United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 18, 2001 Decided March 30, 2001

No. 00-5350

American Bioscience, Inc.,
Appellant

v.

Tommy G. Thompson, Secretary of Health
and Human Services, et al.,
Appellees

Appeal from the United States District Court
for the District of Columbia
(00cv02247)

Joseph F. Coyne, Jr. argued the cause for appellant. With him on the briefs were Carlton A. Varner, Robert F. Green, Arthur Y. Tsien, David F. Weeda and Jacqueline H. Eagle. David L. Durkin entered an appearance.

Howard S. Scher, Attorney, U.S. Department of Justice, argued the cause for federal appellees. With him on the brief

were David W. Ogden, Assistant Attorney General, Douglas N. Letter, Attorney, Wilma A. Lewis, U.S. Attorney, and Annamarie Kempic, Counsel, Food and Drug Administration.

Philip A. Sechler argued the cause for appellees Baker Norton Pharmaceuticals, Inc. and Zenith Goldline Pharmaceuticals, Inc. With him on the brief was Richard M. Cooper.

Before: Edwards, Chief Judge, Sentelle and Randolph, Circuit Judges.

Opinion for the Court filed by Circuit Judge Randolph.

Randolph, Circuit Judge: This appeal from the district court's judgment denying a preliminary injunction against the Food and Drug Administration requires us to consider once again the Supreme Court's opinion in Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402 (1971). Although the procedural background of the appeal is complex, our reasons for vacating and remanding are simple: the administrative record was never filed in court and we cannot tell on what basis the Food and Drug Administration took the agency action the plaintiff seeks to enjoin.

The statutory framework is as follows. A company wishing to market a drug must seek FDA approval usually by completing a "New Drug Application" (NDA) containing data from tests showing the drug's safety and effectiveness. See Mova Pharmaceutical Corp. v. Shalala, 140 F.3d 1060, 1063 (D.C. Cir. 1998). The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act in 1984 made it easier for drug manufacturers to obtain approval of generic drugs. See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections of 21, 35 & 42 U.S.C.). Under these amendments, a generic drug producer need not undertake the complicated and time-consuming testing process associated with an NDA and can instead file an "Abbreviated New Drug Application" (ANDA), relying on the NDA filed by the original manufacturer. See 21 U.S.C. s 355(j); Mova Pharmaceutical Corp., 140 F.3d at 1063.

While making it easier to bring generic drugs to market, Congress also wanted to protect patent holders whose rights might be infringed by the generic drugs. The law, therefore, requires that NDAs contain a list of any patents "which claim[ ] the drug ... or which claim[ ] a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. s 355(b)(1). If new patents claiming the drug or a method of using the drug are filed after the drug has been approved, the approved applicant must inform the Food and Drug Administration within 30 days. See 21 U.S.C. s 355(c)(2). The FDA keeps all of this information in a publication officially titled Approved Drug Products with Therapeutic Equivalence, commonly called the Orange Book. See 21 U.S.C. s 355(j)(7)(A).

The statute also includes patent protections when an Abbreviated New Drug Application is filed. For "each patent which claims" the drug the applicant would like to distribute in a generic version, the applicant must certify (1) that no patent has been filed with the FDA; or (2) that the patent has expired; or (3) that the patent has not expired, but will expire on a particular date; or (4) that the patent is either invalid or the generic drug will not infringe it. See 21 U.S.C. s 355(j)(2)(A)(vii).

The fourth of these options, known as a Paragraph IV certification, is central to the case as the parties have framed it. When a generic drug applicant certifies that a patent is invalid or that its proposed generic drug will not infringe upon it, it must also certify that it will give notice to the patent holder that it has entered the Paragraph IV certification. See 21 U.S.C. s 355(j)(2)(B). If the patent holder has not filed a patent infringement action within 45 days of receiving this notice, the FDA may immediately approve the ANDA. See 21 U.S.C. s 355(j)(5)(B)(iii). However, if a patent infringement action is filed within 45 days, the FDA may not approve the ANDA for 30 months, or until the patent dispute has been resolved, whichever is sooner. See 21 U.S.C. s 355(j)(5)(B)(iii).

Bristol Meyers-Squibb has FDA approval to manufacture and distribute Taxol, an anti-cancer drug with the active ingredient paclitaxel. American Bioscience allegedly developed a new process that permits a patient to receive higher doses of Taxol with fewer side effects. American Bioscience received U.S. Patent Number 6,906,331 (the '331 patent) for this process on August 1, 2000. Bristol Meyers refused to inform the FDA of this new patent. See 21 U.S.C. s 355(c)(2). American Bioscience then sued Bristol Meyers in the Central District of California, asking the court to compel Bristol Meyers to submit the patent for listing in the FDA's Orange Book. On August 11, the court entered a temporary restraining order requiring Bristol Meyers to list the drug with the FDA immediately. The restraining order also included a provision requiring Bristol Meyers to "take all steps under its control to cause the de-listing of the Taxol Patent from the FDA's Orange Book" should it ultimately lose the case.

Bristol Meyers sent a letter to the FDA indicating that it was submitting information on the '331 patent for listing "pursuant to an order of the United States District Court." On September 7, 2000, the District Court for the Central District of California dissolved the temporary restraining order on the ground that under the Federal Food, Drug and Cosmetic Act, American Bioscience had no private right of action to compel Bristol Meyers to list the patent. The court ordered Bristol Meyers to make its best efforts to remove the patent listing from the Orange Book.

Enter Baker Norton Pharmaceuticals. Baker Norton filed an Abbreviated New Drug Application for a generic form of Taxol in 1997. That application was postponed because of other infringement actions. After the '331 patent was listed, Baker Norton amended its application and included a Paragraph IV certification that its generic drug either did not infringe on the '331 patent or that the '331 patent was not valid. It did not give notice either to Bristol Meyers or to American Bioscience that it had included this certification in its ANDA. American Bioscience discovered Baker Norton's Paragraph IV certification when Baker Norton intervened in

the action in California. American Bioscience then sued Baker Norton for infringing the '331 patent.

Meanwhile, approval of Baker Norton's ANDA was proceeding. On September 8 and September 14, 2000, Baker Norton sent the FDA two letters amending its ANDA and informing the FDA of the proceedings in California. Because the '331 patent was to be "de-listed" pursuant to the California court's order dissolving the temporary restraining order, Baker Norton wished to amend its application, certifying that there were no additional patents listed that it was required to account for and removing its Paragraph IV certification regarding the '331 patent. On September 15, 2000, the Food and Drug Administration sent Baker Norton a letter approving its ANDA. The FDA's letter referred to Baker Norton's September 8 and 14 letters amending the application but included no other discussion of the '331 patent.

American Bioscience brought this action against Baker Norton and the FDA in the United States District Court for the District of Columbia Circuit, seeking an injunction to prevent the FDA from approving Baker Norton's application. Foremost among American Bioscience's many legal arguments was its claim that its patent had never been "de-listed" because Bristol Meyers never intended to have it removed from the Orange Book. If the FDA had approved Baker Norton's ANDA on this basis, reasoned American Bioscience, it had done so contrary to fact. Moreover, American Bioscience contended before the district court and contends here that the Hatch-Waxman Act merely directs the FDA to "list" patents as they are received. Because its role is ministerial, it is not authorized to remove patents from the listing once they are received.

American Bioscience also contends that the FDA could not have approved the application under the "late listing" regulation, which only requires an ANDA applicant to amend its application to include a late-listed patent if the patent was listed before the application was submitted. See 21 C.F.R. s 314.94(a)(12)(vi) (2000). If the FDA could rely on the

regulation to approve the ANDA, American Bioscience argues, the regulation itself is invalid.

The district court denied American Bioscience's motion for a preliminary injunction, in part on the ground that it had not shown a probability of success on the merits. In reaching this conclusion the court determined that the patent had been "de-listed" by Bristol Meyers, that Baker Norton's ANDA was protected by the FDA's late listing regulation, and that the late listing regulation is valid.

As to "de-listing," there is not adequate support for the district court's conclusion that the FDA approved Baker Norton's ANDA on that basis. The court referred to the "FDA's determination that [Bristol Myers] had not listed [American Bioscience's] patent within thirty days of the patent's issuance" and the FDA's "finding that [Bristol Myers] did not list the '331 patent within thirty days...." American Bioscience v. Shalala, No. 00-2247, slip op. at 10, 13 (D.D.C. Oct. 3, 2000). But the FDA's approval letter contains no such "determination" and no such "finding."

The district court also concluded "that the FDA's interpretation and application of the 'late listing' regulation are not 'plainly erroneous or inconsistent with the regulation.' " American Bioscience, slip op. at 19 (citation omitted). But there is nothing in the FDA's approval letter to indicate how it interpreted this regulation; in fact, the letter does not even say whether the FDA was relying on the regulation.

The short of the matter is that we do not know whether the FDA approved the application because it considered the '331 patent to have been "de-listed"; whether it considered the court-ordered listing ineffective for purposes of the Hatch-Waxman Act; whether it treated the application as one covered by the late-listing regulation; or whether, if it did, why it thought the regulation applied. For all we know, the FDA made a clerical error in approving the application even though it thought that the '331 patent had been continually listed.

These problems and others stem partly from the fact that in an "informal adjudication" such as this, the Administrative Procedure Act, see 5 U.S.C. s 554, requires neither agency findings of fact nor conclusions of law. As Overton Park tells us, judicial review nevertheless must proceed, but not by trial de novo. The review must "be based on the full administrative record that was before the [FDA] at the time [it] made its decision." 401 U.S. at 420. Overton Park arose on a motion for a preliminary injunction (to halt construction of a highway); this case too comes to us upon the denial of a preliminary injunction. Here, as in Overton Park, the administrative record was never filed, despite APA s 706's direction that judicial review shall be performed by "review[ing] the whole record or those parts of it cited by a party...." 5 U.S.C. s 706; see Overton Park, 401 U.S. at 419. Rather than calling for the administrative record, the district court appears to have relied on the parties' written or oral representations to discern the basis on which the FDA acted. Surely that was not sufficient. For all we know, the attorneys were merely speculating. In any event, the Supreme Court in Overton Park held that even sworn affidavits filed during the litigation would not suffice to explain the action of the Secretary of Transportation. Id. at 419.

As in Overton Park, we leave to the district court the determination of how best to proceed on remand in light of what the administrative record reveals. See 401 U.S. at 420-21; Camp v. Pitts, 411 U.S. 138 (1973) (per curiam); National Nutritional Foods Ass'n v. FDA, 491 F.2d 1141 (2d Cir. 1974) (Friendly, J.). We hold only that the court, before assessing American Bioscience's probability of success on the merits, should have required the FDA to file the administrative record and should have determined the grounds on which the FDA granted Baker Norton's application. Cf. Gordon G. Young, Judicial Review of Informal Agency Action on the Fiftieth Anniversary of the APA: The Alleged Demise and Actual Status of Overton Park's Requirement of Judicial Review "On the Record," 10 Admin. L.J. Am. U. 179, 226 (1996).

The judgment of the district court is vacated and the case is remanded for further proceedings consistent with this opinion.

So ordered.