UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

AUGUST TERM 2016

(ARGUED: SEPTEMBER 16, 2016 DECIDED: FEBRUARY 8, 2017)

Docket No. 15-3364

IN RE ACTOS END-PAYOR ANTITRUST LITIGATION

UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, 199 SEIU-NATIONAL BENEFIT FUND,

Plaintiffs-Appellants,

CROSBY TUGS, LLC, INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 132 HEALTH AND WELFARE FUND, PAINTERS DISTRICT COUNCIL NO. 30 HEALTH AND WELFARE FUND, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, NECA-IBEW WELFARE TRUST FUND, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, CITY OF PROVIDENCE, RHODE ISLAND INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, MINNESOTA AND NORTH DAKOTA BRICKLAYERS AND ALLIED CRAFTWORKERS HEALTH FUND, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED, NEW ENGLAND ELECTRICAL WORKERS BENEFIT FUND, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, MAN-U SERVICE CONTRACT TRUST FUND, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED,

Consolidated Plaintiffs-Appellants,

PLUMBERS & PIPEFITTERS LOCAL 178 HEALTH & WELFARE TRUST FUND, FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, A.F. OF L. A.G.C. BUILDING TRADES WELFARE PLAN, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, GREATER METROPOLITAN HOTEL EMPLOYERS-EMPLOYEES HEALTH AND WELFARE FUND, ON BEHALF OF THEMSELVES AND ALL OTHER SIMILARLY SITUATED, LOCAL 17 HOSPITALITY BENEFIT FUND, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED, DENNIS KREISH, ON BEHALF OF HIMSELF AND ALL OTHERS SIMILARLY SITUATED, TEAMSTERS UNION LOCAL 115 HEALTH & WELFARE FUND, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED,

Consolidated Plaintiffs,

-v.-

TAKEDA AMERICA HOLDINGS, INC., TAKEDA PHARMACEUTICALS, U.S.A., INC., TAKEDA DEVELOPMENT CENTER AMERICAS, INC., TAKEDA PHARMACEUTICALS COMPANY LIMITED,

Defendants-Appellees,

RANBAXY LABORATORIES, LTD., MYLAN, INC., MYLAN PHARMACEUTICALS INC., ACTAVIS PLC, F/K/A ACTAVIS, INC., WATSON LABORATORIES, INC., RANBAXY, INC., RANBAXY PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC.,

Defendants.

Before: JACOBS and LIVINGSTON, *Circuit Judges*, and RAKOFF, *District Judge*.[1]

Plaintiffs-appellants allege that defendants-appellees delayed competitors from marketing generic versions of a drug by falsely describing two patents to the Food and Drug Administration, thereby causing plaintiffs to pay monopoly prices for the drug in violation of state-law analogs of the Sherman Act. The district court (Abrams, *J.*) dismissed the complaint for failure to plausibly allege that the false descriptions caused the delay. The judgment of the district court is AFFIRMED IN PART, VACATED IN PART, and REMANDED for further proceedings consistent with this opinion.

STEVE D. SHADOWEN (Jayne A. Goldstein, Pomerantz LLP, Weston, FL; Kenneth A. Wexler, Wexler Wallace LLP, Chicago, IL, *on the brief*), Hilliard & Shadowen LLP, Austin, TX, *for Plaintiffs-Appellants.*

ROHIT K. SINGLA (Blanca F. Young, Munger, Tolles & Olson LLP,San Francisco, CA; Jeffrey I. Weinberger, Adam R. Lawton, Munger, Tolles & Olson LLP, Los Angeles, CA, *on the brief*), Munger, Tolles & Olson LLP, San Francisco, CA, *for Defendants-Appellees.*

Thomas M. Sobol, Davis S. Nalven, Gregory T. Arnold, Kristen A. Johnson, Hagens Berman Sobol Shapiro LLP, Cambridge, MA; Linda P. Nussbaum, Bradley J. Demuth, Nussbaum Law Group, P.C., New York, NY, *for amicus curiae Direct Purchasers in support of no party.*

[1] Judge Jed S. Rakoff, of the United States District Court for the Southern District of New York, sitting by designation.

RAKOFF, *District Judge*:

Plaintiffs allege that the defendants-appellees (collectively "Takeda") prevented competitors from timely marketing a generic version of Takeda's diabetes drug ACTOS by falsely describing two patents to the Food and Drug Administration. Plaintiffs claim that these false patent descriptions channeled Takeda's competitors into a generic drug approval process that granted the first-filing applicants a 180-day exclusivity period, which in turn acted as a 180-day "bottleneck" to all later-filing applicants. Of the ten generic applicants, nine took that route. However, one generic manufacturer, Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"), sought approval via another regulatory mechanism, but was thwarted when the FDA announced that all generic manufacturers would be required to take the bottlenecked route. The FDA's announcement was expressly based on Takeda's representations that it had correctly described its patents. Thereafter, Takeda settled pending patent infringement suits with the three first-filing generic manufacturers and Teva on terms that kept them out of the market until August 2012 (though Teva, unlike the three first-filing generics, could only enter the market as an authorized distributor at that time), and with the other six later-filing generic manufacturers on terms that kept them out of the market for another 180 days after that, *i.e.*, until at least February 2013.

Plaintiffs and the class they seek to represent are drug purchasers who allege that they were wrongfully obliged to pay monopoly prices for ACTOS from January 2011, when Takeda's patent on the active ingredient in ACTOS expired, to at least February 2013, when the mass of generic market entry occurred.

The district court dismissed plaintiffs' antitrust claims for failing to plausibly allege that

Takeda's false patent descriptions caused any delay in generic market entry. The district court reasoned that, *inter alia*, plaintiffs failed to identify a viable regulatory route for generic drug approval that would have avoided the 180-day bottleneck, and that even if they had, they failed to plausibly allege how the generic manufacturers would have avoided Takeda's infringement lawsuits, all of which were voluntarily settled. Plaintiffs appealed.

To the extent plaintiffs' theory posits a delay in the marketing of generic alternatives to ACTOS by all the generic applicants other than Teva, we affirm, because plaintiffs' theory presupposes that these applicants were aware of Takeda's allegedly false patent descriptions when they filed their applications, which is not supported by well-pleaded allegations. However, because plaintiffs' theory as to Teva does not require any knowledge of the false patent descriptions, we reach other issues as to Teva and find that plaintiffs plausibly alleged that Takeda delayed Teva's market entry. We therefore vacate the judgment of the district court to that limited extent.

Discussion

Although the violations of which plaintiffs ultimately complain are antitrust violations, they occur in the context of the pharmaceutical regulatory scheme governed by the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (the "Hatch-Waxman Act"), and various rules promulgated thereunder. We focus in this appeal on two complementary aspects of that regulatory scheme: an initial applicant's duty to inform the FDA of patents covering a proposed new drug, and a subsequent applicant's duty to assure the FDA that a proposed generic version of the drug will not infringe those patents.

More specifically, under the Hatch-Waxman Act, an initial or "brand" manufacturer, before marketing a new drug, must obtain approval from the FDA by filing a New Drug Application ("NDA"). 21 U.S.C. § 355(b).[2] An NDA must include, *inter alia*, "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *Id.* § 355(b)(1). The NDA must classify these patents as "drug" (or "drug substance"), "drug product," or "method of use" patents. *See* 21 C.F.R. §§ 314.53(c)(1)(ii), 314.53(b) (1999) & (2002).

The FDA publishes the brand applicants' patent submissions, including the patent descriptions, in a tome titled Approved Drug Products with Therapeutic Equivalence Evaluation, commonly known as the "Orange Book." *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012); 21 C.F.R. § 314.53(e). The FDA considers its role in publishing the Orange Book to be purely ministerial. *See, e.g.*, *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 237 (4th Cir. 2002). Thus, it does not review the brand applicants' patent submissions for substantive accuracy; instead, it simply publishes them as submitted. *See Caraco*, 132 S. Ct. at 1677.

After a new drug has been approved, an applicant seeking to market a generic version may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j)(2)(A). Among the many requirements a generic applicant must fulfill is to "assure the FDA that its proposed generic drug will not infringe the brand's patents." *See Caraco*, 132 S. Ct. at 1676. Generic applicants learn which patents they must address by consulting the Orange Book, *see id.*,

[2] Unless otherwise indicated, this opinion cites the here-applicable 2000 edition of Title 21 of the U.S. Code and 2003 edition of Title 21 of the Code of Federal Regulations.

and may satisfy their obligation of assuring the FDA of non-infringement in several different ways. *See* 21 U.S.C. § 355(j)(2)(A)(vii)–(viii). Of relevance here, when a generic applicant wishes to market a drug in seeming competition with one or more of an existing brand manufacturer's patents, it has two choices:

One option is to certify that each of the brand's patents "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(j)(2)(A)(vii)(IV). Filing such a "Paragraph IV certification" is a justiciable act of patent infringement entitling the patent holder to sue. *See* 35 U.S.C. § 271(e)(2)(A). To encourage these certifications despite the risk of litigation, the first generic filer that submits a Paragraph IV certification and has its ANDA approved receives a valuable 180-day window of exclusivity during which it alone is permitted to market a generic version of the drug. 21 U.S.C. § 355(j)(5)(B)(iv); *see also FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228–29 (2013). Before December 8, 2003, the Hatch-Waxman Act did not provide any mechanism by which this 180-day exclusivity period could be lost. *See Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1306–07 (D.C. Cir. 2010).

A second option is available when a brand's patent covers a method of using a drug. In that circumstance, an applicant seeking to market a generic version of the drug for a non-patented use can submit a "Section viii statement" that "carves out" any patented uses from its proposed label. 21 U.S.C. § 355(j)(2)(A)(viii). This route "is typically used when the brand's patent on the drug compound has expired and the brand holds patents on only some approved methods of using the drug." *See Caraco*, 132 S. Ct. at 1677. Filing a Section viii statement is not a justiciable act of infringement, so applicants that take this route are not immediately vulnerable to suit. Moreover, while a successful applicant is not entitled to an exclusivity period, it is

exempt from any other generic's exclusivity period pursuant to Paragraph IV. *See Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879–80 (D.C. Cir. 2004). In other words, a successful Section viii application is not subject to the 180-day "bottleneck" delay.

In the instant case, three patents are principally at issue. In the 1980s, Takeda obtained U.S. Patent No. 4,687,777 (the "'777 patent"), which claims the invention of pioglitazone hydrochloride (commonly known simply as pioglitazone), the active ingredient in ACTOS. Plaintiffs do not allege any invalidity connected to the filing of the '777 patent. Its relevance here is simply that its expiration date of January 17, 2011 marks the earliest point at which generic forms of ACTOS could have been marketed with appropriate label carve-outs or certifications.

The alleged misconduct involves two other patents related to ACTOS: U.S. Patent Nos. 5,965,584 (the "'584 patent") and 6,329,404 (the "'404 patent"), both of which expired on June 19, 2016. These patents claim pharmaceutical compositions consisting of pioglitazone with a biguanide (the '584 patent) and with an insulin secretion enhancer (the '404 patent); and both also claim methods of using ACTOS. Takeda also has eight other patents that cover only methods of using ACTOS.

On January 15, 1999, Takeda submitted its NDA for ACTOS to the FDA, which approved the application on July 15, 1999. In connection with the ACTOS NDA, Takeda submitted the '777 patent for listing in the Orange Book as a drug substance patent. Subsequently, however, Takeda represented to the FDA (on November 5, 1999 and January 3, 2002, respectively) that both the '584 and '404 patents were drug product, as well as method-of-use, patents relating to ACTOS. Plaintiffs allege that Takeda's descriptions of the '584 and '404 patents as drug product patents were false, because neither one "claims" ACTOS (*i.e.*, pioglitazone) by itself; they only claim combinations of ACTOS and other drugs, as well as

methods of using ACTOS. In other words, according to plaintiffs, neither patent actually prohibits a generic marketing of pioglitazone after January 17, 2011, but Takeda in effect falsely misrepresented that such a marketing would infringe the later-expiring patents.

On July 15, 2003, Actavis plc f/k/a Watson Laboratories, Inc. ("Actavis"), Mylan Pharmaceuticals, Inc. ("Mylan"), and Ranbaxy Laboratories, Ltd. ("Ranbaxy") became the first manufacturers to file ACTOS ANDAs. These first-filers all submitted Paragraph IV certifications as to the drug product claims of the '584 and '404 patents, and Section viii statements as to Takeda's assorted method-of-use claims. Because they all filed their ANDAs on the same day, the FDA found that they were entitled to share the 180-day exclusivity period. Seven other generic manufacturers ultimately also filed ANDAs. Six of these generics, like the first-filers, made Paragraph IV certifications as to the '584 and '404 patents.

Teva, however, took a different course. On or around July 14, 2004, Teva filed an ANDA that made only Section viii statements as to the '584 and '404 patents. According to plaintiffs, this was because Teva believed that Takeda had falsely described these patents as drug product patents.

The FDA tentatively approved the ANDAs filed by Mylan and Actavis in November 2004 and December 2005, respectively.[3] In 2006, the FDA also tentatively approved Teva's ANDA.[4]

[3] In general, the FDA grants tentative approval when a generic's drug meets all regulatory requirements, but final approval may be prohibited because of another manufacturer's exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd) (2003).

[4] *See* FDA, Tentative Approvals – February 2006, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/ucm064278.htm. Teva's tentative approval date is judicially noticeable because it is publicly available and its accuracy

On October 17, 2003, Takeda filed suit against Mylan, Ranbaxy, and Actavis, alleging that their generic ACTOS products would infringe the drug product claims of the '584 and '404 patents, as well as induce infringement of the method-of-use claims of those patents and Takeda's other method-of-use patents. Takeda filed similar infringement suits against the six other generics whose later-filed ANDAs also made Paragraph IV certifications as to the '584 and '404 patents. In March 2010, Takeda settled its infringement suits with the first-filers under terms that allowed them to begin marketing generic ACTOS on August 17, 2012. Takeda settled its lawsuits with the six other generics under terms that allowed them to begin marketing generic ACTOS 180 days later, in February 2013.

In May 2009, Takeda also filed an infringement suit against Teva in the Southern District of New York.[5] While the suit was pending, Sandoz, Inc. ("Sandoz"), one of the six later-filing generics that relied on Paragraph IV certifications, filed a "citizen petition"[6] with the FDA in August 2009, arguing that a generic application for ACTOS without a Paragraph IV certification as to the '584 and '404 patents—*i.e.*, Teva's Section viii application—should not be approved. *See* Sandoz Citizen Pet., Dkt. No. FDA-2009-P-0411-0001 (Aug. 25, 2009). In connection with

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cannot reasonably be questioned. *See Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2d Cir. 2016).

[5] *See Takeda Pharm. Co. Ltd. v. Teva Pharm. Indus., Ltd.*, No. 09-cv-4665 (S.D.N.Y. 2009). Because Teva's 2004 ACTOS ANDA did not make Paragraph IV certifications as to the '584 and '404 patents, Takeda was not eligible to immediately sue Teva for infringement. Takeda's 2009 suit followed Teva's application to market a generic version of a related Takeda drug (ACTO*plus* met). Although the complaint here also alleges a variety of misconduct connected to that drug, plaintiffs have not pursued on their appeal claims arising out of that alleged misconduct.

[6] "Citizen petitions are a means by which any 'interested person' can request that the FDA 'issue, amend, or revoke a regulation or order,' or 'take or refrain from taking any other form of administrative action.'" Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. 249, 260 (2012) (quoting 21 C.F.R. §§ 10.25, 10.30).

the citizen petition, Takeda, on January 22, 2010, confirmed to the FDA that its patents had been (in its view) correctly described as both drug product and method-of-use patents in its ACTOS NDA. *See* Takeda Comment, Dkt. No. FDA-2009-P-0411-0008 (Jan. 22, 2010). On March 15, 2010, the FDA granted the citizen petition, *see* FDA Resp. to Sandoz Citizen Pet., No. FDA-2009-P-0411-0010, at 11 (Mar. 15, 2010), stating that the "FDA will consider any ANDA referencing Actos that lacks appropriate [Paragraph IV] certifications to the '584 and '404 patents ineligible for final approval." The FDA's ruling was expressly based on the fact that Takeda had described these patents to the FDA as drug product patents. As was its practice, the FDA declined to make its own independent evaluation of these representations. *Id.* at 9–10.

After the FDA granted the Sandoz citizen petition, Teva moved to amend its answer in the Takeda infringement litigation to assert a counterclaim challenging Takeda's patent descriptions. Before the court in the Southern District of New York could rule on that motion, however, Takeda and Teva settled under terms that allowed Teva to distribute Takeda-manufactured ACTOS product beginning in August 2012, and otherwise enter the market 180 days later. This was considerably later than Teva could have begun marketing the drug if its tentatively approved ANDA had not been derailed by the FDA's decision on the citizen petition based on Takeda's representations about the nature and scope of its '584 and '404 patents.

Plaintiffs timely commenced this lawsuit on December 31, 2013. On August 22, 2014, plaintiffs filed a third amended complaint (the operative complaint here) alleging, *inter alia*, that Takeda falsely described the '584 and '404 patents to the FDA as claiming the ACTOS drug product, which ultimately delayed Takeda's competitors from selling generic ACTOS until after the expiration of the '777 patent and thereby caused plaintiffs to pay monopoly prices after January 2011. Specifically, because no generic entry took place until August 2012, and mass

generic entry did not take place until February 2013, plaintiffs claim that they were forced to pay monopoly prices for ACTOS from January 2011, when the '777 patent covering the active ingredient in ACTOS expired, until at least February 2013.

Claims 1 and 2—the only claims at issue on this appeal—allege monopolization and attempted monopolization of the market for ACTOS under various state antitrust laws, to wit, state-law analogs to Section 2 of the Sherman Act, which imposes liability on "[e]very person who shall monopolize[] or attempt to monopolize . . . any part of the trade or commerce among the several States."[7] *See* 15 U.S.C. § 2. It is not disputed that the standards governing federal antitrust claims apply to these claims so far as the issues raised on this appeal are concerned.

As noted, the district court dismissed the complaint for failing to adequately plead causation with respect to the alleged delay. The Court of Appeals reviews a district court's grant of a motion to dismiss *de novo*. *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 99–100 (2d Cir. 2015). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

"Causation in fact is, of course, a necessary element of any claim for relief . . . ." *Argus Inc. v. Eastman Kodak Co.*, 801 F.2d 38, 41 (2d Cir. 1986). An antitrust plaintiff must show that a defendant's anticompetitive act was a "material" and "but-for" cause of plaintiff's injury, although not necessarily the sole cause. *See In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 65–66 (2d Cir. 2012). Further, "a plaintiff need not exhaust all possible alternative sources of injury

[7] Federal jurisdiction in this case is provided by the Class Action Fairness Act of 2005. *See* 28 U.S.C. § 1332(d).

in fulfilling his burden of proving compensable injury." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969); *see also In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 695 (2d Cir. 2009). For purposes of analyzing causation, we, like the district court, will assume that plaintiffs plausibly alleged that Takeda falsely described its patents in its submissions to the FDA.

Here, the plaintiffs offer two causal theories, one applying to the generic applicants who addressed the '584 and '404 patents with Paragraph IV certifications, and one applying just to Teva, which instead relied on Section viii statements. We find that plaintiffs' former theory does not satisfy *Iqbal* and *Twombly*, but that the latter does.

For their first theory, plaintiffs argue that Takeda's allegedly false descriptions of its '584 and '404 patents forced the generics to file Paragraph IV certifications, which triggered a 180-day exclusivity period for first-filers and a corresponding 180-day delay (the "bottleneck") for all subsequent filers. Under the law and regulations in place at that time, first-filers could not disclaim or lose their statutory exclusivity period, so when Takeda settled its infringement suits against the first-filers on terms that allowed them to begin selling ACTOS in August 2012, all subsequent filers were kept out of the market for at least another 180 days. Consistent with that exclusivity requirement, Takeda thereafter settled by granting licenses to the subsequent filers allowing them to begin selling ACTOS after the statutory exclusivity period ended. Plaintiffs claim that but for the false patent descriptions, applicants would not have been forced to make Paragraph IV certifications, no bottleneck would have arisen, and one or more generics would have entered the market as early as January 2011.

Although we agree with the district court that this causal theory does not satisfy *Iqbal* and *Twombly*, we do so on a somewhat different basis than the district court relied upon. We find that

this theory is implausible because it rests on a necessary premise that is not supported by well-pleaded factual allegations.

In particular, because plaintiffs claim that the generic manufacturers filed their Paragraph IV certifications as to the '584 and '404 patents under duress, their theory presupposes that the generic manufacturers *knew* that Takeda had described them as drug product patents when they filed their ANDAs. If the generic manufacturers did not know this, then the causal chain would be broken at the first link, because the generic applicants would necessarily have filed their Paragraph IV certifications for some other reason, such as a belief that the Hatch-Waxman Act required them to do so. It was thus incumbent upon plaintiffs to allege that the generic applicants were aware of the descriptions when they filed their ANDAs in 2003 and 2004. The complaint is bereft of any such allegations.

Given that generic applicants must themselves assure the FDA that they will not infringe brand patents, and given that this duty turns at least in part on how a brand describes its patents, *see Caraco*, 132 S. Ct. at 1677, one might expect that plaintiffs could easily allege how the generics learned of Takeda's patent descriptions. But it turns out that the Orange Book—the go-to source of brand patent information—had a significant flaw at the time: for patents submitted before August 2003, it could reflect only one description (*i.e.*, drug substance, drug product, or method of use) per patent. If a brand indicated that a patent claimed both a method of using a drug and the drug product itself, the Orange Book would only list it as a method-of-use patent. Indeed, there is no dispute that the Orange Book listed the '584 and '404 patents as only method-of-use patents. The Orange Book therefore cannot plug the gap in plaintiffs' causal theory.[8]

[8] The FDA's approach to this difficulty at that time created a "Catch-22" in which generic applicants were required to address brand patents submitted to the FDA, but directed to consult a source that did not always reflect what the brands submitted. *See* FDA Resp. to Sandoz, Inc.

In their papers, plaintiffs suggest that the generics could plausibly have learned of the allegedly false patent descriptions through an FDA-specific information disclosure provision or by consulting a supplemental Takeda filing on the FDA's website. Even if this had been alleged in their complaint, it would not have sufficed. For one thing, nothing in the plain terms of the disclosure provision suggests that a generic could obtain patent descriptions thereunder. *See* 21 C.F.R. § 314.53(e). As for the supplemental filing, while it lists the '584 patent as both a drug product and method-of-use patent, it lists the '404 patent only as a method-of-use patent, and so plainly was not a dependable source of patent information for generic applicants.[9] But the more fundamental flaw is that even if these were viable methods to learn of the alleged false patent descriptions, plaintiffs needed to allege facts in support of these theories in their complaint, which—even after amending their complaint several times—they totally failed to do.

Even more abstractly, plaintiffs argue that because the generic applicants were required to address Takeda's patents in their ANDAs, there must have been some way to learn how Takeda described them, and that it is therefore reasonable to infer that they did so. *See, e.g.*, *Chase Grp. Alliance LLC v. City of N.Y. Dep't of Fin.*, 620 F.3d 146, 150 (2d Cir. 2010) ("[W]e

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Citizen Pet., Dkt. No. FDA-2009-P-0411-0010, at 10 (Mar. 15, 2010) ("[T]he statute requires certification where the patent (or patent claim) claims a listed drug, and where the NDA holder is required to submit and has submitted that patent information to FDA. This obligation to certify attaches regardless of whether that submission is accurately reflected in the Orange Book."). We do not doubt that this made it more difficult for generics to comply with the Hatch-Waxman Act, but that does not change the fact that the plaintiffs here cannot simply rely on the Orange Book listings at that time to show that generics had notice of the patent descriptions.

[9] *See* Center for Drug Evaluation & Research, Approval Package for Application Number NDA 21-073/S-020, at 109, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/021073_S020_ACTOS%20TABLETS_AP.pdf (last visited Feb. 7, 2017). Moreover, plaintiffs fail to show that this document, which is easily accessible today, was as readily available in 2003 and 2004, when the generics filed their ACTOS ANDAs.

review the grant of a Rule 12(b)(6) motion to dismiss *de novo*, . . . drawing all reasonable inferences in the plaintiff's favor."). We cannot sustain plaintiffs' antitrust claims on the basis of wishful thinking. Plaintiffs are due all reasonable inferences, but they must allege some factual basis from which to make those inferences. Here, there are simply no allegations from which we can infer that the generics were aware of the alleged false patent descriptions at the core of this case. In the absence of such facts, plaintiffs' theory of causation must fail.

However, plaintiffs propose a different causal mechanism for Teva, which addressed the '584 and '404 patents with Section viii statements rather than Paragraph IV certifications. Teva's application received preliminary approval from the FDA in 2006, *see supra* note 4, and if Teva had been granted final approval, then it would not have been subject to the first-filers' 180-day exclusivity period, and could have begun marketing generic ACTOS for non-patented uses as soon as the '777 patent expired in January 2011. Teva's application stalled, however, when the FDA, on the express basis of Takeda's own patent descriptions, announced in response to a citizen petition that it would not finally approve an ACTOS ANDA that made only Section viii statements to the '584 and '404 patents. *See* FDA Resp. to Sandoz, Inc. Citizen Pet., No. FDA-2009-P-0411-0010 (Mar. 15, 2010). Plaintiffs claim that but for the false patent descriptions, the FDA would not have made this announcement, and Teva would have entered the market sooner than it did.

Unlike plaintiffs' first theory of causation, this second theory does not depend on Teva's knowledge of Takeda's description of its patents as drug product patents, because the FDA's 2010 announcement was itself expressly based on Takeda's repeated and allegedly false patent descriptions. *See id.* at 9–10 (explaining that because "Takeda's original patent declaration to FDA for the '584 and '404 patents stated that the patents included drug product claims and

method-of-use claims," the agency "will consider any ANDA referencing Actos that lacks appropriate certifications to the '584 and '404 patents ineligible for final approval"). Thus, even if Teva originally filed only a Section viii ANDA, not because it knew of Takeda's false descriptions but, *e.g.*, because the Orange Book failed to include such descriptions, their otherwise valid Section viii ANDA was derailed because the FDA, made aware of the product claims in the '584 and '404 patents, automatically credited Takeda's allegedly false assurances of the accuracy of those claims.

This theory of causation is highly plausible. As noted, the FDA first preliminarily approved Teva's application, then entertained a citizen petition seeking to force all applicants to make Paragraph IV certifications as to the '584 and '404 patents, and then publicly announced that certifications would indeed be required. In so doing, the FDA expressly stated that certifications would be required precisely *because* Takeda had described these patents as drug product patents. In other words, the FDA made no attempt to evaluate whether the descriptions were true, but simply accepted them at face value—thus frustrating Teva's Section viii application. While Teva thereafter sought to challenge the truthfulness of these descriptions in its litigation with Takeda (but settled before the issue was resolved), the damage had been done. A plaintiff could hardly ask for a clearer causal connection.[10]

Takeda nonetheless argues (and the district court seemingly agreed) that this theory is implausible because it fails to rule out a litany of alternative possible causes of Teva's delayed

[10] *Gatt Communications, Inc. v. PMC Associates, LLC*, 711 F.3d 68 (2d Cir. 2013), upon which Takeda relies, is not to the contrary. There, we found that a member of a bid-rigging conspiracy lacked antitrust standing to sue the orchestrator of the scheme in part because it failed to allege that it could lawfully have won the contracts absent the conspiracy. *See id.* at 79. For one thing, Takeda has never challenged plaintiffs' antitrust standing; and for another, Teva had no trouble in receiving tentative approval to market generic ACTOS notwithstanding the alleged antitrust violation, and ultimately did succeed in entering the market.

market entry. Takeda claims, for example, that Teva's market entry was also delayed because Teva voluntarily settled Takeda's infringement suit on terms that kept it out of the market until August 2012; because Takeda had lawfully sought to delay Teva's market entry through its own citizen petition, which was still pending when Teva eventually did enter the market; and because the FDA did not ultimately grant final approval to Teva's ANDA until 2014. Takeda argues that since the complaint does not allege how any of these barriers would have been overcome, plaintiffs' theory that Takeda delayed Teva's market entry is too speculative to survive a motion to dismiss.

It is Takeda, however, that is here engaging in gross speculation. While it is possible that one or more of these factors may turn out to be barriers to plaintiffs' causation theory at later stages of the litigation, they do not mandate dismissing the complaint now. *See Zenith Radio Corp.*, 395 U.S. at 114 n.9; *see also DDAVP*, 585 F.3d at 695. Indeed, even at summary judgment, an antitrust plaintiff may be entitled to a presumption of causation where the anticompetitive conduct "is deemed wrongful because it is believed significantly to increase the risk of a particular injury" and that injury occurred. *See Publ'n Paper*, 690 F.3d at 66. If plaintiffs reach the summary judgment stage and make that showing, then it would be *Takeda*'s burden to show that some other factors, such as the ones identified above, are the "true" cause of the delay, and therefore the "true" cause of the artificially high drug prices plaintiffs paid. Dismissal at this early stage on the basis of speculation about possible and not inherently more plausible alternative causes would be premature.[11]

[11] Takeda also argues that even if it had not described the '584 and '404 patents as drug product patents, the generics—including Teva—would have been required to submit Paragraph IV certifications anyway. The district court appeared to accept a version of Takeda's argument, holding that because the patents were listed in the Orange Book as method patents, generics would have had to make an "appropriate certification" even if Takeda had not elsewhere

Finally, we note in passing that the parties have here raised on appeal several arguments not reached by the district court. Takeda argues, for example, that it in fact correctly described the '584 and '404 patents as drug product patents under 21 U.S.C. § 355(b). In the alternative, Takeda argues that even if it incorrectly described the patents, plaintiffs have failed to plausibly allege that Takeda did so fraudulently and in bad faith. *See, e.g.*, *Phonetele, Inc. v. AT&T Co.*, 664 F.2d 716, 737–38 (9th Cir. 1981) ("If a defendant can establish that, at the time the various anticompetitive acts alleged here were taken, it had a reasonable basis to conclude that its actions were necessitated by concrete factual imperatives recognized as legitimate by the regulatory authority, then its actions did not violate the antitrust laws."). On remand, the district court can consider such issues in the first instance.[12]

For the foregoing reasons, the district court's decision is affirmed in part, vacated in part, and remanded for further proceedings consistent with this decision.

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described the '584 and '404 patents as drug product patents. The district court went on to explain that such an "appropriate certification" would have to be either a Paragraph IV certification or "a request for FDA approval for a 'carve out' label that did not overlap with the patented methods of use," and that plaintiffs' allegations that the generics could have relied on Section viii statements were "inconsistent with the applicable statutory requirements[.]"

This, however, is not correct. Indeed, as the district court recognized elsewhere, a Section viii statement *is* a request for a label carving out non-patented uses, so to the extent the district court treated them separately, it erred. *See Caraco*, 132 S. Ct. at 1677 ("[W]hether section viii is available to a generic manufacturer depends on how the brand describes its patent."). We do not reach Takeda's broader argument that the generics would have been required to submit Paragraph IV certifications in any event, and leave that issue for the district court to address in the first instance.

[12] Takeda also asks that we affirm the dismissal of the claims plaintiffs did not pursue on appeal, including the portions of the monopolization and attempted monopolization claims premised on supposedly anticompetitive settlements. Because these questions are not properly before us, we decline to do so.