United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 26, 1999 Decided July 20, 1999

No. 99-5022

Teva Pharmaceuticals, USA, Inc.,
Appellant

v.

United States Food and Drug Administration, et al.,
Appellees

Consolidated with
No. 99-5027

Appeals from the United States District Court
for the District of Columbia
(No. 99cv00067)

Geoffrey M. Levitt and James N. Czaban argued the cause for appellant. With them on the briefs was David M. Malone.

Robert A. Dormer, James R. Phelps and Douglas B. Farquhar were on the brief for appellant Purepac Pharmaceutical Company.

Andrew E. Clark, Attorney, U.S. Department of Justice, argued the cause for the federal appellees. With him on the brief were David W. Ogden, Acting Assistant Attorney General, Eugene Thirolf, Jr., Director, Office of Consumer Litigation, and Drake S. Cutini, Attorney.

James D. Miller argued the cause for intervenors-appellees TorPharm, a Division of Apotex, Inc., et al. With him on the brief were Eugene M. Pfeifer, Peter M. Todaro, Donald O. Beers and David E. Korn.

Before: Edwards, Chief Judge, Rogers, Circuit Judge and Buckley, Senior Circuit Judge.

Opinion for the Court filed by Circuit Judge Rogers.

Rogers, Circuit Judge: Teva Pharmaceuticals and Purepac Pharmaceutical Company appeal the denial of injunctive relief requiring the Food and Drug Administration ("FDA") to recognize the dismissal of a declaratory judgment complaint for patent infringement as a "court decision" under the Abbreviated New Drug Application ("ANDA") statute. See 21 U.S.C. s 355(j)(5)(B)(iv)(II) (Supp. III 1997). Appellants are "subsequent" ANDA applicants hoping to market ticlopidine tablets, a generic version of the name-brand drug "Ticlid," used to treat stroke victims.1 To meet the require-

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1 Purepac has joined in the argument presented in the brief filed by Teva, having been unsuccessful in a previous challenge to the FDA's interpretation of the ANDA statute in Purepac Pharmaceutical Co. v. Friedman, 162 F.3d 1201 (D.C. Cir. 1998). Purepac now seeks reversal of the district court's denial of injunctive relief and a remand for entry of an order directing the FDA to make all approved ANDAs for generic ticlopidine products, including Purepac's, effective as of February 10, 1999. Teva seeks a similar

ments of the ANDA statute, Teva sued the patent holder2 in the Central District of California in order to obtain a "court decision" that would start, or trigger, a 180-day period of market exclusivity for the first ANDA applicant, and thereafter allow appellants to market their generic drug. The California court dismissed the complaint for lack of subject-matter jurisdiction after finding, based on the patent holder's admission of non-infringement, that Teva lacked a reasonable apprehension of suit by the patent holder. The FDA nevertheless refused to recognize the dismissal as a triggering "court decision" under the ANDA statute. Because we conclude that the FDA's refusal was arbitrary and capricious inasmuch as the FDA has taken an inconsistent position in another case and failed to explain adequately the inconsistency, we reverse and remand the case to the district court to determine anew whether injunctive relief is appropriate.

I.

The statutory background is succinctly summarized as follows. In 1984, Congress amended the Food and Drug Act in order to expedite the approval of generic versions of name-brand drugs that already have FDA approval, thus making available more low-cost generic drugs. See Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, tit. I, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. s 355 (1994 & Supp. III 1997)); see also H.R. Rep. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N.

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remedy: reversal and remand, with the district court ordering the FDA to make Teva's ANDA effective as of February 10th.

2 Syntex (U.S.A.), Inc., the holder of Patent No. 4,591,592 (" '592 patent" or "patent") that covers a finished dosage formulation of a ticlopidine tablet, but not the active pharmaceutical ingredient ticlopidine hydrochloride, and Hoffmann-LaRoche Laboratories Inc., which markets ticlopidine tablets under the brand-name "Ticlid," are two of the intervenors. For ease of reference we refer to Syntex and Hoffmann-LaRoche collectively as "Syntex." Also intervening is TorPharm, which has identified itself as the first applicant to file its ANDA.

2647, 2647. Under the so-called Hatch-Waxman amendments, an abbreviated new drug application process allows applicants, upon meeting certain requirements, to proceed more quickly to the marketplace. The ANDA applicant must show that: (i) the use of the drug has been previously approved; (ii) the new drug contains the same active ingredient(s) as the previously approved drug, or document the differences; (iii) the new drug has the same route of administration, dosage form, and strength of the previously approved drug, or document the differences; (iv) the new drug is the bioequivalent or has the same therapeutic effect as the previously approved drug; (v) the new drug has the same labeling as the previously approved drug, or the differences are approved; and (vi) it has complied with other statutory requirements, which include providing a full list of articles used as components, a full statement of composition, samples of the drug, labeling specimens, and a description of manufacturing, processing, and packaging. See 21 U.S.C. s 355(j)(2).

To avoid the patent infringement problems inherent in such a statutory scheme, the ANDA applicant must provide the FDA with a certificate establishing that the marketing of the generic drug will not infringe the patent for the listed drug. To this end, the applicant must certify that: (I) the patent information has not been filed, (II) the patent has expired, (III) the patent will expire on a specified date, or (IV) the "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. s 355(j)(2)(A)(vii). As part of a certification under Paragraph IV, the ANDA applicant must notify the patent holder and approved applicants of its application and include a statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed. See id. s 355(j)(2)(B). Under FDA regulations, the applicant may also certify that the patent is unenforceable. See 21 C.F.R. s 314.94(a)(12)(i)(A)(4) (Westlaw 1999).

ANDA applicants who submit Paragraph IV certifications are subject to a "market-exclusivity provision," see 21 U.S.C.

s 355(j)(5)(B)(iv), under which previous applicants are granted 180 days during which subsequent applications cannot be approved.3 This period is started, or triggered, by the earlier of (1) the date the Secretary of Health and Human Services receives notification from the previous applicant of the first commercial marketing of its drug or (2) the date of a "decision of a court" in a patent or declaratory judgment action "holding" that the patent is either "invalid or not infringed." Id.; see also id. s 355(j)(5)(B)(iii) (describing suits for patent infringement or declaratory judgment).

Heretofore, the court invalidated the FDA's "successful defense" requirement, whereby the first ANDA applicant could obtain 180 days of market exclusivity only after successfully defending a patent lawsuit. See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1076 (D.C. Cir. 1998). Accord Granutec, Inc. v. Shalala, No. 97-1873, 1998 WL 153410, at *7 (4th Cir. April 3, 1998). In response, the FDA issued a "Guidance for Industry" announcing its intention to promulgate new regulations on market exclusivity and "until such time as the rulemaking process is complete," to "regulate directly from the statute, and ... make decisions on 180-day generic drug exclusivity on a case-by-case basis." See Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act 4 (June 1998) ("Guidance for Industry"). The court upheld this approach in Purepac Pharmaceutical Co. v. Friedman, 162 F.3d 1201, 1204-05 (D.C. Cir. 1998): the FDA may regulate directly from the statute and is not required to maintain any litigation requirement in determining the first applicant's entitlement to 180 days of market exclusivity.

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3 As interpreted by the FDA, the statute does not guarantee the first ANDA applicant a 180-day period of exclusivity. The court-decision trigger can be activated by any subsequent ANDA applicant's litigation whether or not the first applicant has enjoyed a period of exclusivity. See Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act 5 (June 1998).

II.

Teva challenges the denial of injunctive relief on the principal ground that the FDA's refusal to treat the dismissal of Teva's declaratory judgment action as a triggering "court decision" is inconsistent with the ANDA statute and hence, the district court erred in ruling that Teva had failed to demonstrate a likelihood of success on the merits. Basically, Teva contends that the California dismissal is functionally equivalent to a final decision of noninfringement and unenforceability on the merits because it was based on the patent holder's express representation to Teva and the California court that Teva's formulation did not infringe the patent and that the patent holder would not sue Teva for infringement. Indeed, Teva goes so far as to maintain that its interpretation of the statute is the only possible alternative to the FDA's impermissible construction under the circumstances of this case; otherwise, subsequent ANDA applicants' efforts to use the Hatch-Waxman procedure could be thwarted anytime a patent holder stated that it did not intend to enforce its patent, thus preventing the courts from exercising subject matter jurisdiction to issue the holding of noninfringement that the FDA's position requires.

According to Teva's complaint, on June 20, 1997, Teva filed its ANDA to market ticlopidine, a generic version of the drug "Ticlid." While it awaited tentative approval of its application, Teva sued Syntex, seeking a declaratory judgment of noninfringement of Syntex's patent for a finished dosage formulation of ticlopidine tablets.4 On the same day, Syntex sent Teva a letter expressing the opinion that Teva would not infringe Syntex's patent, declaring: "We will make no claim of patent infringement based on the sale of ticlopidine hydrochloride tablets having the formulation you have disclosed to us." Thereafter, Teva prepared a joint motion for entry of

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4 Syntex had previously sued Teva and others for possible infringement of its process patent for ticlopidine, but voluntarily dismissed its complaint against Teva without prejudice once Teva revealed its process. That litigation was unrelated to the formulation patent at issue in the declaratory judgment action.

consent judgment that would hold Syntex's patent not infringed; but Syntex instead moved to dismiss the complaint for lack of subject-matter jurisdiction, explaining:

> Given Syntex's express assurance that it would not bring suit against Teva on the '592 patent, Teva can have no reasonable apprehension that it will face a lawsuit for infringement of the '592 patent. Without such reasonable apprehension, no actual case or controversy exists of sufficient immediacy or reality to base jurisdiction over Teva's declaratory judgment claim.

Accompanying the motion was a declaration by John Parise, counsel for Syntex, referring to the June 8, 1998, letter that Syntex sent Teva stating that Syntex would make no claim of patent infringement against Teva. Noting that under Federal Rule Civil Procedure 12(b)(1) the district court could consider materials outside of the pleadings, see Dreier v. United States, 106 F.3d 844, 847 (9th Cir. 1997), Syntex attached a proposed order with three findings, including that Teva "lacked and lacks a reasonable apprehension of suit by Syntex for infringement of [the] ... [p]atent." The district court granted Syntex's motion, adopting its findings, specifically that Teva "lacks a reasonable apprehension of suit by Syntex for infringement of [the patent];" hence there was "no justiciable case or controversy between the parties concerning any infringement by Teva of the '592 [p]atent," and consequently the court lacked subject matter jurisdiction over the action.

On October 29, 1998, the FDA tentatively approved Teva's ANDA to market ticlopidine. However, the FDA informed Teva that because there was a previous ANDA applicant and neither commercial marketing nor a court decision had occurred, its application was ineligible for final approval. Teva attempted to persuade the FDA that the California dismissal satisfied the "court decision" requirement, but the FDA did not respond to Teva's request for an effective approval date and on December 2, 1998, notified Teva that it refused to meet to discuss the issue. Teva then filed the instant lawsuit in district court for a declaratory judgment that Teva is

entitled to have its ANDA become effective on February 10, 1999 (180 days after the California dismissal), an injunction making Teva's ANDA effective on that date, and a temporary restraining order to forestall the FDA from approving the first ANDA application if such approval would give the first applicant any exclusive marketing beyond February 10, 1999.

The district court declined to award injunctive relief. It concluded for three reasons that Teva could not demonstrate a likelihood of success on the merits. First, the district court ruled that the California dismissal did not fall within the plain language of s 355(j)(5)(B)(iv)(II), and, second, that even if Teva could show that the statute was ambiguous, it was unlikely to succeed in showing that the FDA's interpretation was impermissible, or that Teva's interpretation was the only permissible alternative. The district court concluded, third, that Teva's reliance on patent law decisions of the Federal Circuit was misplaced because they had no direct bearing on the "court decision" provision in ANDA. Consequently, the district court reasoned, in view of language in decisions of this court,5 that the triggering "court decision" provision required nothing less than a decision on the merits. The district court was also unpersuaded by Teva's arguments concerning irreparable harm, injury to the other parties, and the public interest.6

III.

On appeal, Teva contends that the district court erred in denying injunctive relief because the California dismissal qualified as a "court decision" under s 355(j)(5)(B)(iv)(II) and the FDA's refusal to recognize the dismissal as such was arbitrary and capricious, an abuse of discretion, and based on an unreasonable and impermissible interpretation of the statute. Our review of the denial of injunctive relief is for abuse of discretion, but we review de novo the district court's

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5 See Purepac, 162 F.3d at 1205 n.6; Mova, 140 F.3d at 1073 & n.18.

6 See Mova, 140 F.3d at 1066 (outlining standard for preliminary injunctions).

conclusion of law, namely that Teva was unlikely to prevail in its challenge to the FDA's refusal to treat the California dismissal as a triggering "court decision." See Mova, 140 F.3d at 1066 (citing CityFed Financial Corp. v. Office of Thrift Supervision, 58 F.3d 738, 746 (D.C. Cir. 1995)).

The FDA maintains that its interpretation of the "court decision" provision is entitled to deference under Chevron U.S.A., Inc. v. Natural Resources Defense Counsel, Inc., 467 U.S. 837, 842-44 (1984). In fact, however, the FDA has offered no particular interpretation of that provision, relying instead on its authority to interpret the provision narrowly until it promulgates a new rule. Without regard to how the FDA should address the issue in its next rulemaking, it is clear that the FDA, consistent with its statement that it would "regulate directly from the statute" on a "case-by-case basis," see Guidance for Industry at 4; see also Purepac, 162 F.3d at 1205, cannot avoid the merits of Teva's contention that the California dismissal satisfies the "court decision" requirement under s 355(j)(5)(B)(iv)(II). We review the FDA's response to Teva's claim guided by settled principles of administrative law. See 5 U.S.C. s 706 (1994); Southwestern Bell Tel. Co. v. FCC, 168 F.3d 1344, 1352 (D.C. Cir. 1999). Upon a review of the record, we conclude that the FDA's response was arbitrary and capricious.

First, the FDA concedes that its refusal to recognize the California dismissal as a triggering "court decision" is not compelled by the statutory language. The statute requires a "decision of a court holding the patent ... invalid or not infringed." See 21 U.S.C. s 355(j)(5)(B)(iv)(II). A "decision" can take several forms, including final judgment after a full trial, summary judgment or partial summary judgment, or even a dismissal for failure to state a cause of action. The term "holding," most often contrasted with the term "dicta," is also susceptible to interpretation. See, e.g., Seminole Tribe of Fla. v. Florida, 517 U.S. 44, 66-67 (1996); Wilder v. Apfel, 153 F.3d 799, 803-04 (7th Cir. 1998); Gersman v. Group Health Ass'n, 975 F.2d 886, 897 (D.C. Cir. 1992). Furthermore, the significance of a court's "decision" or "holding" often lies in its preclusive effect. Of course, as intervenors

maintain, not every court action can be construed as a "decision" with a "holding"; for example, a dismissal for lack of personal jurisdiction is not a decision on the merits and has no preclusive effect.

But the California dismissal cannot be classified as a typical dismissal for lack of subject matter jurisdiction. Although, as a general rule, such a dismissal has no preclusive effect because the court lacked authority or competence to hear and decide the case, see Prakash v. American Univ., 727 F.2d 1174, 1182 (D.C. Cir. 1984) (citing 5 C. Wright & A. Miller, Federal Practice s 1350, at 554 (1969)),7 here the dismissal was based exclusively and necessarily on Syntex's declaration that Teva's product would not infringe its patent and its express disavowal of an intent to sue. Syntex expressly sought to have the California court consider more than the pleadings, notwithstanding its request for dismissal for lack of subject matter jurisdiction, noting in its motion papers that the court could grant a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1) based on materials in addition to the pleadings themselves. Before the California court was Syntex's June 8th letter stating that Teva's "formulation ... does not infringe" the patent, and the declaration of Syntex's counsel that Teva's "formulation did not warrant bringing a patent infringement action." It also had express findings of fact proposed by Syntex, including the one necessary for a finding of no case or controversy, namely that Teva lacked a reasonable apprehension of suit by Syntex for infringement. Syntex not only remained silent after receiving Teva's notice of its ANDA filing and failed to file an infringement suit within 45 days after receiving Teva's Paragraph IV notification, but it also sought to have Teva's complaint dismissed for lack of subject matter jurisdiction. It was able to file such a motion, however, only because of its own statements and actions eliminating any case or controversy about the enforceability of the patent against Teva. Its motion was granted on the basis of an express finding of fact by the California court

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7 See also 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure s 1350, at 225 (2d ed. 1990).

regarding Teva's reasonable nonapprehension of suit, as Syntex itself had proposed as part of its motion to dismiss. From the perspective of the California court, then, Syntex's declaration and conduct eliminated the need for a declaratory judgment because Syntex would be estopped from challenging Teva's marketing of its generic drug on the ground of patent infringement.

The FDA and intervenor TorPharm (the first ANDA filer) conceded at oral argument that the California dismissal prevents Syntex from suing Teva for infringement. The conclusion that the California dismissal has estoppel effect is supported by the decisions of the United States Court of Appeals for the Federal Circuit. That court has recognized that a dismissal of a declaratory judgment action for lack of a case or controversy due to the patent holder's disavowal of any intent to sue for infringement has preclusive effect. See Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1059 (Fed. Cir. 1995); Spectronics Corp. v. H.B. Fuller Co., 940 F.2d 631, 636-38 (Fed. Cir. 1991); see also Fina Research, S.A. v. Baroid Ltd., 141 F.3d 1479, 1483-84 (Fed. Cir. 1998) (discussing Super Sack and Spectronics). Although the district court here correctly noted that the Federal Circuit was confronted only with cases in which the plaintiff sought a declaratory judgment in order to avoid litigation and liability for infringement, and did not consider whether such a decision would have any collateral effect or additional significance under the ANDA statute, the relevant consideration is the estoppel of the patent holder from later claiming that the ANDA applicant is liable for patent infringement.

Put otherwise, the California dismissal appears to meet the requirements of a triggering "court decision" because that court had to make a predicate finding with respect to whether Syntex would ever sue Teva for infringement in order to conclude that there was no case or controversy between the parties. In dismissing Teva's complaint for lack of subject matter jurisdiction, the California court expressly found that Teva "lacks a reasonable apprehension of suit by Syntex for infringement of [its patent]." According to Syntex's motion to dismiss Teva's complaint, that finding could only have been

based on the patent holder's declaration of counsel and its June 8th letter to Teva. Although the dismissal was not a judgment on the merits after consideration of evidence presented by the parties, there was no need for such a procedure here because the dismissal sufficed to estop Syntex from suing Teva for patent infringement. See Super Sack, 57 F.3d at 1059; Spectronics Corp., 940 F.2d at 638. This is the result that appears to be the purpose of the triggering "court decision" provision. A contrary view, as Teva contends, means that the patent holder could manipulate the system in order to block or delay generic competition by stating that the patent holder will not enforce its patent against the Paragraph IV challenger. See Mova, 140 F.3d at 1073 & n.18. For these reasons, the California dismissal would appear to meet the requirements of a "court decision" under s 355(j)(5)(B)(iv)(II). On remand, of course, the FDA will have the opportunity to explain why it fails to meet them.

Second, it is unclear that a triggering "court decision" need explicitly hold the patent at issue is "invalid" or is "not infringed" in order to trigger the 180-day period of market exclusivity. Both the FDA and the Federal Circuit recognize that a certification that a patent is "unenforceable" suffices for purposes of the Paragraph IV certification, see 21 C.F.R. s 314.94(a)(12)(i)(A)(4); Merck & Co. v. Danbury Pharmacal, Inc., 694 F. Supp. 1, 2-3 (D. Del. 1988), aff'd, 873 F.2d 1418 (Fed. Cir. 1989), even though the statute provides that such certification must state that the patent is "invalid" or "will not be infringed," see 21 U.S.C. s 355(j)(2)(A)(vii)(IV). When it promulgated the final regulations on ANDA applications, the FDA explained that it included "unenforceability" because "[t]he alternative interpretation, precluding applicants challenging patents as unenforceable from filing certifications under paragraph IV, would be contrary to Congress' obvious intent in allowing patent challenges under [ANDA] and would lead to absurd results." 59 Fed. Reg. 50,338, 50,339 (1994). Likewise reflecting the same concerns, see id. at 50,353, the FDA regulations provide that a "court decision" need not hold the patent is "invalid" or "not infringed" but alternatively

may hold the patent unenforceable, see 21 C.F.R. s 314.107(c)(1)(ii) (Westlaw 1999).

Intervenors' attempt to assert that unenforceability, which is included in the regulation, and estoppel, which is presented here, should be treated differently under s 355(j)(5)(B)(iv)(II) is unpersuasive. Although it is true that a determination of unenforceability, such as for inequitable conduct, applies generally, preventing the patent holder from enforcing the patent against any entity, see Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F.3d 28, 30, 32 (Fed. Cir. 1999), and the estoppel arising from the California dismissal operates only against Syntex as to Teva, see generally 18 Charles Alan Wright et al., Federal Practice and Procedure s 4443, at 381-91 (1981); see also Cotton v. Heyman, 63 F.3d 1115, 1119 (D.C. Cir. 1995), this appears to be a distinction without difference for purposes of the "court-decision" requirement. To start, or trigger, the period of market exclusivity by a "court decision," an ANDA applicant need only obtain a judgment that has the effect of rendering the patent invalid or not infringed with respect to itself; the statute does not require, nor does any party contend that it requires, the patent to be invalidated as to any and all ANDA applicants. See 21 U.S.C. s 355(j)(5)(B)(iv)(II). As the FDA and Tor-Pharm concede, Syntex cannot sue Teva for patent infringement as a result of the California dismissal. In its regulations, the FDA added "unenforceability" to the list of what qualifies as a "court decision" because it concluded that implementing the statute in any other way would be contrary to Congress' intent and produce absurd results. See 59 Fed. Reg. at 50,353 (referring to 59 Fed. Reg. at 50, 339). However, the situation presented here appears no less absurd because Teva can never be sued by Syntex for patent infringement, but the FDA has nevertheless concluded that the California dismissal cannot satisfy the "court decision" requirement of the statute. Thus, the FDA's application of the statute to this case runs counter to its explanation for permitting unenforceability to qualify as a "court decision."

Third, the FDA's treatment of the California dismissal appears contrary to the FDA's "Guidance for Industry" in

two respects. Cf. Cherokee Nation of Okla. v. Babbitt, 117 F.3d 1489, 1499 (D.C. Cir. 1997) ("An agency is required to follow its own regulations.") First, the FDA has effectively declined to proceed on a "case-by-case basis," proposing instead to consider Teva's interpretation as part of the rule-making process. Although the FDA generally has discretion to determine whether to proceed by adjudication or rulemaking, see Mobil Oil Exploration & Producing Southeast Inc. v. United Distribution Cos., 498 U.S. 211, 230 (1991); SEC v. Chenery Corp., 332 U.S. 194, 203 (1947); Arkansas Power & Light Co. v ICC, 725 F.2d 716, 723 (D.C. Cir. 1984), litigants also have a right to adjudication of their claims, see AT&T v. FCC, 978 F.2d 727, 731-33 (D.C. Cir. 1992). The FDA has been mute in response to Teva's request for a complete explanation of the rejection of its interpretation. Noting the language of the statute, its purposes, and ambiguities, the FDA has recognized in its brief to this court, as the court in Mova did, see 140 F.3d at 1073 n.18, that a dismissal could be sufficient to satisfy the "court decision" requirement. See Federal Appellee's Br. at 20-21. Yet, the FDA says in its brief that it is "not at this time prepared to conclude that dismissal of Teva's declaratory judgment action for lack of subject matter jurisdiction is a 'decision of a court' under section 355(j)(5)(B)(iv)(II)." Id. at 20. Contrary to the FDA's view, nothing in our decision in Purepac, 162 F.3d 1201, relieved the FDA of its obligation to abide by the commitments it made in the "Guidance for Industry" as to how it would proceed until a new rulemaking was completed.

How the FDA can justify this approach to Teva's interpretation of the California dismissal in light of its treatment of other cases remains a mystery; presumably in a "case-by-case" analysis the FDA is obligated to explain such differences. See ANR Pipeline Co. v. FERC, 71 F.3d 897, 901 (D.C. Cir. 1995); Pontchartrain Broad. Co. v. FCC, 15 F.3d 183, 185 (D.C. Cir. 1994). Specifically, the FDA has not explained why it would recognize a grant of partial summary judgment, based on the patent holder's admission of non-infringement, as a "court decision" in Granutec, 1998 WL 153410, at *5, but decline to give similar effect to a dismissal

based on a finding of no reasonable apprehension of suit arising from the patent holder's admission of non-infringement. In Granutec, the FDA argued that the partial grant of summary judgment in a prior case satisfied the "court decision" requirement. See id.; see also Glaxo, Inc. v. Boehringer Ingelheim Corp., 954 F.Supp. 469 (D. Conn.1996), final judgment entered, 962 F. Supp. 295 (D. Conn.1997), aff'd, 119 F.3d 14 (Fed. Cir. 1997) (unpublished opinion). That Boehringer involved a judgment on the merits, while Teva's complaint was dismissed for lack of subject-matter jurisdiction, does not detract from the fact that both proceedings prevent the patent holder from suing the ANDA applicant for patent infringement. Given that the California dismissal supports estoppel to the same extent as the grant of partial summary judgment at issue in Granutec, it is unclear why the California dismissal would not satisfy the "court decision" requirement of s 355(j)(5)(B)(iv)(II). At least the FDA has not provided an explanation wherein there is a material difference for purposes of triggering the "court decision" provision.

Second, the FDA's response to Teva's interpretation of the "court decision" requirement is not easily viewed as "regulat[ing] directly from the statute," as the FDA committed to do in its "Guidance for Industry." The FDA "acknowledges that its current interpretation of the court decision trigger is narrower than the statute may be able to support.... [and] that Teva's interpretation of the court decision trigger may be permissible." Yet if the FDA's interpretation of section 355(j)(5)(B)(iv)(II) is "narrower than the statute [is] able to support," then its interpretation cannot stand without justification because the FDA must interpret the statute to avoid absurd results and further congressional intent. See Robinson v. Shell Oil Co., 519 U.S. 337, 346 (1997); R.G. Johnson Co. v. Apfel, 172 F.3d 890, 895 (D.C. Cir. 1999). A narrow interpretation cannot be reasonable simply because it is narrower than it could be; to the contrary that interpretation may in fact be narrower than it should be given the purposes of the statutory scheme and congressional intent. See Process Gas Consumers Group v. United States Dep't of Agricul-

ture, 694 F.2d 778, 792 (D.C. Cir. 1982) (in banc); see generally Oil, Chemical & Atomic Workers Int'l Union v. NLRB, 46 F.3d 82, 90 (D.C. Cir. 1995); Association of Civilian Technicians v. FLRA, 22 F.3d 1150, 1153 (D.C. Cir. 1994). It is the narrowness of the interpretation that must be justified, and the court can only review that choice of narrowness based on the reasons provided by the FDA, see Chenery, 332 U.S. at 196; here, it has provided none.

As a result of the FDA's current construction of the "court decision" requirement and its treatment of Teva's application, generic ticlopidine tablets were not available in the marketplace for a number of months despite the fact that appellants both stood ready to market them. Syntex remained the exclusive manufacturer of "Ticlid," and the first ANDA applicant's market exclusivity period had not begun because the FDA had yet to approve that applicant's filing. On July 1, 1999, the FDA finally approved TorPharm's ANDA, and TorPharm commenced marketing on July 6, so now at least one generic version of ticlopidine tablets is available.8 Yet, this series of events may well not have been what Congress contemplated in enacting the Hatch-Waxman amendents to expedite generic drug approvals. See H.R. Rep. No. 98-857, pt. 1, at 14-15, reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48; cf. Mova, 140 F.3d at 1073. Be that as it may, our decision to reverse the denial of injunctive relief rests on the FDA's failure to explain adequately its refusal to treat the California dismissal as a triggering "court decision" under s 355(j)(5)(B)(iv)(II), particularly in view of its announcement in its "Guidance for Industry" of how it would proceed pending a new rulemaking. Although the FDA is likely

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8 The FDA's approval of TorPharm's ANDA does not moot this appeal because Teva sought a preliminary injunction against the FDA compelling it to deem Teva's application effective as of February 10, 1999. Though Teva will be able to market its ticlopidine tablet 180 days after July 6 without fail, in the interim Teva and Purepac face continued harm because of their denied access to the market, see Byrd v. EPA, 174 F.3d 239, 244 (D.C. Cir. 1999), harm potentially heightened because of TorPharm's period of market exclusivity.

correct that Teva's interpretation is not the only permissible construction of the "court decision" requirement, Teva has demonstrated that the FDA's refusal to treat the California dismissal as a trigger was arbitrary and capricious in light of the FDA's response in another case.

Accordingly, we reverse, and because our conclusion could well affect the district court's evaluation of appellants' other arguments concerning harm, injury, and the public interest, we remand the case to the district court to consider anew the request for injunctive relief.