1-11-2021

Fresenius Kabi USA LLC v. Par Sterile Products LLC

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 20-1618

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FRESENIUS KABI USA, LLC,

Appellant

v.

PAR STERILE PRODUCTS, LLC; PAR PHARMACEUTICAL COMPANIES, INC.

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Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 2-16-cv-04544)
District Judge: Honorable Susan D. Wigenton

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Argued December 15, 2020

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Before: GREENAWAY, JR., SHWARTZ, and FUENTES, Circuit Judges

(Filed: January 11, 2021)

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OPINION*

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* This disposition is not an opinion of the full Court and, pursuant to I.O.P. 5.7, does not constitute binding precedent.

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SHWARTZ, Circuit Judge.

Plaintiff Fresenius Kabi USA, LLC, a drug manufacturer, sued its competitors Par Sterile Products, LLC and Par Pharmaceutical Companies, Inc. (collectively "Par"), alleging that Par violated federal and state antitrust law. The District Court granted Par's motion for summary judgment. Because the District Court declined to engage in the analysis required by In re Wellbutrin XL Antitrust Litigation Indirect Purchaser Class, 868 F.3d 132 (3d Cir. 2017), we will vacate and remand.

I

A

The events at issue arise from the development of vasopressin injection ("vasopressin"), a drug used to increase blood pressure in adults. To obtain approval to introduce a new drug to the market, a manufacturer must file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA"). See 21 U.S.C. § 355(a)-(b); 21 C.F.R. § 314.50. Manufacturers seeking to sell the generic version of a previously

approved drug must file an Abbreviated New Drug Application ("ANDA"). See 21 U.S.C. § 355(j); 21 C.F.R. § 314.92. Both applications must contain descriptions of the drug's chemical makeup, including its active pharmaceutical ingredient ("API"). See 21 C.F.R. §§ 314.50(d), 314.94(a)(5). Though not technically required, one way for applicants to provide the necessary technical information about the API is to reference the API supplier's drug master file ("DMF").[1] See 21 C.F.R. § 314.420(a). This allows an API supplier to support the manufacturer's application without revealing to the manufacturer confidential proprietary information.[2]

Certain drugs, including vasopressin, were on the market before the FDA required manufacturers to follow the NDA and ANDA processes. Accordingly, Fresenius Kabi, Par's predecessor, and other manufacturers initially sold vasopressin without having filed those applications. To encourage manufacturers to seek approval of their drugs, the FDA adopted a policy of removing unapproved products from the market once it approved an NDA for the same product.

In September 2012, Par's predecessor, JHP Pharmaceuticals, filed the first vasopressin NDA using API provided by BCN Peptides. The NDA was approved in

[1] A DMF contains information concerning, among other things, a drug's composition and the materials used to prepare it. 21 C.F.R. § 314.420(a). The FDA does not substantively review the contents of a DMF when submitted, id., but performs a completeness review to ensure the DMF contains all relevant information. The FDA will substantively review a DMF only in connection with NDAs, ANDAs, and similar submissions. Id.

[2] An API supplier is not required to have a DMF to provide API. In addition, DMF development and drug manufacturing can occur simultaneously. A DMF need not be finalized until the drug application is filed.

April 2014 and Par introduced the product into the market as Vasostrict in November 2014 and obtained patents on its formulations in 2016 and 2017. Consistent with its policy, the FDA ordered others, including Fresenius Kabi, to stop selling their unapproved vasopressin products, leaving Vasostrict as the only vasopressin product on the market.

Because Par already secured the NDA for vasopressin, Fresenius Kabi transitioned its efforts away from filing an NDA and toward filing an ANDA for a generic version of Vasostrict in the fall of 2014. In the early development of its ANDA, Fresenius Kabi obtained API from BCN and received assurances that BCN would provide it access to its DMF. In the summer of 2015, however, Fresenius Kabi learned that BCN and Par were negotiating an exclusive supply agreement. In December 2015, BCN told Fresenius Kabi that it would consider an offer from Fresenius Kabi to enter an exclusive arrangement with it instead of Par, but Fresenius Kabi declined to provide a counteroffer. By the fall of 2015, Fresenius Kabi began looking for alternative API suppliers. Fresenius Kabi initially contacted Bachem and PolyPeptide—the only two API suppliers other than BCN with then-active DMFs—but both suppliers were also in exclusive arrangements with Par.[3] Fresenius Kabi widened its search to non-DMF-holding suppliers, and at least two, Gyma/CS Bio and Flavine/Lummy, offered in December 2015 to supply vasopressin API samples as they became available. Gyma/CS Bio had developed vasopressin API at a

[3] The parties dispute whether Par entered into exclusivity agreements with PolyPeptide and Bachem, but for the purposes of this appeal of a summary judgment ruling, we will view the fact in Fresenius Kabi's favor.

pilot scale and offered to provide samples to Fresenius Kabi. Flavine/Lummy indicated that it had the technology necessary to produce the API. After narrowing the field to Hemmo, CS Bio, and AmbioPharm, Fresenius Kabi decided to work with Hemmo in March 2017. Fresenius Kabi thereafter switched to Bachem upon learning that Bachem was no longer in an exclusive supply arrangement with Par. In July 2019, Fresenius Kabi submitted its ANDA for a generic vasopressin injection. At least five other drug manufacturers secured an API supplier quickly enough to also develop a generic vasopressin and file an ANDA. Two manufacturers, Eagle and Sandoz, filed their ANDAs about a year or more before Fresenius Kabi, in April 2018 and August 2018, respectively.[4]

B

Fresenius Kabi sued Par for violating the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2, for violating New Jersey antitrust law, N.J. Stat. Ann. § 56:9-1 et seq., and for common law tortious interference, alleging that Par's exclusivity agreements with BCN, Bachem, and PolyPeptide were anticompetitive.[5] After discovery, the parties moved for summary judgment. Although the District Court recognized that the "heart of Fresenius' claims is

[4] Hemmo provided API for Eagle and Bachem provided API for Sandoz and permitted Sandoz to reference its DMF in the ANDA.

[5] Fresenius Kabi forfeited its tortious interference claim because it only mentioned the claim in the procedural history, in the "ruling presented for review" section, and in a point heading of its opening brief, and it provided no arguments in support of the claim. See FTC v. AbbVie Inc., 976 F.3d 327, 368 n.3 (3d Cir. 2020) ("[A]rguments raised in passing . . . but not squarely argued[] are forfeited on appeal." (internal quotation marks omitted) (quoting John Wyeth & Bro. Ltd. v. CIGNA Int'l. Corp., 119 F.3d 1070, 1076 n.6 (3d Cir. 1997))); United States v. Pelullo, 399 F.3d 197, 222 (3d Cir. 2005) (stating that failure to raise an argument in an opening brief constitutes waiver).

that Par . . . delayed generic Vasopressin manufacturers' entrance into the market by entering into exclusive [supply] agreements," Fresenius Kabi, USA, LLC v. Par Sterile Prods., LLC, No. 16-4544, 2020 WL 901967, at *3 (D.N.J. Feb. 25, 2020), it did not evaluate whether the exclusive arrangements were anticompetitive. Rather, the Court focused on whether Par's patents broke "the chain of causation" between the allegedly anticompetitive conduct and Fresenius Kabi's purported injury because the patents "independently would have prevented market entry." Id. (internal quotation marks omitted) (quoting Wellbutrin, 868 F.3d at 165). Fresenius Kabi argued that the patents would not have blocked entry because they are invalid and, even if valid, the product for which it originally planned to file an ANDA would not infringe them. The Court declined to evaluate Fresenius Kabi's patent validity and noninfringement claims because there was no actual patent litigation or filed ANDA on which a jury could consider these claims and thus the Court would be undertaking a purely hypothetical patent exercise. Id. at *4-5, *5-7. As a result, the Court concluded that Par's patents broke the chain of causation and so Fresenius Kabi's antitrust claims could not succeed. Id. at *7.

Fresenius Kabi appeals.

II[6]

"To establish an actionable antitrust violation, [a plaintiff] must show both that [the defendant] engaged in anticompetitive conduct and that [the plaintiff] suffered

[6] The District Court had jurisdiction under 15 U.S.C. § 15(a) and 28 U.S.C. §§ 1331, 1367. We have jurisdiction under 28 U.S.C. § 1291.

"We employ a de novo standard of review to grants of summary judgment, applying the same standard as the District Court." Eisai, Inc. v. Sanofi Aventis U.S.,

antitrust injury as a result." Eisai, Inc. v. Sanofi Aventis U.S., LLC, 821 F.3d 394, 402 (3d Cir. 2016).[7] The District Court focused on the element of antitrust causation and concluded that because Par's patents would have blocked Fresenius Kabi's entry into the market, Fresenius Kabi could not show that the exclusivity agreement Par had with BCN caused an antitrust injury.

In Wellbutrin, 868 F.3d at 132, we considered how to handle an assertion that a patent would have blocked an antitrust plaintiff's entry into the market, and the patent would therefore break the chain of causation between the defendant's allegedly anticompetitive conduct and the plaintiff's injury. Because a patent would break the chain of causation, we discussed whether a district court, as part of an antitrust case, must consider challenges to the patents. Id. at 166-67. We recognized that when a product infringes a valid patent, that patent blocks the plaintiff's entry into the market and

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LLC, 821 F.3d 394, 402 (3d Cir. 2016) (internal quotation marks omitted) (quoting Montone v. City of Jersey City, 709 F.3d 181, 189 (3d Cir. 2013)). We "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion," and we "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Id. (italics and internal quotation marks omitted) (quoting Montone, 709 F.3d at 189; Fed. R. Civ. P. 56(a)). However, "antitrust law limits the range of permissible inferences that can be drawn from ambiguous evidence." Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 73 (3d Cir. 2010) (internal quotation marks omitted) (quoting Harrison Aire, Inc. v. Aerostar Int'l, Inc., 423 F.3d 374, 380 (3d Cir. 2005)). Accordingly, "the plaintiff in an antitrust case responding to a summary judgment motion must overcome a higher threshold, which is imposed in order to avoid deterring innocent conduct that reflects enhanced, rather than restrained, competition." Id. (internal quotation marks omitted) (quoting In re Flat Glass Antitrust Litig., 385 F.3d 350, 357 (3d Cir. 2004)).

[7] This test governs both federal and state law antitrust claims. See Eisai, 821 F.3d at 402 & n.11.

precludes a claim that the defendant's allegedly anticompetitive conduct caused the plaintiff's injury. Id. at 165. Accordingly, we held that the district court "must consider the substance of" those patent claims, id. at 167, because where a valid patent independently blocks the plaintiff's entry into the relevant market, the defendant's allegedly anticompetitive conduct cannot be the cause of the plaintiff's injury, id. at 167 n.58.

Here, the District Court declined to engage in this analysis because Fresenius Kabi had not filed an ANDA and there was no litigation challenging the patents.[8] Fresenius Kabi, USA, 2020 WL 901967, at *6-7. Wellbutrin, however, does not require that patent litigation be commenced or that an ANDA be filed for a court to determine whether the patent breaks the chain of causation.[9] 868 F.3d at 167. Rather, an argument that a patent would have blocked an antitrust plaintiff's market entry, and a response that the patent is either invalid, or unenforceable, or the product at issue does not infringe it, triggers a patent analysis under Wellbutrin. The analysis of such a hypothetical infringement suit or patent challenge may in some cases be predicted based on binding legal precedents,

[8] The District Court rejected two expert reports for the same reasons. For example, the Court rejected Dr. Ralph Tarantino's report because he did not review a draft ANDA or other elements that would have been in the proposed ANDA. Fresenius Kabi USA, 2020 WL 901967, at *5. The Court also rejected Dr. John Thomas's report because he opined on the likely success in a patent action that had never been filed and was purely hypothetical. Id. at *6. While there may be other grounds to reject their opinions, the absence of a filed ANDA or an actual lawsuit challenging the patents does not provide a basis under Wellbutrin to decline considering patent challenges in the context of this antitrust case. See Wellbutrin, 868 F.3d at 167.

[9] While the absence of a filed ANDA alone does not absolve a district court from engaging in this analysis, ambiguities in what the proposed ANDA would have contained, or other deficiencies in the record, may.

including statutory and case law.[10] Whether the record permits the District Court to engage in such an analysis of course will be for it to decide.[11]

Because Wellbutrin required the District Court to examine the record to determine whether a reasonable jury could find that Par's patents would have blocked Fresenius Kabi's market entry, we will remand.[12]

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[10] This scenario stands in contrast to City of Pittsburgh v. West Penn. Power Company, where the resolution of the underlying dispute was subject to the prerogative of an independent state administrative agency with broad supervisory power. 147 F.3d 256, 259–60, 267–68 (3d Cir. 1998).

[11] The Northern District of Georgia's decision in In re AndroGel Antitrust Litig. (No. II), No. 1:09-CV-955, 2018 WL 2984873 (N.D. Ga. June 14, 2018), should not influence this analysis. That case is irreconcilable with Wellbutrin. See AndroGel, 2018 WL 2984873, at *14 (stating that experts who testify as to the likely outcome of underlying patent litigation, "like the expert relied upon in Wellbutrin, are coming up with probabilities out of whole cloth" (footnote omitted)).

[12] On remand, the District Court may choose to consider whether the exclusivity agreement even constitutes anticompetitive conduct because if it does not, then no patent analysis is needed. An exclusivity agreement is unlawful under the rule of reason "only if the probable effect of the arrangement is to substantially lessen competition, rather than merely disadvantage rivals." Eisai, 821 F.3d at 403 (internal quotation marks omitted) (quoting ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 271 (3d Cir. 2012)). To evaluate the legality of such agreements, courts consider "whether a plaintiff has shown substantial foreclosure of the market for the relevant product," and "the likely or actual anticompetitive effects of the exclusive dealing arrangement, including whether there was reduced output, increased price, or reduced quality in goods or services." Id. Whether the defendant qualifies as a monopolist will also bear on this analysis. Id. at 404.

Various facts shed light on the issue of substantial foreclosure. For example, the record shows that exclusivity arrangements are "fairly normal with generics," App. 1065, and, in fact, Fresenius Kabi has entered into such arrangements. The record also shows that Fresenius Kabi was offered the chance to compete for an exclusive arrangement with BCN for its API via a competitive monetary offer but declined to pursue it. Race Tires, 614 F.3d at 79, 84 (holding, under the facts of that case, that "to offer more money" is not coercive). The record also reveals that there were other API suppliers who were willing to provide API to Fresenius, although they either had not yet begun or were in the early stages of producing vasopressin API. In addition, other manufactures worked with suppliers other than BCN, and those manufacturers eventually filed ANDAs. The District Court may consider whether these API suppliers were viable during the relevant

III

For the foregoing reasons, we will vacate the District Court's order granting summary judgment for Par and remand for further proceedings.

period, see Geneva Pharms. Tech. Corp. v. Barr Lab'ys, Inc., 386 F.3d 485, 489-91, 502, 509 (2d Cir. 2004) (vacating grant of summary judgment for the defendant drug manufacturers because there were disputed facts concerning whether viable alternate sources of API were available "to generic [drug] manufacturers during the period at issue"), or whether Par "foreclose[d] so large a percentage of the available supply" as to present a threat to competition, not just disadvantage to a rival, ZF Meritor, LLC, 696 F.3d at 271, 284 (quoting Race Tires, 614 F.3d at 76). In conducting this analysis, the absence or presence of a DMF is not in itself dispositive. A manufacturer need not partner with a supplier with an active DMF during its development of an ANDA, and sometimes a drug applicant may choose to not reference a DMF in its ANDA filing at all. Fresenius Kabi itself has worked with API suppliers without an active DMF when developing other drugs, and since 2008 has filed six NDAs or ANDAs that did not reference a DMF. If the District Court chooses to consider whether Par engaged in anticompetitive conduct, it is for that Court to decide whether there are disputes of material fact concerning these points and others that may be relevant to determining whether Par's arrangement with BCN "bar[red] a substantial number of rivals or severely restrict[ed] the market's ambit." Eisai, 821 F.3d at 403 (quoting United States v. Dentsply Int'l, Inc., 399 F.3d 181, 191 (3d Cir. 2005)).