United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued November 25, 2003 Decided January 20, 2004

No. 02-5410

PUREPAC PHARMACEUTICAL COMPANY,
APPELLEE

v.

TOMMY G. THOMPSON,
SECRETARY OF HEALTH AND HUMAN SERVICES, AND
LESTER M. CRAWFORD JR., DEPUTY COMMISSIONER OF
FOOD AND DRUGS,
APPELLEES

TORPHARM, INC. AND APOTEX, INC.,
APPELLANTS

Consolidated with
03-5121

Appeals from the United States District Court
for the District of Columbia
(No. 02cv01657)
(No. 03cv00254)

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

William A. Rakoczy argued the cause for appellants. With him on the briefs were *Hugh S. Balsam* and *Arthur Y. Tsien*. *Hugh L. Moore*, *Jacqueline H. Eagle*, and *Matthew O. Brady* entered appearances.

Andrew E. Clark, Attorney, U.S. Department of Justice, argued the cause for the federal appellees. With him on the brief were *Peter D. Keisler*, Assistant Attorney General; *Eugene M. Thirolf*, Director; *Alex M. Azar II*, General Counsel, U.S. Department of Health & Human Services; *Daniel E. Troy*, Chief Counsel; and *Karen E. Schifter*, Associate Chief Counsel. *Christine N. Kohl*, Attorney, U.S. Department of Justice; *Douglas N. Letter*, Litigation Counsel; and *Howard S. Scher*, Attorney, entered appearances.

Charles J. Raubicheck argued the cause for appellee Purepac Pharmaceutical Company. With him on the brief was *Steven M. Amundson*. *James M. Webster*, *Mark C. Hansen*, and *Richard H. Stern* entered appearances.

Before: GINSBURG, *Chief Judge*, and EDWARDS and TATEL, *Circuit Judges*.

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

TATEL, *Circuit Judge*: To encourage the marketing of low-cost generic drugs, the 1984 Hatch-Waxman amendments to the Food, Drug, and Cosmetic Act grant companies that successfully challenge drug patents the right to sell their generic drugs without competition for 180 days. In this case, two companies, each seeking to market a generic drug, competed for the right to exclusivity. The Food and Drug Administration ruled that neither company could earn exclusivity by challenging the first of two patents, but it awarded exclusivity to one of the companies based on that company's challenge to the second patent. The district court rejected challenges to these two decisions, and the company denied exclusivity now appeals. Finding no error in the district court's two thorough and well-reasoned opinions, we affirm in all respects.

I.

The Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–99 (FDCA), provides that a company wishing to market a new brand-name drug must submit a New Drug Application, known as an NDA, to the Food and Drug Administration. *See id.* § 355(b)(1) (2000 & Supp. III 2003). Usually quite lengthy, NDAs must include, among other things, evidence of the drugs' safety and effectiveness, as well as information about patents that cover or might cover the drugs. *Id.*

In 1984, Congress passed the "Hatch-Waxman" amendments to the FDCA. *See* The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984) (codified in scattered sections of titles 21, 35, and 42 U.S.C.). Enacted to expedite the process by which companies gain approval to sell generic versions of already-approved brand-name drugs, the amendments allow companies seeking such approval to submit Abbreviated New Drug Applications, known as ANDAs, that "piggyback" on the safety-and-effectiveness information that the brand-name manufacturers submitted in their NDAs. *See* 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94(a)(3) (2003). "The result [is] to make practical the manufacture of generic copies which theretofore had been uneconomical." *Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988).

Like NDAs, ANDAs must address patents that cover or might cover the relevant drugs. For each patent, companies can satisfy this requirement by including in their ANDAs one of several "certifications" that explain why the FDA should approve the application despite the patent's claim on the drug. 21 U.S.C. § 355(j)(2)(A)(vii). The certification at issue in this case—a "paragraph IV certification," named for the subsection of the law that describes it—states "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug." *Id.* § 355(j)(2)(A)(vii)(IV). In

essence, applicants use paragraph IV certifications to challenge the validity of brand-name manufacturers' patents.

An applicant that includes one or more paragraph IV certifications in its ANDA must inform both the patent holder and the company that submitted the NDA on which the ANDA "piggybacks." *Id.* § 355(j)(2)(B)(i). Once an applicant gives notice, the FDA must wait forty-five days before approving the ANDA, thereby giving the patent holder that much time to file a patent-infringement suit. *Id.* § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2). If the patent holder sues, the FDA must wait thirty months from the notice date before approving the ANDA unless the applicant wins the suit sooner or the court hearing the suit shortens the thirty-month period. 21 U.S.C. § 355(j)(5)(B)(iii).

In order to encourage paragraph IV challenges, thereby increasing the availability of low-cost generic drugs, the FDCA provides that the first company to win FDA approval of an ANDA containing a paragraph IV certification has the right to sell its drug without competition for 180 days. *Id.* § 355(j)(5)(B)(iv). The statute and the implementing regulation create this exclusivity period by prohibiting the FDA from approving any other ANDA that contains a paragraph IV challenge to the same patent until 180 days after the first company markets its drug or 180 days after the first company wins a patent-infringement suit involving that patent, whichever comes first. *Id.*; 21 C.F.R. § 314.107(c)(1).

Paragraph IV certifications are not the only way for ANDA applicants to satisfy their obligation to address all relevant patents. Applicants can instead submit one or more "section viii statements," named, again, after the relevant FDCA subsection—section 505(j)(2)(A)(viii). A section viii statement indicates that a patent poses no bar to approval of an ANDA because the applicant seeks to market the drug for a use other than the one encompassed by the patent. *See* 21 U.S.C. § 355(j)(2)(A)(viii). For example, if a brand-name manufacturer's patent covers a drug's use for treating depression, and the ANDA applicant seeks approval to use the drug to treat any other condition, then a section viii statement would be

appropriate. Thus, whereas applicants use paragraph IV certifications to challenge the validity of admittedly applicable patents, they use section viii statements to assert that patents do not apply. The FDA has long required that for every patent ANDA applicants use either a paragraph IV certification or a section viii statement—they may not use both. As the FDA puts it, "either the applicant is seeking approval for the use claimed in the patent, or it is not." *TorPharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 77 (D.D.C. 2003) (quoting the record in that case) (internal quotation marks omitted).

Paragraph IV certifications and section viii statements have quite different consequences. Applicants submitting section viii statements have no obligation to provide notice, nor must they wait thirty months for FDA approval. As the district court explained, "the FDA may [thus] approve a section viii application immediately, making it an attractive route for generic manufacturers, even though a section viii statement does not entitle a successful applicant to the 180–day period of exclusivity bestowed on paragraph IV applicants." *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 195 (D.D.C. 2002).

In order to determine what patents cover existing brand-name drugs and hence whether any paragraph IV certifications or section viii statements are needed, applicants look in the "Orange Book," an FDA publication that includes all patent information that companies have submitted to the agency. "Method-of-use patents"—which cover specific uses for drugs—can be included in the Orange Book only if they cover drug uses that the FDA has approved. 21 C.F.R. § 314.53(b). In other words, companies cannot use the Orange Book to claim protection for uses that the FDA has not approved. The FDA, however, does not evaluate patent information that companies submit to it; it just passively publishes information it receives. This means that if one company submits patent information that a second company believes is false or violates the FDA's regulation prohibiting the listing of unapproved-use patents, the second company—after having the FDA verify the information's accuracy with the first company—must go to court to resolve the dispute.

Meanwhile, the second company must, if it submits an ANDA, treat the disputed patent as valid. In other words, it must include in its ANDA either a paragraph IV certification or a section viii statement.

This case involves gabapentin, a drug sold by Pfizer, Inc. that the FDA has approved for treating epilepsy. In 1998, appellee Purepac Pharmaceutical Company submitted an ANDA seeking permission to sell a generic version of Pfizer's brand-name drug, Neurontin. Purepac's ANDA listed three patents that Warner-Lambert Company, which later assigned Pfizer the rights to the drug, had included in its gabapentin NDA. One of the three—the only one relevant to this case—was No. 5,084,479 (the '479 patent), a method-of-use patent. Seeking to sell its drug as a treatment for epilepsy, Purepac submitted a section viii statement about this patent because as it read the Orange Book, the patent covered gabapentin's unapproved use for treating neurodegenerative diseases. That is, Purepac asserted that the '479 patent posed no bar to FDA approval of its ANDA because the patent covered a use other than the one for which Purepac sought permission. Given that under FDA regulations, only approved-use method-of-use patents may be listed in the Orange Book, Purepac's interpretation of the '479 patent would, if true, have meant that the patent's inclusion in the Orange Book was improper.

About a month after Purepac submitted its ANDA, appellant TorPharm, Inc. filed its own ANDA, similarly seeking permission to market a generic version of Neurontin. Unlike Purepac, TorPharm submitted both a paragraph IV certification and a section viii statement regarding the '479 patent. By doing so, TorPharm effectively hedged its bets on whether the information that Warner-Lambert had submitted to the FDA showed that the patent covered gabapentin's use for treating epilepsy or for treating neurodegenerative diseases. TorPharm's notice to Warner-Lambert, however, indicated that TorPharm agreed with Purepac's interpretation of what use the '479 patent covered: the notice stated that TorPharm's generic drug posed no danger of infringement because "[a]ll of the claims of the '479 patent are directed to a method of using gabapentin and its derivatives in the treat-

ment of neurodegenerative diseases." *Warner-Lambert Co. v. Apotex Co.*, No. 98 C 4293, 2001 WL 1104618, at *2 (N.D. Ill. Sept. 14, 2001) (quoting the record in that case) (internal quotation marks omitted).

The FDA initially informed Purepac that because Warner-Lambert claimed that the '479 patent covered gabapentin's use for treating epilepsy, Purepac should have filed a paragraph IV certification. Purepac protested that this represented a reversal by the FDA, pointing out that when the agency first listed the patent in the Orange Book, the concomitant "use code"—the code the FDA assigns to identify the use that a patent covers—bore the title "treatment of neurodegenerative diseases." By contrast, the use code that the FDA gave to another of the patents that Warner-Lambert had mentioned in its NDA was entitled "epilepsy." Since the FDA acknowledges that "in assigning use codes it relies exclusively on the NDA holder's statements regarding a patent's coverage," *Purepac*, 238 F. Supp. 2d at 198 n.10, Purepac argued that the FDA's choice of use code indicated that the agency had previously decided that according to Warner-Lambert, the '479 patent covered gabapentin's use for treating neurodegenerative diseases rather than epilepsy. According to Purepac, it therefore needed to file a section viii statement.

Unconvinced, the FDA informed Purepac that the company would have to add a paragraph IV certification before its ANDA could be approved. Purepac did not follow this instruction. Instead, perhaps recognizing that complying with the FDA's demand would mean that TorPharm would receive the 180–day exclusivity as the first company to submit an approvable ANDA containing all necessary paragraph IV certifications, Purepac sued the FDA in the United States District Court for the District of Columbia, arguing that the FDA's rejection of its section viii statement and the agency's insistence that the company submit a paragraph IV certification were arbitrary and capricious.

The district court, through Judge Huvelle, ruled for Purepac, holding that the FDA should have concluded on the basis

of the evidence before it that the '479 patent covered gabapentin's use for treating neurodegenerative diseases. Because Purepac sought approval for a different use, the district court directed the FDA to accept the company's section viii statement. *See Purepac*, 238 F. Supp. 2d at 212. The court's ruling did not entitle Purepac to exclusivity, however, as only paragraph IV certifications can earn exclusivity. It simply required the FDA to accept Purepac's ANDA as of the date the company originally submitted it, which occurred before TorPharm filed its ANDA. That was important because both Purepac's and TorPharm's ANDAs contained paragraph IV challenges to other patents, and whichever company first submitted its ANDA would be eligible for exclusivity based on those other challenges.

Although the district court required the FDA to accept Purepac's section viii statement, it declined to decide what the agency should do about TorPharm's paragraph IV certification. Noting that the FDA had long insisted that paragraph IV certifications and section viii statements were mutually exclusive, the court observed that the agency "has not taken a definitive position as to whether equitable considerations might ultimately persuade it to . . . approve TorPharm's application with a paragraph IV certification to the '479 patent even if the Court were to direct the agency to accept Purepac's application with a section viii statement." *Id.* at 211. This question was critical, for if the FDA allowed TorPharm to submit a paragraph IV certification, then TorPharm would be entitled to exclusivity as the first applicant to win FDA approval for an ANDA containing a paragraph IV challenge to the '479 patent. The district court decided to allow the FDA to address that issue on remand. The FDA did not appeal.

On remand, the FDA stood by its position that paragraph IV certifications and section viii statements are mutually exclusive, ruling TorPharm's paragraph IV certification as to the '479 patent improper. At approximately the same time, the FDA asked Pfizer to consent to the removal of the patent from the Orange Book, pointing out that the patent claimed protection for a use that the agency had yet to approve.

When Pfizer consented, the FDA removed the patent from the Orange Book. As a consequence, neither TorPharm nor any other company that had submitted a gabapentin-related application had any obligation to address the '479 patent in its ANDA. In fact, the FDA instructed all applicants to amend their ANDAs by removing any section viii statements or paragraph IV certifications about the patent. This meant that no company would enjoy the 180–day exclusivity period based on the '479 patent because no company could submit a proper paragraph IV certification regarding it.

TorPharm then sued the FDA, challenging the removal of the patent from the Orange Book and the agency's refusal to accept the company's paragraph IV certification. Again speaking through Judge Huvelle, the district court rejected TorPharm's claim, concluding "that the FDA acted reasonably in not departing from its well-settled rule that a section viii statement and paragraph IV certification cannot be filed as to the same patent, [and that] the agency's corresponding conclusion that no applicant was entitled to exclusivity on the '479 patent must be upheld." *TorPharm*, 260 F. Supp. 2d at 85.

In its decision, the district court also addressed the FDA's ruling about the other gabapentin-related patent at issue in this case, No. 6,054,482 (the '482 patent). Whereas the '479 patent is a method-of-use patent, the '482 patent is a "drug-product" patent, covering the drug's overall composition and formulation. Warner-Lambert first submitted information about the '482 patent to the FDA after TorPharm and Purepac filed their ANDAs, at which point both companies amended their ANDAs by adding paragraph IV challenges to the '482 patent. Although the FDCA requires applicants to provide notice "when" they file their amended ANDAs, 21 U.S.C. § 355(j)(2)(B)(iii), and although the implementing regulation requires notice "at the same time" as filing, 21 C.F.R. § 314.95(d), Purepac did not send notice to Warner-Lambert about its paragraph IV certification until June 13, 2000, some two-and-a-half weeks after the FDA received, and deemed filed, Purepac's amended ANDA on May 26. TorPharm also sent its notice to Warner-Lambert on June 13, the same day

it mailed its amended ANDA to the FDA. The FDA, however, deemed TorPharm's ANDA to have been filed on June 16, the day it received the ANDA. This meant that Purepac, despite the lag between its filing with the FDA on May 26 and its notice to Warner-Lambert on June 13, completed both tasks first. The FDA thus awarded the 180–day exclusivity period to Purepac.

In the district court, TorPharm argued that the FDA's award of exclusivity to Purepac effectively eliminated the statutory and regulatory requirements of simultaneous notice. The district court disagreed, concluding that neither the statute nor the regulation specify the penalty for failing to notify immediately and ruling that the FDA had reasonably filled that gap by stating that if a company waits to provide notice, it runs the risk that another company will both file and provide notice first, thereby winning exclusivity. *TorPharm*, 260 F. Supp. 2d at 79–81. The district court also rejected TorPharm's challenge to the FDA's decision to use a date-of-receipt rule rather than a mailbox rule, seeing nothing arbitrary or capricious in the agency's choice. *See id.* at 81–82.

Appealing both district court decisions, TorPharm argues that the court erred by (1) reversing the FDA's determination about the claimed scope of the '479 patent (*Purepac*), (2) upholding the FDA's decision to "delist" the '479 patent and deny exclusivity based on that patent (*TorPharm*), and (3) sustaining the FDA's award of exclusivity to Purepac based on Purepac's challenge to the '482 patent (also *TorPharm*). "Because the district court entered a summary judgment, we review its decision de novo and therefore, in effect, review directly the decision of the [agency]." *Lozowski v. Mineta*, 292 F.3d 840, 845 (D.C. Cir. 2002). We will set aside an FDA decision only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) (2000). FDA interpretations of the FDCA receive deference, *Serono Labs, Inc. v. Shalala*, 158 F.3d 1313, 1319 (D.C. Cir. 1998), as do its interpretations of its own regulations, *id.* at 1320.

II.

We start our analysis with the district court's *Purepac* decision. In that case the court had to answer the following question: According to the information that Warner-Lambert submitted to the FDA, what use of gabapentin did the '479 patent cover? In other words, setting aside the question of what use the patent *actually* covered—a question the FDA leaves to the courts—what use did Warner-Lambert *say* the patent covered? As noted, the FDA told Purepac that according to Warner-Lambert the patent covered gabapentin's use for treating epilepsy. This meant that Purepac, like TorPharm, had to include a paragraph IV challenge to the patent in its ANDA. It also meant that TorPharm, as the first to have submitted a paragraph IV challenge to the patent, would be eligible to earn exclusivity.

We agree with the district court that the FDA's conclusion about the claimed coverage of the '479 patent was arbitrary and capricious. In the Orange Book, the FDA assigned the patent a use code corresponding to neurodegenerative diseases. Having thus concluded that Warner-Lambert asserted that the patent covered gabapentin's use for treating such diseases, the FDA, when evaluating Purepac's and TorPharm's ANDAs, could not change course and decide that Warner-Lambert claimed that the patent covered the drug's use for treating epilepsy. Yet in rejecting Purepac's section viii statement, the FDA did just that. Because this unexplained reversal represents the height of arbitrary and capricious decision making, the district court rightly disallowed it. As we have said, "[w]hile the scope of review under the arbitrary and capricious standard is narrow and a court is not to substitute its judgment for that of the agency, neither may a court sanction agency action when the agency . . . fails to justify seeming inconsistencies in its approach." *Prof'l Pilots Fed'n v. FAA*, 118 F.3d 758, 771 (D.C. Cir. 1997) (internal quotation marks omitted).

TorPharm argues that the FDA's choice of use code has no relevance because "use codes are not required by statute . . . [or] by the controlling regulation." Appellant's Reply Br. at 5

(internal quotation marks omitted). This misses the point. That use codes are not required by statute has nothing whatsoever to do with the fact that the FDA has given no reason for making one decision for purposes of selecting a use code and a different decision for purposes of determining whether ANDA applicants had to submit paragraph IV certifications or section viii statements.

In fact, the FDA's action was doubly flawed. Not only did the agency make inconsistent decisions, but evidence before the FDA did not support its conclusion that Warner-Lambert claimed that the '479 patent covered gabapentin's use for treating epilepsy. As the district court pointed out, Warner-Lambert repeatedly told the FDA that the patent "covers a method for treating neurodegenerative diseases with gabapentin." At no time did Warner-Lambert tell the FDA that the patent covered a method of treating epilepsy. As the district court aptly put it, "[t]he agency . . . tried to construct a legal fiction about the scope of the '479 patent and to use that construct to ignore crucial facts (i.e. what Warner-Lambert actually said) about that patent's reach, facts that reveal the ultimate falsity of the agency's fiction." *Purepac*, 238 F. Supp. 2d at 208.

TorPharm points out that in each of the documents in which Warner-Lambert stated that the patent covered neurodegenerative diseases, the company also said that the patent covered "the use" of Neurontin. According to TorPharm, because Neurontin has only one approved use—the treatment of epilepsy—and because FDA regulations permit listing approved uses only, the phrase "the use" must have referred to the approved use, epilepsy. But as the district court explained, the fact that an FDA regulation allows the listing of only approved-use method-of-use patents does not prove that every method-of-use patent in the Orange Book actually covers an approved use. The reason is obvious: the FDA does not evaluate information that applicants submit about patents, but simply accepts that information passively. Thus, we have no reason to believe that because applicants are *supposed* to submit information about approved uses only, they *in fact* do so. Such a benign view, the district court concluded, "represents the triumph of hope over reality." *Id.*

Here, moreover, Warner-Lambert's repeated claims that the patent covered neurodegenerative diseases gave the FDA ample reason to suspect that the company had chosen to ignore the regulations. The FDA's "decision [wa]s thus factually unsupportable and irreconcilable with the language and intent of the FDCA. For these reasons, it violate[d] the APA." *Id.* at 212.

TorPharm also calls our attention to a letter that Pfizer sent to the FDA "confirm[ing] that the '479 patent was properly listed in the Orange Book." Appellant's Reply at 4 (citing the record). But Pfizer did not say that the patent belonged in the Orange Book because it covered the only approved use of gabapentin. Rather, Pfizer stated that the patent belonged in the Orange Book because in the company's opinion, the FDA regulation limiting the Orange Book to approved uses violated the FDCA. Undermining TorPharm's position, moreover, the letter includes the following statement: "Pfizer agrees that the '479 patent does not claim methods of use for which Neurontin has been approved. Pfizer reconfirms that neither Pfizer nor Warner-Lambert ever represented to FDA that the '479 patent claimed an approved use."

In essence, then, TorPharm argues that the FDA rightly ignored Warner-Lambert's repeated explicit assertions about neurodegenerative diseases in favor of oblique references to "the use" and other unhelpful statements. Perhaps recognizing the weakness of this position, TorPharm asserts that Warner-Lambert's express statements "were not required by statute or any FDA regulation and therefore had no regulatory significance." Appellant's Br. at 25. This argument is no more convincing than the company's similar claim regarding use codes. Obligated like any agency to base its decisions on the entire record, *see Achernar Broad. Co. v. FCC*, 62 F.3d 1441, 1446 (D.C. Cir. 1995) ("Failure to weigh the entire record would constitute reversible error. . . ."), the FDA may not ignore some evidence before it just because an entity submitted that evidence despite the absence of a legal requirement to do so.

In sum, we agree with the district court that "the FDA's determination that the '479 patent claims the use of treating epilepsy 'runs counter to the evidence before the agency,' and is thus arbitrary and capricious." *Purepac*, 238 F. Supp. 2d at 210 (quoting *Sinclair Broad. Group, Inc. v. FCC*, 284 F.3d 148, 159 (D.C. Cir. 2002)). According to TorPharm, this conclusion contravenes the FDA's longstanding policy under which it refuses to determine independently what use a patent covers and instead accepts at face value the use claimed by the patent holder. But the district court did not decide that the FDA should have scrutinized the claimed use, nor did it address what the patent actually covered. The court simply deemed the FDA's conclusion regarding what Warner-Lambert claimed about the patent to be unjustified. Under the district court's analysis, what use the patent actually covered had no relevance, and properly so.

Having considered TorPharm's other challenges to *Purepac* and finding them without merit, we will affirm the judgment of the district court.

III.

We next consider the district court's rulings about the '479 patent in *TorPharm*. In that case, the court reviewed the FDA's post-*Purepac* decision against making an exception to its longstanding rule that for every patent only one of two approaches—a section viii statement or a paragraph IV certification—is appropriate. Although the FDA had indicated in *Purepac* that on remand it would consider granting an exception to this rule by accepting TorPharm's paragraph IV certification, the agency ultimately decided against such an exception, deeming the certification improper. The district court found this decision neither arbitrary nor capricious, explaining that the refusal "to make an equitable exception from this rule was within the FDA's discretion, and TorPharm has pointed to nothing in the statute or regulations to cast doubt on the rule itself." *TorPharm*, 260 F. Supp. 2d at 84. Recognizing the narrow scope of review, the district court concluded that the FDA's rule deserved judicial defer-

ence "in the absence of some indication that it conflicts with any of the constraints on the agency's regulatory authority, is inconsistent with the agency's own prior pronouncements, or is otherwise poorly reasoned or unpersuasive. There are no such indications here." *Id.* (citation omitted). TorPharm gives us no basis for questioning the district court's sound reasoning.

This, however, does not end our task, for the FDA did more than simply deny TorPharm an exception to the agency's rule. With Pfizer's consent, it also removed the '479 patent from the Orange Book. At that time, TorPharm was defending against an infringement lawsuit that Warner-Lambert had filed against it in response to its paragraph IV challenge to the '479 patent. Before delisting the patent, therefore, the FDA had to determine, as required by its regulation, whether to delay such action because TorPharm had the potential to earn exclusivity by prevailing in the already-initiated lawsuit. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B) ("A patent that is the subject of a lawsuit [charging infringement] shall not be removed from the list until FDA determines . . . that no delay in effective dates of approval [of other ANDAs] is required . . . as a result of the lawsuit. . . .").

The FDA concluded that the regulation posed no bar to the delisting. The district court's opinion in *Purepac* combined with Pfizer's post-*Purepac* letter to the FDA stating that "at all times, Warner-Lambert and Pfizer made clear to FDA that the '479 patent claimed the use of gabapentin (Neurontin) for treating neurodegenerative diseases," convinced the agency that it had erred in believing that Warner-Lambert claimed that the '479 patent covered epilepsy. The FDA thus decided that it should never have listed the patent in the Orange Book and that no ANDA applicant had to submit, or could maintain, either a section viii statement or a paragraph IV certification regarding that patent. This meant that even if TorPharm won its infringement lawsuit, it would not be entitled to exclusivity. The FDA therefore decided that its regulation did not prevent it from delisting the patent.

Attacking this conclusion, TorPharm focuses on the fact that the FDA, in explaining its view that it had to remove the patent from the Orange Book, cited not only *Purepac* and Pfizer's letter, but also the Federal Circuit's decision in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), the suit that Warner-Lambert filed against TorPharm. The Federal Circuit held that because the '479 patent covered gabapentin's use for treating neurodegenerative diseases—a fact the two parties agreed about—Warner-Lambert could not win an infringement suit against TorPharm, which sought to sell its drug as a treatment for epilepsy. *See id.* at 1362 ("Because [TorPharm] is not submitting an application to sell a drug for treatment of neurodegenerative diseases, *which is the only use covered by the patent involved in this case*, we conclude that [TorPharm] is entitled to summary judgment of noninfringement." (emphasis added)). According to TorPharm, the FDA's use of Warner-Lambert's failed infringement lawsuit as a basis for delisting the '479 patent—and, more important, for denying exclusivity—had the effect of eviscerating the incentive structure established by the FDCA. Pointing out that the Act created the exclusivity period precisely to encourage companies to have infringement lawsuits brought against them, TorPharm argues that it is absurd to tell a company which won such a lawsuit that because its victory established the challenged patent's invalidity and hence that the patent never needed to be challenged, the company was entitled to no exclusivity.

The district court agreed, deeming the FDA's reliance on the Federal Circuit's decision "problematic." *TorPharm*, 260 F. Supp. 2d at 83 n.15. According to the court, however, the other two bases on which the FDA rested its conclusion—the court's ruling in *Purepac* and Pfizer's letter to the FDA confirming that "neither Pfizer nor Warner-Lambert ever represented to FDA that the '479 patent claimed an approved use"—were enough to support that conclusion. Because these other bases eliminated or greatly ameliorated the danger of upsetting the FDCA's incentive structure, the district court concluded, the FDA properly delisted the patent. *See id.* at 83–84.

Disagreeing with the district court, TorPharm argues that reliance on either *Purepac* or Pfizer's letter to the FDA would still risk undermining the FDCA's incentive structure because both were tainted by Warner-Lambert's lawsuit against TorPharm. Although acknowledging, as it must, that *Purepac* and the letter predated the Federal Circuit's decision, TorPharm points out that they did not predate the Illinois district court decision that the Federal Circuit affirmed. In that decision, the district court noted that the '479 patent covered gabapentin's use for treating neurodegenerative diseases. *See Warner-Lambert Co.*, 2001 WL 1104618, at *1. TorPharm insists that both *Purepac* and Pfizer's letter were influenced by that ruling, after which the district court here "had no choice but to conclude that the '479 patent claims an unapproved use." Appellant's Reply at 16.

TorPharm misreads the *TorPharm* decision. The district court in that case did not conclude that the '479 patent claimed an unapproved use. Rather, the court found that given the evidence the FDA had before it at the time it made its decision, it was arbitrary and capricious for the agency to have found that Warner-Lambert claimed the '479 patent covered gabapentin's use for treating epilepsy. Nothing in the Illinois district court's decision compelled that holding; rather, the evidence before the FDA and the agency's earlier choice of use code compelled it. Had the evidence before the FDA been different, or had the agency not given the patent a use code corresponding to neurodegenerative diseases, it would have been entirely possible for the district court here to sustain the FDA's initial decision despite the Illinois district court's ruling. Put another way, the two district courts answered different questions: the Illinois district court considered whether Warner-Lambert could win an infringement lawsuit against TorPharm given that the '479 patent covered neurodegenerative diseases and given that TorPharm wanted to sell an epilepsy drug, while the district court here considered whether the FDA's conclusion about what Warner-Lambert claimed the '479 patent covered ran counter to the evidence before the agency.

TorPharm also contends that the FDA could not rely on *Purepac* because the case was wrongly decided. This makes no sense. Not only did the FDA have no authority to ignore *Purepac*, but as we have explained, the decision is unassailable. *See supra* pages 11–14. Because *Purepac* provided an adequate basis for the FDA's post-remand decision to delist the '479 patent, the agency's reference to the Federal Circuit's ruling, as the district court concluded, did not fatally undermine its decision.

TorPharm's view of this issue—and, to a certain extent, of this entire case—rests on its belief that "TorPharm played by the rules, [while] Purepac didn't." Appellant's Br. at 21. It "played by the rules," it says, because it filed a paragraph IV certification about the '479 patent, thereby inviting an infringement lawsuit, whereas Purepac filed a section viii statement and then sued the FDA when the agency rejected that statement. But no "rules" required Purepac (or anyone else) to accept everything the FDA did, regardless of the lawfulness of the agency's actions. Put simply, Purepac acted quite properly: it (1) interpreted the '479 patent as covering neurodegenerative diseases, as has every court to have looked at the issue, the patent holder, and (eventually) the FDA; (2) accordingly filed a section viii statement; and (3) refused to accept the FDA's unlawful rejection of that statement, a refusal that subsequent events have vindicated. The fact that TorPharm chose a different—and ultimately unsuccessful—legal strategy means neither that Purepac flouted the rules nor that TorPharm deserved exclusivity. Indeed, one might well think that the equities, which TorPharm frequently invokes, actually favor Purepac, the party that pursued the correct legal strategy even though that strategy required it to take on the heavy burden of charging the FDA with arbitrary and capricious behavior.

For its final argument, TorPharm claims that the FDA's actions following the *Purepac* remand reveal an inconsistency with the agency's actions regarding the drug mirtazapine. Having nothing to add to the district court's sound reasons for rejecting this argument, *see TorPharm*, 260 F. Supp. 2d at 85–86, we will affirm.

IV.

This brings us finally to the '482 patent. Recall that the FDA awarded exclusivity to Purepac even though Purepac delayed sending notice to Warner-Lambert until June 13, 2000, eighteen days after the FDA received Purepac's paragraph IV certification, whereas TorPharm mailed both its certification to the FDA and its notice to Warner-Lambert on the same day—June 13, 2000—the day Purepac finally sent notice. TorPharm argues that the district court improperly sustained this award of exclusivity. It also contends that the court erroneously upheld the FDA's decision to use a receipt date rather than a mailing date in deciding when TorPharm had submitted its amended ANDA.

As to the first argument, TorPharm insists that the FDA should have declared that Purepac's delay in providing notice rendered the company's certification invalid. Had the FDA done so, TorPharm would have been entitled to exclusivity, as it would have been the first applicant to have submitted an ANDA containing a valid certification. Instead, the FDA ruled that if an applicant fails to provide notice at the same time that it files its amended ANDA, the certification becomes effective only when the applicant ultimately provides notice, rather than when the applicant files its amended ANDA. Under this rule, applicants who do not immediately give notice run the risk that another company will file a certification and provide notice first, thereby winning the right to exclusivity. By failing to give immediate notice, moreover, such applicants delay FDA approval of their ANDAs, meaning that they must wait longer before they can market their drugs. According to TorPharm, the FDA's decision to impose this penalty, instead of declaring Purepac's certification invalid for exclusivity purposes, effectively reads the requirement of simultaneous notice and filing out of both the statute and the regulation. We disagree.

As the district court pointed out, the statute (as well as the regulation, we note) "is in fact silent on the issue of what follows from an applicant's failure to follow the mandate of simultaneity." *TorPharm*, 260 F. Supp. 2d at 80. Put anoth-

er way, the FDA recognized that Congress could have added either of two equally plausible sentences to the statute: one would have said "failure to provide simultaneous notice shall render the paragraph IV certification invalid," while the other would have said "failure to provide simultaneous notice shall delay the certification's effective date until notice is provided." That TorPharm would have preferred the FDA to fill this gap by adopting the first approach hardly makes the agency's decision to adopt the second arbitrary or capricious. The district court correctly and appropriately noted this court's longstanding recognition that "the breadth of agency discretion is, if anything, at zenith when the action assailed relates primarily not to the issue of ascertaining whether conduct violates the statute, or regulations, but rather to the fashioning of policies, remedies and sanctions." *Niagara Mohawk Power Corp. v. Fed. Power Comm'n*, 379 F.2d 153, 159 (D.C. Cir. 1967), *quoted in TorPharm*, 260 F. Supp. 2d at 80.

TorPharm insists that the FDA's choice of sanction violates the FDCA because the statute links the simultaneity requirement to the award of exclusivity. "Certification, notice, and exclusivity . . . are all bound up together in the statutory scheme." Appellant's Reply at 22. Not so. Nothing in the statute says that applicants earn exclusivity by simultaneously filing and providing notice. In fact, the simultaneity requirement and the provisions regarding exclusivity appear in different provisions of the statute. The simultaneity requirement appears in FDCA section 505(j)(2), which lays out the required elements of an ANDA. *See* 21 U.S.C. § 355(j)(2)(B)(iii). The exclusivity provisions are in FDCA section 505(j)(5), which addresses FDA approval of ANDAs. *See id.* § 355(j)(5)(B)(iv). The district court thus properly concluded that the FDA's choice of penalty permissibly filled a statutory gap.

As to the second issue, TorPharm argues that the FDA's decision to use mailing dates rather than receipt dates is inconsistent with the agency's use of mailing dates for materials submitted to its Dockets Management Branch. The FDA persuasively points out, however, that "materials relating to

NDAs and ANDAs are submitted to the agency's Center for Drug Evaluation and Research . . . , and [these] have consistently been governed by the 'date of receipt' rule." FDA Br. at 30 n.7.

Equally without merit is TorPharm's assertion that the use of receipt dates is arbitrary and capricious. TorPharm, the district court noted, "points to nothing in the statute that precludes the FDA's date-of-receipt rule, or that mandates an alternative mailbox rule." *TorPharm*, 260 F. Supp. 2d at 81. Although it is true that "[n]either the statute nor the regulation—neither of which even mentions 'receipt' dates—requires" the FDA's approach, Appellant's Br. at 48 (citations omitted), that (again) misses the point. The question is whether either the statute or the regulation *precludes* the FDA's approach. Neither does. Each uses the verb "submitted," which the FDA reasonably interprets to mean "received" rather than "mailed." Moreover, the FDA's rationale for using receipt dates—to avoid ambiguity that might arise with mailing dates because of, for example, a conflict between the date on the ANDA itself and the date of the postmark—seems perfectly reasonable to us. We thus agree with the district court that TorPharm has offered no basis for overturning the FDA's reliance on receipt dates.

TorPharm argues that the FDA's use of receipt dates gave Purepac "an unfair advantage" and that upholding the agency's approach creates an incentive "to game the system by certifying first." *Id.* at 47. TorPharm is right about the incentive. An applicant that completes its amended ANDA before completing its notice—as often happens because certifications are simple one-page documents whereas notices are typically quite long—can avoid a lag in the effective date of its ANDA by sending the ANDA immediately rather than waiting until it completes the notice. By not waiting, the applicant increases the chance that the FDA will have received the ANDA (including the paragraph IV certification) when the applicant notifies, in which case the certification will become effective as soon as the applicant mails the notice. (The FDA relies on mailing dates for notices because applicants send their notices to the patent holder rather than to

the FDA.) If the applicant instead waits to send its ANDA until it completes its notice and can mail that as well, then the certification will only become effective a day or more later, when the FDA receives the ANDA in the mail. For this reason, the FDA's approach gives applicants an incentive to disregard the statutory and regulatory mandates to provide notice "when" and "at the same time" that they file their amended ANDAs.

Contrary to TorPharm's argument, however, the existence of this incentive does not mean that the FDA's approach is unlawful. As we explained, the FDA imposes a penalty on those who notify after they filed their amended ANDAs, i.e., certifications become effective only upon notification. *See supra* page 19. This penalty creates an incentive for companies to notify patent holders as soon as possible after filing their ANDAs. In other words, the FDA's penalty acts as a counterweight to the incentive that TorPharm describes, encouraging companies to file ANDAs and provide notice "at the same time." Given the scope of the FDA's discretion and the benefits that the agency's approach provides, any incentive to delay that companies might have despite this counterweight provides no basis for invalidating the FDA's approach.

As to the contention that the FDA's reliance on receipt date creates an "unfair advantage," TorPharm's counsel acknowledged at oral argument that the advantage existed only as between TorPharm and Purepac, and that with the FDA's approach now clarified, every company will have the same incentives and opportunities. Purepac's "advantage," which derived simply from the fact that the FDA agreed with Purepac's interpretation of the statute rather than with TorPharm's, hardly warrants setting aside the FDA's decision.

V.

The district court's judgments are affirmed in all respects.

So ordered.