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A Question of First Impression: What Happens When the PTAB Fails to Meet the Statutory Deadline for Issuing a Final Written Decision?

Tuesday, December 19th

4:00-5:00PM

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Purdue Pharma LP v Collegium Pharmaceutical, Inc., No. 2022-1481 (Fed. Cir. Nov. 21, 2023)

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

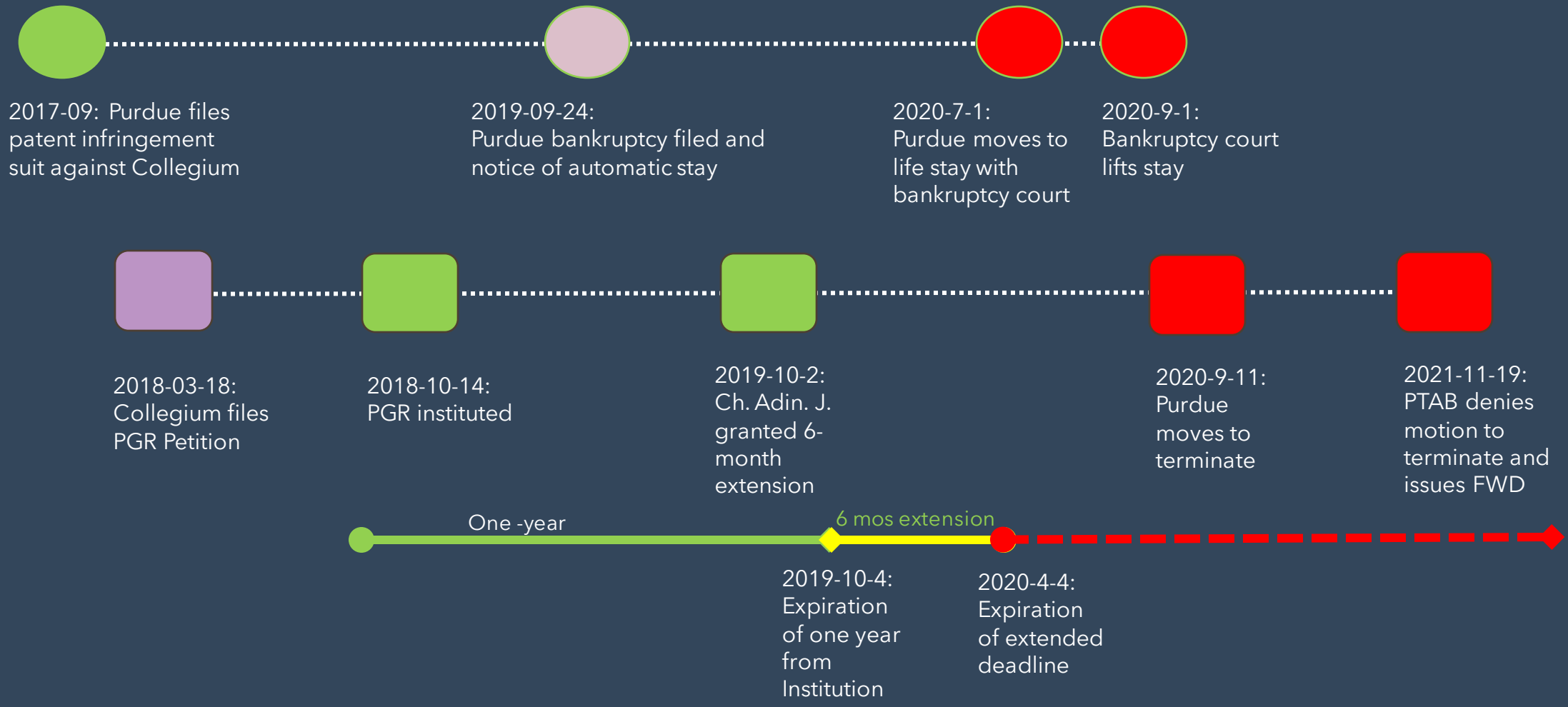
Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. PGR2018-00048.

Decided: November 21, 2023

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.

Time line of *Purdue v. Collegium*



PTAB Decision Denied Motion to Dismiss

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 issu- ing a final written decision does not divest us of our author- ity to issue our final written decision."

J.A. 78.

Statutory Deadline

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

(a) Regulations—The Director shall prescribe regulations—

...

(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)[.]

Regulatory Deadline

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.

Supreme Court Guidance on statutory deadlines

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).

Federal Circuit Application of SCOTUS law on statutory deadlines

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.

Application by *Purdue* Court

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.

The *Purdue* Court found that no indication in the statutory language to support Board Loses its authority

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.***

The *Purdue* Court found that no indication in the statutory language to support Board Loses its authority

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.

CLE Code

The *Purdue* Court found that no indication in the statutory language to support Board Loses its authority

Third, Purdue contends the statutory language bars ac- tion 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 non-jurisdictional.'" *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.***

The *Purdue* Court found that no indication in the statutory language to support Board Loses its authority

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." *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.

The *Purdue* Court found that no indication in the statutory language to support Board Loses its authority

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.***

The *Purdue* Court found 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.

The *Purdue* Court found the legislative history likewise does not support denying the authority to act after the one-year period passes.

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."

This is not accurate. The Board may not ignore statutory deadlines.

- 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.

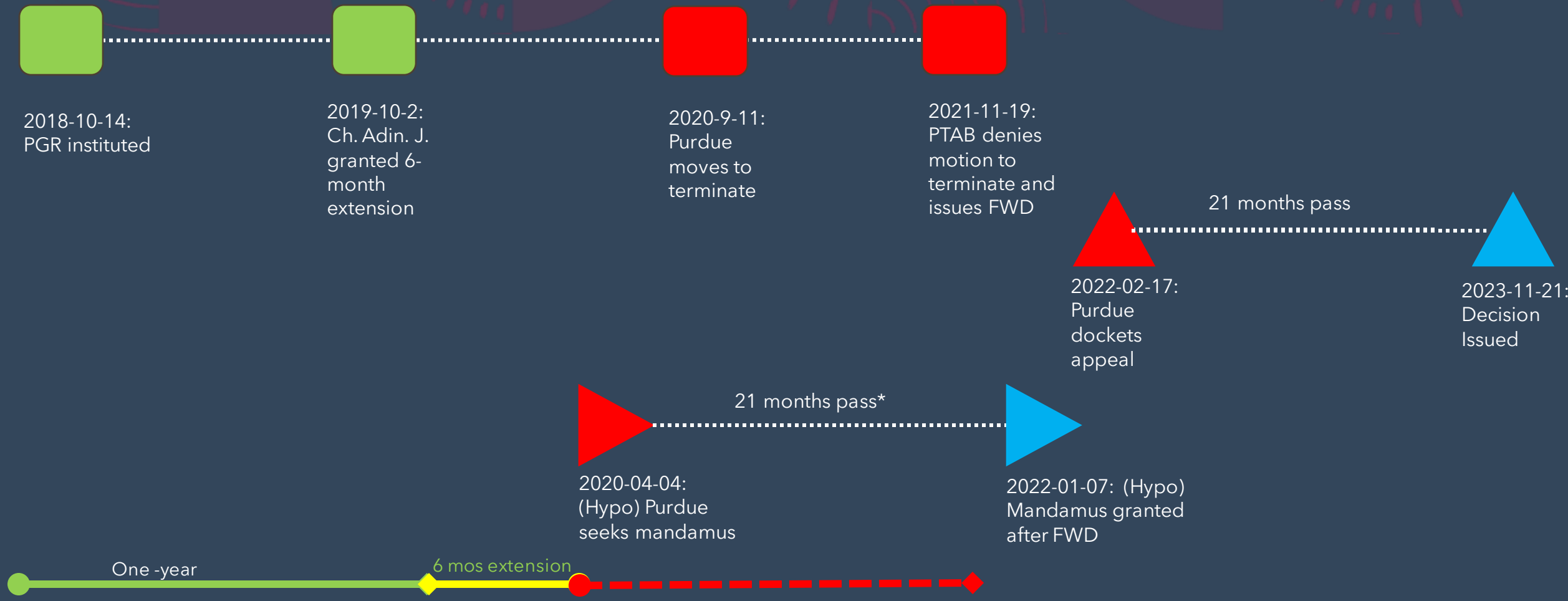
Mandamus As an Available Remedy

- "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." Opinion at 11.
- *But see Cheney v. US Dist. Ct.,* 542 U.S. 367, 380 (2004) (Mandamus is "a drastic and extraordinary remedy reserved for really extraordinary causes." (internal quotations omitted); *see also Mylan Labs. Ltd. v. Janssen Pharm.*, 989 F.3d 1375, 1381 (Fed. Cir. 2021) (quoting Cheney, denying mandamus for review of decision not to institute).

Three Conditions for Writ to Be Satisfied

- "As the writ is one of the most potent weapons in the judicial arsenal, three conditions must be satisfied before it may issue." The petitioner must: (1) show that it has **a clear and indisputable legal right;** (2) show it **does not have any other adequate method of obtaining relief**; and (3) convince the court that the writ is **appropriate under the circumstances**. *Mylan Labs*, 989 F.3d at 1381-82, citing *Cheney*.

Would Mandamus Have Been Useful?



*Parties seeking Mandamus relief often are given a decision re: Mandamus more quickly. For example, the court in *Mylan Labs.* issued a decision March 12, 2021, following a September 16, 2020 Board decision.

What About the APA?

- 5 U.S.C. § 555(b): ". . . With due regard for the convenience and necessity of the parties or their representatives and **within a reasonable time, each agency shall proceed to conclude a matter** presented to it. . . ."
- 5 U.S.C. § 706: "The reviewing court shall—

  (1) **compel agency action unlawfully withheld or unreasonably delayed** . . ."
- "A claim under §706(1) can proceed only where a plaintiff asserts that an agency has failed to take a *discrete* agency action that it is *required to take*. . . . [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*, 542 U.S. 55 (2004) (italics in original).

All Much Ado About Nothing?

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).

Left unanswered …

We do not reach the question of whether the bankruptcy automatic stay applies to PGRs. This would require interpretation of the Bankruptcy Code.

The *Purdue* Court's conclusion

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.

Questions?