United States Court of Appeals for the Federal Circuit

DEY PHARMA, LP AND DEY INC.,
Plaintiffs-Appellees,

v.

SUNOVION PHARMACEUTICALS INC.,
Defendant-Appellant.

2011-1507

Appeal from the United States District Court for the District of Delaware in case no. 08-CV-0372, Judge Leonard P. Stark.

Decided: April 16, 2012

ELIZABETH A. LEFF, Frommer Lawrence & Haug LLP, of Washington, DC, argued for plaintiffs-appellees. With her on the brief were EDGAR H. HAUG and SAM V. DESAI, of New York, New York.

ERIC W. DITTMANN, Paul Hastings, LLP, of New York, New York, argued for defendant-appellant. With him on the brief were JOSEPH M. O'MALLEY, JR., BRUCE M. WEXLER and PRESTON K. RATLIFF, II; STEPHEN B. KINNAIRD, of Washington, DC.

Before BRYSON, DYK, and MOORE, *Circuit Judges*.

DYK, *Circuit Judge*.

Dey Pharma, LP and Dey Inc. ("Dey") brought suit against Sunovion Pharmaceuticals, Inc. ("Sunovion") seeking a declaratory judgment that Dey's generic pharmaceutical product does not infringe Sunovion's U.S. Patent No. 6,451,289 ("the '289 patent"), and that the '289 patent is invalid. The district court concluded that it had subject-matter jurisdiction over the action, and the parties thereafter stipulated to a final judgment of noninfringement. *See Dey Pharma, L.P. v. Sunovion Pharms. Inc.*, No. 08-372 (D. Del. June 20, 2011) (final judgment); *Dey LP v. Sepracor Inc.*, No. 08-372, 2009 WL 1043892 (D. Del. Apr. 16, 2009) (denying motion for certification); *Dey, L.P. v. Sepracor, Inc.*, 595 F. Supp. 2d 355 (D. Del. 2009) (denying motion to dismiss).[1] Sunovion appeals, challenging the district court's subject-matter jurisdiction. We affirm.

BACKGROUND

I

This declaratory judgment action involves the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 ("Hatch-Waxman Act"), in which "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market," *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). Under the Hatch-Waxman framework, a brand-name company seeking

[1] Sunovion was formerly known as Sepracor.

FDA approval of a new drug must file a new drug application ("NDA") with the Food and Drug Administration ("FDA"), which must include information about patents "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1). The FDA publishes this patent information, *see id.*, in a publication known as the "Orange Book."

A generic company may then seek FDA approval using an abbreviated new drug application ("ANDA") with a certification for each patent in the Orange Book, such as a "paragraph III certification" (that approval is not sought until the patent expires) or a "paragraph IV certification" ("that such patent is invalid or will not be infringed"). *Id.* § 355(j)(2)(A)(vii). If an ANDA contains only paragraph IV certifications, the ANDA may be approved unless the NDA holder sues the ANDA filer for patent infringement within 45 days. *See id.* § 355(j)(5)(B)(iii).[2] The first generic company to file an ANDA containing a paragraph IV certification receives a 180-day exclusivity period from the date of its "first commercial marketing" before other generic companies will be approved by the FDA to enter the market. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day period is not impacted by the NDA filer's decision not to sue a subsequent ANDA filer on patents listed in the subsequent filer's paragraph IV certifications.

Before the 2003 amendments to the Hatch-Waxman Act, the first generic filer's 180-day exclusivity period was triggered by either its "first commercial marketing" or a court judgment "holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Under the 2003 amendments, the exclusivity period is only triggered by the first-filing

[2] The filing of the ANDA is treated as an act of infringement. *See* 35 U.S.C. § 271(e)(2).

generic's first commercial marketing, but the exclusivity period can be forfeited under certain conditions, including failure to launch after a final court judgment of noninfringement or invalidity. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, § 1102, 117 Stat. 2066, 2457-60. For example, if a second ANDA filer obtained a final judgment that the patents were invalid or not infringed, then the first ANDA filer would forfeit its 180-day exclusivity period if it did not market the drug within 75 days. *See* 21 U.S.C. § 355(j)(5)(D). This change in the statutory trigger makes no difference to the issues in this case, and for simplicity we refer to a final judgment that triggers the 75-day countdown to forfeiture of the exclusivity period as a "trigger" of the 180-day exclusivity period.

Also before the 2003 amendments, "NDA holders employed several methods of delaying the early resolution of patent disputes." *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1357 (Fed. Cir. 2008). "For example, the brand drug company might have several patents listed in the . . . Orange Book with respect to a particular drug. It could be in the company's interest to bring suit within 45 days on one patent and to hold the others in reserve." *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1343-44 (Fed. Cir. 2007) (quoting 149 Cong. Rec. 31,784 (2003) (statement of Sen. Edward Kennedy)). The benefits of this strategy were noted in the legislative history, including the threat of an infringement suit on the reserved patent against the first ANDA filer after it secured FDA approval, and the ability to delay triggering the first ANDA filer's exclusivity period by preventing adjudication of noninfringement or invalidity of the reserved patent. *See* 149 Cong. Rec. 31,784.

To address this problem, Congress specified that an ANDA filer who is not sued within 45 days could bring a

declaratory judgment action under 28 U.S.C. § 2201 against the NDA holder, *see* 21 U.S.C. § 355(j)(5)(C), and that the federal courts would have declaratory judgment jurisdiction "to the extent consistent with the Constitution," 35 U.S.C. § 271(e)(5). Under this amended Hatch-Waxman framework, if the first ANDA filer "parked" its 180-day exclusivity under an agreement with the brand-name company, a subsequent ANDA filer could independently trigger the first filer's exclusivity period through a declaratory judgment action leading to a final judgment of invalidity or noninfringement, thereby accelerating the second ANDA filer's ability to market its drug.

II

This case involves such a declaratory judgment claim by the second ANDA filer (Dey) against the patent holder and NDA filer (Sunovion), designed to trigger the first ANDA filer's (Breath's) exclusivity period. The FDA approved Sunovion's NDA 20-837 for Xopenex in 1999. Sunovion listed three patents relating to Xopenex in the Orange Book: U.S. Patent No. 5,362,755 ("the '755 patent"), U.S. Patent No. 5,547,994 ("the '994 patent"), and the '289 patent.[3] The '755 patent expires on March 25, 2013; the '994 patent expires on August 20, 2013; and the '289 patent expires on March 21, 2021.

In June 2005, Breath filed the first ANDA for generic Xopenex, which contained paragraph IV certifications for all three patents. In October 2005, Sunovion sued Breath for infringement of all three patents in a case that was transferred to the U.S. District Court for the District of Massachusetts. In May 2008, the suit was dismissed

[3] Three other patents, U.S. Patent Nos. 5,760,090, 5,844,002, and 6,083,993, were also listed, but they have expired and are not pertinent here. For simplicity we omit them from the description of the litigation.

based on a settlement agreement between Sunovion and Breath. *Sepracor Inc. v. Breath Ltd.*, No. 06-10043 (D. Mass. May 1, 2008). Under the settlement, Breath, by paying a license fee, may sell generic Xopenex under its ANDA starting on August 20, 2012 (or on the date of an earlier third-party commercial launch). *See* J.A. 187-88.

In July 2005, Dey filed a second ANDA for generic Xopenex, which also contained paragraph IV certifications for all three Orange Book patents. In February 2006, Sunovion sued Dey over two of the patents in the District Court for the District of Delaware, but Sunovion did not assert the '289 patent. Dey later filed a different ANDA on a "concentrate" version of Xopenex, and after Sunovion again sued Dey with respect to the two patents but not the '289 patent, the actions were consolidated in district court in December 2006. On June 20, 2008, Dey brought this declaratory judgment action, seeking a declaration that the '289 patent is invalid or not infringed by either ANDA product. In response, Sunovion provided Dey with a covenant not to sue on the '289 patent and moved to dismiss the declaratory judgment action for lack of subject-matter jurisdiction.

On January 30, 2009, the district court denied Sunovion's motion to dismiss in a thorough and well-reasoned opinion. *Dey*, 595 F. Supp. 2d at 362-63. In accordance with our precedent, the court held that the covenant not to sue did not defeat declaratory judgment jurisdiction. *See id.* at 360, 362. The court also agreed with Dey that even if it invalidated the two Orange Book patents asserted by Sunovion, the '289 patent would remain a legal barrier to its ANDA approval, and that this potential barrier was a cognizable injury that could be redressed through the declaratory judgment action under our decisions in *Caraco* and *Janssen*, discussed below. *See id.* at 358-62 (citing *Caraco Pharm. Labs., Ltd. v. Forest Labs.,*

Inc., 527 F.3d 1278 (Fed. Cir. 2008); *Janssen*, 540 F.3d 1353).

Pursuant to a stipulation of the parties, the district court entered a final judgment of noninfringement on June 20, 2011. *Dey Pharma, L.P. v. Sunovion Pharms. Inc.*, No. 08-372 (D. Del. June 20, 2011). Sunovion timely appealed solely on jurisdictional grounds. This court has jurisdiction over the appeal under 28 U.S.C. § 1295(a)(1).

Sunovion's Delaware suit against Dey over the '755 and '994 patents is still pending. On February 14, 2012, the district court entered judgment following a jury verdict in favor of Sunovion on the infringement and invalidity claims. *See Sunovion Pharms. Inc. v. Dey Pharma, L.P.*, No. 06-113 (D. Del. Feb. 14, 2012), ECF No. 581. The district court is currently considering post-trial motions.

DISCUSSION

I

Whether an "actual controversy" exists that is sufficient to sustain federal jurisdiction under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), is a question of law that we review de novo. *Teva v. Novartis*, 482 F.3d at 1336. In the Hatch-Waxman context, Congress extended declaratory judgment jurisdiction to ANDA paragraph IV disputes, 21 U.S.C. § 355(j)(5)(C), and has directed federal courts to exercise jurisdiction over these disputes "to the extent consistent with the Constitution," 35 U.S.C. § 271(e)(5). Under the Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, declaratory judgment jurisdiction is created when "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the

issuance of a declaratory judgment." 549 U.S. 118, 127 (2007) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)) (internal quotation mark omitted).

In a number of past cases we have considered the scope of declaratory jurisdiction in this context. Most pertinent are our decisions in *Caraco* and *Janssen*. In *Caraco*, 527 F.3d at 1286, the patents listed in the Orange Book were U.S. Patent No. RE34,712 ("the '712 patent"), which expired in 2012, and U.S. Patent No. 6,916,941 ("the '941 patent"), which expires in 2023. The first ANDA filer (Ivax) was entitled to launch upon the expiration of the '712 patent.[4] The NDA holder (Forest) sued the second ANDA filer (Caraco) for infringement of the '712 patent. *Id.* at 1288. Caraco then brought a declaratory judgment action over the later-expiring '941 patent. *Id.* To trigger the first ANDA filer's 180-day exclusivity, the court concluded that Caraco would have needed to succeed in both the declaratory judgment action over the '941 patent and the separate infringement suit over the '712 patent. *Id.* at 1287. We held there was declaratory jurisdiction because the NDA holder's actions were "potentially exclud[ing] non-infringing generic drugs from the market." *Id.* at 1292. We also held that the declaratory judgment action was not mooted by Forest's covenant not to sue Caraco over the '941 patent because only a court judgment of noninfringement or invalidity would trigger Ivax's exclusivity period and accelerate Caraco's market entry. *Id.* at 1297.

---

[4] The NDA holder only sued Ivax for infringement of the '712 patent, and we affirmed a judgment that the patent was valid and infringed. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007). Because the NDA holder did not sue over the '941 patent, the FDA could approve Ivax's ANDA upon the expiration of the '712 patent. *See Caraco*, 527 F.3d at 1287.

In *Janssen*, 540 F.3d at 1357-58, the patents listed in the Orange Book were U.S. Patent No. 4,804,663 ("the '663 patent"), which expired in 2008, and U.S. Patent Nos. 5,453,425 and 5,616,587 ("the '425 and '587 patents"), which both expire in 2014. The first ANDA filer (Teva) was entitled to launch upon the expiration of the '663 patent.[5] The NDA holder (Janssen) sued the second ANDA filer (Apotex) for infringement of the '663 patent. *Id.* at 1358. Apotex then asserted declaratory judgment counterclaims over the later-expiring '425 and '587 patents. *Id.* We held that there would have been declaratory judgment jurisdiction under *Caraco*, except that Apotex stipulated to the validity, infringement, and enforceability of the '663 patent. *Id.* at 1360. Thus, unlike in *Caraco*, there was no immediate controversy: Apotex's success on the '425 and '587 patents would not trigger Teva's 180-day exclusivity period. *Id.* at 1361. And once the '663 patent expired in 2008, Teva was entitled to launch, so Apotex would only be "excluded from the market by Teva's 180-day exclusivity period—a period to which Teva is entitled to under the Hatch-Waxman Act." *Id.*

II

We first address the question whether, under our decisions in *Caraco* and *Janssen*, declaratory judgment jurisdiction existed when Dey first brought this action on June 20, 2008. We agree with the district court that Dey has done "nothing equivalent to Apotex's stipulation to the infringement and validity of the [first-expiring] patent [in *Janssen*]." *Dey*, 595 F. Supp. 2d at 362. Just as in

---

[5] Teva filed a paragraph III certification for the '663 patent and was not sued over the '425 and '587 patents (for which it filed paragraph IV certifications), so the FDA would approve Teva's ANDA upon the expiration of the '663 patent. *See id.* at 1358.

Caraco, the second ANDA filer (Dey) brought a declaratory judgment action over the last-expiring Orange Book patent (the '289 patent) after the NDA holder (Sunovion) only sued for infringement of the other Orange Book patents (the '755 and '994 patents). And like the second ANDA filer in *Caraco*, Dey "alleges it is being excluded from selling a non-infringing product," and this injury is "fairly traceable" to Sunovion and "redressible by a declaratory judgment that the ['289 patent] is not infringed." 527 F.3d at 1291-93.

As Sunovion conceded at argument, its only argument against finding that declaratory jurisdiction existed in June 2008 is that success in the declaratory judgment action alone is insufficient to redress Dey's injury because Dey would still need to succeed in the separate infringement litigation over the other Orange Book patents. *See* Oral Argument at 30:52–31:28. But this was also true in *Caraco*. We concluded that "only a judgment of invalidity or noninfringement with respect to *both* the '712 and '941 patents can trigger [the first ANDA filer's] exclusivity period." *Caraco*, 527 F.3d at 1295 (emphasis added).[6] We further explained the redressibility element:

> If Caraco obtains a favorable judgment [in its declaratory judgment action], then it will only need a judgment of invalidity or noninfringement on [the other Orange Book patent] in order to acti-

[6] Sunovion argues that *Caraco* is distinguishable because Caraco, in fact, could have triggered Ivax's exclusivity period with a final judgment on the '941 patent in its declaratory judgment action (because Ivax enjoyed exclusivity only with respect to the '941 patent), and that the '712 patent challenge was thus immaterial. *See* Appellant's Br. 23. But our decision in *Caraco* did not rest on this ground. We assumed that success was required for both patents.

> vate [the first ANDA filer's] exclusivity period and obtain FDA approval as swiftly as possible. Thus, a favorable judgment in this action would eliminate the potential for the [declaratory judgment] patent to exclude Caraco from the drug market.

Id. at 1293. Similarly, a favorable declaratory judgment for Dey on the '289 patent will eliminate the potential for that patent to exclude Dey from the market, and Dey would then only need a judgment of invalidity or noninfringement on the other Orange Book patents to trigger Breath's exclusivity period.

Under Sunovion's logic, if the Orange Book patents were divided between two declaratory judgment actions, then each case would preclude a finding of jurisdiction in the other. But the only reason there are two cases here is that Sunovion declined to sue Dey on all the Orange Book patents, and there is no reason to deny jurisdiction over the second action until the initial litigation has been resolved. As we held under materially identical facts in *Caraco*, simply eliminating one barrier is sufficient for declaratory jurisdiction, so long as litigation is also pending that could eliminate the other barriers. *See* 527 F.3d at 1293.

III

Having concluded that jurisdiction existed when Dey filed its declaratory judgment action in June 2008, we turn to Sunovion's argument that jurisdiction no longer exists. Sunovion does not attempt to argue that its covenant not to sue Dey over the '289 patent moots this case, as that argument is foreclosed by our contrary holding in *Caraco*. *See* 527 F.3d at 1297. Rather, Sunovion's argument has two parts: (1) It urges that as a practical matter, the separate litigation over the '755 and '994 patents cannot be concluded by a final judgment before Breath is

entitled to launch its generic product on August 20, 2012;[7] the final resolution of that litigation is necessary to trigger Breath's exclusivity period. (2) Sunovion further argues that once Breath is entitled to launch its generic product, there will no longer be a case or controversy necessary to support declaratory judgment jurisdiction. In other words, Sunovion argues that under the *MedImmune* "all the circumstances" test, the court should not allow a declaratory action challenging *any* Orange Book patent to proceed unless *all* actions challenging the Orange Book patents can be completed before the date of potential generic entry will arrive and, in Sunovion's view, deprive the district court of jurisdiction.

The problem with Sunovion's view is that its last assumption is incorrect. The district court will not lose jurisdiction simply because the period of possible first generic market entry arrives. Even after Breath is entitled to launch, the possibility remains that Breath will not do so. Breath has not announced plans to launch on August 20, and it is well known that the first generic often elects to delay entry for various reasons, including possible payments from the brand-name manufacturer to delay the launch. In the debate leading up to the 2003 Hatch-Waxman amendments, Congress was concerned by

---

[7] Under its settlement with Sunovion, Breath may launch generic Xopenex on August 20, 2012, which would trigger its exclusivity period and allow Dey to launch its product 180 days later. Sunovion urges that the correct date is actually June 6, 2012, which is 75 days before the August 20 date. It urges that to cause Breath to forfeit its exclusivity under 21 U.S.C. § 355(j)(5)(D), Dey must obtain a final judgment on all Orange Book patents more than 75 days before Breath may launch on August 20; i.e., by June 6, 2012. Whether the correct date is August 20 or June 6 makes no difference for purposes of the legal issues involved here.

the Federal Trade Commission ("FTC") report that "the [180-day] exclusivity has at times been parked through collusive agreements between brand and generic companies." 149 Cong. Rec. 31,783 (2003) (statement of Sen. Edward Kennedy). For example, brand-name companies were alleged to have paid the first generic filer to not enter the market. Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration*, at vii-viii (2002).[8] Indeed, it is that very concern that in part led Congress to enact the forfeiture provisions of the 2003 amendments, which were discussed earlier. *See* MMA § 1102. While those forfeiture provisions are not directly applicable here unless there is a judgment of noninfringement or invalidity on all Orange Book patents, the forfeiture legislation confirms that the first generic entry may often be delayed. *See also* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking To Preserve Drug Competition*, 109 Colum. L. Rev. 629, 646-47 (2009) (finding that 60 out of 143 Hatch-Waxman settlements between 1984 and 2008 involved delayed generic entry and some form of payment from the brand-name company to the generic). If Breath chooses to delay triggering its 180-day exclusivity period, Dey and other generics could

---

[8] The 2002 FTC report also noted that under some settlement agreements, the "generic was marketing the brand-name company's product as a generic," rather than "under its own ANDA." *Id.* at vii. In this case, Breath and Sunovion have entered into a separate supply agreement, under which Breath could purchase Xopenex from Sunovion on a cost-plus-margin basis to sell under Sunovion's NDA, also effective August 20, 2012. *See* J.A. 132, 507. We do not decide whether this would necessarily be "commercial marketing" that triggers the 180-day exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv)(I). We also note that because no discovery has been allowed in this case, it is unclear whether Breath has incentives to delay triggering its 180-day exclusivity period.

potentially be kept off the market until the expiration of the '289 patent in 2021, absent a judgment of noninfringement or invalidity.

Sunovion urges, however, that we held in *Janssen* that "a possible delay in the future of a first Paragraph IV ANDA filer in launching its generic product does not give rise to declaratory judgment jurisdiction." Appellant's Br. 34 (quoting *Janssen*, 540 F.3d at 1363). What Sunovion ignores is that there is a difference between finding that a controversy exists to initiate a suit and determining that the controversy has become moot. While Article III requires that "an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed," the question of whether a controversy exists at a later stage of the proceeding is governed by mootness doctrine. *Arizonans for Official English v. Arizona*, 520 U.S. 43, 67 (1997) (quoting *Preiser v. Newkirk*, 422 U.S. 395, 401 (1975)). As the Supreme Court explained in *Cardinal Chemical Co. v. Morton International, Inc.*:

> [W]hile the initial burden of establishing the trial court's jurisdiction rests on the party invoking that jurisdiction, once that burden has been met courts are entitled to presume, absent further information, that jurisdiction continues. If a party to an appeal suggests that the controversy has, since the rendering of judgment below, become moot, that party bears the burden of coming forward with the subsequent events that have produced that alleged result.

508 U.S. 83, 98 (1993). As we noted in *Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1345 (Fed. Cir. 2007), *Cardinal Chemical* requires that the party arguing that a case has become moot bears "[t]he burden of bringing forth such further information" of mootness. "The

'heavy burden of persua[ding]' the court" that a case is moot "lies with the party asserting mootness." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000) (quoting *United States. v. Concentrated Phosphate Exp. Ass'n*, 393 U.S. 199, 203 (1968)).

We conclude that Sunovion has not met this burden. Indeed, Sunovion conceded at argument that this case will not be moot until Breath actually goes on the market in a way that would trigger its 180-day exclusivity period. *See* Oral Argument at 10:50; *see also Eisai Co. v. Teva Pharms. USA, Inc.*, 131 S. Ct. 2991 (2011) (remanding a case with instructions to dismiss as moot where the first ANDA filer launched prior to a final judgment in the second ANDA's declaratory judgment action). It is uncontested that Breath has not yet marketed generic Xopenex, and that its failure to do so, absent a triggering event, could delay Dey's ability to market until 2021, when the '289 patent expires. Since there was jurisdiction when Dey filed this declaratory judgment action in June 2008, this case may proceed until rendered moot. We affirm the district court's judgment of noninfringement.

AFFIRMED

COSTS

Costs to appellees.