NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 21-3026

PERRIGO CO; PERRIGO ISRAEL PHARMACEUTICALS, LTD, NKA Padagis Israel Pharmaceuticals LTD; PERRIGO COMPANY OF SOUTH CAROLINA, INC, NKA Padagis Israel Pharmaceuticals LTD,
Appellants

v.

ABBVIE INC; ABBOTT LABORATORIES; UNIMED PHARMACEUTICALS LLC; BESINS HEALTHCARE INC

On Appeal from the United States District Court
for the District of New Jersey
(No. 2:20-cv-17560)
U.S. District Judge: Honorable Brian R. Martinotti

Submitted Under Third Circuit L.A.R. 34.1(a)
July 5, 2022

Before: SHWARTZ, KRAUSE, and ROTH, Circuit Judges.

(Filed: July 21, 2022)

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.

SHWARTZ, Circuit Judge.

Plaintiffs Perrigo Co. and its corporate relatives sued Defendants Abbvie Inc., Abbott Laboratories, and others for violating the Sherman Act. Because the District Court correctly held that the parties' 2012 settlement agreement released Plaintiffs' claim, we will affirm the order dismissing the complaint.

I

A

AndroGel is a brand-name topical gel used to treat hypogonadism. Defendants Unimed and Besins hold U.S. Patent No. 6,503,894 ('894 patent), which claims a pharmaceutical composition that treats this condition.[1] Fed. Trade Comm'n v. AbbVie, Inc., 976 F.3d 327, 341 (3d Cir. 2020). Defendants AbbVie and Abbott sell and distribute two types of AndroGel covered by the '894 patent, including AndroGel 1%. In 2000, the Food and Drug Administration ("FDA") approved AndroGel 1% and Defendants launched the brand-name product.

B

Plaintiffs produce a generic version of AndroGel 1% (the "1% generic"). In 2011, Plaintiffs filed a hybrid New Drug Application ("NDA") seeking FDA approval to produce the 1% generic. Pursuant to the Hatch-Waxman Act,[2] 21 U.S.C.

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[1] The '894 patent expired in August 2020. AbbVie, 976 F.3d at 342.

[2] A generic pharmaceutical manufacturer may apply for FDA approval using a hybrid New Drug Application under § 505(b)(2) of the Food, Drug, and Cosmetics Act, 21 U.S.C. § 355(b)(2); 21 C.F.R. § 314.54(a). Under that section, the generic manufacturer must submit a paragraph IV notice in which it certifies that "manufacture,

§ 355(b)(2)(A)(iv), Plaintiffs sent Defendants a "paragraph IV notice[]," which stated that the 1% generic does not infringe the '894 patent, App. 51, and that "a lawsuit asserting the '894 patent against [Plaintiffs] would be objectively baseless and a sham . . . for the improper purpose of, inter alia, delaying [Plaintiffs'] NDA approval," D. Ct. ECF No. 70-7 at 55. Within 45 days of receiving the notice, Defendants sued Plaintiffs for patent infringement. Abbott Prods., Inc. v. Perrigo Co., No. 3:11-cv-06357 (D.N.J. 2011) ("the Litigation"). The Litigation triggered the Hatch-Waxman Act's automatic 30-month stay on the FDA's ability to approve the 1% generic. 21 U.S.C. § 355(j)(5)(B)(iii).

Before Plaintiffs filed an answer, the parties settled.[3] Among other things, the parties agreed to a mutual release, which states:

> [T]he respective Parties and parents . . . hereby fully, finally and forever release . . . the other Parties and each of their respective Affiliates . . . from any and all claims, demands, damages, liabilities, obligations, and causes of action accruing prior to the Effective Date (including without limitation, costs, expenses, and attorneys' fees, and those capable of being asserted in any complaint, answer, affirmative defenses, counterclaims and amendments thereto or any other filings that were or could have been filed in the Litigation), arising out of, related to, or in connection with: (i) the Litigation, . . . and/or (iv) for acts, transactions, activities, facts, matters or omissions

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use, or sale" of the generic will not infringe patents relating to the brand-name drug. 21 U.S.C. § 355(b)(2)(A)(iv). Upon receipt of a paragraph IV notice, the patent holder has 45 days to decide whether to sue for patent infringement. 21 U.S.C. § 355(c)(3)(C). "If the patentee sues within the time limit, the FDA cannot approve the company's application for a generic drug until . . . (1) a court holds that the patent is invalid or has not been infringed; (2) the patent expires; or (3) 30 months elapse, as measured from the date the patentee received the paragraph IV notice." AbbVie, 976 F.3d at 340 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).

[3] The agreement granted Plaintiffs a license to begin marketing the 1% generic no later than December 27, 2014—more than five years before the '894 patent would expire—and $2 million for avoided litigation expenses.

> that are or could have been the subject matter of the Litigation, whether known or unknown, and in each case arising before the Effective Date[.]

App. 112. The "Effective Date" is March 27, 2012.

In 2013, the FDA approved Plaintiffs' 1% generic and issued a favorable therapeutic equivalence (TE)[4] rating for the product in 2014. Plaintiffs launched the 1% generic on December 27, 2014.[5]

C

In 2020, Plaintiffs sued Defendants for violating Section 2 of the Sherman Act, 15 U.S.C. § 2. Plaintiffs allege that the Litigation was a "sham" that "delayed [Plaintiffs'] launch of its generic version of AndroGel 1%." App. 41 ¶ 2. They further allege that because of the sham lawsuit, Defendants "were able to maintain monopoly power" by

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[4] Certain TE ratings trigger state law requirements that pharmacists "dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug." AbbVie, 976 F.3d at 340 (quotation marks, citations, and alterations omitted).

[5] Plaintiffs also sought FDA approval in 2013 to market the 1.62% generic, and Defendants again sued for patent infringement. Unimed Pharms. LLC v. Perrigo Co., No. 1:13-cv-00236 (D. Del. Feb. 15, 2013). Plaintiffs asserted in a counterclaim that the 2013 litigation was a sham. As in 2012, the parties settled, and this second agreement granted Plaintiffs a license to market the 1.62% generic beginning in October 2018 and included a similar release of claims. Because Plaintiffs' instant suit is based only on allegations that the 2011 litigation about the 1% generic was a sham—and because the 2013 litigation concerned only the 1.62% generic—the 2013 litigation is irrelevant.

"delaying the entry of much less expensive competitive generic products." App. 63 ¶ 79.

In their answer, Defendants asserted, in relevant part, an affirmative defense that Plaintiffs' claim is barred by the 2012 settlement agreement, which Defendants attached as an exhibit.

Defendants moved for judgment on the pleadings, which the District Court granted with prejudice. Perrigo Co. v. AbbVie Inc., No. 2:20-cv-17560, 2021 WL 4551397, at *10-11 (D.N.J. Sept. 30, 2021). The Court found that the release barred Plaintiffs' claim because (1) the claim accrued before the Effective Date of the settlement agreement, id.; (2) the absence of FDA approval on the 1% generic did not preclude Plaintiffs from establishing an injury when the Litigation was filed, id. at *8; and (3) the speculative damages exception to the general accrual rule did not apply because Plaintiffs faced only uncertainty that related to "the scope of [their] damages, not whether [they] had, in fact, suffered an injury," id. at *9.

Plaintiffs appeal.

II[6]

A

Under the Noerr-Pennington doctrine, "a party who petitions the government for redress generally is immune from antitrust liability." Cheminor Drugs, Ltd. v. Ethyl

[6] The District Court had jurisdiction under 28 U.S.C. §§ 1331 and 1337. We have jurisdiction under 28 U.S.C. § 1291. "We review an order granting or denying a motion for judgment on the pleadings de novo. Judgment will not be granted unless the movant clearly establishes there are no material issues of fact, and he is entitled to judgment as a matter of law." Bedoya v. Am. Eagle Express Inc., 914 F.3d 812, 816 n.2 (3d Cir. 2019)

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