United States Court of Appeals for the Federal Circuit

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P.,
Appellants

v.

COLLEGIUM PHARMACEUTICAL, INC.,
Appellee

KATHERINE K. VIDAL, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2022-1482

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. PGR2018-00048.

Decided: November 21, 2023

JENNIFER L. SWIZE, Jones Day, Washington, DC, argued for appellants. Also represented by GREGORY A. CASTANIAS, JOHN R. BOULE, III; GASPER LAROSA, JOHN JOSEPH NORMILE, JR., New York, NY; PABLO DANIEL HENDLER, Potomac Law Group PLLC, New York, NY.

CHRISTOPHER A. PINAHS, Robins Kaplan LLP, Minneapolis, MN, argued for appellee. Also represented by JACOB M. HOLDREITH, BRENDA L. JOLY, EMILY TREMBLAY; OREN D. LANGER, New York, NY.

FARHEENA YASMEEN RASHEED, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by PETER J. AYERS, MAUREEN DONOVAN QUELER.

Before DYK, HUGHES, and STOLL, *Circuit Judges*.

DYK, *Circuit Judge*.

Purdue Pharma L.P. ("Purdue") appeals from a judgment of the Patent Trial and Appeal Board ("Board") finding claims 1–17 of U.S. Patent No. 9,693,961 ("'961 patent") unpatentable for lack of written description and anticipation. The Board issued its Final Written Decision after the statutory deadline, concluding that the passing of the deadline did not deprive it of authority. Purdue contends the Board lost jurisdiction once the deadline passed, and that, if the Board did not lose jurisdiction, the Board's decision was incorrect. We affirm.

BACKGROUND

Purdue is the owner of the '961 patent which issued on July 4, 2017. The patent is titled "Pharmaceutical Formulation Containing Gelling Agent" and is meant to "prevent[] or deter[] the abuse of opioid analgesics by the inclusion of at least one aversive agent in the dosage form." '961 patent, col. 5, ll. 54–56. Specifically, the addition of an aversive agent "helps to prevent injection, inhalation, and/or oral abuse by decreasing the 'attractiveness' of the dosage form to a potential abuser." *Id.* at col. 2, ll. 59–61. Representative claim 1 recites:

> 1. A method of preparing an abuse deterrent controlled release dosage form comprising:
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> combining oxycodone or a pharmaceutically acceptable salt thereof as active agent, polyglycolyzed glycerides, a C_{12} to C_{40} fatty acid or a mixture thereof, carnauba wax and beeswax, to form a homogenous mixture, wherein the oxycodone or pharmaceutically acceptable salt thereof is the sole active agent in the dosage form;
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> preparing particles from the homogenous mixture; and containing the particles in a capsule;
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> the abuse deterrent dosage form providing a therapeutic effect for about 12 hours or longer when orally administered to a human patient, and
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> the abuse deterrent dosage form being abuse deterrent when subjected to tampering comprising heating at a temperature greater than about 45° C.

Id. at col. 41, ll. 37–52.

Purdue brought suit against Collegium Pharmaceutical, Inc. ("Collegium") for infringement of the '961 patent in September 2017. On March 13, 2018, Collegium petitioned the Board for post grant review ("PGR") of claims 1–17 of the '961 patent. The district court infringement case proceeded in parallel to the PGR.

In the PGR, Purdue argued that the '961 patent was not subject to PGR as it claimed priority to an August 6, 2001, application, and applications filed before March 16, 2013, were not subject to PGR. The Board found the challenged claims eligible for PGR because the pre-America Invents Act ("AIA") application to which Purdue claimed

priority did not contain sufficient written description support for the claimed invention, and the effective filing date was therefore after March 16, 2013. Based on that finding, and a finding of likely lack of sufficient written description in the '961 patent itself, the Board instituted PGR. Under 35 U.S.C. § 326(a)(11) and 37 C.F.R. § 42.200(c), the Board had one year to issue a Final Written Decision subject to a six-month extension for "good cause."

On September 24, 2019, Purdue filed a Notice of Bankruptcy Filing and Imposition of Automatic Stay. The Board subsequently stayed the PGR proceeding, and the parallel district court case was also stayed.

The one-year deadline fell on October 4, 2019. Before the deadline, on October 2, 2019, the Chief Administrative Patent Judge found good cause to grant a six-month extension so the bankruptcy court could assess whether the automatic stay applied to PGRs. Petitioner Collegium took the position that the Automatic Stay provision was not applicable to Board proceedings. Purdue contended that the bankruptcy automatic stay applied to PGRs. The Board advised that "Petitioner should seek any relief it deems appropriate from the Bankruptcy Court." J.A. 868.

Neither party sought guidance from the bankruptcy court nor asked the bankruptcy court to lift the stay during the six-month extension period. The April 4, 2020, extended deadline passed. On July 2, 2020, Purdue moved at the bankruptcy court for the automatic stay to be partially lifted so the district court case could proceed. Collegium opposed the request and argued that if the stay were lifted for the district court case, it should also be lifted for the PGR proceeding. The bankruptcy court lifted the stay for both the district court case and the PGR proceeding on September 1, 2020.

On September 11, 2020, Purdue filed a motion to terminate the PGR proceeding, arguing the Board no longer had the authority to issue a Final Written Decision as the

18-month deadline had passed. On November 19, 2021, the Board denied Purdue's motion, explaining that "[a]pplying the principles from the Supreme Court cases assessing statutes without consequences for noncompliance with time limits, we hold that, under the circumstances of this case, the AIA's silence as to a consequence for timely issuing a final written decision does not divest us of our authority to issue our final written decision." J.A. 78. That same day the Board issued its Final Written Decision, finding claims 1–17 of the '961 patent unpatentable for lack of written description and anticipation.[1]

Purdue appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).[2]

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[1] The anticipation finding flowed from the lack of written description in the claimed priority application.

It is unclear why the Board took over a year after the stay was lifted to issue its Final Written Decision. As an intervenor in the case, the Patent and Trademark Office ("PTO") claims it was the result of Purdue's late argument that the Board lacked authority to issue a Final Written Decision, which necessitated more briefing. Additionally, because of the length of this PGR proceeding, there was turnover in the panel, and two panel change orders were issued.

[2] Collegium argues that Purdue's appeal was not timely as it occurred more than sixty-three days after the Board issued its Final Written Decision. We disagree that Purdue solely sought review of the motion to terminate, which Collegium argues is subject to a fourteen-day deadline pursuant to 37 C.F.R. § 42.71(d)(1). Purdue also sought Director review of the Final Written Decision which, contrary to Collegium's argument, was subject to a thirty-day deadline. This tolled Purdue's time to appeal, and once the Director denied review on February 7, 2022, Purdue timely appealed on February 16, 2022.

DISCUSSION

I

Purdue contends that if the Board fails to meet the deadline established by 35 U.S.C. § 326(a)(11) and 37 C.F.R. § 42.200(c) (one year plus the six-month extension), the Board no longer has the authority to issue a Final Written Decision. This appears to be the only proceeding in which the Board has failed to meet the statutory deadline, and this is accordingly a matter of first impression. Statutory interpretation is an issue of law reviewed de novo. *Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1330 (Fed. Cir. 2020).

Section 326(a)(11) of Title 35 provides:

> (a) Regulations—The Director shall prescribe regulations—
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> . . .
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> (11) requiring that the final determination in any post-grant review be issued not later than 1 year after the date on which the Director notices the institution of a proceeding under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 325(c)[.]

And 37 C.F.R. § 42.200(c) provides:

> (c) A post-grant review proceeding shall be administered such that pendency before the Board after institution is normally no more than one year. The time can be extended by up to six months for good cause by the Chief Administrative Patent Judge, or adjusted by the Board in the case of joinder.

The Supreme Court has established that "if a statute does not specify a consequence for non-compliance with statutory timing provisions, the federal courts will not in the ordinary course impose their own coercive sanction." *United States v. James Daniel Good Real Prop.*, 510 U.S. 43, 63 (1993); *see also Nielsen v. Preap*, 139 S. Ct. 954, 967 (2019); *Dolan v. United States*, 560 U.S. 605, 611 (2010); *Barnhart v. Peabody Coal Co.*, 537 U.S. 149, 159 (2003); *Regions Hosp. v. Shalala*, 522 U.S. 448, 459 n.3 (1998); *United States v. Montalvo-Murillo*, 495 U.S. 711, 717 (1990). We have "faithfully applied this rule of law as formulated by the Supreme Court . . . that, 'even in the face of a statutory timing directive, when a statute does not specify the consequences of non-compliance, courts should not assume that Congress intended that the agency lose its power to act.'" *Hitachi Home Elecs. (Am.), Inc. v. United States*, 661 F.3d 1343, 1347 (Fed. Cir. 2011) (quoting *Liesegang v. Sec'y of Veterans Affs.*, 312 F.3d 1368, 1376–77 (Fed. Cir. 2002)); *see also Transpacific Steel LLC v. United States*, 4 F.4th 1306, 1320–21 (Fed. Cir. 2021). Where "the statute does not specify" the "consequences of the missed deadline . . . [the Supreme] Court has looked to statutory language, to the relevant context, and to what they reveal about the purposes that a time limit is designed to serve," in order to determine the impact of the deadline. *Dolan*, 560 U.S. at 610. The statute at issue here does not provide consequences for non-compliance with the deadline.

Thus, following the Supreme Court's rule, the Board has authority to issue a Final Written Decision even after the deadline proscribed in the statute has passed absent any contrary indication in the language, structure, or legislative history of the statute.

A

Purdue argues there are indications in the statutory language that support the view that the Board loses its

authority to issue a Final Written Decision after the deadline expires.

First, Purdue argues that the use of "shall" and "requiring" in section 326(a)(11) deprives the Board of authority to issue a Final Written Decision after the deadline. Purdue's argument is contrary to the Supreme Court's decision in *Brock*. In *Brock*, the Court held the "requirement that the Secretary 'shall' take action within 120 days does not, standing alone, divest the Secretary of jurisdiction to act after that time." *Brock v. Pierce Cnty.*, 476 U.S. 253, 266 (1986). Purdue contends that *Brock* is distinguishable because the statute contains more than just "shall . . . standing alone," *see id.*, because it reads the "Director *shall* prescribe regulations– . . . *requiring* that the final determination in any post-grant review be issued not later than 1 year." 35 U.S.C. § 326(a)(11) (emphases added). The word "requiring" simply is the equivalent of "shall," and *Brock* governs.

Second, Purdue, relying on *French v. Edwards*, 80 U.S. 506 (1871), contends that the "negative words" of "not later than 1 year" and "by not more than 6 months" in section 326(a)(11) show "the acts required shall not be done in any other manner or time than that designated." *Id.* at 511. But *French* did not involve a statutory deadline, and in later cases, the Supreme Court has held that similar statutory language as that involved here does not result in a loss of authority. *Barnhart*, 537 U.S. at 161 (statute set the deadline as "not later than 60 days after the enactment date"); *Dolan*, 560 U.S. at 607 (statute required action "not to exceed 90 days after sentencing"). Similarly, we have held that a statute containing "not later than" created "timing provisions [that] are at best precatory rather than mandatory." *Liesegang*, 312 F.3d at 1371, 1377.

Third, Purdue contends the statutory language bars action after the statutory deadline because section 326(a)(11) is linked to the Board's jurisdictional grant in section 6 of

35 U.S.C. Section 326(c) provides that "[t]he Patent Trial and Appeal Board shall, *in accordance with section 6*, conduct each post-grant review instituted under this chapter" (emphasis added). The Board has identified section 6 as the source of its jurisdiction, *see* J.A. 3, thus Purdue argues that when the deadline in section 326(a)(11) passes, the Board's jurisdiction also expires. This is not correct. The Supreme Court has "repeatedly held that procedural rules, including time bars, cabin a court's power only if Congress has 'clearly state[d]' as much" and "absent such a clear statement, . . . 'courts should treat the restriction as nonjurisdictional.'" *United States v. Wong*, 575 U.S. 402, 409 (2015) (alteration in original) (quoting *Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 153 (2013)). The mere mention that PGRs shall be conducted "in accordance" with section 6 or PGRs be conducted "pursuant to" chapter 32 does not rise to the level of a clear statement that section 326(a)(11) is jurisdictional.

Fourth, Purdue argues that the exceptions in section 326(a)(11) for "good cause" and "joinder" show those are the only two limited circumstances under which the Board may issue a Final Written Decision after the one-year deadline.[3] Purdue further argues this precludes recognizing other exceptions, relying on *United States v. Johnson*, 529 U.S. 53, 58 (2000). The existence of statutory exceptions does not show that the Board is without authority to act once the deadline passes. In *Barnhart*, the statute provided for two exceptions to the deadline and the Court ultimately held the "[i]nitial assignment[s] made after [the deadline were] valid despite [their] untimeliness."

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[3] Section 326(a)(11) provides two exceptions to the one-year deadline. "[T]he Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 325(c)."

Barnhart, 537 U.S. at 152.[4] The Court found that "enunciation of two exceptions does not imply an exclusion of a third," "nor does it require the absolute finality of assignments urged by the companies." *Barnhart*, 537 U.S. at 170–71. Thus, exceptions to the deadline do not strip the Board of authority to issue a Final Written Decision after the deadline passed.

Finally, it is significant that section 328(a) mandates that the Board issue a Final Written Decision. And other provisions of the AIA use quite different language to bar action after deadlines pass. Section 315(b) contains explicit language denying agency power after a time deadline, saying "[a]n inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner . . . is served with a complaint alleging infringement of the patent." (emphasis added); *see also* section 321(c) ("A petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent or of the issuance of a reissue patent" (emphasis added)). Had Congress meant to deprive the agency of power in section 326(a)(11), it knew how to do it, and, significantly, it did not use language in section 326(a)(11) similar to that used in other sections.

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[4] The statute in *Barnhart* provided that the Commissioner of Social Security "shall, before October 1, 1993," assign each coal industry retiree who was eligible for benefits under the Coal Act to an operating company to fund said benefits. 26 U.S.C. § 9706(a); *Barnhart*, 537 U.S. at 152. There were "two exceptions [to the deadline] recognizing changes for initial error or the demise of an assignee operator." *Barnhart*, 537 U.S. at 170 (referring to 26 U.S.C. § 9704(f)(2)).

B

Just as the structure of the statute does not support denying the Board authority after the deadline, the legislative history likewise does not support denying the authority to act after the one-year period passes. Congress enacted the AIA in part to replace inter partes reexaminations. Congress complained that inter partes reexaminations were lengthy and inefficient, often lasting three to five years. 157 Cong. Rec. 3429 (Mar. 8, 2011). The AIA provided for PGRs and IPRs, which were "designed to allow parties to challenge a granted patent through a[n] expeditious and less costly alternative to litigation." Introduction of Patent Reform Act, 153 Cong. Rec. E774 (Apr. 18, 2007). Congress had a clear intent to make patent review expeditious, which was reflected in the deadline in section 326(a)(11). But the importance of the deadline does not support denying authority after the deadline passes. To the contrary, forbidding the Board to issue a Final Written Decision after the deadline has passed would go against Congressional intent. If the Board could not issue a Final Written Decision, the parties would be forced to pursue the issue in district court litigation. This is the exact opposite of the purpose of the AIA, which is meant to create a more efficient alternative to district court litigation. Further, some of the work done during the PGR would be lost and the parties would have to duplicating briefing and arguments. This certainly is not the efficient process contemplated by the AIA.

Purdue argues that under the Board's reading "[section] 326(a)(11) would mean nothing more than the undefined timing for reexamination that Congress disliked and replaced." Brief of Appellants Purdue Pharma L.P. and Purdue Pharmaceuticals L.P. at 15. This is not accurate. The Board may not ignore statutory deadlines. *See, e.g., Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426 (Fed. Cir. 1988) (holding the Board may not indefinitely stay an ex parte reexamination in light of parallel district court litigation

via the "special dispatch" standard). "[W]hen an agency is compelled by law to act within a certain time period . . . a court can compel the agency to act." *Norton v. Southern Utah Wilderness All.*, 542 U.S. 55, 65 (2004). The appropriate remedy is mandamus. *Telecommunications Rsch. & Action Ctr. v. F.C.C.*, 750 F.2d 70, 76 (D.C. Cir. 1984); *Mylan Lab'ys Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1380–81 (Fed. Cir. 2021) (quoting *Int'l Union, United Mine Workers of Am. v. U.S. Dep't of Lab.*, 358 F.3d 40, 43 (D.C. Cir. 2004)) ("[U]nreasonable delay of agency action . . . 'defeats [our] prospective jurisdiction' . . . [t]o protect our future jurisdiction, we have jurisdiction to review [a] petition for a writ of mandamus"); *In re Paralyzed Veterans of Am.*, 392 F. App'x 858, 859–860 (Fed. Cir. 2010) (non-precedential); *see also* 5 U.S.C. § 706(1). Contrary to the PTO's arguments, mandamus is available immediately upon the deadline's expiring, assuming that the other requirements for issuance of the writ are satisfied. There is no requirement to show unreasonable delay in the issuance of the decision—only that the deadline has passed.

Here, Purdue had an available mandamus remedy and simply chose not to seek to compel an earlier decision from the Board. Failure to seek relief by mandamus does not, however, mean a loss of the Board's authority to act. [5]

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[5] We do not reach the question of whether the bankruptcy automatic stay applies to PGRs. This would require interpretation of the Bankruptcy Code. The Bankruptcy Code provides that a bankruptcy petition stays "the commencement or continuation . . . of a judicial, administrative, or other action or proceeding against the debtor." 11 U.S.C. § 362(a)(1). There is an exception to the automatic stay for "the commencement or continuation of an action or proceeding by a governmental unit . . . to enforce such governmental unit's or organization's police and regulatory

Despite Purdue's numerous arguments for cabining the Board's authority, we conclude that the Board's failure to comply with the statutory deadline does not deprive it of authority thereafter to issue a final written decision.

II

Having concluded the Board retained the authority to act, we consider the Board's holding that the claims lacked written description support.[6] Whether a patent claim satisfies the written description requirement of 35 U.S.C. § 112 is a question of fact reviewed for substantial evidence. *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1354 (Fed. Cir. 2015). To satisfy the written description requirement, the description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (alteration in original) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)). "[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* We have required that the specification "provide sufficient 'blaze marks' to guide a reader through the forest of disclosed possibilities toward the claimed compound." *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346 (Fed. Cir. 2013). The

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power, including the enforcement of a judgment other than a money judgment, obtained in an action or proceeding by the governmental unit to enforce such governmental unit's or organization's police or regulatory power." *Id.* § 362(b)(4). The question is whether this exception applies to PTO IPR or PGR proceedings.

[6] As noted earlier, there was also an anticipation ground argued in the PGR, which was dependent on written description in the priority application.

issue here is whether the '961 specification adequately discloses the claimed polyglycolyzed glycerides ("PGGs") as an aversive agent. The Board found the claimed formulation was not disclosed. We conclude that substantial evidence supports the Board's finding.

Although the '961 claims on their face do not require an aversive agent, the specification makes clear that the claims require "inclusion of at least one aversive agent" and the parties agree that the claims require the use of an aversive agent. '961 patent, col. 5, ll. 53–56. The specification of the '961 patent states an aversive agent is "a bittering agent, an irritant, a gelling agent, or combinations thereof." *Id.* at col. 4, ll. 28–29. Long lists of potential bittering agents and gelling agents are provided. *See id.* at col. 5, l. 64–col. 6, l. 14; col. 6, l. 64–col. 7, l. 23. Among the extensive list of possible gelling agents, surfactants are given as an example. *Id.* at col. 7, l. 11. Later in the specification, PGGs are identified as a possible surfactant "useful in accordance with the present invention." *Id.* at col. 28, ll. 35–41.

While the specification discloses that some surfactants can be gelling agents and that gelling agents can satisfy the aversive agent requirement, the parties agree that not all surfactants are gelling agents. Oral Argument at 16:54–17:01. The specification does not say that PGGs are gelling agents, as Purdue's expert witness admitted. J.A. 3184 (79:9–18, 80:7–11). In fact, the only time PGGs are mentioned in the specification, they are described as a surfactant, and not as a gelling agent, and surfactants generally are described as "useful in accordance with the present invention." '961 patent, col. 28, ll. 36–37. In other parts of the specification, the patent recognizes that surfactants can be used completely separate from and in addition to the gelling agent. *Id.* at col. 25, ll. 45–46 (surfactants can be used as an "absorption enhancer"). Just because the specification states PGGs are useful for the invention does not suggest how PGGs are gelling agents. The disclosure of the

application does not reasonably convey to those skilled in the art that the inventor had possession of the claimed drug formula containing PGGs as a gelling agent (aversive agent). In other words, there are insufficient blaze marks.

The parties agree that the '961 patent "has substantially the same disclosures as the specification of" U.S. Provisional Application No. 60/310,534 ("'534 application") to which Purdue claims priority. J.A. 14. The specification for the '961 patent does not provide adequate written description support, and neither does the '534 application. Because the claims do not satisfy the written description requirement, we need not reach the issue of anticipation.

CONCLUSION

We affirm that the Board has authority to issue a Final Written Decision after the statutory deadline has passed. We also affirm the Board's determination that claims 1–17 of the '961 patent are unpatentable for lack of written description under 35 U.S.C. § 112.

AFFIRMED