United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 6, 2004 Decided December 21, 2004

No. 04-5211

APOTEX, INC.,
APPELLANT

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 04cv00605)

William A. Rakoczy argued the cause for appellant. With him on the briefs were *Christine J. Siwik*, *Matthew O. Brady*, *Amy D. Brody*, *Lara Monroe-Sampson*, and *Arthur Y. Tsien*.

Charles J. Raubicheck argued the cause for appellee Purepac Pharmaceutical Company. With him on the brief was *William B. Schultz*. *Ronald H. Weich* entered an appearance.

Howard S. Scher, Attorney, U.S. Department of Justice, argued the cause for federal appellees. With him on the brief were *Peter D. Keisler*, Assistant Attorney General, *Kenneth L. Wainstein*, U.S. Attorney, *Douglas N. Letter*, Attorney, *Alex M. Azar, II*, General Counsel, U.S. Department of Health & Human

Services, *Daniel E. Troy*, Chief Counsel, and *Karen E. Schifter*, Counsel.

Before: EDWARDS, SENTELLE, and RANDOLPH, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* EDWARDS.

EDWARDS, *Circuit Judge*: Since December 2002, the District Court has issued three decisions in connection with disputes between Apotex, Inc. ("Apotex") and Purepac Pharmaceutical Co. ("Purepac") over the marketing of a generic version of the drug gabapentin. The Food and Drug Administration ("FDA" or "agency") has approved gabapentin, sold by Pfizer, Inc. ("Pfizer") under the brand name Neurontin, for the treatment of epilepsy. The first two decisions, *Purepac Pharmaceutical Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002) ("*Purepac I*"), and *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69 (D.D.C. 2003) ("*TorPharm*"), were affirmed by this court in a consolidated appeal. *See Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004) ("*Purepac II*").

At issue in this case is a dispute over the proper interpretation and application of the *pre-amended version* of the 180-day generic marketing exclusivity provision of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(5)(B)(iv) (2000) (amended 2003). The parties disagree over whether the pre-2003 version of this statutory provision adopts a "patent-based" approach or "first-filer" approach in establishing the 180-day period for generic marketing exclusivity. Applying a patent-based interpretation of § 355(j)(5)(B)(iv), FDA awarded Purepac two separate periods of 180-day exclusivity for the same generic gabapentin drug. Purepac's first exclusivity period has expired. But the second exclusivity period, which FDA awarded on the basis of a later-listed patent, is now running and will not expire until April 2005. Meanwhile, FDA has delayed final approval of Apotex's

application to market its generic version of gabapentin pending the expiration of Purepac's period of marketing exclusivity. Apotex claims that FDA erred in awarding multiple 180-day periods of marketing exclusivity for the same drug when, in its view, the statute allows only awards for a single period of exclusivity to the first applicant.

Apotex filed the present suit in District Court against FDA and federal officials (collectively "federal appellees"), advancing Apotex's interpretation of § 355(j)(5)(B)(iv) and seeking an injunction directing FDA to issue final approval for Apotex's gabapentin application. Purepac intervened as a defendant. After consolidating Apotex's motion for a preliminary injunction and defendants' motions to dismiss or for summary judgment, the District Court granted summary judgment to defendants. The District Court's judgment rested on two grounds. First, the District Court ruled that *res judicata* barred Apotex's action, because the parties in this case are the same parties who appeared in *TorPharm*; a final judgment was rendered against Apotex in *TorPharm*; the causes of action in this case and *TorPharm* share a common nucleus of facts; there has been no intervening change in the law; and there have been no material changes in the facts since the judgment in *TorPharm*. In the alternative, the District Court held that, even if *res judicata* did not apply, the defendants would be entitled to summary judgment, because FDA's interpretation of § 355(j)(5)(B)(iv) was reasonable and thus entitled to deference.

We agree that *res judicata* bars Apotex from bringing this suit. Therefore, we affirm the judgment of the District Court on this ground alone. We vacate the District Court's alternative holding reaching the merits of whether FDA's interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) is reasonable.

I. BACKGROUND

A. *Statutory and Regulatory Framework*

The FDCA requires that companies seeking to market a drug that has not previously been approved by FDA submit a New Drug Application ("NDA") to FDA. *See* 21 U.S.C. § 355(b)(1) (2000), *amended by* Pediatric Research Equity Act of 2003, Pub. L. No. 108-155, § 2(b), 117 Stat. 1936, 1941 (2003). NDAs are usually lengthy, and they must include, among other things, evidence surrounding the drug's safety and information about any patents that cover or might cover the drug. *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004) ("*Purepac II*") (citing 21 U.S.C. § 355(b)(1)).

In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman"). Hatch-Waxman eased the process of generic drug approval by allowing companies seeking to market generic versions of approved drugs to submit Abbreviated New Drug Applications ("ANDAs"). ANDAs must contain, among other things, information demonstrating that the generic version is the bioequivalent of the approved version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv) (2000).

ANDAs must also address patents that apply or might apply to the drug for which the ANDA is submitted. ANDA applicants can satisfy this requirement by making one of four certifications with regard to the patent's claim on the drug. *Id.* § 355(j)(2)(A)(vii). The relevant certification for the purposes of this case, known as a "paragraph IV certification," requires an ANDA applicant to certify that "such patent 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). When an ANDA includes a paragraph IV certification, the ANDA applicant must notify the owner of the

patent and the holder of the NDA for the approved drug. *See id.* § 355(j)(2)(B)(i). If a patent infringement lawsuit is brought against the ANDA applicant within 45 days from the date notice is received, FDA's approval of the ANDA is automatically stayed for 30 months. *See id.* § 355(j)(5)(B)(iii).

An ANDA applicant who submits a paragraph IV certification is entitled under certain circumstances to a 180-day period of generic marketing exclusivity during which no other company can market a generic version of the drug. *See id.* § 355(j)(5)(B)(iv). This exclusivity provision was amended in 2003, but this case arose under § 355(j)(5)(B)(iv) as it existed prior to the 2003 Amendments. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102, 117 Stat. 2066, 2457-60 (2003) ("2003 Amendments"). All references to § 355(j)(5)(B)(iv) are to the statute as it existed prior to the 2003 Amendments.

Because we conclude that Apotex is barred by *res judicata* from bringing this case, we need not provide an elaborate discussion of this generic marketing exclusivity provision. Rather, what is important here is that the parties have advanced competing interpretations of § 355(j)(5)(B)(iv). These competing interpretations emanate from the fact that NDA holders may receive additional patents that claim an approved drug, or that claim a method of use for the drug, after the approval of their NDAs. Thus, an ANDA applicant who filed the first ANDA with a paragraph IV certification for a particular drug may not be the first ANDA applicant to file paragraph IV certifications for all patents that claim the drug.

Consistent with FDA's determination in this case, the federal appellees and Purepac understand § 355(j)(5)(B)(iv) to allow a company to be eligible for a period of generic marketing exclusivity if it was the first ANDA applicant to file a paragraph IV certification for a particular patent, once the other statutory triggers are satisfied, even if another company had previously

filed a paragraph IV certification for another patent claiming the same drug. Under this interpretation, multiple companies could be eligible for generic marketing exclusivity, and multiple periods of exclusivity are possible. This is the so-called "patent-based approach." By contrast, Apotex argues that § 355(j)(5)(B)(iv) should be interpreted to grant generic marketing exclusivity only once – *i.e.*, only to the generic manufacturer who filed the first ANDA with a paragraph IV certification for any patent involving a particular drug product, and only based on that first paragraph IV certification. This is the "first-filer approach."

Although no court had addressed these competing interpretations before January 2004, the possible tension between them has been apparent since at least 1999. In August of that year, FDA issued a proposed rule that would have adopted the first-filer approach. *See* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,875 (Aug. 6, 1999) ("August 1999 proposed rule"). The agency never implemented the August 1999 proposed rule, however, and instead continued to apply the patent-based approach in disputes surrounding generic marketing exclusivity. *See, e.g.*, Letter from FDA's Office of Generic Drugs ("OGD") to Genpharm, Inc. of 11/16/01, Joint Appendix ("J.A.") 1124, 1128-30; Letter from OGD to American Pharmaceutical Partners, Inc. of 2/4/03, J.A. 1149, 1152-54. The August 1999 proposed rule was formally withdrawn in 2002. *See* 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 67 Fed. Reg. 66,593 (Nov. 1, 2002).

Before turning to the factual background of the present dispute, we note that the four types of certifications enumerated in 21 U.S.C. § 355(j)(2)(A)(vii) are not the only mechanisms by which an ANDA applicant can address a potentially relevant patent. A generic company can instead submit a statement

pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) ("section viii statement"). A section viii statement asserts that a patent does not prevent FDA from approving the company's ANDA because the ANDA applicant seeks to market the drug for a use other than that covered by the patent. *See* 21 U.S.C. § 355(j)(2)(A)(viii). As we have previously explained, applicants use paragraph IV certifications to challenge the validity of applicable patents, whereas they submit section viii statements to assert that patents do not apply. *Purepac II*, 354 F.3d at 880. ANDA applicants who submit section viii statements are not eligible for generic marketing exclusivity pursuant to 21 U.S.C. § 355(j)(5)(B)(iv).

B. ***Facts***

As noted above, this case involves gabapentin, a drug sold by Pfizer under the name Neurontin, which FDA has approved for the treatment of epilepsy. In 1993, FDA approved Neurontin capsules based on a NDA submitted by Warner-Lambert Co. ("Warner-Lambert"), which later assigned Pfizer the rights to Neurontin. In 1997, Warner-Lambert submitted information to FDA on two patents that were not part of its original NDA filing: U.S. Patent Nos. 4,894,476 ("'476 patent"), claiming a crystal form of gabapentin, and 5,084,479 ("'479 patent"), claiming a method for using gabapentin to treat neurodegenerative diseases. *See* Letter from Parke-Davis to FDA of 7/1/97, J.A. 445, 448. In 2000, Warner-Lambert submitted information on an additional patent, U.S. Patent No. 6,054,482 ("'482 patent"), claiming a pharmaceutical composition of gabapentin. *See* Submission from Warner-Lambert to FDA of 4/25/00, J.A. 452, 453.

In 1998, Purepac submitted ANDAs for a generic version of gabapentin. Purepac's ANDAs contained a paragraph IV certification for the '476 patent and a section viii statement for the '479 patent. In May 2000, Purepac submitted a paragraph IV certification to FDA with respect to the '482 patent. Purepac

was the first ANDA applicant to file paragraph IV certifications for the '476 and '482 patents. *See Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 198-200 (D.D.C. 2002) ("*Purepac I*").

Apotex also submitted an ANDA for gabapentin in 1998, and Apotex ultimately submitted paragraph IV certifications for all three patents, as well as a section viii statement for the '479 patent. *Id.* at 200. (Apotex was at that time an affiliate of TorPharm Corp.; the distinction between Apotex and TorPharm Corp. is of no relevance for this appeal, and we refer to the companies both individually and collectively as "Apotex.")

In two separate proceedings filed in 1998, Warner-Lambert sued Purepac and Apotex for infringement of the '476 and '479 patents. Although Warner-Lambert ultimately lost both suits, the ANDAs filed by Purepac and Apotex were stayed for 30 months pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). *See Purepac I*, 238 F. Supp. 2d at 200-01 & n.14. In 2000, Warner-Lambert initiated lawsuits against both Purepac and Apotex for infringement of the '482 patent. Under FDA's then-prevailing interpretation of the statute, these lawsuits triggered additional 30-month stays before FDA could approve the companies' ANDAs. *See id.* at 201 & n.15. Purepac's 180-day exclusivity period based on the paragraph IV certification for the '476 patent began in 2001, when all statutory conditions were satisfied. However, Warner-Lambert's '482 infringement suit precluded FDA from granting final approval of Purepac's ANDA, so Purepac's exclusivity period passed without Purepac having the opportunity to market the drug.

In April 2002, FDA notified Purepac that, because, in the agency's view, a section viii statement was not appropriate for the '479 patent, Purepac could not receive final approval of its ANDA before it filed a certification for the '479 patent. *See id.* at 199. Purepac filed suit in District Court challenging FDA's decision. Purepac also sought to enjoin FDA from approving

Apotex's ANDA for gabapentin, because of the adverse consequences of such approval for any exclusivity Purepac would have pursuant to its paragraph IV certification for the '482 patent. *See id.* at 211 & n.27. Apotex intervened as a defendant, arguing among other things that Purepac's claims were barred by the doctrine of laches. *See id.* at 201. Apotex did not present the first-filer interpretation of § 355(j)(5)(B)(iv). Because Purepac's paragraph IV certification for the '476 patent was the first paragraph IV certification submitted for any patent claiming gabapentin, the first-filer approach would not have promoted generic marketing exclusivity for the ANDAs relating to the '479 an '482 patents. Rather, an argument founded on the first-filer approach would have rested on the premise that *no* ANDA, save for the one related to the '476 patent, could serve as the basis for generic marketing exclusivity to the disadvantage of competing claims. Apotex did not raise this argument in the *Purepac I* litigation.

The District Court ruled in Purepac's favor on the section viii issue, ordering FDA to accept Purepac's section viii statement. *See Purepac I*, 238 F. Supp. 2d at 193. However, the court declined to enjoin FDA from approving Apotex's ANDA, stating that it was up to FDA to determine, in the first instance, the effect of the court's decision. *See id.* at 211-12.

In response to *Purepac I*, FDA sought comments from generic gabapentin applicants, including Apotex and Purepac. *See* Letter from OGD to Apotex of 12/18/02, J.A. 741; Letter from OGD to Purepac of 12/18/02, J.A. 896. Apotex submitted several letters, which argued that, notwithstanding *Purepac I*, Apotex was entitled to at least share in any exclusivity period with Purepac, because Apotex was the first to file a paragraph IV certification for the '479 patent. In addition, the letters asserted that Apotex was the first company to submit a valid paragraph IV certification for the '482 patent. Once again, Apotex did not raise the first-filer approach to §

355(j)(5)(B)(iv). *See, e.g.*, Letter from Gilbert's to OGC of 1/7/03, J.A. 984; Letter from Gilbert's to OGC of 1/9/03, J.A. 1031.

On January 28, 2003, FDA issued a letter ruling addressing the dispute between Purepac and Apotex concerning generic marketing exclusivity for gabapentin. FDA sided with Purepac, ruling that Apotex was not entitled to any exclusivity based on its paragraph IV certification for the '479 patent, and that Purepac alone would be entitled to exclusivity based on the '482 patent. Letter from OGD to Apotex and Purepac of 1/28/03, J.A. 743, 744, 747-50.

Apotex challenged FDA's actions in District Court. Once again, Apotex failed to advance the first-filer interpretation of 21 U.S.C. § 355(j)(5)(B)(iv). Rather, Apotex argued for a patent-based interpretation of the statute, contending that Apotex was entitled to exclusivity based on its paragraph IV certification for the '482 patent, or that Apotex should at least be eligible for a period of shared exclusivity along with Purepac based on Apotex's submission of the first paragraph IV certification for the '479 patent. *See* Letter from OGD to TorPharm of 2/6/04, J.A. 802, 803 (quoting TorPharm's Memorandum in Support of its Motion for Preliminary Injunction (Feb. 14, 2003)). In April 2003, the District Court rejected Apotex's challenge, entering summary judgment in favor of FDA. *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 71 (D.D.C. 2003) ("*TorPharm*").

Apotex appealed the District Court's decisions in both *Purepac I* and *TorPharm*. Once again, Apotex failed to advance the first-filer interpretation of 21 U.S.C. § 355(j)(5)(B)(iv). This court consolidated the appeals and affirmed the District Court's rulings in all respects on January 20, 2004. *Purepac II*, 354 F.3d at 878-79.

Less than two weeks before this court's decision in *Purepac II*, District Court Judge Roberts issued a written order

memorializing an oral decision in a separate action filed by Apotex regarding generic marketing exclusivity for the drug paroxetine. *TorPharm, Inc. v. FDA*, No. Civ. A. 03-2401, 2004 WL 64064 (D.D.C. Jan. 8, 2004) ("*Paroxetine*"), *vacated as moot*, No. 04-5046 (D.C. Cir. Dec. 17, 2004). In *Paroxetine*, Judge Roberts ruled that the plain language of 21 U.S.C. § 355(j)(5)(B)(iv) compelled the first-filer as opposed to the patent-based interpretation of the statute. *See id.* Based on *Paroxetine*, Apotex submitted a letter to FDA requesting immediate approval of its gabapentin ANDA. For the first time, Apotex asserted that FDA was bound to follow the first-filer approach in awarding generic marketing exclusivity for gabapentin. As explained above, under the first-filer approach, Purepac's exclusivity for gabapentin stemmed solely from the '476 patent, and that exclusivity period had expired. *See* Letter from TorPharm to OGD of 1/15/04, J.A. 761, 762.

On February 6, 2004, FDA rejected Apotex's request. The agency concluded that Apotex had waived the argument as the company had not previously raised it before FDA, the District Court, or this court, despite having had the opportunity to do so in the previous litigation concerning gabapentin. In fact, FDA noted that Apotex had taken the opposite position – making exclusivity arguments premised on the patent-based reading of the statute. According to FDA, the doctrine of judicial estoppel barred Apotex from advancing these inconsistent positions. *See* Letter from OGD to TorPharm of 2/6/04, J.A. 802, 802-04. The agency also rejected Apotex's contention that collateral estoppel required that FDA adopt the first-filer approach in line with *Paroxetine*, and announced that it would continue to apply the patent-based approach in determining exclusivity for gabapentin ANDAs. *See id.*, J.A. 804.

Apotex challenged FDA's decision in District Court, and Purepac intervened as a defendant. Speaking through Judge Huvelle, the District Court ruled for the agency. *Apotex, Inc. v.*

FDA, No. Civ. A. 04-605 (D.D.C. June 3, 2004) (oral decision), *reprinted in* J.A. 8-34. The court held that Apotex's claims were barred by *res judicata*, and that collateral estoppel did not prevent FDA from implementing the patent-based approach to § 355(j)(5)(B)(iv) concerning gabapentin ANDAs. *See id.*, J.A. 32. Judge Huvelle also went on to consider the merits of the statutory interpretation question. Recognizing that she was not bound by Judge Roberts' *Paroxetine* decision, Judge Huvelle concluded that FDA's patent-based interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) was reasonable, and that the court would defer to it. *See id.*, J.A. 32-34. Apotex filed the present appeal.

II. ANALYSIS

A. *Standard of Review*

We review the District Court's grant of summary judgment *de novo*. *Cruz v. Am. Airlines, Inc.*, 356 F.3d 320, 328 (D.C. Cir. 2004). Because the material facts of this case are not in dispute, "our task is to ensure that the District Court correctly applied the relevant law to the undisputed facts." *Beckett v. Air Line Pilots Ass'n*, 995 F.2d 280, 284 (D.C. Cir. 1993).

B. *Res Judicata*

Also known as claim preclusion, the doctrine of *res judicata* holds that a judgment on the merits in a prior suit bars a second suit involving identical parties or their privies based on the same cause of action. *Drake v. FAA*, 291 F.3d 59, 66 (D.C. Cir. 2002). *Res judicata* plays a central role in advancing the "purpose for which civil courts have been established, the conclusive resolution of disputes within their jurisdictions." *Montana v. United States*, 440 U.S. 147, 153 (1979). As the Supreme Court has explained: "To preclude parties from contesting matters that they have had a full and fair opportunity to litigate protects their adversaries from the expense and vexation attending multiple lawsuits, conserves judicial

resources, and fosters reliance on judicial action by minimizing the possibility of inconsistent decisions." *Id.* at 153-54.

In this case, Apotex does not dispute that *TorPharm* was a judgment on the merits by a court of competent jurisdiction involving the identical parties. Rather, Apotex argues *res judicata* does not bar its suit because the cause of action here is not identical to the cause of action in *TorPharm*. Apotex's argument is unpersuasive.

"Whether two cases implicate the same cause of action turns on whether they share the same 'nucleus of facts.'" *Drake*, 291 F.3d at 66 (quoting *Page v. United States*, 729 F.2d 818, 820 (D.C. Cir. 1984)). In pursuing this inquiry, the court will consider "'whether the facts are related in time, space, origin, or motivation, whether they form a convenient trial unit, and whether their treatment as a unit conforms to the parties' expectations or business understanding or usage.'" *I.A.M. Nat'l Pension Fund v. Indus. Gear Mfg. Co.*, 723 F.2d 944, 949 n.5 (D.C. Cir. 1983) (quoting 1B J. MOORE, MOORE'S FEDERAL PRACTICE ¶ 0.410[1] (2d ed. 1983)).

Apotex maintains that the facts of this case are not related in time, space, origin, or motivation to those of *TorPharm* and that they would not form a convenient trial unit. But *TorPharm* and the case at bar each involve a dispute between Apotex and Purepac over generic marketing exclusivity and final ANDA approval for the drug gabapentin. Moreover, the relevant patents – and the companies' submissions relating to those patents – have not changed since Apotex filed suit in *TorPharm*. Thus, the underlying facts of the two cases are closely related in time, space, origin, and motivation, and they would have formed a convenient trial unit.

Apotex nonetheless insists that this case involves submissions relating to the '476 patent, whereas *TorPharm* involved submissions surrounding the '482 and '479 patents.

Apotex Br. at 53-55. This is not an accurate description of the two cases. Apotex chose not to present the first-filer interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) before the court in *TorPharm*. Apotex's argument in this case is that, *following the first-filer approach*, FDA has no authority under § 355(j)(5)(B)(iv) to award multiple 180-day periods of generic marketing exclusivity for the same drug. Apotex could have presented the same argument to challenge FDA's decision in *TorPharm*. Apotex chose not to do so. There are no new facts. Apotex is simply raising a new legal theory. This is precisely what is barred by *res judicata*. *See Drake*, 291 F.3d at 66 ("[U]nder *res judicata*, 'a final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or *could have been raised* in that action.'") (quoting *Allen v. McCurry*, 449 U.S. 90, 94 (1980)) (emphasis in original).

Apotex also argues that *res judicata* does not apply here, because Judge Roberts' decision in *Paroxetine* effected a significant change in circumstances after *TorPharm* had issued. *Res judicata* does not bar parties from bringing claims based on material facts that were not in existence when they brought the original suit. *Drake*, 291 F.3d at 66. And, in a small set of cases, a change in controlling legal principles may allow a party to relitigate a claim that would otherwise be barred by *res judicata*. *See Hardison v. Alexander*, 655 F.2d 1281, 1288-89 (D.C. Cir. 1981) (stating that in general *res judicata* applies even if there has been a subsequent change in the law of the circuit, but noting that there are exceptions for reasons of compelling public policy, such as cases involving important questions of constitutional law). Neither exception applies here.

It is true that Judge Roberts' opinion in *Paroxetine* embraced the legal theory that Apotex is advancing in this case, but this was not a "change" either in the facts or the law sufficient to overcome the effects of *res judicata*. The relevant

facts here involve the effect of paragraph IV certifications submitted by Purepac and TorPharm for the '476 and '482 patents. These certifications were submitted well before Apotex brought suit in *TorPharm*. Moreover, Judge Roberts' decision in *Paroxetine* is not a change in controlling legal principles. Judge Huvelle was not bound by Judge Roberts' decision, from which an appeal was pending, and neither Judge Roberts' nor Judge Huvelle's decision established the law of the circuit. *See In re Executive Office of the President*, 215 F.3d 20, 24 (D.C. Cir. 2000) ("District Court decisions do not establish the law of the circuit, nor, indeed, do they even establish the law of the district.") (citations and internal quotations omitted).

Apotex presents two additional arguments as to why *res judicata* should not apply in this case, neither of which have merit. First, Apotex argues that it would have been impracticable for Apotex to have presented the first-filer interpretation of 21 U.S.C. § 355(j)(5)(B)(iv) in *TorPharm*, because the company elected to argue that it was entitled to generic marketing exclusivity for gabapentin under the patent-based approach to the statute. This argument fails. It is true that *res judicata* does not prevent parties from later bringing claims that "would have been utterly impracticable to join" in an earlier suit. *United States Indus., Inc. v. Blake Constr. Co.*, 765 F.2d 195, 205 n.21 (D.C. Cir. 1985). But it would not have been "utterly impractical" for Apotex to raise the first-filer argument to advance its cause in *TorPharm*. Indeed, at oral argument, Apotex's counsel did not deny that Apotex could have presented the first-filer approach as an alternative argument in *TorPharm*. Recording of Oral Argument at 7:52-:59. Rather than seeking the advantage that flows from having *alternative* arguments, either of which in Apotex's view would have supported its claim in *TorPharm*, Apotex chose instead to argue solely in favor of the patent-based approach, which is diametrically opposed to the first-filer theory that Apotex advances in this case.

Second, Apotex claims that public policy considerations weigh against applying *res judicata* in this case. We disagree. There is no general public policy exception to the operation of *res judicata*. *See Federated Dep't Stores, Inc. v. Moitie*, 452 U.S. 394, 401 (1981) (rejecting the court of appeals' reliance on "simple justice" and "public policy" in declining to apply *res judicata*, and stating: "There is simply 'no principle of law or equity which sanctions the rejection by a federal court of the salutary principle of *res judicata*.'") (quoting *Heiser v. Woodruff*, 327 U.S. 726, 733 (1946)). If there is any "public policy" exception to *res judicata*, it applies only in very limited circumstances, *e.g.*, in cases implicating significant questions of constitutional law where there has been a change in controlling legal principles. *See Hardison*, 655 F.2d at 1288-89.

The only argument Apotex offered in its opening brief as to why this case might fit within the scope of a public policy exception to *res judicata* is that, absent a favorable ruling from this court, FDA will continue to apply the 180-day generic marketing exclusivity provision under § 355(j)(5)(B)(iv) in a way that defies congressional intent. Obviously, this argument does not save Apotex from the *res judicata* bar in this case. The statutory question raised by Apotex is no doubt compelling. But its resolution must await another day, *i.e.*, when a suit is properly before the court calling into question FDA's interpretation of 21 U.S.C. § 355(j)(5)(B)(iv).

Finally, because we affirm the District Court's judgment on *res judicata* grounds, we vacate the District Court's alternative holding addressing the merits of the statutory interpretation question.

III. CONCLUSION

Res judicata bars Apotex from bringing this suit. Therefore, we affirm the judgment of the District Court on this ground alone. We vacate the District Court's alternative holding

purporting to resolve the parties' dispute over the interpretation of 21 U.S.C. § 355(j)(5)(B)(iv).

So ordered.