UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 14-1522

MYLAN PHARMACEUTICALS, INCORPORATED,

Plaintiff – Appellant,

and

WATSON LABORATORIES, INCORPORATED; LUPIN PHARMACEUTICALS, INCORPORATED,

Intervenors/Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant – Appellee,

TEVA PHARMACEUTICALS USA, INCORPORATED,

Intervenor/Defendant – Appellee.

No. 14-1529

MYLAN PHARMACEUTICALS, INCORPORATED,

Plaintiff,

WATSON LABORATORIES, INCORPORATED,

Intervenor/Plaintiff,

and

LUPIN PHARMACEUTICALS, INCORPORATED,

Intervenor/Plaintiff – Appellant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant – Appellee,

TEVA PHARMACEUTICALS USA, INCORPORATED,

Intervenor/Defendant – Appellee.

No. 14-1593

MYLAN PHARMACEUTICALS, INCORPORATED,

Plaintiff,

LUPIN PHARMACEUTICALS, INCORPORATED,

Intervenor/Plaintiff,

and

WATSON LABORATORIES, INCORPORATED,

Intervenor/Plaintiff – Appellant,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendant – Appellee,

TEVA PHARMACEUTICALS USA, INCORPORATED,

Intervenor/Defendant – Appellee.

Appeals from the United States District Court for the Northern District of West Virginia, at Clarksburg. Irene M. Keeley, District Judge. (1:14-cv-00075-IMK)

Argued: September 17, 2014 Decided: December 16, 2014

Before WILKINSON, SHEDD, and WYNN, Circuit Judges.

Reversed and remanded by unpublished opinion. Judge Wynn wrote the opinion, in which Judge Wilkinson and Judge Shedd joined.

ARGUED: Douglas Brooke Farquhar, HYMAN, PHELPS & MACNAMARA, P.C., Washington, D.C.; Chad Allen Landmon, AXINN, VELTROP & HARKRIDER LLP, Hartford, Connecticut; Arthur Y. Tsien, OLSSON FRANK WEEDA TERMAN MATZ, PC, Washington, D.C., for Appellants. Daniel Tenny, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Michael David Shumsky, KIRKLAND & ELLIS LLP, Washington, D.C., for Appellees. **ON BRIEF:** John H. Tinney, Jr., THE TINNEY LAW FIRM, PLLC, Charleston, West Virginia, for Appellant Lupin Pharmaceuticals, Incorporated. Jennifer M. Thomas, HYMAN, PHELPS & MCNAMARA, P.C., Washington, D.C.; Ralph S. Tyler, VENABLE LLP, Washington, D.C., for Appellant Mylan Pharmaceuticals, Incorporated. Mark D. Alexander, AXINN, VELTROP & HARKRIDER LLP, Hartford, Connecticut, for Appellant Watson Laboratories, Incorporated. Stuart F. Delery, Assistant Attorney General, William B. Schultz, General Counsel, Scott R. McIntosh, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; William J. Ihlenfeld, II, United States Attorney, OFFICE OF THE UNITED STATES ATTORNEY, Wheeling, West Virginia; Elizabeth H. Dickinson, Associate General Counsel, Annamarie Kempic, Deputy Chief Counsel, UNITED STATES FOOD AND DRUG ADMINISTRATION, Rockville, Maryland; Shoshana Hutchinson, Associate Chief Counsel, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Washington, D.C., for Appellee United States Food and Drug Administration. John C. O'Quinn, John K. Crisham, Stephen S. Schwartz, KIRKLAND & ELLIS LLP, Washington, D.C., for Appellee TEVA Pharmaceuticals USA, Incorporated.

Unpublished opinions are not binding precedent in this circuit.

WYNN, Circuit Judge:

In April 2014, the U.S. Food and Drug Administration ("FDA") issued a letter decision regarding the rights of patent holders and the ease with which generic drugs could enter the market place under the Hatch-Waxman Act. Though disclaiming that it was adjudicating the rights of any specific parties, this letter effectively prevents Appellants Mylan Pharmaceuticals, Inc., Watson Laboratories, Inc., and Lupin Pharmaceuticals, Inc. from bringing their generic versions of celecoxib, an arthritis treatment drug currently sold under the brand name Celebrex, to the market until June 2015. The FDA based its decision on its interpretation of a Hatch-Waxman Act provision it deemed ambiguous. However, as explained below, we find the pertinent provision unambiguous in context. Accordingly, we reverse the district court's opinion upholding the FDA's letter decision.

I.

In 1984, Congress amended the Food, Drug, and Cosmetic Act to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H.R. Rep. No. 98-857, part 1, at 14. See The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act" or "Hatch-Waxman"), Pub. L. No. 98-417, 98

Stat. 1585 (1984), formerly codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, 282. In furtherance of this goal, the Hatch-Waxman Act created a truncated approval process for generic drugs and, crucially for this case, the potential for a 180-day period of market exclusivity for the first company to bring its generic drugs to market. The statute, and specifically the language at issue in this case, has since been amended by the Medicare Prescription Drug Improvement and Modernization Act, Pub L. No. 108-173, 117 Stat. 2066 (2003). Because the initial Abbreviated New Drug Applications at issue in this case were filed prior to the enactment of this revision, the pre-amendment version of the statute applies.

Before marketing a new drug, a drug company must submit a New Drug Application, an elaborate document detailing, among other things, the drug's safety and efficacy. See 21 U.S.C. § 355(b)(1). A New Drug Application also must contain "the patent number and the expiration date of any patent which claims the drug . . . or which claims a method of using such drug[.]" Id. The FDA publishes information about those patents and methods of use "in a fat, brightly hued volume called the Orange Book[.]" Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012).

Generic drug companies, by contrast, need not submit a complete New Drug Application to seek FDA approval of their

drugs. Under Hatch-Waxman, they may instead file an Abbreviated New Drug Application, in which they may "rely on the clinical studies performed by the pioneer drug manufacturer" instead of having "to prove the safety and effectiveness of [their] generic drug from scratch." aaiPharma, Inc. v. Thompson, 296 F.3d 227, 231 (4th Cir. 2002). "[T]he generic manufacturer must prove only that its drug is bioequivalent to the brand name drug it wants to copy." Id.

In its Abbreviated New Drug Application, a generic drug company must make one of four certifications regarding the non-infringement of "listed" patents referenced in the Orange Book. See 21 U.S.C. § 355(j)(2)(A)(vii). With the fourth certification option (a "Paragraph IV certification"), the relevant one for this case, generic drug makers confirm that any patent for the pioneer drug is invalid or will not be infringed. Id. Additionally, the Abbreviated New Drug Application applicant must also certify to "later-listed patents" when they are published in the Orange Book. Id. § 355(j)(2)(B).

If, as in this case, a generic drug company makes a Paragraph IV certification, it must provide notice of its Abbreviated New Drug Application to the owner of any patent covered by the Paragraph IV certification and to the brand-name company that filed the New Drug Application. Id. § 355(j)(2)(B)(i). Hatch-Waxman treats a Paragraph IV

certification as an artificial act of patent infringement by the generic drug company. Id. §§ 355(j)(2)(B)(i)-(ii); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). If the brand-name company wants to defend its patent, it must bring an infringement action within forty-five days of receiving the generic company's notice. 21 U.S.C. § 355(j)(5)(B)(iii).

In general, the FDA "shall approve or disapprove" the generic drug application within 180 days of receiving the Abbreviated New Drug Application. Id. § 355(j)(5)(A). However, the effective date of the FDA's approval is dependent on several factors, including which of the four certifications the generic company used. In the case of a Paragraph IV certification, the timing of the FDA's approval of an Abbreviated New Drug Application depends on whether the brand-name company brings an action to defend its patent. If it does, the FDA's approval of the Abbreviated New Drug Application is stayed for 30 months. Id. If, during that 30-month stay, "a court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision." Id. § (j)(5)(B)(iii)(I).

If more than one applicant submits an Abbreviated New Drug Application with a Paragraph IV certification, the statute provides that a later-filed "application shall be made effective not earlier than one hundred and eighty days after" either (1)

the date that the FDA received notice that the first-filer began marketing the drug; or (2) "the date of a decision of a court in an action [brought by the brand-name company against the company filing the Abbreviated New Drug Application] holding the patent which is the subject of the certification to be invalid or not infringed"—also known as the "court-decision trigger." Id. § (j)(5)(B)(iv). This 180-day exclusivity period, potentially worth millions of dollars, is meant to incentivize generic pharmaceutical companies to bear the costs of the patent infringement lawsuit. Teva Pharm., USA, Inc. v. Leavitt, 548 F.3d 103, 104 (D.C. Cir. 2008).

Finally, when multiple patents protect a brand-name drug from competition, the FDA, under the pre-amendment version of Hatch-Waxman at issue in this case, took a "patent-by-patent approach" in determining whether a generic drug company is entitled to the 180-day exclusivity period. As it explained in its letter decision:

> eligibility for 180-day exclusivity would be based on which company submitted the first paragraph IV certification challenging each listed patent. Therefore, in cases where multiple patents are listed, different applicants may have the first paragraph IV certification as to different patents and multiple ANDA applicants may simultaneously be eligible for 180-day exclusivity as to the particular patents on which they were first.

J.A. 43. None of the parties challenge the FDA's patent-by-patent approach (while recognizing that the law has, in the interim, changed and that the FDA now uses a drug-by-drug approach).

II.

Pfizer produces the brand-name arthritis drug Celebrex. Celebrex was protected by the following patents listed in the Orange Book as of 2003: 5,466,823 ("the '823 patent"); 5,563,165 ("the '165 patent"); 5,760,068 ("the '068 patent"); and one other patent not at issue in this case. In 2003, Teva filed Abbreviated New Drug Application 76-898, which contained Paragraph IV certifications as to the '823, '165, and '068 patents. Pfizer sued Teva for patent infringement, and the District Court of New Jersey held that all three patents were valid and infringed by Teva. Pfizer, Inc. v. Teva Pharms. USA, Inc., 482 F. Supp. 2d 390 (D.N.J. 2007). The Federal Circuit, however, reversed in part, deeming eleven of the claims in the '068 patent invalid. Pfizer, Inc. v. Teva Pharms. USA, Inc., 518 F.3d 1253 (Fed. Cir. 2008).

Teva then resubmitted its certifications as to the '823 and '165 patents as "Paragraph III certifications"—that is, they sought approval of their Abbreviated New Drug Application only subsequent to the expiration of those two patents. See 21

U.S.C. § 355(j)(2)(A)(vii). Meanwhile, several other generic drug manufacturers, including Mylan, Watson and Lupin, filed Abbreviated New Drug Applications for Celebrex based on Paragraph IV certifications.

On March 5, 2013, the United States Patent and Trademark Office ("PTO") reissued the invalidated '068 patent as RE44048 ("the '048 patent"), Pfizer notified the FDA, and two days later, the FDA listed the '048 patent in the Orange Book. On March 7, 2013, Teva, Mylan, and Watson amended their Abbreviated New Drug Applications so that their Paragraph IV certifications included the reissued patent. And Lupin amended its Abbreviated New Drug Application on March 28, 2013. Again, Pfizer sued for patent infringement.

One year later, in March 2014, the District Court for the Eastern District of Virginia deemed the '048 patent invalid for substantially the same reasons that the '068 patent had been invalidated. G.D. Searle LLC v. Lupin Pharms., Inc., No. 2:13-cv-00121 (E.D. Va. Mar. 12, 2014). Teva and Pfizer entered into a settlement agreement allowing Teva to market celecoxib in December 2014. Mylan and Watson also settled with Pfizer. Only Lupin remains in the appeal of that decision, which is pending in the Federal Circuit.

During the litigation of the '048 patent, the various drug manufacturers engaged in letter writing and private meetings

with the FDA inquiring into how the agency would approach approval of their celecoxib Abbreviated New Drug Applications. On April 24, 2014, the FDA issued a letter decision addressed to "Celecoxib ANDA Applicant." The question the FDA purported to answer was "whether a prior court decision on the original patent triggered (and exhausted) any exclusivity to which a first applicant on the original patent was entitled." J.A. 41. Underlying the FDA's question was the assumption "that the reissued patent cannot be the basis for a new period of 180-day exclusivity[.]" J.A. 49. The FDA concluded that:

> for purposes of 180-day exclusivity, upon the listing of a reissued patent, a prior court decision on the original patent is not regarded as having triggered 180-day exclusivity for the single bundle of patent rights represented by the original and reissued patent. In such a case, eligibility for 180-day exclusivity is only available to the applicant that first filed a paragraph IV certification to the original patent, and that applicant must make a timely submission of a paragraph IV certification to the reissued patent to remain eligible for 180-day exclusivity.

J.A. 51. The letter decision stated that the FDA was merely clarifying "the regulatory framework to be applied to the relevant ANDAs when such exclusivity determination is made[,]" and "not making a determination with respect to 180-day exclusivity in a particular case[.]" J.A. 46.

The following day, April 25, 2014, Mylan sought injunctive and declaratory relief against the FDA regarding its letter

decision. Mylan sought to prevent the FDA from granting any other company a 180-day exclusivity period. Watson and Lupin intervened as plaintiffs, and Teva intervened as a defendant. The district court consolidated the hearing on Mylan's preliminary injunction motion with a trial on the merits, granted Mylan's motion for judgment, but in favor of the FDA, and dismissed the case. Mylan Pharmaceuticals, Inc., v. FDA, No. 1:14-cv-00075-IMK Doc. 125 (N.D. W.Va. June 16, 2014). This appeal followed.

III.

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). We review a grant of summary judgment de novo, Nat'l Audubon Soc'y v. Dep't of the Navy, 422 F.3d 174, 185 (4th Cir. 2005), taking the facts in the light most favorable to the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

Under the Administrative Procedure Act, 5 U.S.C. § 551 et seq., we must set aside an agency action that is "not in accordance with law." Id. § 706(2)(A). To determine whether the FDA's interpretation of the Hatch-Waxman Act was "in accordance with law," we engage in the analysis set out by

Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842 (1984). The first inquiry under Chevron is whether "Congress has directly spoken to the precise question at issue." Id. at 842. "If the statute is clear and unambiguous 'that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" Bd. of Governors of the Fed. Reserve Sys. v. Dimension Fin. Corp., 474 U.S. 361, 368 (1986) (quoting Chevron, 467 U.S. at 842-43). In determining whether Congress has "directly spoken," we "begin by examining the plain language and give the relevant terms their common and ordinary meaning." Yi Ni v. Holder, 613 F.3d 415, 424 (4th Cir. 2010) (internal quotation marks and citation omitted). "This is because we must 'assum[e] that the ordinary meaning of that language accurately expresses the legislative purpose.'" Id. (quoting Gross v. FBL Fin. Servs., Inc., 557 U.S. 167, 175 (2009)). When ascertaining the ordinary meaning of words we may refer to standard reference works such as legal dictionaries. See, e.g., Id. at 425; Dickenson-Russell Coal Co., LLC v. Sec'y of Labor, 747 F.3d 251, 258 (4th Cir. 2014). Further, we are not to limit our inquiry solely to a precise statutory provision in isolation, as "[t]he meaning—or ambiguity—of certain words or phrases may only become evident when placed in context." Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132 (2000).

If step one leads to the conclusion that Congress has spoken clearly, that is the end of the Chevron inquiry. We move to Chevron step two only if "devices of judicial construction have been tried and found to yield no clear sense of congressional intent." Gen. Dynamics Land Sys., Inc. v. Cline, 540 U.S. 581, 600 (2004). See also Chamber of Commerce of U.S. v. N.L.R.B., 721 F.3d 152, 160 (4th Cir. 2013) ("Only if the statute is silent or ambiguous with respect to the specific issue are we to proceed to Chevron's second step, asking whether the agency's answer is based on a permissible construction of the statute." (internal quotation marks omitted)).

Here, Congress has spoken directly regarding the court-decision trigger. The statute makes plain that the 180-day exclusivity runs from "the date of a decision of a court in an action . . . holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. §355(j)(5)(B)(iv). As to generic celecoxib, such a decision was reached by the Federal Circuit in 2008. Pfizer Inc. v. Teva Pharms. USA, Inc., 518 F.3d 1253 (Fed. Cir. 2008). That decision struck eleven of the claims in Pfizer's '068 patent as invalid. Id. The '068 patent was the subject of the Paragraph IV certification that Teva submitted to FDA. Teva's 180-day exclusivity period as to the '068 patent began to run from the date the Federal Circuit issued its mandate in May 2008. And

the exclusivity period expired on November 9, 2008, i.e., 180 days later.

Hatch-Waxman does not define "patent" nor does it specifically speak to reissued patents. This does not, however, render the statute ambiguous. The "court-decision trigger" speaks of "the patent which is the subject of the certification." 21 U.S.C. §355(j)(5)(B)(iv) (emphasis added). FDA's interpretation of this language treats the original patent and the reissued patent as a single "bundle of rights" which can only be the subject of one Paragraph IV certification and therefore provides only a single 180-day exclusivity period. However, this interpretation is contrary to the plain statutory language.

Black's Law Dictionary defines "patent" as "[t]he governmental grant of a right, privilege, or authority." Black's Law Dictionary 1300 (10th ed. 2014). It also defines "reissue patent" as "[a] patent that is issued to correct unintentional or unavoidable errors in an original patent, such as to revise the specification or to fix an invalid claim." Id. at 1301. In other words, a reissue patent exists because of some mistake in the original patent. It does not grant the same "right[s], privilege[s], or authorit[ies]" as the original patent because the original cannot protect the rights it claims—it was issued in error or was otherwise mistake-ridden.

Instead, it is a separate grant of rights, even if elements of the reissued patent overlap with those of the original patent. See 35 U.S.C. § 251 (describing the reissue of defective patents).

The original 2008 court decision triggered a 180-day exclusivity period regarding the '068 patent. That patent was thus "the patent which" was "the subject of the certification" Teva sent to FDA in 2003. Because the '068 patent could not protect the rights it claimed, Teva's marketing of celecoxib would not infringe the original patent, at least to the eleven invalidated claims. Teva's successful challenge of the '068 patent, however, could not address its rights as to the '048 patent, which did not come into existence until years later. The reissued '048 patent represented a new set of rights granted by the PTO, due to the court-recognized mistake in the original '068 patent. The reissue necessitated new Paragraph IV certifications and a subsequent legal challenge to determine the patent's validity. Because the statute requires recertification as to a reissued patent, the '048 reissued patent thus was also "the patent which" was "the subject of the certification[s]" that Mylan, Teva, and Watson issued in 2013 and that led to litigation.

The plain language of the statute indicates that each patent that is the subject of a certification may trigger

exclusivity. The Hatch-Waxman Act required Abbreviated New Drug Application applicants to certify as to both the original and reissued patents; each could be "the patent which is the subject of the certification." 21 U.S.C. §355(j)(5)(B)(iv). Because we find that FDA's interpretation to the contrary violated the plain statutory language, we must set it aside. Household Credit Servs., Inc. v. Pfennig, 541 U.S. 232, 239 (2004) ("If [Congress has spoken to the question at issue], courts, as well as the agency, must give effect to the unambiguously expressed intent of Congress."). See also Mylan Pharms., Inc. v. FDA, 454 F.3d 270, 274-75, 276-77 (4th Cir. 2006) (holding that 21 U.S.C. § 355(j)(5)(B)(iv) was plain and therefore the court had no choice but to enforce the language as written).

IV.

For the reasons above, we reverse and remand with instructions for the district court to proceed with adjudicating the rights of the Abbreviated New Drug Application applicants consistent with this opinion.

REVERSED AND REMANDED