UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

Sun Pharma Advanced Research Co., Ltd. v. Becerra

Sun Pharma · No. Civil Action No. 2024-0946 (APM) · Decided December 1, 2025

OPINION

PER CURIAM.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA _____) SUN PHARMA ADVANCED) RESEARCH CO., LTD., et al.,)) Plaintiffs,)) v.) Case No. 24-cv-00946 (APM)) ROBERT F. KENNEDY JR., 1) Secretary of Health and) Human Services, et al.,)) Defendants.) _____) MEMORANDUM OPINION I. INTRODUCTION This case concerns whether the U.S. Food and Drug Administration (FDA) acted unlawfully when it declined to issue a priority review voucher to Plaintiffs Sun Pharma Advanced Research Co., Ltd. and Sun Pharmaceutical Industries, Inc. following the approval of their drug Sezaby to treat neonatal seizures, a rare condition in babies under four weeks old.

A priority review voucher entitles its holder to an expedited six-month timeline for a future drug application, a benefit worth tens of millions of dollars. Among the statutory criteria to receive a priority review voucher is that the new drug cannot contain an active moiety "that has been previously approved in any other application under subsection (b)(1), (b)(2), or (j) of section 355 of [Title 21]." The FDA denied Plaintiffs a priority review voucher on the ground that the active moiety in Sezaby, phenobarbital sodium, was "previously approved." 1 Pursuant to Rule 25(d) of the Federal Rules of Civil Procedure, the court substitutes the current Secretary of Health and Human Services Robert F. Kennedy Jr. as defendant in place of his predecessor in office.

That decision was erroneous. The FDA's withholding of the priority review voucher was contrary to law because no drug product containing phenobarbital sodium was "previously approved" as that term is used in the statute.

Accordingly, for the reasons explained below, the court grants Plaintiffs' Motion for Summary Judgment, ECF No. 21 [hereinafter Pls.' Mot.], 2 and denies Defendants' Cross-Motion for Summary Judgment, ECF No. 28 [hereinafter Defs.' Mot.]. II. BACKGROUND A. Relevant Statutory Framework In 2012, Congress amended the Food, Drug, and Cosmetic Act (FDCA) to create what are known as Section 529 priority review vouchers to encourage drug manufacturers to develop treatments for rare pediatric diseases.

See 21 U.S.C. § 360ff(a); see also Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 908, 126 Stat. 993, 1094–95 (2012). A priority review voucher entitles the

holder to a six-month expedited application review timeline for a future drug application. See 21 U.S.C. § 360ff(a), (b)(1). Congress renewed the program in 2021. See Ensuring Innovation Act of 2021, Pub.

L. No. 117-9, § 1(a)(4), 135 Stat. 256, 257. Priority review vouchers are valuable. Not only can they be used to expedite the review timeline for a future drug, but Congress also made them transferrable. 21 U.S.C. § 360ff (b)(2)(A). Vouchers have been sold for sizeable sums, oftentimes in excess of $100 million. See U.S. Gov't Accountability Off., GAO-20-251, Drug Development: FDA's Priority Review Voucher Programs 15 fig.

4, 31 app. 1 (2020). An applicant must satisfy several criteria to receive a priority review voucher. See 21 U.S.C. at § 360ff(a)(4). First, the application must be a new drug application (NDA) made 2 Plaintiffs filed their Motion for Summary Judgment and Memorandum of Points and Authorities as one document. Page references to that filing are to the Memorandum of Points and Authorities.

2 under Section 505(b)(1) of the FDCA. Id. § 360ff(a)(4)(B)(i)(II) (referencing id. § 355(b)(1)). Second, the drug must be intended "for the prevention or treatment of a rare pediatric disease." Id. § 360ff(a)(4)(A).

Third, the NDA must be "deem[ed] eligible for priority review." Id. § 360ff(a)(4)(C). Fourth, the NDA must rely on clinical data from a study evaluating a pediatric population and dosages for that population. Id. § 360ff(a)(4)(D). Fifth, the NDA must not seek approval for an adult indication. Id. § 360ff(a)(4)(E). Sixth, the NDA must be approved after September 30, 2016, and before September 30, 2026.

Id. § 360ff(a)(4)(F), (b)(5)(B). Finally, the NDA must seek approval for "a drug... that contains no active moiety... that has been previously approved in any other application under subsection (b)(1), (b)(2), or (j) of section 355 of this title."3 Id. § 360ff(a)(4)(B)(i)(I).

The last of these criteria is the subject of the parties' dispute. Pls.' Mot. at 3; Defs.' Mot. at 5, 7−8. B. Factual and Legislative History On November 17, 2022, Plaintiffs Sun Pharma Advanced Research Company, Ltd. and Sun Pharmaceutical Industries, Inc. received approval from the FDA for their drug Sezaby to treat neonatal seizures. Administrative R., ECF No. 36 [hereinafter AR], at 124.

The same approval letter informed Plaintiffs that the FDA had denied their request for a rare pediatric disease priority review voucher. Id. at 125. The FDA determined that the NDA for Sezaby "is not an application for a drug 'that contains no active moiety... that has been previously approved in any other application under subsection (b)(1), (b)(2), or (j) of section 505' of the FD&C Act." Id. The agency explained its rationale in a separate letter.

Although the FDA had not "identif[ied] any applications for phenobarbital containing drugs that were approved after the Hatch-Waxman amendments were passed in 1984," it had "identified at least one NDA for a drug 3 The referenced "section 355 of this title" is a cross-reference to the statute detailing new drug approval pathways (also referred to as Section 505 of the FDCA).

See 21 U.S.C. § 355. 3 product containing phenobarbital as an active moiety that came into effect before 1962 and was deemed approved by the 1962 Amendments: NDA 000597 for Phenobarbital and Atropine." Id. at 155–56 (emphasis added).

The agency explained that this prior "deemed" approval of NDA 000597 blocked Plaintiffs' receipt of a priority review voucher. See id. at 155–58. NDA 000597 has a long and interesting history. The application was submitted in 1939 for a tablet containing a combination of phenobarbital and atropine for limited distribution only to licensed physicians. Id. at 001–002.

The application became effective weeks later under Section 505 of the original FDCA, id., which "provided that an NDA would automatically become effective unless a contrary order were issued." USV Pharm. Corp. v. Weinberger, 412 U.S. 655, 660–61 (1973); see also Act of June 25, 1938, Pub L. No. 717, ch. 675, § 505(c), 52 Stat. 1040, 1052.

In other words, NDA 000597 became effective not by any positive agency action but by its inaction. In 1962, Congress dramatically reworked the regulatory regime. It amended the FDCA to require "affirmative agency approval" based on "'substantial evidence' that the drug is effective." Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 613–14 (1973); Drug Amendments of 1962, Pub L. No. 87-781, § 104(b), 76 Stat. 780, 784.

The new legislation directed the FDA to "refuse approval of an NDA and to withdraw any prior approval if 'substantial evidence' that the drug is effective for its intended use is lacking." Weinberger, 412 U.S. at 613.

The same legislation addressed the status of NDAs, like NDA 000597, that were made "effective" under the prior statutory regime. Such applications would be "deemed... 'approved' by the Secretary within the meaning of the basic Act as amended by this Act." § 107(c)(2), 76 Stat. at 788. Such drugs therefore could continue to be marketed. But, while a drug "deemed" approved was not subject to the amendments' requirements "relat[ing] to the effectiveness of drugs," those 4 requirements would apply to any "supplement" to such drug's application.

Id. § 107(c)(3)(A). Further, Congress prohibited the FDA from suspending a "deemed" drug based on ineffectiveness for two years. Id. § 107(c)(3)(B); Cooper Lab'ys, Inc. v. Comm'r, 501 F.2d 772, 776 n.12 (D.C. Cir. 1974) ("The 1962 legislation contemplated that withdrawals would commence two years after the Act's effective date."). Taken together then, these provisions permitted a drug "deemed" approved to remain on the market after 1962, but the FDA after two years could order its removal, unless it was shown to be effective under the new regime.

See USV Pharm., 412 U.S. at 663 (“It seems apparent that by reason of § 107(c)(3) the industry was assured it could continue to market previously approved NDA’s unless and until the NDA was withdrawn and that before such withdrawal they would be given a minimum of two years within which to submit ‘substantial evidence’ to support the claims for their products.”).

NDA 000597 would not survive the greater scrutiny imposed by the 1962 Amendments. In 1972, the FDA determined that there was a lack of substantial evidence to support the effectiveness of the drug, 37 Fed. Reg. 15026 (July 27, 1972), and in 1977, the agency proposed to withdraw NDA 000597 because its sponsor failed to provide studies showing the drug’s effectiveness, 42 Fed.

Reg 41917–18 (Aug. 19, 1977). The drug’s sponsor discontinued distribution weeks later and, in 1978, “request[ed] the withdrawal” of the application and “waive[d] the right to a hearing.” AR 004. In 1982, the FDA formally withdrew “approval” of NDA 000597. 47 Fed. Reg. 23568 (May 28, 1982). Two years after the FDA withdrew NDA 000597, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch–Waxman Amendments.

Pub. L. No. 98-417, §§ 101–105, 98 Stat. 1585, 1586–1597. The Amendments “were designed to simplify and expedite the process by which generic drugs are 5 brought to market.” Mylan Pharms., Inc. v. Sebelius, 856 F. Supp. 2d 196, 199–200 (D.D.C. 2012) (citing Serono Lab’ys, Inc. v. Shalala, 158 F.3d 1313, 1316 (D.C. Cir. 1998)). Hatch–Waxman defined three pathways for approval.

Under the first, already in place before 1984, a drug manufacturer may submit an NDA and demonstrate with its own clinical trial data that the drug is safe and effective. See 21 U.S.C. § 355(b)(1). Under the second, the applicant may rely on studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (that is, permitted use of another party’s confidential data).

Id. § 355(b)(2); Otsuka Pharm. Co. v. Price, 869 F.3d 987, 989 (D.C. Cir. 2017) (stating that “a ‘(b)(2) application’... requires an applicant to show the propriety of relying on the preexisting studies to demonstrate the applied-for drug’s safety and efficacy”).

Third, an applicant may obtain approval of a “bioequivalent,” or generic, version of a previously approved drug by filing an abbreviated new drug application, which adopts the safety and efficacy data already submitted to the FDA by the pioneer drug manufacturer. See 21 U.S.C. § 355(j); see also Mylan Lab’ys, Inc. v. Thompson, 389 F.3d 1272, 1274–75 (D.C. Cir.

2004). These three approval pathways remained in place in 2012, when Congress created the Section 529 priority review voucher program. III. LEGAL STANDARD The Administrative Procedure Act (APA) requires courts to “hold unlawful and set aside” any “agency action” that is

"arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

Courts do not as a matter of course defer to agency interpretations in reviewing agency action. See Loper Bright Enters. v. Raimondo, 603 U.S. 369, 398–99 (2024). In "determining whether an agency's interpretation of its governing statute is contrary to law," courts must exercise their "'independent judgment' and 'apply[] all relevant 6 interpretive tools' to reach 'the best reading of the statute.'" Env't Def.

Fund v. EPA, 124 F.4th 1, 11 (D.C. Cir. 2024) (quoting Loper Bright, 603 U.S. at 394, 400). Agency action that is "not contrary to law" must still be "reasonable and reasonably explained." Id. (quoting Fed. Commc'ns Comm'n v. Prometheus Radio Project, 592 U.S. 414, 423 (2021)). And it is "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Solondz v. FAA, 141 F.4th 268, 276 (D.C.

Cir. 2025) (quoting Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)). The summary judgment standard under Federal Rule of Civil Procedure 56 does not apply to claims arising under the APA. See Am. Biosci., Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001). Instead, "the district judge sits as an appellate tribunal" and the "'entire case' on review is a question of law." Id. (citation omitted).

The court must "decid[e], as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." Sierra Club v. Mainella, 459 F. Supp. 2d 76, 90 (D.D.C. 2006). IV. DISCUSSION A. The Parties' Arguments The court begins with the parties' positions. Recall, to qualify for a Section 529 priority review voucher, an applicant must establish that its application is for a drug to treat a rare pediatric disease that "contains no active moiety... that has been previously approved in any other application under subsection (b)(1), (b)(2), or (j) of section 355 of this title." Id. § 360ff(a)(4)(B)(i)(I).

The parties disagree whether Congress intended for the NDA of a drug 7 "deemed" approved under the 1962 Amendments to constitute a drug "previously approved in any other application under subsection (b)(1), (b)(2), or (j)." Plaintiffs make two arguments.

First, they contend that the FDA was wrong to deny them a voucher "because NDA 000597 is not an 'application under subsection (b)(1), (b)(2), or (j)' of section 505 of the FDCA." Pls.' Mot. at 4. Their logic is straightforward. "[W]hen Congress cross-referenced 'subsections (b)(1), (b)(2), and (j)' in 2012 and 2021, it was specifying the Hatch- Waxman pathways as they existed at those

times." Pls.' Combined Reply in Supp. of Pls.' Mot. & Opp'n to Defs.' Mot., ECF No. 32 [hereinafter Pls.' Reply], at 4.

NDA 000597 therefore cannot be an "application under subsection (b)(1), (b)(2), or (j)," because those Hatch–Waxman approval pathways did not exist in 1939 when NDA 000597 went into effect. Id. Second, Plaintiffs maintain that, even if NDA 000597 somehow qualifies as an application "under (b)(1), (b)(2), or (j)," it was not "approved" as Congress contemplated.

Pls.' Mot. at 4. According to Plaintiffs, "the word 'approved' has a 'precise and undisputed meaning' in the FDCA" that "requires a 'review' that is 'affirmative and thorough,' culminating in a 'single decision' as to whether the data in the application 'reliably demonstrate the drug's efficacy and safety.'" Id. at 16 (quoting Sandoz Inc. v. Becerra, 57 F.4th 272, 280 (D.C.

Cir. 2023)). No such "single decision" occurred with respect to NDA 000597. It was submitted in 1939, became effective by agency inaction, and was only "deemed" approved under the 1962 Amendments. See id. at 16–17. That chain of events does not constitute an "approval" as required by Section 529. Defendants offer counterpoints to both arguments. They insist that NDA 000597 was an "application under subsection (b)(1)." Defs.' Mot. at 7–8.

This argument proceeds in two steps: "(1) an application deemed approved under the 1962 Amendments (like NDA 597) was an application under § 505(b) as then amended, and (2) that amended version of § 505(b) was 8 incorporated into § 505(b)(1) in 1984" by the Hatch–Waxman Amendments. Id. at 10.

In other words, according to Defendants, Congress in 2012 contemplated that an "application under subsection (b)(1)" for purposes of Section 529 included applications submitted under the pre-1962 version of the FDCA under then-Section 505(b). Next, they say, NDA 000597 was "previously approved." Id. at 8. That argument rests on the "deemed" approval provision of the 1962 Amendments. "Under ordinary principles of statutory construction," Defendants assert, "an application deemed approved is approved.

And since phenobarbital was one of the active moieties in approved NDA 597, the active moiety phenobarbital in Sun Pharma's drug had been 'previously approved' by the FDA." Id. B. Analysis When "addressing a question of statutory interpretation, [the court] begin[s] with the text." City of Clarksville v. FERC, 888 F.3d 477, 482 (D.C. Cir. 2018). "To construe [the] text, [the court] look[s] to the ordinary meaning of its key terms." Novartis Pharms.

Corp. v. Johnson, 102 F.4th 452, 460 (D.C. Cir. 2024) (citation omitted). It is a "'fundamental canon of statutory construction' that words generally should be 'interpreted as taking their ordinary, contemporary, common meaning... at the time Congress enacted the statute.'" Wisconsin Cent. Ltd v. United States, 585 U.S. 274, 284 (2018) (alteration in original) (citation omitted).

A straightforward reading of Section 529 favors Plaintiffs. Though the FDCA nowhere defines the term "approved," it has a "precise and undisputed meaning." Mead Johnson Pharm. Grp. v. Bowen, 838 F.2d 1332, 1336 (D.C. Cir. 1988). "Approval" in that context means a formal positive decision on an application by the FDA. See id. That was the D.C. Circuit's conclusion in Sandoz.

There, too, the court interpreted the meaning of "approved" in an FDCA provision intended to provide drug developers a period of 9 marketing exclusivity to incentivize the manufacturing of new drugs. 57 F.4th at 280 (interpreting § 355(j)(5)(F)(ii)).

The section at issue grants a period of exclusivity to a new chemical entity "for a drug, no active ingredient[4]... of which has been approved in any other" drug application. Id. (alteration in original). The court turned to dictionaries to define "approved": "To 'approve' means '[t]o sanction officially.' Approve, BLACK'S LAW DICTIONARY (6th ed. 1990); see also Approve, v.1, OXFORD ENGLISH DICTIONARY (2d ed.

1989) (meaning '[t]o confirm authoritatively; to sanction'); Approve, MERRIAM-WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY (1983) (meaning 'to accept as satisfactory' or 'to give formal or official sanction to')." Id. (alterations in original). Applying those definitions here leads to the conclusion that the active moiety in NDA 000597 was never "previously approved," as required by Section 529.

The FDA did not "sanction officially" phenobarbital, or "confirm [it] authoritatively," or "accept [it] as satisfactory." To the extent it was ever "approved," it was only "deemed" approved in 1962 under a statutory transition period during which drugs deemed "effective" under the original FDCA could continue to be marketed until their efficacy was established to the FDA's satisfaction.

NDA 000597 never secured such acceptance. The FDA determined in the early 1970s that there was no evidence to support the drug's effectiveness and, in 1978, its sponsor asked to withdraw the application, a request the FDA granted in 1982.

In no ordinary sense then was NDA 000597 ever "approved." Defendants do not grapple with this plain meaning understanding of "approved." Instead, they argue that "an application deemed approved is approved." Defs.' Mot. at 9. And a "deemed" 4 The FDCA was later amended to substitute the term "active moiety" for "active ingredient." Sandoz, 57 F.4th at 274 n.1.

10 approval is an "approval for all intents and purposes." Id. at 10. But that contention misses the mark for two reasons. For one, "[a] thing that is deemed to be something else does not become that something else. 'Deem' means: 'To treat (something) as if (1) it were really something else, or (2) it has qualities that it doesn't have.'" Chao v. Russell P. Le Frois Builder, Inc., 291 F.3d 219, 229 (2d Cir.

2002) (quoting Black's Law Dictionary 425 (7th ed. 1999)). So, the fact that Congress "deemed" "approved" NDAs like NDA 000597, which had become effective by agency inaction, did not make those drugs "approved" in the same sense as one receiving affirmative FDA approval, as the 1962 Amendments required going forward. Nowhere did Congress indicate it meant to make them equivalent for all purposes.

To the contrary, Congress in 1962 intended for "deemed" approval status to function only temporarily, until the drug sponsor submitted substantial evidence backing the drug's effectiveness. See USV Pharm., 412 U.S. at 663; Cooper Lab'ys, 501 F.2d at 776 n.12. Decades later, when it enacted Section 529, Congress gave no hint that it intended for this ancient category of "deemed approved" drugs to block a novel pediatric drug from receiving a priority review voucher.

Defendants' reading also does not square with Section 529's full text. The "any other application" "previously approved" must be one made "under subsection (b)(1), (b)(2), or (j)." The three enumerated subsections track the three approval pathways created by the Hatch– Waxman Amendments. Each of those subsections requires "[t]he FDA [to] make[] a single decision whether to approve or reject the drug." Sandoz, 57 F.4th at 280.

The FDA must determine "whether the proposed drug meets a variety of criteria—including whether pharmacological tests reliably demonstrate the drug's efficacy and safety and whether the manufacturing process will preserve the drug's purity." Id. But, of course, NDA 000597 was never "approved" in that manner. 11 It enjoyed "approved" status only as a temporary designation, which required no demonstration of safety or efficacy.

By cross-referencing the three Hatch–Waxman pathways in Section 529, Congress clearly signaled that any "previous approval" had to have successfully navigated one of the pathways. Defendants respond that it is not fatal to their position that Section 529 specifically refers to the Hatch–Waxman pathways. They point out that what would become Section 505(b)(1) under the Hatch–Waxman Amendments was previously codified in Section 505(b).

See Defs.' Mot. at 10. According to Defendants, that provision, as amended in 1962, "contained the same approval standard requiring the establishment of safety and effectiveness that § 505(b)(1) contained at the time § 529 was enacted in 2012 and extended in 2021." Id. at 14.

Thus, Defendants contend, "even if the word 'approved' in § 529 incorporates whatever approval standard existed at the time of [its] enactment or amendment, Congress deemed NDA 597 to be 'approved' under that standard." Id. But this argument incorrectly assumes that Congress in 2012 (and again in 2021) equated "deemed" approvals from 1962 with the "sanction officially"– approval that Congress made the standard in the 1962 Amendments.

For the reasons already discussed, there is no reason to believe Congress drew such equivalency for purposes of Section 529. Finally, Defendants' construction is at odds with what Congress meant to accomplish in Section 529, and this case illustrates exactly why Congress created the voucher program.

As Plaintiffs explain and Defendants do not dispute, Sezaby is the first "phenobarbital product to ever establish efficacy." Pls.' Mot. at 6 (alteration omitted). There was previously no approved drug on the market to treat neonatal seizures, and the only marketed drug identified containing the same active moiety was one that qualified for distribution through agency inaction in 1939 and that ultimately was never proven to be effective.

See id. at 11, 14. Defendants offer no explanation 12 why Congress would have meant for a drug that was never able to show efficacy and that was ultimately pulled from the market to erect an obstacle to future developments in the treatment of rare pediatric diseases. Congress could not have intended such a result, which plainly conflicts with Section 529's purpose.

Accordingly, the court holds that NDA 000597 was not a "previously approved" application under "(b)(1), (b)(2), or (j)" of Section 505 for purposes of Section 529. The FDA therefore acted contrary to law in denying Plaintiffs a priority review voucher upon the agency's approval of Sezaby.

V. CONCLUSION For the foregoing reasons, Plaintiffs' Motion for Summary Judgment, ECF No. 21, is granted, and Defendants' Cross-Motion for Summary Judgment, ECF No. 28, is denied. Plaintiffs' pending Motion for Judicial Notice and to Complete the Administrative Record, ECF No. 22, is denied as moot. A final, appealable order accompanies this Memorandum Opinion.

Dated: December 1, 2025 Amit P. Mehta United States District Judge 13