

No. 23-1231

In the Supreme Court of the United States

CELECT, LLC,

Petitioner,

v.

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

Respondent.

**On Petition for Writ of Certiorari to the United
States Court of Appeals for the Federal Circuit**

**BRIEF OF THE AMERICAN INTELLECTUAL
PROPERTY LAW ASSOCIATION AS *AMICUS
CURIAE* IN SUPPORT OF CERTIORARI**

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COLLINS DICTIONARY, https://www.collinsdictionary.com/us/dictionary/english/adjust	5, 6

- Dennis Crouch, *Major Proposed Changes to Terminal Disclaimer Practice (and You are Not Going to Like it)*, PATENTLY-O (May 9, 2024), <https://patentlyo.com/patent/2024/05/proposed-terminal-disclaimer.html>..... 19
- Dennis Crouch, *Terminal Disclaimers: A Growing Concern in Patent Practice*, PATENTLY-O (May 10, 2024), <https://patentlyo.com/patent/2024/05/terminal-disclaimers-practice.html> 19, 21
- H.R. Rep. No. 106-287, Section 203 (1999)..... 5, 12
- Veera Korhonen, *Number of patents issued in the U.S. FY 2000-FY 2023*, STATISTA (Nov. 28, 2023), <https://www.statista.com/statistics/256571/number-of-patent-grants-in-the-us>..... 17
- Mark A. Lemley & Jason Reinecke, *Our More-Than-Twenty-Year Patent Term* (Stanford Law and Economics Olin Working Paper No. 586, Aug. 3, 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4529670. 17, 20
- MERRIAM-WEBSTER’S DICTIONARY,
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- Patent Term Adjustment Data April 2024*, USPTO PATENTS DASHBOARD,
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**STATEMENT OF INTEREST
OF *AMICUS CURIAE*¹**

The American Intellectual Property Law Association (“AIPLA”) is a national bar association representing the interests of approximately 7,000 members engaged in private and corporate practice, government service, and academia. AIPLA’s members represent a diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trade secret, trademark, and copyright law, as well as other fields of law relating to intellectual property. AIPLA’s members represent both owners and users of intellectual property. AIPLA’s mission includes providing courts with objective analyses to promote an intellectual property system that stimulates and rewards invention, creativity, and investment while accommodating the public’s interest in healthy competition, reasonable costs, and basic fairness.

¹ In accordance with Supreme Court Rule 37.6, AIPLA states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AIPLA and its counsel. Specifically, after reasonable investigation, AIPLA believes that (i) no member of its Board or Amicus Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to the litigation in this matter; (ii) no representative of any party to this litigation participated in the authorship of this brief; and (iii) no one other than AIPLA, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief. All parties received notice of AIPLA’s intention to file an amicus brief on June 12, 2024 due to a clerical error. Following notice, no party has objected to the filing of this brief.

AIPLA has no stake in any of the parties to this litigation or in the result of this case. AIPLA's only interest is in seeking correct and consistent interpretation of the law as it relates to intellectual property issues.

SUMMARY OF ARGUMENT

This case concerns the Federal Circuit's improper redrafting of 35 U.S.C. § 154(b), holding that the judge-made, equitable doctrine of non-statutory obviousness-type double patenting ("ODP") can invalidate a patent simply because it has a later expiration date than a reference patent due to Congress's guarantee of full patent term. Notably, this case does not involve the minutiae of how patent terms are actually calculated, whether under patent term adjustments ("PTA") or patent term extensions ("PTE"). Nor does it require addressing the underlying merits of the doctrine of ODP. Rather, this case turns on basic principles of statutory construction, which the Federal Circuit violated in *In re Collect* by reading in a "clear intent" of Congress where none exists in the text. This Court's review is thus critical to correct a fundamental error of statutory interpretation.

Moreover, in writing an equitable doctrine into Section 154, the Federal Circuit stripped that doctrine of all equity. ODP was intended as a judicial limit on patent term mischief. It exists to prevent patentees from filing a series of slight variations on an original "reference" patent and thus *unjustly extending* its limited monopoly. But the purpose of "adjusted" patent term under PTA is to guarantee a full period of exclusivity for patentees affected by delay entirely

outside of their control. It is, therefore, neither unjust nor an extension of term. It should not, therefore, expose a patent to invalidation under ODP.

Finally, the impact of the Federal Circuit's decision has already been significant and will only increase. Indeed, inconsistent applications already abound. Delay also continues to rise at the U.S. Patent and Trademark Office ("PTO"), resulting in more PTA awarded. Patentees expect and depend on patent term certainty; billions of dollars in investment, including in R&D, depend on it. Now, however, patentees are being forced to either disclaim their PTA en masse, thereby shortening exclusivity and reducing incentives to invent, or risk invalidation of their foundational patents—which is already happening in the lower courts. Because the Federal Circuit has expanded the doctrine of ODP far beyond its equitable roots to effectively eliminate Congressionally guaranteed patent term, AIPLA urges the Court to grant certiorari.

ARGUMENT

I. The Panel's Decision Improperly Expands a Judicially Created Doctrine to Override Statutorily Authorized Patent Term Adjustments.

A. Patent Term "Adjustments" Are Not "Unjust Extensions" of Term.

Under our patent system, issued patents are presumed valid and provide their holders with a limited period of exclusivity, referred to as "patent term." 35 U.S.C. § 282(a); *Id.* § 154(a)(2). Against a simple statutory backdrop concerning the appropriate

length of that term, the Federal Circuit conjured a “clear intent” of Congress to permit the equitable, judicially created doctrine of ODP to cut short patentees’ statutorily guaranteed term. But that purported “clear intent” conflicts with Section 154’s plain meaning. And even if it were necessary to reach beyond the statutory text in this case, the “clear intent” identified by the Federal Circuit is anything but.

“When interpreting a statute, we look first and foremost to its text.” *United States v. Alvarez-Sanchez*, 511 U.S. 350, 356 (1994); *see also Rutledge v. Pharm. Care Mgmt. Ass’n*, 592 U.S. 80, 92 (2020) (Thomas, J., concurring). Section 154 broadly covers the contents and term of patents. Section 154(a)(2) specifically provides that a patent term “begin[s] on the date on which the patent issues and end[s] 20 years from the date on which the application for the patent was filed in the United States, or, if the application contains a specific reference to an earlier filed application or applications,” then 20 years “from the date on which the earliest such application was filed.” That is, patent “term” does not exist (or begin) until the patent issues, but is capped at 20 years from the filing date of the earliest application in the chain.

Because of this, any delay in patent issuance necessarily shortens the length of time from issuance to expiration, and hence the overall length of the patent’s term. While applicant-caused delays may fairly reduce the length of term, Congress recognized the inherent unfairness of PTO-caused delays depriving an applicant of the full life of its patent. To address this unjust deprivation of a patentee’s

intellectual property rights, Congress created PTA in the American Inventors Protection Act of 1999 (“AIPA”), which was codified under Section 154(b). Pub. L. 106–113, 113 Stat. 1501A-557; *see* H.R. Rep. No. 106-287, Section 203 (1999) (noting that before enactment of the AIPA, “no adjustments were provided for administrative delays caused by the PTO that were beyond the control of the applicant”).

The purpose of PTA is plain from the statute’s text: Section 154(b) is entitled “*Adjustment of Patent Term*” and subsection 154(b)(1) is entitled “*Patent Term Guarantees*.” (emphases added). Thus, Section 154(b) provides adjustments of patent term as a “[g]uarantee of prompt patent . . . office responses.” 35 U.S.C. § 154(b)(1)(A). Where “the issue of an original patent is delayed due to the failure of the Patent and Trademark Office” to respond timely to a patent applicant in various circumstances, “the term of the patent *shall* be extended 1 day for each day” of delay. *Id.* (emphasis added). Although the statute does use the word “extended” when discussing how the patent term “adjustment” is made on a day-by-day basis, the meaning of Section 154 as a whole reflects that patent term is not actually “extended” by PTA but rather “adjusted”² to what was originally “guaranteed.”

² Congress’s use of the word “adjustment” in the title of this section is telling. To “adjust,” according to Merriam-Webster, is “to bring to a more satisfactory state: settle, resolve, rectify.” *Adjust*, MERRIAM-WEBSTER’S DICTIONARY, <https://www.merriam-webster.com/dictionary/adjustment> (last visited June 18, 2024). Collins includes the definitions “to fit,” “to make accurate by regulating,” and “to arrange rightly,” and Cambridge “to make [something] more correct.” *Adjust*, COLLINS DICTIONARY,

The following example is illustrative. Say a patent application is filed January 1, 2020, and thus will expire January 1, 2040. If the application proceeds promptly through prosecution, it will issue on January 1, 2024, and thus receive a “term” that runs from that date to January 1, 2040—that is, 16 years. If, however, the PTO does not act promptly and the patent does not issue until January 1, 2026, the patent’s term is only 14 years. Two years of patent term will be lost. To make up that lost term, awarding PTA will push the expiration date out to January 1, 2042. However, this is not truly an “extension” of term; since the patent issued later due to the PTO’s delay, the “term” of the patent as defined by Section 154 from January 1, 2026 (its issuance date), to January 1, 2042 (its adjusted expiration date), remains 16 years—that is, what it should have been absent PTO delay.

Thus, focusing on the expiration date alone for patents with PTA in applying ODP misses the mark—the public is not deprived of any time to freely practice the invention, since the patentee’s period of exclusivity conferred by a patent’s “term” started later. See *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014) (ODP is “based on the core principle that, in exchange for a patent, an inventor must fully disclose his invention and promise to permit free use of it at the end of his patent term”). Put simply, there is no unjust *extension* of term by

<https://www.collinsdictionary.com/us/dictionary/english/adjust> (last visited June 18, 2024); *Adjust*, CAMBRIDGE DICTIONARY, <https://dictionary.cambridge.org/us/dictionary/english/adjust> (last visited June 18, 2024).

PTA, but rather recovery of unjustly *lost* term due exclusively to PTO delay.³

B. Section 154 Does Not Address ODP.

Critically, nowhere does Section 154 (or any other section of the Patent Act) reference ODP. Nevertheless, the Federal Circuit determined that Congress implicitly intended to subvert its own explicit guarantee of term through PTA by way of a narrow limitation under Section 154(b)(2)(B). This section discusses “Disclaimed term” as one of the “Limitations” to “Adjustment of Patent Term” and simply recites that a patent whose term has already been disclaimed beyond a certain date may not “be adjusted . . . beyond the expiration date specified in the disclaimer.” Put differently, Section 154(b)(2)(B) provides a commonsense limitation on PTA: if an applicant has already specified a patent’s expiration date by disclaiming some amount of term (a “terminal disclaimer”), the applicant may not go beyond that

³ In contrast, Section 156 is expressly entitled “*Extension of patent term*” and contemplates such patent term “extensions” (PTE) for patents relating to drug products, methods of using such products, and methods of manufacturing such products to make up for regulatory delay. In the case of PTE, regulatory delay does not directly cut short patent “term” (that is, regulatory delay does not impact when the patent issues, as compared to PTO delays during prosecution). Instead, the rationale behind PTE is that regulatory delays effectively cut short the benefit and enjoyment of exclusivity provided by patent term when a patented product is not yet on the market. As noted above, Congress intentionally chose to use the word “adjustment” for PTA instead.

date, regardless of whether PTA should have guaranteed the full term of her patent.

The Federal Circuit ruled, however, that because terminal disclaimers and ODP are allegedly “two sides of the same coin,” Section 154(b)(2)(B)’s limitation on what happens if a disclaimer is filed also means that where one is *not* filed, ODP may invalidate the patent, even if the sole reason for the patent’s later expiration date is through PTA.⁴ *In re Collect, LLC*, 81 F.4th 1216, 1228-29 (Fed. Cir. 2023). “[I]n the absence of such disclaimers,” the Federal Circuit reasoned, “it would frustrate the clear intent of Congress for applicants to benefit from their failure, or an examiner’s failure, to comply with established practice concerning ODP, which contemplates terminal disclaimers as a solution to avoid invalidation of patents claiming obvious inventions.” *Id.* at 1229. Thus, while acknowledging that this narrow limitation in Section 154(b)(2)(B) “is not directly applicable to the present case” (since no terminal disclaimers were filed), the Federal Circuit

⁴ The Federal Circuit fails to note that it was the courts, not Congress, who originally tied terminal disclaimers to ODP. In deciding whether terminal disclaimers could overcome ODP rejections, the *In re Robeson* court noted that the “legislative history and Reviser’s Notes shed little light on exactly why Congress enacted” Section 252, which provides for terminal disclaimers. 331 F.2d 610, 613-14 (C.C.P.A. 1964). The court relied solely on the impressions of a Congressional staffer as the basis for Congress’s intent to link terminal disclaimers with ODP: “No specific reason for this provision appears in the printed record, but its proponents contemplated that it might be effective in some instances, in combatting a defense of double patenting.” *Id.* at 614 n.4.

nonetheless held the provision “critical” and “tantamount to a statutory acknowledgment that ODP concerns can arise when PTA results in a later-expiring claim that is patentably indistinct.” *Id.* at 1228.

That was error. “The ‘strong presumption’ that the plain language of the statute expresses congressional intent is rebutted only in ‘rare and exceptional circumstances.’” *United States v. Clintwood Elkhorn Mining Co.*, 553 U.S. 1, 11 (2008) (quoting *Ardestani v. INS*, 502 U.S. 129, 135 (1991)). No such circumstances exist here. Rather, the statute’s plain meaning controls. *Conn. Nat’l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) (“We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there.”). Courts may not invoke Congressional intent to overcome an unambiguous statutory guarantee. *Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1749 (2020) (“Judges are not free to overlook plain statutory commands on the strength of nothing more than suppositions about intentions or guesswork about expectations.”). Where Congress has stated that the term of a delayed patent “shall” be adjusted for each day of delay, its use of that word “creates an obligation impervious to judicial discretion.” *Smith v. Spizzirri*, 144 S. Ct. 1173, 1177 (2024) (quoting *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998)); *Petrella v. MGM*, 572 U.S. 663, 685 (2014) (equitable doctrine cannot “entirely . . . override the statute of limitations Congress prescribed”).

Even if looking past the statute's plain meaning were permissible here, a negative inference from a limited exception is not evidence of Congressional intent. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997) (“[L]imited congressional action should not be overread for negative implications.”); *Leo Sheep Co. v. United States*, 440 U.S. 668, 679 (1979) (“Given the existence of such explicit exceptions, this Court has in the past refused to add to this list by divining some ‘implicit’ congressional intent.”).

Moreover, the negative inference is improper: just because Section 154(b) permits an applicant to voluntarily surrender statutorily granted PTA via a terminal disclaimer does not mean that Congress intended to nullify PTA entirely by exposing PTA-adjusted patents, where no terminal disclaimer is filed, to ODP. Had Congress truly intended for patents with PTA to be de facto subject to ODP, it would have said so in the statute. *Cf. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 568 U.S. 123, 131 (2019) (merely adding a catchall phrase “would be a fairly oblique way of attempting to overturn” settled law, and thus “is simply not enough of a change for us to conclude that Congress intended to alter the meaning of” a statute); *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 109-10 (2011) (“[H]ad Congress intended to drop the heightened standard of proof . . . [.] we assume it would have said so expressly.”). Indeed, Congress logically could have referenced ODP in Section 101 itself (the doctrine’s purported statutory hook, *see Robeson*, 331 F.2d at 614) rather than in an ancillary statute relating to PTA. It did not. *See Bostock*, 140 S. Ct. at 1749

("[U]nexpected applications of broad language reflect only Congress's 'presumed point [to] produce general coverage—not to leave room for courts to recognize ad hoc exceptions.'") (quoting Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 101 (2012)).

At any rate, Congress could not possibly have had the intent the Federal Circuit imputes to it. ODP as we know it today did not exist when Congress enacted Section 154(b) in 1999. Not until the Federal Circuit's 2014 *Gilead* decision did ODP even look to the *expiration* date of a patent instead of its *issuance* date. See *Gilead*, 753 F.3d at 1218 (Rader, C.J., dissenting) (the court "craft[ed] a new rule" making the "expiration dates of the patents govern the [ODP] inquiry irrespective of filing or issue dates"). The Federal Circuit's reference to Congress's "clear intent" is thus an anachronism. See *Thompson v. Thompson*, 484 U.S. 174, 179 (1988) (examining Congressional intent with reference to "the circumstances of [a statute's] enactment"). Congress could not have intended in 1999 to both guarantee patents their full term by PTA and also expose them to invalidation by ODP, fifteen years before ODP ever focused on expiration dates.⁵

⁵ In fact, Congress intended to guarantee nothing less than full patent term. According to the House Report for the AIPA, the Act seeks to "compensate applicants *fully* for PTO-caused administrative delays." To accomplish that goal, "*no patent applicant* diligently seeking to obtain a patent will receive a term of less than . . . 17 years" and "*[o]nly those who purposely manipulate the system* to delay the issuance of their patents will

Ultimately, the Federal Circuit did not unearth Congress’s hidden intent—it just rewrote the statute. *Iselin v. United States*, 270 U.S. 245, 251 (1926) (“What the Government asks is not a construction of a statute, but, in effect, an enlargement of it by the court, so that what was omitted, presumably by inadvertence, may be included within its scope. To supply omissions transcends the judicial function.”); *see also* Scalia & Garner, *supra*, at 93. If Congress wishes for PTO delay to invalidate patents, Congress—not the courts—may amend Section 154. *See United States v. Rutherford*, 442 U.S. 544, 559 (1979) (“Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference.”). Until then, as the Federal Circuit itself has recognized, a “judge-made doctrine” may not “cut off a statutorily-authorized time extension.” *Novartis v. Ezra Ventures, LLC*, 909 F.3d 1367, 1375 (Fed. Cir. 2018).

II. The Federal Circuit’s Decision Represents Yet a Further Departure from the Equitable Underpinnings of ODP.

Not only did the Federal Circuit allow a judge-made equitable doctrine to override a clear statutory command, but it also simultaneously gutted that doctrine of its equitable purpose. *See Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020) (ODP is an “equitable doctrine”); *Ga.-Pac. Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1326 (Fed. Cir. 1999) (“Obviousness-type double patenting is a

be penalized” under the Act. H.R. Rep. No. 106-287, Section 203 (1999) (emphasis added).

judicially created doctrine grounded in public policy . . .”).

ODP’s purpose is to prevent “gamesmanship . . . through structuring of priority claims.” *Novartis*, 909 F.3d at 1374. In other words, ODP exists to “curtail [the] practice” of “fil[ing] successive continuations [to] obtain additional patent term for obvious modifications of . . . earlier claims.” *Gilead*, 753 F.3d at 1217.⁶

Unsurprisingly, prior to the Federal Circuit’s opinion in this case, courts dusted off ODP when needed to address gamesmanship. *See, e.g., Abiomed, Inc. v. Maquet Cardiovascular LLC*, Civil Action No. 16-10914-FDS, 2023 U.S. Dist. LEXIS 104095, at *101 (D. Mass. June 15, 2023) (“The gamesmanship concerns that underly [sic] the ODP doctrine are not present here.”); *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*, 533 F. Supp. 3d 170, 214 (D.N.J. 2021) (no ODP where “the granting of a PTA does not present the potential for gamesmanship by inventors to secure a second, later expiring patent for the same invention”); *Abbott Lab’s v. Lupin Ltd.*, No. 09-152-LPS, 2011 U.S. Dist. LEXIS 53846, at *26-27 (D. Del. May 19, 2011) (ODP “address[es] *unjustifiable* extensions of patent terms. Here, however, there is no

⁶ Although not before the Court now, ODP has also served to curb another form of gamesmanship and potential harassment: split ownership of multiple, patentably indistinct inventions by different entities. In this scenario, a party may unfairly have to defend itself from multiple lawsuits, or otherwise be forced to obtain and pay for licenses from multiple parties as to the same overall invention.

undeserved, extended patent term resulting from improper gamesmanship by the patentee.”).

The Federal Circuit itself recognized ODP’s limited purpose in *Novartis v. Ezra*. There, the patentee elected to apply PTE to an earlier-filed, earlier-issued patent. The challenger sought to invalidate that earlier-issued patent based on ODP, arguing that the PTE improperly extended the life of the later-issued one. The court disagreed, as the case did “not raise the traditional concern with [ODP] of a patent owner ‘extending his exclusive rights to an invention through claims in a later-filed patent that are not patentably distinct from claims in the earlier filed patent.’” 909 F.3d at 1374-75 (quoting *Proctor & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009)). See also *Gilead*, 753 F.3d at 1216-17 (finding gamesmanship extended patent term); *In re Braat*, 937 F.2d 589, 595 (Fed. Cir. 1991) (“[O]nly if the extension of patent right is *unjustified* is a double patenting rejection appropriate. There are situations where the extension is justified.”).

Novartis notwithstanding, the Federal Circuit’s opinion jettisons equity in favor of a bright-line rule. Now, “[a]n applicant’s ability to show that it did not engage in gamesmanship in obtaining a grant of PTA is not sufficient to overcome a finding that it has received an unjust timewise extension of term.” *Cellect*, 81 F.4th at 1230. Considering ODP’s deep roots in equity, this new rule represents a dramatic change and expansion from the century-long application of the doctrine. And courts and the Patent

Trial and Appeal Board (PTAB) already have used it to invalidate duly issued patents.

For example, in *Allergan USA, Inc. v. MSN Lab's Priv. Ltd.*, No. 19-1727-RGA, 2023 U.S. Dist. LEXIS 172641 (D. Del. Sep. 27, 2023), the District of Delaware invalidated a first-filed patent as obvious over two later-filed continuations, where the first-filed patent only expired after the latter two because of PTA. In invalidating the first-filed patent, the court noted that under *Collect*, “ODP depends solely on patent expiration dates *and should not [be] influenced by equitable concerns.*” *Id.* at *60 (emphasis added). The court further stated that “*Collect* recognizes no exception to the rule it announced, whether for first-filed, first-issued claims or otherwise. I am bound by the Federal Circuit’s holding.”⁷

Similarly, in *Ex parte Clantech, Inc.*, an appeal from a reexamination of an issued patent, the PTAB also followed the Federal Circuit’s opinion and rejected the challenged claims where they had a later expiration date due solely to PTA. 2024 Pat. App. LEXIS 1724 (P.T.A.B. Apr. 30, 2024). In rejecting the patentee’s arguments, the PTAB relied on *Collect*’s

⁷ In contrast, another judge in the same district ruled that “claims in the challenged patent were earlier-filed and thus are entitled to their full term, including the PTA.” *ACADIA Pharm. Inc. v. Aurobindo Pharma Ltd.*, No. 20-985-GBW, 2023 U.S. Dist. LEXIS 221663, at *21 (D. Del. Dec. 13, 2023). The court noted that “the logic and purpose of OTDP is flipped on its head” where a later-filed patent is used as a reference against an earlier-filed one: “rather than preventing a patent owner from unjustifiably extending the term of a patent, OTDP would operate to cut off a patent term that would have been valid but for a later-filed patent.” *Id.*

holding that “[t]he ability of the applicant to show good faith during prosecution does not entitle it to a patent term *to which it is otherwise not entitled.*” *Id.* at *7 (emphasis added) (quoting *Collect*, 81 F.4th at 1230). The problem, of course, is that PTA is term to which the applicant *is*, by statute, entitled. As noted above, PTA is not an unjust extension of term; it is recovered term that had been lost by PTO delay.

Neither case involved any of the types of gamesmanship described in ODP precedent,⁸ and in both cases patentees were unfairly deprived of their duly issued, presumed-valid patents. Review by this Court is thus urgently warranted to eliminate this bright-line rule and curb the reach of ODP back to what it was originally intended to accomplish.

III. The Panel’s Decision Has Created Great Uncertainty, Upset Settled Expectations, and Will Disincentivize Innovation.

As *Allergan* and *Clantech* make clear, the Federal Circuit’s decision hurts inventors and threatens settled expectations. Hundreds of thousands of patents may be imperiled if *Collect* stands.

⁸ Alarmingly, the PTAB appeared to blame the patentee for choosing to file its claims in multiple applications—under standard continuation practice—rather than filing them all in a single application. *Id.* at *7. Utilizing standard tools of prosecution practice, however, is not the same thing as gamesmanship, and it should not expose a patentee to invalidation of its patents via ODP.

In 2023, the PTO issued some 340,000 patents, and nearly two-thirds of issued patents receive PTA.⁹ According to Professor Mark Lemley’s comprehensive study of over 4 million patents issued between 2000-2023, for patents receiving PTA, the average number of adjusted days is 411 days—that is, well over a year of lost term that must be made up according to the PTA statute.¹⁰ Indeed, 25% of patents receiving PTA get more than one year, 5% get 1,000 days or more, and 1% get over four years.¹¹ Critically, despite these numbers, Lemley’s study found no “clear evidence of patentees unfairly taking extra patent term. Most of the PTA results from the fact that for large parts of this century the PTO has been slow to issue patents.”¹² At most, “PTA produces a patent term that is shifted in time, resulting in less term on the front end and additional term on the back end.”¹³

Besides those whose patents have already been invalidated under *Collect*, patentees are now scrambling to evaluate their ODP risk. This requires patentees to spend valuable time and resources they

⁹ Veera Korhonen, *Number of patents issued in the U.S. FY 2000-FY 2023*, STATISTA (Nov. 28, 2023), <https://www.statista.com/statistics/256571/number-of-patent-grants-in-the-us/>; Mark A. Lemley & Jason Reinecke, *Our More-Than-Twenty-Year Patent Term* (Stanford Law and Economics Olin Working Paper No. 586 at 1, Aug. 3, 2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4529670.

¹⁰ Lemley, *supra* note 9, at 1.

¹¹ *Id.* at 1-2.

¹² *Id.* at 3.

¹³ *Id.* at 17.

might otherwise devote to developing new technologies, negotiating licenses, and forming collaborations. In the post-*Collect* world, patent owners must examine their entire patent portfolios, claim-by-claim,¹⁴ to determine whether their prior acceptance of Congress’s “fix” for PTO delays (via PTA) has now endangered their patents under ODP. The decision has improperly “disrupt[ed] the settled expectations of the inventing community.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002).

As a practical matter, *Collect* forces patentees to make a difficult choice that Congress never intended in providing PTA: either (i) affirmatively file terminal disclaimers, thus forgoing statutorily guaranteed full patent term, regardless of whether the PTO actually rejected any claims for ODP;¹⁵ or (ii) face

¹⁴ Because ODP is evaluated on a claim-by-claim basis, while a terminal disclaimer limits term for the entire patent (*see Collect*, 81 F.4th at 1231), the analysis of whether to file terminal disclaimers preemptively to avoid ODP is a complicated and unduly burdensome task involving a claim-by-claim assessment, where a patent can have tens, and even hundreds, of claims.

¹⁵ Since *Collect*, on May 10, 2024, the PTO has also issued a new proposed rule on “Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting.” Under that proposed rule, to obtain a terminal disclaimer, an applicant would need to agree with the PTO that the terminally disclaimed patent would be unenforceable if tied to (1) a patent in which any claim has been held unpatentable or invalid under 35 U.S.C. §§ 102 or 103 or (2) a statutorily disclaimed patent following a §§ 102 or 103 challenge. Commentators have warned that this rule “fundamentally alters the effect of terminal disclaimers” in that “[f]iling a terminal disclaimer with the new requirements means

real risk that their patents, including first-filed, foundational patents, may be invalidated simply because they have PTA. The sudden loss of expected patent term due to a late-filed terminal disclaimer, years after a patent's issuance, could be devastating, particularly in the life sciences industry where patent protection fuels research and drug development. Equally concerning, however, is the risk of losing key patents, including the earliest filed patents, which are often the most critical for investment and protection purposes. That patentees have been forced to engage in the de-risking process is clear: from 2022 to 2023, the percentage of terminally disclaimed patents spiked from 13% to about 19%, an increase of nearly 50%.¹⁶

Further, *Collect* threatens the continuation patent as we know it. *See Festo*, 535 U.S. at 733 (if a “firmly entrenched part of the settled rights protected by the patent . . . is to be discarded, it is Congress and not the Court that should do so”). Expressly authorized under 35 U.S.C. § 120, continuation patents are an essential feature of our patent system that simultaneously provide public notice of an

accepting the risk that an entire patent's enforceability could hinge on the strength of a single claim in another patent.” Dennis Crouch, *Major Proposed Changes to Terminal Disclaimer Practice (and You are Not Going to Like it)*, PATENTLY-O (May 9, 2024), <https://patentlyo.com/patent/2024/05/proposed-terminal-disclaimer.html>.

¹⁶ Dennis Crouch, *Terminal Disclaimers: A Growing Concern in Patent Practice*, PATENTLY-O (May 10, 2024), <https://patentlyo.com/patent/2024/05/terminal-disclaimers-practice.html>.

invention’s full scope and permit inventors to improve and refine their patent claims efficiently before the patent office. Moreover, as Lemley comments, continuation patents do not actually permit applicants to “game prosecution” through PTA, as “PTA applies only to the patent for which the adjustment was issued.”¹⁷

Under *Collect*, however, multiple members of a family of continuation patents are now exposed to invalidation risk—even where those patents would all expire simultaneously but for PTA. While it is true that to mitigate this risk, applicants may instead file a single, omnibus application including all possible patent claims, such applications would be unduly burdensome on both patentees and the PTO and will only exacerbate delay. Moreover, effectively forcing patentees to forgo the use of standard prosecution tools such as continuation applications—which are expressly provided by statute—by way of ODP is yet another instance of improperly overriding Congressional intent with judge-made policy.

PTO delays also continue to persist. The PTO’s data dashboard provides that in the last two years, the percentage of patent applications that receive their first office action within fourteen months of their filing dates, in compliance with Section 154(b)(1)(A)(i), is just 31%.¹⁸ Additionally, 20% of the PTO’s responses to mailed actions fall outside of statutorily mandated

¹⁷ Lemley, *supra* note 9, at 44, 44 n.105.

¹⁸ *Patent Term Adjustment Data April 2024*, USPTO PATENTS DASHBOARD, <https://www.uspto.gov/dashboard/patents/patent-term-adjustment-new.html> (last visited June 18, 2024).

timeframes.¹⁹ As a result, more and more PTA “shall” be awarded under Section 154, which puts more and more patents in jeopardy. That is, more patentees are losing patent term due to office delays, but under *Cellect*, they cannot risk accepting Congress’s guarantee of full patent term. As in all cases where courts effectively rewrite a statute without Congressional action, the Federal Circuit’s fundamental error in statutory construction here has had, and will continue to have, a dramatic impact on innovation and the patent system as a whole.

CONCLUSION

For these reasons, AIPLA respectfully requests that the Court accept this case for review and restore PTA to its original, statutory purpose: to guarantee full patent term, rather than as a means to expose patents to invalidation via ODP.

¹⁹ *Id.* Terminal disclaimers are also on the rise. Just 9% of patents in 2006 had terminal disclaimers. In 2023, that number was almost 19%. *See also* Crouch, *supra* note 16.

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