United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Decided June 6, 2006

No. 06-5105

APOTEX, INC.,
APPELLANT

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLEES

TEVA PHARMACEUTICALS USA, INC., ET AL.,
INTERVENORS

On Motion for Summary Affirmance

Appeal from the United States District Court
for the District of Columbia
(No. 06cv00627)

Jay P. Lefkowitz, *Steven A. Engel*, *John C. O'Quinn*, and *Michael D. Shumsky* filed the motion for summary affirmance and the reply thereto for intervenor Teva Pharmaceuticals USA, Inc.

Arthur Y. Tsien, *William A. Rakoczy*, and *Christine J. Siwik* filed the opposition for appellant.

Before: HENDERSON, TATEL, and BROWN, *Circuit Judges*.

Opinion for the Court filed PER CURIAM.

PER CURIAM: This case is the latest flare-up in a long-running dispute between the Food and Drug Administration (FDA) and several generic drug manufacturers as to what qualifies under the Hatch-Waxman Act as "a decision of a court . . . holding [a challenged] patent . . . to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv) (2000) (amended 2003). The stakes are high: any such decision triggers the start of a 180-day exclusivity period during which one generic manufacturer—the first to file an abbreviated new drug application (ANDA) with FDA—can market its product without competition from other manufacturers. We assume familiarity with this complicated regulatory scheme, which we have described in detail elsewhere. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063-65 (D.C. Cir. 1998).

The present dispute arises out of a 1998 FDA decision finding that a district court order dismissing a patent suit for lack of subject matter jurisdiction could not qualify as a "court decision" sufficient to trigger the exclusivity period. An aggrieved generic drug manufacturer, Teva Pharmaceuticals, challenged FDA's decision, which we set aside because "FDA[] fail[ed] to explain adequately its refusal to treat the . . . dismissal as a triggering 'court decision.'" *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1012 (D.C. Cir. 1999) (*Teva I*). We flagged three issues for FDA's attention. First, and most important, we observed that "the significance of a court's 'decision' or 'holding' often lies in its preclusive effect," *id*. at 1008, and pointed out that

> the . . . dismissal [for lack of jurisdiction] appears to meet the requirements of a triggering 'court decision'

> because [the] court had to make a predicate finding with respect to whether [the patent holder] would ever sue [the generic drug manufacturer] for infringement in order to conclude that there was no case or controversy between the parties. . . . On remand, of course, the FDA will have the opportunity to explain why it fails to meet them.

Id. at 1009. Second, we noted that FDA never explained why a decision holding a patent unenforceable was a triggering court decision, but that a dismissal based on a finding of unenforceability was not. *Id*. at 1009-10. And third, we explained that FDA's position appeared to conflict with an internal agency guidance document as well as *Granutec*, one of the agency's earlier decisions. *See Granutec, Inc. v. Shalala*, No. 97-1873, 1998 WL 153410 (4th Cir. Apr. 3, 1998) (reviewing FDA's *Granutec* decision). *Teva I*, 182 F.3d at 1010-11.

On remand, FDA reached the same conclusion. This time around, however, it justified its decision by establishing a hard-and-fast rule: the agency will never look beyond the face of a court order to ascertain whether it qualified as a triggering court decision. Because a dismissal for lack of subject matter jurisdiction does not, on its face, make any "holding" on the invalidity, noninfringement, or unenforceability of a patent, FDA found that the dismissal did not trigger exclusivity. As an "explanation" in support of this rule, FDA submitted a short affidavit from Douglas Sporn, then director of the Office of Generic Drugs. In his affidavit, Sporn gave just one reason for the new rule, namely, that a more sophisticated inquiry "could place an unbearable burden upon [FDA] staff and would require a substantial use of [FDA]'s limited resources" because "[FDA] lacks the expertise to make accurate determinations about the legal effect, such as estoppel, of representations relating to

patents that are not embodied in a court decision." Sporn Aff. at 6, *reprinted in* Tsien Decl. Ex. F. We rejected this self-serving justification in *Teva II*, explaining that "FDA did not meaningfully address [the] question [posed in *Teva I*] on remand." *Teva Pharms., USA, Inc. v. FDA*, No. 99-5287, 2000 WL 1838303, at *1 (D.C. Cir. Nov. 15, 2000) (*Teva II*).

Several years later, Teva filed the first ANDA to market a generic version of Pravachol, a Bristol-Myers Squibb Co. (BMS) product, in ten, twenty, and forty milligram tablets. BMS's patent on the Pravachol molecule expired on April 20, 2006, at which point Teva expected to roll out its product and take advantage of its 180-day exclusivity period. But one of Teva's competitors had other plans. In an effort to trigger Teva's 180-day exclusivity period long before Teva could market its generic product, Apotex, Inc., appellant herein, filed suit against BMS in the Southern District of New York in October 2003 seeking a declaratory judgment that its own generic version of Pravachol did not violate various BMS patents. Although BMS moved to dismiss the complaint for lack of subject matter jurisdiction, BMS and Apotex ultimately resolved the dispute by agreeing to a "stipulation and order" stating that BMS had no intention of suing Apotex and that the complaint should be dismissed "for lack of subject matter jurisdiction." Stipulation & Order at 3, *Apotex Inc. v. Bristol-Myers Squibb Co.*, No. 04 CV 2922 (S.D.N.Y. July 23, 2004), *reprinted in* Tsien Decl. Ex. I. The district court signed the "stipulation and order" on July 23, 2004.

Apotex then asked FDA whether the signed stipulation qualified as a triggering court decision. Believing itself bound by substantive holdings it saw in *Teva I* and *Teva II*, FDA replied that the signed stipulation did qualify and that Teva's 180-day exclusivity period had long since run its course. Determined not to lose its exclusivity period, Teva filed suit

challenging FDA's decision. In *Teva Pharmaceuticals USA, Inc. v. FDA*, 441 F.3d 1, 5 (D.C. Cir. 2006) (*Teva III*), we held that "FDA mistakenly thought itself bound by our decisions" and that its "error render[ed] its decision arbitrary and capricious."

On remand from *Teva III*, FDA reversed itself, finding Apotex's "stipulation and order" insufficient to trigger Teva's 180-day exclusivity. Justifying this reversal, it re-adopted its earlier rule that a triggering "court decision" must include an "actual 'holding' . . . evidenced by language on the face of the court's decision showing that the determination of invalidity, noninfringement, or unenforceability has been made by the court." Letter from Gary Buehler, Dir., Office of Generic Drugs, to Tammy McIntire, Apotex Corp. 2 (Apr. 11, 2006), *reprinted in* Tsien Decl. Ex. A (Buehler Letter). Given the vagaries of patent law and FDA's lack of expertise in patent matters, the agency explained that inquiring into the estoppel effects of representations embodied in district court opinions would spawn litigation and lead to unpredictability in the marketplace. Concluding that "[i]t is in the public's interest, as well as FDA's own interest, to have exclusivity triggering determinations governed by a legal regime that is clear and easily administered," *id*. at 14, FDA found that the "stipulation and order" never triggered the 180-day exclusivity period.

Apotex filed suit challenging FDA's decision as arbitrary and capricious, and the district court granted Teva's motion to intervene. Apotex then moved for a temporary restraining order and a preliminary injunction forbidding FDA from allowing Teva to begin exclusive marketing of a generic version of Pravachol. The district court denied the motion, reasoning that Apotex had no chance of prevailing on the merits:

> Not only did the agency's fifteen-page, single-spaced remand decision thoughtfully deconstruct the multifaceted implications of the estoppel and holding-on-the-merits approaches, but it also sufficiently addressed each of the three concerns raised in *Teva I* and recalled in *Teva III*. There is no "want of reasoned decisionmaking" here.

Apotex, Inc. v. FDA, No. 06-cv-00627, slip op. at 29-30 (D.D.C. Apr. 19, 2006).

Apotex now appeals, and Teva has moved for summary affirmance. On April 24, 2006 we denied Apotex's request for a stay pending appeal. *Apotex, Inc. v. FDA*, No. 06-5105 (D.C. Cir. Apr. 24, 2006). We now summarily affirm the district court's refusal to grant the preliminary injunction.

Apotex argues that "FDA's decision merely regurgitates the same tired explanations and rationales that this Court previously rejected" in *Teva II*, Apotex's Emergency Mot. for Injunctive Relief Pending Appeal 6, and that therefore it has a strong likelihood of demonstrating the decision's unreasonableness. We disagree.

Apotex correctly points out that we rejected FDA's previous effort to adopt the rule that a holding of invalidity, noninfringement, or unenforceability must be evident on the face of a court order. *See Teva II*, 2000 WL 1838303. But we never suggested such a rule was untenable; rather, we found that it "fail[ed] for want of reasoned decisionmaking." *Id*. at *2. In sharp contrast to the decision at issue in *Teva II*, FDA's rejection of Apotex's "stipulation and order" as a triggering court decision addressed concerns identified in *Teva I*. Indeed, FDA provided entirely new justifications for declining to look beyond

the face of a court order. To be sure, those justifications share a common premise with the drain-on-resources rationale laid out in the Sporn affidavit—that "applying the estoppel standard articulated by the *Teva I* court would often require FDA to resolve factually intensive questions with little guidance from the courts on how to apply the facts to the law." Buehler Letter 8. But the validity of this premise is not in question. FDA is indisputably correct that equitable estoppel in the patent law context rarely presents pure issues of law amenable to easy resolution. As FDA pointed out, the Federal Circuit has established a context-specific three-element inquiry into whether patent holders are equitably estopped from enforcing their patents. *See A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1028 (Fed. Cir. 1992) (en banc). We have little doubt that applying this standard would force FDA, an agency lacking patent law expertise, to resolve borderline questions about the estoppel effects of patent-holder declarations.

As FDA sees it, the uncertainty inherent in an estoppel-based inquiry would lead to two inter-related problems, neither of which relates to the drain-on-resources rationale set forth in the quite brief Sporn affidavit the agency relied on in *Teva II*. First, FDA believes that the uncertainty would "undermin[e] marketplace certainty and interfer[e] with business planning and investment." Buehler Letter 14. And second, FDA worries that forcing it to parse court decisions will invite fruitless litigation from generic drug manufacturers seeking to trigger, or to avoid triggering, exclusivity periods. In FDA's view,

> [w]ere [the agency] to adopt a standard less objective and clear than the "holding-on-the-merits" standard, the opportunities for disputes regarding the tripping of the court decision trigger would increase. . . . Encouraging highly-interested and well-financed litigants to pursue ever-finer distinctions, ever farther removed from the

> language of the statute and from its purposes, does not advance the public's interest. It offers no guarantee of more rapid generic drug approvals, only a high likelihood of delay due to litigation . . . .

Id. In our view, these perfectly reasonable propositions adequately support FDA's position that an estoppel-based approach to the court decision trigger is ill-advised.

Apotex also argues that FDA's decision cannot stand because the agency failed to address a concern discussed in *Teva I*, namely, a possible inconsistency between its holding-on-the-merits approach and *Granutec*. Apotex is wrong. Not only did FDA address the *Granutec* issue, but it did so persuasively by pointing out that the summary judgment order at issue in *Granutec* was "clearly a holding on the merits of patent noninfringement as a matter of law." Buehler Letter 12; *see also Teva II*, 2000 WL 1838303, at *3 (Edwards, J., dissenting) ("It is clear from the face of the summary judgment order at issue in *Granutec* that the court there had issued a decision on the merits."). By contrast, the "stipulation and order" here, as well as the dismissal for lack of subject matter jurisdiction at issue in *Teva I*, make no such holding on their faces.

Next, Apotex argues that FDA cannot justify treating court decisions that include a patent holder's promise not to sue differently from decisions explicitly holding a patent unenforceable. But we see nothing inconsistent about FDA saying on the one hand that a court order holding a patent unenforceable will trigger the 180-day period, and on the other that it will not look beyond the face of a court order to see if the patent may be unenforceable because of one of the party's representations. While Apotex's claim might have merit if FDA failed to explain why it chose to adopt such a rule, here it provided an ample explanation.

Finally, Apotex contends that FDA's interpretation "nullifies" the declaratory judgment mechanism underlying the Hatch-Waxman Act. As Apotex observes, no generic manufacturer can maintain an action against a patent holder who has promised never to sue for infringement since, under settled Federal Circuit case law, any such promise would relieve the challenger of a reasonable apprehension of suit and moot a declaratory judgment action. *See Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed. Cir. 1995). According to Apotex, this creates an anomalous situation: although a patent might be unenforceable because of a patent holder's representations, no court would have jurisdiction to render a holding to that effect. This arguable anomaly, however, nullifies nothing in the Hatch-Waxman Act. Congress knew that federal courts lack jurisdiction where no case or controversy exists, yet it nonetheless chose to make the exclusivity trigger "a decision of a court . . . holding the [challenged] patent . . . to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv) (2000) (amended 2003). Congress's regulatory scheme thus depends in large measure on whether courts can maintain jurisdiction over patent suits. If a court cannot constitutionally assert jurisdiction, then certainly one reasonable view is that it cannot issue a "decision" that "holds" anything. This is FDA's position, and while it may not reflect the only possible interpretation of the court decision trigger, *see Teva I*, 182 F.3d at 1012 (noting that "FDA is likely correct that [an estoppel-based] interpretation is not the only permissible construction of the 'court decision' requirement"), it is in no way inconsistent with the plain language of the statute. *See Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1287 (D.C. Cir. 2000) ("As long as the agency stays within Congress' delegation, it is free to make policy choices in interpreting the statute, and such interpretations are entitled to deference." (internal quotation marks and alterations omitted)).

In short, Apotex has little likelihood of succeeding on the merits of its claim. *See CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995) (requiring the moving party to "demonstrate . . . a substantial likelihood of success on the merits"). Thus having no need to address the other preliminary injunction factors, *see City of Las Vegas v. Lujan*, 891 F.2d 927, 935 (D.C. Cir. 1989) (affirming district court's denial of preliminary injunction without addressing irreparable injury because appellant had insufficient likelihood of success on the merits), we affirm the district court's order and remand for further proceedings consistent with this opinion.

So ordered.