7-21-2022

Perrigo Co v. AbbVie Inc

NOT PRECEDENTIAL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.

[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

[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)

Corp., 168 F.3d 119, 122 (3d Cir. 1999) (citations omitted). The doctrine does not apply, however, where a lawsuit is a "mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961).

> To determine whether a lawsuit is a "sham," courts apply a two-part test:
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> > First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. [Second, o]nly if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part . . . , the court should focus on whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon.

Prof'l Real Estate Invs., Inc. v. Columbia Pictures Indus., 508 U.S. 49, 60-61 (1993) (citations omitted). A plaintiff asserting a substantive antitrust violation arising from a sham litigation must also prove that "the challenged lawsuit is 'causally linked' to an antitrust injury." In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 149 (3d Cir. 2017) (quoting Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977)). An antitrust injury is an "injury of the type the antitrust laws were intended to prevent." W. Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 101

(internal quotation marks and citations omitted). In ruling on a motion for judgment on the pleadings, a court may examine the complaint, the answer, "any matter of which the court can take judicial notice for the factual background of the case," L-7 Designs, Inc. v. Old Navy, LLC, 647 F.3d 419, 422 (2d Cir. 2011), and "written instrument[s] that [are] exhibit[s] to a pleading," Fed. R. Civ. P. 10(c), so long as those exhibits are "indisputably authentic documents," Spruill v. Gillis, 372 F.3d 218, 223 (3d Cir. 2004). Because Defendants attached the 2012 settlement agreement to their answer, and Plaintiffs do not dispute the authenticity of the agreement, we may consider the settlement agreement.

(3d Cir. 2010) (quoting Brunswick, 429 U.S. at 489); see also Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334 (1990) ("[An] injury, although causally related to an antitrust violation, nevertheless will not qualify as 'antitrust injury' unless it is attributable to . . . an anti-competitive aspect of [the defendant's] practice under scrutiny.").

Plaintiffs' complaint sets forth allegations supporting a sham litigation claim that "could have been the subject matter of" the Litigation. App. 112. First, Plaintiffs allege that the Litigation was "objectively baseless." App. 60 ¶ 69. This allegation mirrors Plaintiffs' September 2011 paragraph IV notice, anticipating Defendants' lawsuit, which stated, "a lawsuit asserting the '894 patent against [Plaintiffs] would be objectively baseless and a sham." D. Ct. ECF No. 70-7 at 55.

Second, Plaintiffs allege that the Litigation was brought for an improper purpose and thus was "subjectively baseless." See App. 61 ¶ 72. This allegation also tracks the paragraph IV notice, which stated that any infringement suit would be "brought in bad faith for the improper purpose of, inter alia, delaying [Plaintiffs'] NDA approval." D. Ct. ECF No. 70-7 at 55.

Third, Plaintiffs allege that, but for the Litigation, they could have marketed a cheaper 1% generic sooner, and thus the lawsuit reduced competition for AndroGel. The complaint does not allege that the antitrust injury only occurred or could only have been

discovered after March 27, 2012.[7] Instead, Plaintiffs explicitly rely on the "filing" of the Litigation itself, which occurred on October 31, 2011, as blocking their market entry. App. 63 ¶ 79.

Thus, the complaint itself and the documents integral to it show that the injury underlying Plaintiffs' sham litigation claim occurred when the Litigation was filed in 2011.[8] Because the settlement agreement bars "any and all claims . . . accruing prior to [March 27, 2012], . . . arising out of, related to, or in connection with . . . the [Litigation] . . . [or] acts . . . that are or could have been the subject matter of the Litigation . . . arising

[7] Plaintiffs cite Wellbutrin for the proposition that to prove antitrust injury, a party asserting a sham litigation claim in the generic pharmaceuticals context must prove they "could have launched even in the absence of the 30-month stay," 868 F.3d at 152, and argue that they were unable to make such an allegation before March 27, 2012 because they lacked FDA approval. Plaintiffs lacked FDA approval due, in part, to the litigation which stayed FDA activity for thirty months. Furthermore, Wellbutrin is distinguishable because there, the generic manufacturer "could [not] have launched" even without the alleged sham lawsuit because of, among other things, a 180-day first-filer exclusivity period. Id. at 152-53.

In addition, Plaintiffs argue that their complaint did not state facts showing actual injury prior to the Effective Date of the 2012 Settlement Agreement, citing our holding in Host International, Inc. v. MarketPlace, PHL, LLC, that a plaintiff must show "actual injury attributable to something the antitrust laws were designed to prevent, not potential injury." 32 F.4th 242, 251-52 (3d Cir. 2022). Plaintiffs, however, pleaded "actual injury" to competition from "filing sham litigation and delaying the entry of much less expensive generic products," App. 63 ¶ 79, and pleaded that filing occurred on October 31, 2011.

[8] Some courts have held that sham litigation claims are compulsory counterclaims under Fed. R. Civ. P. 13(a) in the patent infringement suit alleged to be a sham. See, e.g., Critical-Vac Filtration Corp. v. Minuteman Intern., Inc., 233 F.3d 697, 700-01 (2d Cir. 2000); U.S. Philips Corp. v. Sears Roebuck & Co., 55 F.3d 592, 595-97 (Fed. Cir. 1995).

before [March 27, 2012]," App. 112, and Plaintiffs' sham litigation claim "accru[ed]" prior to March 27, 2012, it was released.[9]

B

Plaintiffs contend that their sham litigation claim could not have accrued before the March 27, 2012 Effective Date because their damages at the time were speculative. Plaintiffs' argument fails for two reasons.

First, in antitrust cases, a cause of action generally "accrues and the statute [of limitations] begins to run when a defendant commits an act that injures a plaintiff's business." Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 338 (1971). In the sham litigation context, the injury generally occurs when the lawsuit, which is alleged to have been a sham, is filed. See, e.g., Al George, Inc. v. Envirotech Corp., 939 F.2d 1271, 1274 (5th Cir. 1991) (holding the filing of allegedly sham patent-infringement suit,

[9] Plaintiffs argue that the District Court impermissibly required them to anticipate Defendants' release defense in their complaint, citing Wiggins v. Albert Einstein Medical Center, No. 20-3129, 2022 WL 1197015, *2 (3d Cir. 2022) (per curiam). Wiggins is nonbinding and inapt as it involved a motion to dismiss under Rule 12(b)(6), where courts "generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." Pension Ben. Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993). Here, in contrast, the District Court ruled on a motion for judgment on the pleadings under Rule 12(c), which permitted review of Defendants' answer and the 2012 Settlement Agreement attached thereto. See supra n.6.

not actions in prosecuting the litigation, was the "last overt act" for statute of limitations purposes).[10]

Here, Plaintiffs were excluded from the AndroGel market as soon as Defendants filed the Litigation. Under the Hatch-Waxman Act, an infringement suit brought within 45 days of receipt of a paragraph IV notice prevents the FDA from granting approval on a generic pharmaceutical until 30 months elapse or the lawsuit resolves. See 21 U.S.C. § 355(j)(5)(B)(iii). Because Defendants filed the Litigation within 45 days of receiving Plaintiffs' paragraph IV notice regarding the '894 patent, Defendants necessarily delayed FDA approval. That delay, in turn, prevented Plaintiffs from launching the 1% generic, so Plaintiffs "fe[lt] the adverse impact" of the Litigation upon its filing. Zenith, 401 U.S. at 339.

Second, while it has been said that where damages are too speculative, the cause of action has not yet accrued, id., Plaintiffs' damages as of the date the Litigation was filed were not too speculative.[11] Damages are not speculative so long as the jury may

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[10] The filing of a baseless lawsuit triggers the statute of limitations for antitrust claims based on that lawsuit. See Brunswick Corp. v. Rigel Textile Corp., 752 F.2d 261, 271 (7th Cir. 1984) ("Exclusion from a market is a conventional form of antitrust injury that gives rise to a claim for damages as soon as the exclusion occurs . . . even though, in the nature of things, the victim's losses lie mostly in the future."); see also Pace Indus. v. Three Phoenix Co., 813 F.2d 234, 238 (9th Cir. 1987) ("The initiation of [the] lawsuit is the final, immutable act of enforcement of an allegedly illegal contract"); accord Korody-Colyer Corp. v. Gen. Motors Corp., 828 F.2d 1572, 1579 (Fed. Cir. 1987). Because the moment when the statute of limitations runs is defined by when the claim accrues, see 15 U.S.C. § 15b, these cases teach that sham litigation claims generally accrue at the time that the lawsuit alleged to have been a sham was filed.

[11] We have applied Zenith's speculative damages exception twice before, but each case is distinguishable.

"make a just and reasonable estimate of the damages based on relevant data," which can take the form of "probable and inferential as well as . . . direct and positive proof." Bigelow v. RKO Radio Pictures, 327 U.S. 251, 264 (1946).; see also Brunswick, 752 F.2d at 271 (noting that absent "excessively speculative" damages, "the statute of limitations is not tolled simply in order to wait and see just how well the defendant does in the market from which he excluded the plaintiff").

Difficulty ascertaining damages must not be "confused with right of recovery." Bigelow, 327 U.S. at 265; see also Pace, 813 F.2d at 240 ("[U]ncertain damages, which prevent recovery, are distinguishable from uncertain extent of damage, which does not

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In Continental-Wirt, we held that a portion of the plaintiffs' damages—lost value to his business, which he was forced to sell due to an alleged price-fixing scheme by his suppliers—may have been speculative because he had not yet sold the business or had sufficient time to attempt to sell it. Continental-Wirt Electronics Corp. v. Lancaster Glass Corp., 459 F.2d 768, 770 (3d Cir. 1972). There, it was possible that the plaintiff suffered no damages (e.g., if the business sold at a profit) at the time the suppliers began the scheme, so recovery was uncertain. Here, in contrast, the Litigation delayed Plaintiffs from receiving FDA approval because of the Hatch-Waxman Act's 30-month stay. 21 U.S.C. § 355(j)(5)(B)(iii). Thus, they were excluded from the market for some period and unable to profit from selling the 1% generic. It was the Litigation in the first instance that damaged Plaintiffs because it delayed FDA approval.

In Harold Friedman, we held that lost profits from relocating a supermarket due to alleged monopolization by competitors were not ascertainable at a certain date. Harold Friedman Inc. v. Thorofare Markets Inc., 587 F.2d 127, 138-39 (3d Cir. 1978). Two aspects of the case make it inapt here. First, we noted "grave reservations" there about whether the date from which the certainty of damages was evaluated was the last time the plaintiff suffered injury. Id. at 138. Here, in contrast, the complaint states that Plaintiffs were injured when the Litigation was filed. Second, Plaintiffs' complaint includes: (a) estimates of Defendants' profits from selling AndroGel in a market without a competing (and cheaper) 1% generic; and (b) allegations that Defendants "were aware" that the 1% generic would "erode [] sales." See, e.g., App. 62 ¶ 77. Plaintiffs' allegations thereby show that they were capable of quantifying the value of being barred from the market, which provides a "guidelin[e]" for calculating damages that was missing in Harold Friedman. See 587 F.2d at 139.

prevent recovery."). In other words, for Plaintiffs to invoke Zenith's speculative damages exception, they must show that prior to March 27, 2012, it was uncertain whether they would suffer damages, not simply that it was uncertain how much they would suffer. FDA approval was put on hold as soon as Defendants filed the Litigation because of Hatch-Waxman's automatic stay. See 21 U.S.C. § 355(j)(5)(B)(iii). The uncertainty of when the FDA would issue approval—or a TE rating—is thus irrelevant to whether the lawsuit caused delay in Plaintiffs' ability to enter the market.[12]

Furthermore, Plaintiffs' complaint demonstrates that they could have reasonably estimated damages before March 27, 2012. Plaintiffs allege that they "lost sales, lost profits and lost the ability to market [their] version of AndroGel 1% before December 27, 2014," App. 42 ¶ 3, and their complaint specifies Defendants' sales and market share before the allegedly sham lawsuit was filed, see, e.g., App. 62 ¶ 77 (sales); App. 63 ¶ 81 (market share). These figures enabled Plaintiffs to estimate the success of the 1% generic when it reached the market. See Brunswick, 752 F.2d at 271 (holding future profits for a

[12] Plaintiffs argue their damages were speculative because there was uncertainty (1) when the FDA would approve the 1% generic and (2) when and how the FDA would issue a TE rating, and neither were known by March 27, 2012. This assertion, however, appears only in Plaintiffs' briefs, not their complaint. A party may not amend their pleadings by making factual assertions in a brief. Pennsylvania ex rel. Zimmerman v. PepsiCo, Inc., 836 F.2d 173, 181 (3d Cir. 1988).

Plaintiffs also appear to suggest that they might not have marketed the drug at all or made "any money" if contingencies failed, Appellants' Br. at 48-49, but under this reasoning, practically every generic manufacturer—each of which must obtain FDA approval—could wait long after an infringement suit is initiated to claim the lawsuit was a sham, which cannot be true, as that view would render the statute of limitations meaningless. See Brunswick, 752 F.2d at 271 (noting that if the accrual rule allowed plaintiffs to "wait and see," the statute of limitations "would be tolled indefinitely in a very large class of antitrust suits").

competitor kept off the market by a patentee were not speculative because patentee's profits provided a reasonable estimate from which jury could award damages). Thus, Plaintiffs' damages were capable of calculation, based on Defendants' ability to delay competition, when the Litigation was filed.[13]

Thus, based on the pleadings, the speculative damages exception does not apply, and Plaintiffs' claim accrued when Defendants filed the Litigation. The claim is therefore barred by the release, and the District Court correctly granted judgment on the pleadings for Defendants.

III

For the foregoing reasons, we will affirm the District Court's order.

[13] Moreover, courts have rejected arguments from plaintiffs claiming an inability to calculate their lost profits because businesses routinely project future earnings. See, e.g., Charlotte Telecasters, Inc. v. Jefferson-Pilot Corp., 546 F.2d 570, 573 (4th Cir. 1976); City of El Paso v. Darbyshire Steel Co., 575 F.2d 521, 523 (5th Cir. 1978); see also Pace, 813 F.2d at 240. Plaintiffs allege that AndroGel brought in "hundreds of millions of dollars in sales every year," App. 62 ¶ 77, so any argument that they are incapable of projecting the 1% generic's profitability, see, e.g., Appellants' Br. at 20 (suggesting Plaintiffs may have lacked the capacity to bring the 1% generic to market under certain circumstances), is unpersuasive.