direct insulin glargine purchasers who allege that Sanofi violated §2 of the Sherman Act. According to the plaintiffs, Sanofi's improper listing of the '864 patent in the Orange Book resulted in inflated prices through delayed competition in the market.

In October 2018, Magistrate Judge Dein dismissed the plaintiffs' antitrust claims, concluding that, as a matter of law, Sanofi's decision to list the '864 patent was reasonable and not "objectively baseless" in light of ambiguities in the FDA's listing requirements.

The full text of the ruling in *In Re: Lantus Direct Purchaser Antitrust Litigation* can be found at masslawyersweekly.com.

Antitrust claims revived

In assessing the merits of the lower court's dismissal order, Kayatta wrote that the plaintiffs adequately alleged that it was improper for Sanofi to submit its '864 patent for the Lantus SoloSTAR for listing in the Orange Book.

Kayatta explained that 21 U.S.C. §355(c)(3)(C) and applicable FDA regulations permit listing in the Orange Book only for patents that "claim" the relevant drug or a method of using the drug. The judge pointed out that the '864 patent "does not even mention, much less claim" either insulin glargine or any method of using the drug.

Sanofi argued that the terms "drug" as used in pertinent FDA regulations included "drug products" and, therefore, extended to the SoloSTAR self-injection device.

The court rejected that argument.

"[B]ecause the claims of the '864 patent do not mention the drug for which the [supplemental new drug application] was submitted, the patent does not 'claim the drug,' and it was improper for Sanofi to have submitted it for listing in the Orange Book as a drug claiming either insulin glargine or the Lantus SoloSTAR," Kayatta wrote.

In the alternative, Sanofi argued that its submission of the '864 patent for listing was reasonable given the lack of guidance on the issue from the FDA. According to Sanofi, it should be immune from liability under federal antitrust law for what amounted to a "reasonable mistake."

However, Kayatta noted that Sanofi was unable to point to any cases holding that reasonableness alone immunizes monopolists from §2 liability. He observed that several circuits in addressing cases under the federal Communications Act recognized a defense to antitrust liability where the defendant's action was taken as part of a "good faith, reasonable" attempt to comply with a regulatory scheme.

The court was persuaded by those decisions that patent holders must show that a listing in the Orange Book was both reasonable and in good faith in order to establish a defense to antitrust claims such as those against Sanofi.

"[W]e … see no principled reason why the same defense [recognized under the Communications Act] should not arise from a reasonable, good-faith attempt to comply with the regulatory demands of the Hatch-Waxman Amendments," Kayatta wrote. "Deterring reasonable, good-faith attempts at compliance 'would obviously impair the achievement of regulatory goals.'"

In Re: Lantus Direct Purchaser Antitrust Litigation

THE ISSUE	Can purchasers of the diabetes drug Lantus pursue antitrust claims based on allegations that drug maker Sanofi-Aventis U.S. wrongfully extended its monopoly by improperly listing a patent in the U.S. Food & Drug Administration's "Orange Book"?
DECISION	Yes (1st U.S. Circuit Court of Appeals)
LAWYERS	Matthew W.H. Wessler of Gupta Wessler, Washington, D.C.; Thomas M. Sobol of Hagens, Berman, Sobol, Shapiro, Cambridge (plaintiffs) Benjamin C. Mizer (Washington, D.C.) and Laura Diss Gradel (Boston), of Jones Day (defense)