

No.

In the Supreme Court of the United States

CELLECT LLC, PETITIONER

v.

KATHERINE K. VIDAL, DIRECTOR,
UNITED STATES PATENT AND TRADEMARK OFFICE

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT*

PETITION FOR A WRIT OF CERTIORARI

PAUL J. ANDRE
LISA KOBIALKA
JAMES R. HANNAH
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
*333 Twin Dolphin Drive
Redwood Shores, CA 94065*

JONATHAN CAPLAN
JEFFREY PRICE
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
*1177 Avenue of the Americas
New York, NY 10036
(212) 715-9100*

ROY T. ENGLERT, JR.
Counsel of Record
MATTHEW M. MADDEN
DANIEL N. LERMAN
JEFFREY C. THALHOFER
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
*2000 K Street NW
Washington, DC 20006
(202) 775-4500
renglert@kramerlevin.com*

Counsel for Petitioner

QUESTION PRESENTED

Whether a patent procured in good faith can be invalidated on the ground that statutory Patent Term Adjustment, which requires lengthening a patent's term to account for time lost to Patent and Trademark Office delays, can trigger a judge-made patent-invalidation doctrine.

PARTIES TO THE PROCEEDING

Petitioner is Collect LLC, the appellant in the court of appeals.

Respondent is Katherine K. Vidal, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, the appellee in the court of appeals.

CORPORATE DISCLOSURE STATEMENT

Petitioner Collect LLC is a wholly owned subsidiary of Micro Imaging Solutions LLC.

RELATED PROCEEDINGS

United States Court of Appeals (Fed. Cir.):

In re Collect, LLC, Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296 (Aug. 28, 2023).

Patent Trial and Appeal Board:

In re Collect, LLC, Nos. 90/014,453, 90/014,454, 90/014,455, 90/014,457 (Dec. 1, 2021).

United States District Court for the District of Colorado:

Collect, LLC v. Samsung Electronics Co., Ltd., et al., No. 1:19-cv-00438.

TABLE OF CONTENTS

	Page
Opinions below	1
Jurisdiction.....	1
Statutory provisions involved.....	1
Statement	3
Reasons for granting the petition.....	12
I. The Federal Circuit has substituted a judge-made equitable doctrine for patent terms guaranteed by Congress.....	13
A. ODP cannot cut off statutorily mandated PTA.....	13
B. The Federal Circuit’s expansion of ODP departs from the doctrine’s traditional equitable roots	21
II. The question presented is exceptionally important	24
A. The decision below upsets investment-backed expectations.....	24
B. The decision below threatens the invalidation of hundreds of patents worth billions or trillions of dollars	28
III. This case is an ideal vehicle	29
Conclusion	31
Appendix A — Decision of United States Court of Appeals for the Federal Circuit (Aug. 28, 2023)	1a
Appendix B — Decision of Patent Trial and Appeal Board (Dec. 1, 2021).....	30a
Appendix C — Decision of Patent Trial and Appeal Board (Dec. 1, 2021).....	55a
Appendix D — Decision of Patent Trial and Appeal Board (Dec. 1, 2021).....	80a

Appendix E — Decision of Patent Trial and Appeal Board (Dec. 1, 2021).....	105a
Appendix F — Final office action (Nov. 18, 2020)	129a
Appendix G — Final office action (Dec. 10, 2020)	162a
Appendix H — Final office action (Sept. 17, 2020)	242a
Appendix I — Final office action (Dec. 10, 2020)	282a
Appendix J — Order of United States Court of Appeals for the Federal Circuit denying rehearing (Jan. 19, 2024).....	313a
Appendix K — 35 U.S.C. § 154	315a
Appendix L — 35 U.S.C. § 156.....	324a

TABLE OF AUTHORITIES

	Page(s)
Cases:	
<i>Abbott v. Perez</i> , 585 U.S. 579 (2018).....	15, 16, 20
<i>Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.</i> , No. Civ. A. 20-985-GBW, 2023 WL 8803448 (D. Del. Dec. 13, 2023)	25
<i>Allergan USA, Inc. v. MSN Labs. Priv. Ltd.</i> , No. Civ. A. 19-1727-RGA, 2023 WL 6295496 (D. Del. Sept. 27, 2023)	25
<i>Bate Refrigerating Co. v. Sulzberger</i> , 157 U.S. 1 (1895).....	21
<i>Diamond v. Chakrabarty</i> , 447 U.S. 303 (1980).....	14
<i>eBay Inc. v. MercExchange, L.L.C.</i> , 547 U.S. 388 (2006).....	24

	Page(s)
<i>Eli Lilly & Co. v. Medtronic, Inc.</i> , 496 U.S. 661 (1990).....	7, 19
<i>Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.</i> , 535 U.S. 722 (2002).....	24
<i>Jennings v. Rodriguez</i> , 583 U.S. 281 (2018).....	13
<i>Kingdomware Techs., Inc. v. United States</i> , 579 U.S. 162 (2016).....	13
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	24
<i>Miller v. Eagle Mfg. Co.</i> , 151 U.S. 186 (1894).....	22
<i>Monsanto Co. v. Geertson Seed Farms</i> , 561 U.S. 139 (2010).....	24
<i>Munaf v. Geren</i> , 553 U.S. 674 (2008).....	24
<i>New York Times Co. v. Tasini</i> , 533 U.S. 483 (2001).....	24
<i>Nken v. Holder</i> , 556 U.S. 418 (2009).....	24
<i>Novartis AG v. Ezra Ventures LLC</i> , 909 F.3d 1367 (2018).....	4, 10, 11, 15, 19, 21
<i>Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc.</i> , 909 F.3d 1355 (Fed. Cir. 2018).....	18, 19
<i>O’Melveny & Myers v. FDIC</i> , 512 U.S. 79 (1994).....	21
<i>Ortho Pharm. Corp. v. Smith</i> , 959 F.2d 936 (Fed. Cir. 1992).....	25
<i>Petrella v. Metro-Goldwyn-Mayer, Inc.</i> , 572 U.S. 663 (2014).....	20, 21

	Page(s)
<i>United States ex rel. Steinmetz v. Allen</i> , 192 U.S. 543 (1904).....	22
<i>Thomson-Houston Elec. Co. v. Ohio Brass Co.</i> , 80 F. 712 (6th Cir. 1897).....	23
<i>In re U.S. Patent No. 7,601,740</i> , Dkt. ACD-030 (Nov. 21, 2023).....	27
<i>United Sav. Ass’n of Texas v. Timbers of Inwood Forest Assocs., Ltd.</i> , 484 U.S. 365 (1988).....	23
<i>United States v. Davis</i> , 588 U.S. 445 (2019).....	15
<i>United States v. Dubilier Condenser Corp.</i> , 289 U.S. 178 (1933).....	14
<i>United States v. Johnson</i> , 529 U.S. 53 (2000).....	14
<i>United States v. Rutherford</i> , 442 U.S. 544 (1979).....	20
Statutes and Regulations:	
28 U.S.C. § 1253	20
28 U.S.C. § 1292	20
35 U.S.C. § 102	7
35 U.S.C. § 120	10, 27
35 U.S.C. § 154 .. 1, 2, 3, 4, 5, 6, 7, 13, 14, 15, 16, 17, 18, 19, 21, 23	23
35 U.S.C. § 156	2, 4, 7, 13, 15, 16, 21
35 U.S.C. § 253	8, 9, 27
35 U.S.C. § 282	16
American Inventors Protection Act of 1999. Pub. L. No. 106-113, 113 Stat. 1501	6
Hatch-Waxman Act	7, 26

	Page(s)
Uruguay Round Agreements Act.....	5
37 C.F.R. § 1.321	27
Other Authorities:	
David K. Barr & Kaitlyn M. Rodnick, <i>USPTO Rejects “Contingent” Terminal Disclaimer</i> , Mondaq Business Briefing (Jan. 31, 2024), https://perma.cc/3955-U64N	27
Manual of Patent Examining Proc. § 1490(VI)(A)	27

In the Supreme Court of the United States

No.

COLLECT LLC, PETITIONER

v.

KATHERINE K. VIDAL, DIRECTOR,
UNITED STATES PATENT AND TRADEMARK OFFICE

*ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT*

PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-29a) is reported at 81 F.4th 1216. The order of the court of appeals denying rehearing (App., *infra*, 313a), the decisions of the Patent Trial and Appeal Board (App., *infra*, 30a, 55a, 80a, 105a), and the final office actions in each of four reexamination proceedings (App., *infra*, 129a, 162a, 242a, 282a) are not reported.

JURISDICTION

The court of appeals entered judgment on August 28, 2023. A petition for rehearing en banc was denied on January 19, 2024 (App., *infra*, 313a.) On April 8, 2024, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including May 20, 2024.

STATUTORY PROVISIONS INVOLVED

35 U.S.C. § 154 provides in relevant part:

(b) Adjustment of Patent Term.—

(1)

(1) Patent term guarantees.—

(A) Guarantee of prompt patent and trademark office responses.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

(i)–(iv) [providing for appropriate notifications and USPTO response times]

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

* * *

35 U.S.C. § 156 provides in relevant part:

Extension of patent term

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b), if—

(1)–(5) [providing requirements for a grant of PTE]

* * *

The complete text of 35 U.S.C. §§ 154 and 156, including material summarized in brackets here, is at App., *infra*, 315a-342a.

STATEMENT

The decision below invalidates claims in four patents under a judge-made rule that guards against the unjustified extension of a patent's term through "double patenting" similar inventions. That double-patenting rule looks to whether the same holder owns related patents that are not sufficiently distinct. If such related, non-distinct patents expire on different dates, then the double-patenting rule can invalidate the patents or limit their terms to end at the same time. The rule thus roots out attempts to secure unjustified, overlong patent terms through related patent applications.

But petitioner never tried to milk extra patent term by filing patent applications with overlapping subject matter, but a later expiration date, in order to obtain additional patent term. There has never been any allegation of petitioner's bad faith or gamesmanship in its patent prosecution. Instead, petitioner's invalidated patents have different expiration dates than those of related patents *only* because the Patent Office did not comply with its statutory deadlines for acting on patent applications.

Patent Office delay is a problem because under current law a patent's term generally runs for 20 years from the priority date—that is, the filing date of the earliest application in a chain of related applications. To prevent post-filing bureaucratic delay from eating into patents' effective terms, Congress enacted a statutory "guarantee" of patent term, codified at 35 U.S.C. § 154(b), that adds one day of Patent Term Adjustment (PTA) for each day of Patent Office delinquency.

That provision (which is directly at issue in this case) mirrors an earlier-enacted statute, codified at 35 U.S.C. § 156, that likewise provides Patent Term Extension (PTE) to make up for bureaucratic delay that would otherwise eat into the intended period of exclusivity conferred by a patent. Specifically, if a patent has been issued but cannot be used because the patented product requires FDA approval, the FDA's delay in approving the patented products is added to the patent term.

Patent Term Adjustment (under Section 154(b)) and Patent Term Extension (under Section 156) serve the same purpose. In each case, Congress explicitly provided that the term of a patent “shall be extended” to account for delay. 35 U.S.C. § 154(b)(1)(A); *id.* § 156(a). Indeed, the two provisions are expressly linked—adjustments under Section 154(b) are counted before any extension under Section 156.

The court of appeals, however, reads and applies these two provisions very differently. For PTE, awarded under Section 156 after FDA delay, the Federal Circuit respects Congress's patent-term guarantee by declining to truncate an extended term based on the judge-made double-patenting rule. *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1375 (2018). But for PTA, awarded under Section 154(b) after Patent Office delay, the Federal Circuit's decision below *does* cut short the patent term that Congress guaranteed by imposing that judge-made rule notwithstanding the statute.

In petitioner's case, the result of this incongruous ruling was to invalidate the challenged patents altogether, because it is now too late for petitioner to

disclaim the PTA-modified terms of these now-expired patents. In other words, petitioner's challenged patents were invalidated in their entirety, even though it is *only* because of the Patent Office's delay and corresponding PTA that they have been subjected to the double-patenting rule.

That result is nonsensical. It depends on the equally senseless departure from the meaning and effect of a closely related statute. By the lights of the decision below, two closely related statutes serving similar purposes need not be read to row in the same direction, *in pari materia*, but rather can be interpreted as demanding opposite results. The consequence is that, for one statute but not the other, a judge-made doctrine is allowed to usurp a statutory "guarantee" afforded to patent holders by Congress.

1. For most of the history of American patent law, patents expired a set number of years from their *issuance*. With the 1995 enactment of the Uruguay Round Agreements Act, however, Congress tied the length of patent terms to the filing date of the patent *application* (or of an earlier, related application on which the patentee asserts priority). 35 U.S.C. § 154. Whereas patent terms were 17 years from issuance before 1995, they are now 20 years from an application's priority date (usually, as here, the earliest filing date).

A result of that change was that, for the first time, Patent Office delay in approving a patent would cause an inventor to lose some of the benefit of the exclusivity conferred during a patent's term. For example, if the Patent Office takes five years to approve a patent application, then the remaining,

effective term of the patent, once issued, would be only 15 years.

To combat that consequence of bureaucratic delay, Congress established Patent Term Adjustment (PTA) as part of the American Inventors Protection Act of 1999. Pub. L. No. 106-113, 113 Stat. 1501. As codified at 35 U.S.C. § 154(b), the statute “[g]uarantee[s] * * * prompt patent and trademark office responses” to patent applications by adding time to a patent’s term, “[s]ubject to [specified] limitations * * * , if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to [act within a given deadline].” *Id.* § 154(b)(1)(A).

Generally, unless a limitation applies, if the Patent Office takes more than three years to act on a patent application, then “the term of the patent *shall* be extended 1 day for each day after the end of that 3-year period” until the application is approved. 35 U.S.C. § 154(b)(1)(B) (emphasis added). Congress thus ensured that inventors get the benefit of an effective patent term that runs at least 17 years from issuance, as had been the expectation under pre-1995 law.

In establishing PTA in Section 154(b), Congress did not write on a blank slate. Rather, it borrowed from the similar approach it had taken to FDA delays in approving patented products that are subject to FDA regulation. Like Patent Office approval delays, FDA approval delays can likewise eat into a patent’s effective term. Both delays prevent obtaining economic benefit from the patent by bringing the patented product to market.

To account for such FDA approval delays, Congress in the 1984 Hatch-Waxman Act had established Patent Term Extension (PTE), codified at 35 U.S.C. § 156.¹ Under Section 156, “[t]he term of a patent which claims a product, a method of using a product, or a method of manufacturing a product *shall* be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b).” *Id.* § 156(a) (emphasis added).

Congress added that last part of Section 156(a)—“which shall include any patent term adjustment granted under section 154(b)” —when it created PTA in 1999. Congress thereby harmonized the two similar ways in which patent terms may be lengthened. When applying PTE to account for FDA delays after a patent’s issuance, therefore, one starts with the patent term as modified by any PTA applied to account for Patent Office delays before a patent’s issuance. Together, PTA and PTE thus provide for additional patent term to negate the effect on inventors of either kind of bureaucratic delay.

2. This case involves the interpretation of PTA and PTE as those statutes intersect with a judge-made rule against “obviousness-type double-patenting” (ODP). ODP is similar to the requirement that claims be “non-obvious” over another inventor’s prior art in order to be patentable. See 35 U.S.C. § 102(a)(2).

¹ The now-40-year-old Hatch-Waxman Act is important patent legislation specific to the pharmaceutical industry. It has resulted in numerous decisions from this Court, starting in 1990 with *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661.

Unlike the traditional obviousness analysis, which asks whether an invention would have been obvious in light of the prior art, ODP uses an inventor's own related applications, or patents, against one another, and applies only when a holder obtains the *unjustified* extension of a patent's term, practically speaking, by seeking a second, non-distinct patent that expires after the first one. By way of illustration, ODP applies when the owner of a patent for sliced bread goes on to seek related patents for sliced white bread and sliced wheat bread, and prosecutes those patent applications strategically so that they expire after the original patent and enlarge, in effect, the original patent's term through patenting obvious or marginal variations of its claims.

Patent law provides a mechanism by which owners may harmonize the terms of related patents and thereby avoid any ODP. When the Patent Office rejects a patent application for ODP, the patentee may overcome the rejection by arguing that the claims are "patentably distinct" or by filing a "terminal disclaimer." See 35 U.S.C. § 253. As between two non-distinct patents expiring on different dates, a terminal disclaimer forswears any patent term beyond the shorter of the two remaining terms—effectively cutting off the longer remaining term so that both patents expire at the same time.

The application of ODP depends on properly determining related patents' terms. That is so because the rule turns on whether a holder owns one or more patents that unjustifiably extend the effective term of another owned patent. And so it is necessary to determine whether statutory PTA affects that

determination. In other words, should the ODP unpatentability determination be made using the patents' original expiration dates (as it is with PTE) or their expiration dates after they are adjusted by adding PTA?

3. Petitioner designs and develops imaging and photo capture technology for use in cell phones, tablets, automobiles, and recreational cameras (point-and-shoot and video). It holds a family of patents asserting claims relating to image sensors. App., *infra*, 2a.

Each patent in that family claims priority dating back to October 6, 1997, when a single parent patent application was filed. App., *infra*, 3a, 32a. Accordingly, and in the absence of any statutory Patent Term Adjustment, all patents in the family would have expired on October 6, 2017. But Patent Office delay affecting certain of the patents caused them to obtain statutory PTA, and thereby to expire after that date.

During patent prosecution, the examiner did not identify any issues involving ODP. That is unsurprising; there was no suggestion that petitioner engaged in the gamesmanship traditionally thought to make an extension of patent term "unjust." As a result, petitioner had no occasion to disclaim the terms of the patents that extended beyond October 6, 2017, due to Patent Office delays. See 35 U.S.C. § 253 (governing terminal disclaimers).

4. Petitioner sued Samsung Electronics Co. for infringing four patents in its image-sensor patent family. App., *infra*, 3a-4a (identifying U.S. Patent 6,982,742 (the '742 patent), U.S. Patent 6,424,369 (the '369 patent), U.S. Patent 6,452,626 (the '626 patent),

and U.S. Patent 7,002,621 (the '621 patent)). Three of those four patents had obtained PTA in the wake of Patent Office delays, and thus had expiration dates after October 6, 2017 (and different expiration dates from each other). Each was a continuation patent—a patent that is linked to a “parent” patent and shares the parent patent’s priority date. See 35 U.S.C. § 120.

In response to petitioner’s infringement suit, Samsung requested *ex parte* reexamination of the asserted patents by the Patent Office—arguing that they were invalid for ODP. App., *infra*, 3a. Samsung contended that PTA awarded based on Patent Office delay should be accounted for when determining whether patent terms were unjustifiably different. Petitioner argued, to the contrary, that PTA should *not* affect the ODP analysis, pointing to the Federal Circuit’s decision that similar PTE had no such effect. See *Novartis*, 909 F.3d at 1375.

The examiner determined, on reexamination, that “the challenged claims were obvious variants of Collect’s prior-expiring reference patent claims.” App., *infra*, 4a. The four challenged patents were each invalidated as obvious over either one of the other challenged patents or some other patent, and the chains of invalidation all traced back to a single patent (the '036 patent). *Id.* at 4a. The examiner agreed with Samsung that PTA should be included when determining whether one patent unjustly extended the term of another patent.

Petitioner appealed to the Patent Trial and Appeal Board, which upheld the patents’ invalidation. The PTAB acknowledged the Federal Circuit’s holding that “ODP should be considered from the expiration

date of the patent before the addition of PTE,” App., *infra*, 6a, but nevertheless held that a different result should obtain for PTA because it, unlike the PTE statute, provides that an adjustment cannot extend a patent term past a terminal disclaimer, which is a device holders generally use to overcome ODP. *Id.* at 6a-7a.

The Federal Circuit agreed. It held that, “while the expiration date used for an ODP analysis where a patent has received PTE is the expiration date before the PTE has been added, the expiration date used for an ODP analysis where a patent has received PTA is the expiration date after the PTA has been added.” App., *infra*, 17a. The court of appeals, like the Board, concluded that the PTA statute’s reference to terminal disclaimers meant that ODP must be relevant to PTA in a way that is not true of PTE—that is, that ODP should be assessed *before* PTE is added but *after* PTA is added. *Id.* at 21a-22a. The court decided that it would be inconsistent with that design if applicants were to receive any extra patent term based on not having filed a terminal disclaimer. *Id.* at 22a-23a; see also *Id.* at 28a (holding that “[a] terminal disclaimer is not an escape hatch to be deployed after a patent expires”).

The court of appeals distinguished its prior holding in *Novartis* that patent terms should be considered, for purposes of applying ODP, *without regard* to any PTE. The court concluded that “[t]he PTE and PTA statutes have quite distinct purposes,” because PTE “is designed to effectively extend the overall patent term for a single invention due to regulatory delays in product approval,” whereas “PTA is designed to

extend the term of a particular patent due to delays in the processing of that patent.” App., *infra*, 20a. And because of that perceived difference in “purposes”—product-approval delay versus processing delay—the court held that there was “no conflict” between its holding on PTA and its contrary holding on PTE. *Ibid.*

The Federal Circuit also rejected petitioner’s reliance on ODP’s equitable underpinnings. The court concluded that *any* adjustment of one patent’s term, past the end of the term of another, non-distinct patent that did not receive PTA, “constitutes an inappropriate timewise extension for the asserted claims of the challenged patents” because the effect would always be to confer PTA on the earlier-expiring patent to which that patent was not entitled. App., *infra*, 25a. As for risk of harassment by multiple assignees, the court of appeals decided that, “[w]hile Collect has not engaged in actions that resulted in divided ownership in the past, and it has promised that it will not do so in the future, neither fact suffices to abrogate the potential future risk of multiple owners or assignees.” *Ibid.*

REASONS FOR GRANTING THE PETITION

The court of appeals, contradicting the plain text of the statute and departing from traditional canons of statutory interpretation, turned a congressional “guarantee” of a minimum effective patent term on its head by converting that guarantee into a threat to the validity or term of countless continuation patents. Its decision is extremely consequential for innovators, as reflected in the breadth and depth of *amicus* participation below. The question whether a judge-made equitable rule (ODP) can supersede an express statutory grant is cleanly presented. And, of course,

the Federal Circuit's word on the question will be the last one in all patent cases unless this Court grants review. Certiorari should be granted.

I. The Federal Circuit Has Substituted A Judge-Made Equitable Doctrine For Patent Terms Guaranteed By Congress

The text of Section 154(b)(1)(A) is clear. As with Section 156, a patent's term "shall be extended" to account for regulatory delay with exceptions not applicable here. The Federal Circuit violated that mandate. Making matters worse, the Federal Circuit's error is not just a misapplication of traditional tools of interpretation; the court of appeals has also grafted a judge-made doctrine onto the PTA provision. And, in doing so, it twisted the traditional equitable principles underlying that doctrine.

A. ODP cannot cut off statutorily mandated PTA

1. Section 154's plain text forecloses the Federal Circuit's holding. The PTA provisions speak in mandatory language: "[I]f the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to [act within a given deadline]," then "the term of the patent *shall* be extended 1 day for each day after the end of the period specified * * *, until the action described in such clause is taken." 35 U.S.C. § 154(b)(1)(A) (emphasis added).

As this Court has repeatedly recognized, "the word 'shall' usually connotes a requirement." *Jennings v. Rodriguez*, 583 U.S. 281, 300 (2018) (quoting *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016)). The plain and ordinary meaning of Section 154(b)(1)(A), then, is that PTA is a statutorily

required addition to a patent's term, merited by the Patent Office's own failures, and not an optional addition to be negated by equitable doctrines not specified in the statute.

Other provisions of the PTA statute confirm as much. Section 154 specifies the only limitations on a patentee's right to an adjusted patent term, and says nothing about ODP. 35 U.S.C. § 154(b)(2). And the right to PTA is mandatory, "[s]ubject to [specified] limitations." *Id.* § 154(b)(1)(A). The absence of ODP from the specified limitations demonstrates that Patent Office delay should extend a patent regardless whether ODP might otherwise apply—unless, unlike here, an applicant engaged in gamesmanship is directed to file a terminal disclaimer.

"When Congress provides exceptions in a statute, it does not follow that courts have authority to create others. The proper inference * * * is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth." *United States v. Johnson*, 529 U.S. 53, 58 (2000). Even more specifically, this Court has explained that "courts 'should not read into the patent laws limitations and conditions which the legislature has not expressed.'" *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933)). That is just what the Federal Circuit did here by applying the non-statutory ODP doctrine to limit the PTA statute's guarantee.

2. The plain meaning of the PTA statute is confirmed by reading it and the closely related PTE statute *in pari materia*.

The Federal Circuit has correctly held that ODP does *not* apply as between related patents whose terms are different only because of certain patents' PTE resulting from FDA-approval delay. *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1375 (2018). Rather, as far as PTE is concerned, the court of appeals has concluded that applying ODP “would mean that a judge-made doctrine would cut off a statutorily-authorized time extension.” *Ibid.*

Just as the PTE statute protects patent owners from being harmed by the FDA's delay in approving regulated products that have obtained patents, the PTA statute protects patent owners from being harmed by the Patent Office's delay in approving patent applications. Both PTA and PTE thus compensate for regulatory delays affecting the effective period when the patent owner has the exclusive right to market an invention. Accordingly, the two statutes use nearly identical language, including their common edict that a patent term “shall be extended” where the enumerated conditions are satisfied. See 35 U.S.C. §§ 154(b)(1)(A), 156(c).

The court of appeals erred by nevertheless reading the two related statutes differently. It should have presumed “that the same language in related statutes carries a consistent meaning.” *United States v. Davis*, 588 U.S. 445, 458 (2019); see also *ibid.* (“As we've explained, the language of § 924(c)(3)(B) is almost identical to the language of § 16(b), which this Court has read to mandate a categorical approach.”). In *Abbott v. Perez*, 585 U.S. 579 (2018), for example, this Court held that “nearly identical” language in two statutes, one affecting this Court's jurisdiction and

the other affecting the jurisdiction of the courts of appeals, should be construed the same way so as to ensure consistency, when the practical effect of a district court's order is to grant or deny an injunction. *Id.* at 595-597. Those provisions, the Court held in *Perez*, "serve the same purpose" and are "analogous." *Id.* at 596. Here too, the PTA and PTE statutes share a common purpose to guarantee patentees a minimum effective patent term notwithstanding agency delays that hold up patent issuance or product approval.

And also in *Perez*, as here, the provisions "[we]re * * * textually interlocked"; in *Perez*, construing those provisions differently would have led to the anomalous result that jurisdiction would lie in the courts of appeals, but not this Court, even though Congress had "taken pains to provide for review in this Court." 585 U.S. at 596. Here, Congress took pains to make clear that PTE runs from an original patent term that "shall include any patent term adjustment granted under section 154(b)." 35 U.S.C. § 156(a). It would be passing strange to give PTE recipients the full benefit of their statutory extensions but not to give PTA recipients the same benefit even though the statute contemplates that any PTA extension is to be *included* in calculating PTE.

PTA and PTE are connected by statute in other ways, too. For example, in an infringement suit, the "[i]nvalidity of the extension of a patent term or any portion thereof under section 154(b) or 156," is a defense "during the period of the extension of [the patent's] term." 35 U.S.C. § 282(c). Indeed, Section 282(c)'s use of the single word "extension" to refer to both PTA and PTE demonstrates Congress's intent

that these two sources of extended patent term be treated alike.

The court of appeals relied on two perceived differences between the PTA and PTE statutes, but neither distinction justifies reading those statutes differently.

First, the court opted to read an unambiguous limitation of disclaimed patent term as an oblique invocation of ODP. The Federal Circuit relied on the PTA statute's requirement that PTA not extend past a patentee's own terminal disclaimer of its patent's term to conclude that the PTA and PTE statutes must have "distinct purposes." App., *infra*, 20a. The court of appeals reasoned that, because terminal disclaimers are usually filed to overcome ODP objections, this provision is "tantamount to a statutory acknowledgment that ODP concerns can arise when PTA results in a later-expiring claim that is patentably indistinct." *Id.* at 22a.

Not so. Section 154 provides only that, if a patent term has been the subject of a patentee's terminal disclaimer, then any PTA awarded cannot extend beyond that date. In other words, PTA cannot extend a patent's term when circumstances already required the applicant to disclaim patent term. That provision is a tool for determining *whether* a patent should receive PTA and *how much* PTA a patent should get. It is not an oblique invitation to cut off properly granted PTA or to invalidate a patent based on ODP. If Congress wanted to apply ODP to PTA-extended patents, it would, presumably, have said so.

And the court of appeals' contrary reasoning—that it would "frustrate the clear intent of Congress for

applicants to benefit from their failure, or an examiner's failure," to file a terminal disclaimer, App., *infra*, 23a—is refuted by the circumstances of this case. There was no “failure,” by the applicant or the examiner, because, before adding PTA, there were no differences in patent term (let alone allegations of gamesmanship) that would have necessitated a terminal disclaimer. It is easy to see why Congress wanted to avoid granting PTA when the applicant is deemed to have unjustly extended the patent monopoly, but Congress cannot have envisioned ODP to cut off statutorily mandated term extensions or patents being *invalidated* by operation of a provision meant to *guarantee* their full patent terms against bureaucratic delay.

The court of appeals had recognized this point in *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc.*, 909 F.3d 1355, 1366 (Fed. Cir. 2018), where it refused to invalidate one patent over another, on ODP grounds, where those patents' terms had been affected by the 1995 transition from issuance-based to application-based patent terms. The court held that, when Congress provided a transition period during which a patent term “shall be the greater of” the 17 years from issuance (pre-URAA law) or 20 years from filing (post-URAA law), it “intended patent owners who filed patent applications before the transition date * * * to enjoy the maximum possible term available for their resulting patents under either patent term regime.” *Ibid.* (discussing 35 U.S.C. § 154(c)(1)).

That was true even though the transition statute at issue in *Breckenridge* made application of the longer

of the two potential patent terms explicitly “subject to any terminal disclaimers.” 909 F.3d at 1359. The court rejected an argument that this provision *sub silentio* invoked ODP. As the court explained, that argument mistakenly “assumes this statutory language commands how to assess whether a given patent’s term should be terminally disclaimed”; instead, the “ordinary sense” of the text simply recognized “that a patent’s term provided for in this transition provision may be subject to a terminal disclaimer depending on the relevant facts.” *Id.* at 1366 n.4. Section 154(b)’s exclusion of PTA beyond a terminally disclaimed expiration date does the same thing.

Second, the court of appeals believed it to be a meaningful distinction between the PTA and PTE statutes that, while “PTE is designed to effectively extend the overall patent term for a single invention due to regulatory delays in product approval,” “PTA is designed to extend the term of a particular patent due to delays in the processing of that patent.” App., *infra*, 20a. That is a distinction without a difference. PTA and PTE share the purpose of guaranteeing patent term against regulatory delay. Congress intended PTE to “balance * * * the competing interests of new drug developers and low-cost generic competitors.” *Novartis*, 909 F.3d at 1372; see also *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 672 (1990) (discussing the “dual distorting effects of [FDA] regulatory approval requirements”). And it intended PTA to safeguard all patent owners (not only those with FDA-regulated inventions) against Patent Office delay. There is thus no reason to think that Congress intended one response to regulatory delay, but not the

other, to be trumped by ODP. To the contrary, as noted, the PTE statute expressly incorporates adjustments granted under the PTA statute.

Indeed, this Court has often interpreted related statutes consistently, despite differences in purpose greater than these. In *Perez*, for example, this Court held the parallel language and similar purpose of 28 U.S.C. § 1253 and 28 U.S.C. § 1292(a)(1)—both were meant to ease “undue hardship” by making interlocutory injunction orders reviewable—called for a consistent reading of separate provisions governing the courts of appeals’ jurisdiction and this Court’s jurisdiction. See 585 U.S. at 594, 596. The overarching similarity of purpose was enough, even though mandatory appellate jurisdiction in the courts of appeals is, in other respects, quite different from this Court’s “carefully limited” mandatory appellate jurisdiction. See *id.* at 630 (Sotomayor, J., dissenting).

3. The decision below does not merely read closely related statutory provisions differently—it elevates a judge-made doctrine over clear statutory text. As this Court has often reminded, that is not the role of a court. See, e.g., *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.”).

Two such reminders are instructive. In *Petrella v. Metro-Goldwyn-Mayer, Inc.*, this Court held that, in the “face of a statute of limitations enacted by Congress, laches cannot be invoked to bar legal relief.” 572 U.S. 663, 679 (2014). There, as here, a court of appeals applied a “defense developed by courts” to cut

short intellectual property rights conferred by statute. *Id.* at 678-679.

In *O'Melveny & Myers v. FDIC*, 512 U.S. 79 (1994), this Court rejected the application of a “a court-made rule to supplement federal statutory regulation that is comprehensive and detailed.” *Id.* at 85. To “create additional ‘federal common law’ exceptions” in that case would have “alter[ed]” the statutory scheme, not simply “supplement[ed]” it, given the statute’s “extensive framework” enumerating exceptions in which federal law, rather than state law, should apply. *Id.* at 86-87. Here, too, Congress has listed the exceptions to PTA; it is not for courts (or patent examiners) to add others.

As in those cases, the Federal Circuit elevated a judge-made rule over Congress’s clear instructions. As the court of appeals put it, its prior decision on PTE “decline[d]” to allow “a judge-made doctrine [to] cut off a statutorily-authorized time extension.” App., *infra*, 19a (alterations in original) (quoting *Novartis*, 909 F.3d at 1375). The court of appeals was right then and wrong now. Section 154, like Section 156, speaks in plain, mandatory terms. A court has no warrant to amend or supplement them. “It is the province of the legislative branch of the government to say when a patent to an inventor shall expire.” *Bate Refrigerating Co. v. Sulzberger*, 157 U.S. 1, 43 (1895).

B. The Federal Circuit’s expansion of ODP departs from the doctrine’s traditional equitable roots

The decision below also departs from traditional equitable practice in favor of new, Federal-Circuit-specific presumptions.

ODP originated in this Court. It has always been based on two concerns: (i) that a patentee could receive an *unjustified* extension of patent term; and (ii) that the public could thereby be denied the invention's use after its statutory patent term should have ended. Thus, this Court, sitting in equity, explained that "the reason[s] for the rule" were that "the power to create a monopoly is exhausted by the first patent" and that "a new and later patent for the same invention would operate to extend or prolong the monopoly beyond the period allowed by law." *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894). "[A] patentee cannot so split up his invention for the purpose of securing additional results, or of extending or prolonging the life of any or all of its elemental parts." *Id.* at 201. Courts have also pointed to the concern that, if the two linked patents were separately owned, potential infringers could be at risk of "harassment by multiple assignees." *E.g.*, App., *infra*, 23a.

And this Court has warned of the "embarrassment and peril of rights [that] may be caused by a hard and fixed rule regarding the separation of related inventions." *United States ex rel. Steinmetz v. Allen*, 192 U.S. 543, 562 (1904) (citing *Miller*, 151 U.S. 186). After all, "to establish a rule applicable to all cases is not to exercise discretion" but to "ignore[] the differences which invoke discretion." *Ibid.*

But the court of appeals discarded those traditional equitable considerations, instead applying novel, rigid presumptions that ignore whether extension of patent term would be *unjustified* and whether there is any evidence of a risk of harassment.

First, the court held that *any* PTA for Patent Office delay is “unjustified” as an equitable matter. See App., *infra*, 24a-25a. Yet a rule that ODP applies regardless of any gamesmanship—where delay “cannot be charged to the laches or fraud of the patentee”—“would be a hard one,” and was traditionally thought unwarranted unless “required by the express words of the statute.” *Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F. 712, 724, 726 (6th Cir. 1897) (Taft, J.). It is difficult to imagine that Congress implicitly wrote ODP into Section 154 with the goal “not of achieving the principal purpose and function of that rule,” *United Sav. Ass’n of Texas v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 373 (1988)—that is, of barring unjustified extension of patent terms—but of invalidating the patents of inventors whose only misstep was accepting the full statutory term of their patents.

Second, the court held that the ubiquitous theoretical possibility that a patent might be assigned to another owner is a sufficient threat that infringers may end up being harassed by different owners of the same invention. See App., *infra*, 25a. But that holding waters down a traditional equitable consideration underlying ODP to an irrebuttable presumption based on a fact common to *every* patent: that it might be assigned here, in spite of petitioner’s attempt to disclaim separate ownership. And it cannot be reconciled with the Federal Circuit’s (correct) treatment of patents extended by PTE; those patents, no less than patents extended by PTA, can be assigned.

In spurning the traditional, equitable ODP inquiry in favor of rigid presumptions of its own invention, the Federal Circuit repeated an error that this Court has often granted certiorari to correct. Take, for example, *eBay Inc. v. MercExchange, L.L.C.*, where this Court rejected the Federal Circuit’s practice of presuming away the irreparable harm element of the traditional test for an injunction. See 547 U.S. 388, 393 (2006). Or take the myriad other cases shelving presumptions that are not supported by traditional equitable principles. See, e.g., *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 157 (2010); *Nken v. Holder*, 556 U.S. 418, 435, 436 (2009); *Munaf v. Geren*, 553 U.S. 674, 690 (2008); *New York Times Co. v. Tasini*, 533 U.S. 483, 505 (2001). Cf. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007) (“when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs”).

This Court should grant certiorari to reverse the court of appeals’ departure from this Court’s repeated instruction that equitable rules must be applied as traditionally understood.

II. The Question Presented Is Exceptionally Important

A. The decision below upsets investment-backed expectations

The Federal Circuit’s expansion of ODP, and limitation of Patent Term Adjustment, upsets investment-backed expectations contrary to this Court’s admonition that “courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community.” *Festo Corp.*

v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). It does so in several ways.

1. The decision below generates uncertainty as to a patent’s term. To make investment decisions, negotiate licenses, allocate a patent portfolio among different products, and perform many other functions necessary to innovation, inventors must be able to predict the length of their patent terms reliably. The decision below radically undermines that predictability—requiring patentholders to review all of their issued patents, claim by claim,² to determine whether each claim is at risk of invalidation and whether, therefore, the inventor should file a terminal disclaimer, surrendering her statutorily granted patent term. Compounding this uncertainty, trial courts are already diverging on the application of the Federal Circuit’s new rule. Compare *Allergan USA, Inc. v. MSN Labs. Priv. Ltd.*, No. Civ. A. 19-1727-RGA, 2023 WL 6295496, at *22 (D. Del. Sept. 27, 2023) (holding that an earlier-filed patent that received PTA can be invalidated for ODP by reference to a later-filed patent), with *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, No. Civ. A. 20-985-GBW, 2023 WL 8803448, at *8 (D. Del. Dec. 13, 2023) (holding that “putative OTDP references must be earlier-filed to be available as a reference”).

² ODP “must be evaluated, like any other ground of invalidity, against individual claims,” yet terminal disclaimers must disclaim “all claims in the patent, *i.e.*, even those claims which standing alone would not run afoul of the rule against double patenting.” *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 942 (Fed. Cir. 1992). The decision below thus injects unnecessary layers of complication into a straightforward statutory scheme.

This unpredictability would be especially pernicious in long-lead-time, high-investment industries like pharmaceuticals, where the resulting uncertainty can be expected to erode investment and retard the development of lifesaving treatments. See, *e.g.*, Merck Sharp & Dohme et al. C.A. Amici Br. 7-10 (Dkt. 161, Nov. 28, 2023). Indeed, the special needs of innovators in this industry are precisely why, in an industry-specific statute generally intended to bring generic substitutes to market sooner (the Hatch-Waxman Act), Congress thought it crucial to include a provision (PTE) to *delay* generic entry by extending innovators' patent terms to compensate for administrative delay by the FDA. Yet the very entities Congress sought to protect against the FDA's delay are now unprotected against the functionally equivalent bureaucratic delay in the Patent Office. Besides making no sense, that inconsistency highlights the importance of the issue.

What's more, painstakingly combing through long-since-prosecuted patent claims, as the decision below demands, is especially burdensome for smaller businesses. See N.Y. Intell. Prop. Law Ass'n C.A. Amicus Br. 11 (Dkt. 169, Nov. 30, 2023). This Court, not just the Federal Circuit, should examine the issue on the merits before Congress is deemed to have imposed such burdens by indirection.

2. The decision below also upends well-established patent practice. The court of appeals has effectively required that, to ensure that patents are not invalidated, inventors must preemptively file terminal disclaimers *en masse*. Indeed, the inventor risks outright invalidation of her patents if, long after

their prosecution, an infringer successfully raises ODP for the first time in response to a lawsuit. And, because terminal disclaimers cannot be filed after a patent expires, see App., *infra*, 28a—as is often the case during infringement litigation—a risk-averse inventor’s only choice is to file blanket terminal disclaimers to prevent any such unforeseen, retroactive application of ODP. Indeed, the Patent Office has rejected at least one attempt to file a “contingent” terminal disclaimer—that would disclaim patent term only if the relevant claims were held invalid for ODP in pending litigation³—citing a policy against “disclaimers which are conditional and/or contingent.”⁴

These changes are wildly inconsistent with well-established continuation practice. It is very common for inventors to file an initial application that discloses, but does not claim, a variety of related inventions. For example, an inventor may acquiesce to narrow initial claims in applying for a foundational patent so that the patent issues more quickly. Or a parent patent may disclose, but not initially claim, all inventive sub-parts of a broader system. In each case, those initially unclaimed inventions are claimed later, through continuation applications. See 35 U.S.C. § 120. But, if inventors are afraid of losing patent term

³ Contingent Terminal Disclaimer of Granted Patent Under 35 U.S.C. § 253 and 37 C.F.R. § 1.321, *In re U.S. Patent No. 7,601,740*, Dkt. ACD-030 (Nov. 21, 2023).

⁴ David K. Barr & Kaitlyn M. Rodnick, *USPTO Rejects “Contingent” Terminal Disclaimer*, Mondaq Business Briefing (Jan. 31, 2024), <https://perma.cc/3955-U64N>; see Manual of Patent Examining Proc. § 1490(VI)(A).

to ODP, they will be compelled to prepare larger, all-but-the-kitchen-sink applications right out of the gate, thus delaying the arrival of important innovations and then swamping the Patent Office with administrative difficulty. These larger applications take longer to draft and process (delaying the public's access to the innovation)—because, among other things, inventors cannot acquiesce in narrower initial applications. And then, once a parent application has been filed and a patent issued, inventors will lack much of their current incentive to develop and refine the inventions disclosed in the parent patents through continuation practice.

B. The decision below threatens the invalidation of hundreds of patents worth billions or trillions of dollars

On the facts of this case, and certainly others like it, the Federal Circuit threatens retroactive invalidation of valuable patents for blameless inventors. Because petitioner sought to enforce patents against an infringer after those patents had expired, petitioner could no longer have filed a terminal disclaimer, during reexamination, to avoid invalidation for ODP. App., *infra*, 28a. It is cold comfort that the Patent Office “perhaps [had an] obligation” to flag any perceived ODP problem while it still could have been solved. *Id.* at 21a.

Moreover, these are problems of the Patent Office's own making. As long as the Patent Office acts on applications within the statutory deadlines, there is no PTA in the first place. In cases like this one, therefore, there would be no ODP—and no patent invalidation on ODP grounds—but for Patent Office

delay. Inventors should not be punished, *post-hoc*, for dilatory agency action.

III. This Case Is An Ideal Vehicle

This case is an ideal vehicle to answer the question presented. The question whether PTA-lengthed patent terms can be invalidated for ODP, even though PTE-lengthened patent terms cannot, is cleanly presented. There are no underlying disputes of fact; the legal issue—whether ODP should have been assessed before PTA extensions were applied—is dispositive.

In particular, petitioner did not challenge below whether “the asserted claims would have been obvious in view of the respective invalidating ODP references.” App., *infra*, 7a. Rather, the briefing and argument focused almost exclusively on the question presented here.

As a result, the Federal Circuit addressed the legal issue at length, as did the Patent Trial and Appeal Board. Neither tribunal suggested that it would or could invalidate the patents on any alternative grounds. And petitioner does not press, before this Court, an appeal of the mixed question whether Samsung raised the “substantial new question of patentability” required for *ex parte* reexamination.

Furthermore, as the *amicus* briefs filed below demonstrate, this case has an enormous impact on the pharmaceutical industry, for which Congress has shown special sensitivity to the problem of bureaucratic delay. After all, all patents, including pharmaceutical patents, can now be invalidated for ODP based on a PTA in light of the Federal Circuit’s

new rule. The Court can assess PTA and PTE in a single context, with input from well-informed *amici* with much at stake, as well as the parties. This case thus represents an ideal vehicle for the Court to resolve this important question.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

PAUL J. ANDRE
LISA KOBIALKA
JAMES R. HANNAH
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
*333 Twin Dolphin Drive
Redwood Shores, CA 94065*

JONATHAN CAPLAN
JEFFREY PRICE
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
*1177 Avenue of the Americas
New York, NY 10036
(212) 715-9100*

ROY T. ENGLERT, JR.
Counsel of Record
MATTHEW M. MADDEN
DANIEL N. LERMAN
JEFFREY C. THALHOFER
KRAMER LEVIN NAFTALIS &
FRANKEL LLP
*2000 K Street NW
Washington, DC 20006
(202) 775-4500
renglert@kramerlevin.com*

MAY 2024