#### In the

# Supreme Court of the United States

### CELLECT, 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 A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

# BRIEF OF AMICUS CURIAE INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF CERTIORARI

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## **QUESTION PRESENTED**

Whether a patent procured in good faith can be invalidated on the ground that statutory Patent Term Adjustment (PTA), 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 known as obviousness-type double patenting (ODP).

# TABLE OF CONTENTS

Pa	ge
QUESTION PRESENTED	. i
TABLE OF CONTENTS	ii
TABLE OF CITED AUTHORITIES	iii
INTEREST OF THE AMICUS CURIAE	.1
SUMMARY OF THE ARGUMENT	.2
ARGUMENT	.4
CONCLUSION	8

# TABLE OF CITED AUTHORITIES

Page
CASES
Acadia Pharms. Inc. v. Aurobindo Pharma Ltd., 2023 U.S. Dist. LEXIS 221663 (D. Del. 2023)
Allergan USA, Inc. v. MSN Labs. Priv. Ltd., 2023 U.S. Dist. LEXIS 172641 (D. Del. 2023) 6-7
Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722 (2002)7
Henry Schein, Inc. v. Archer & White Sales, Inc., 139 S.Ct. 524 (2019)
In re: Cellect, LLC, 81 F.4th 1216 (Fed. Cir. 2023)
Jennings v. Rodriguez, 583 U.S. 281 (2018)
Novartis AG v. Ezra Ventures LLC, 909 F.3d 1367 (Fed. Cir. 2018)
United States v. Johnson, 529 U.S. 53 (2000)

# iv

# $Cited\ Authorities$

	Page
STATUTES	
35 U.S.C. § 120	
35 U.S.C. § 154	1. 2. 3. 4. 6

#### INTEREST OF THE AMICUS CURIAE

Amicus curiae Intellectual Property Owners Association (IPO)¹ represents some of the most innovative companies in the United States. IPO's almost 200 corporate members develop, manufacture, and sell technology-based products in a wide range of industries. IPO is committed to serving the interests of all intellectual property owners in all industries and all fields of technology.²

IPO's corporate members invest tens of billions of dollars annually on research and development and employ hundreds of thousands of scientists, engineers, and others in the United States to develop, produce, and market innovative new products and services. To protect their inventions, IPO's members collectively hold tens of thousands of U.S. patents and account for a substantial portion of the patent applications filed every year at the United States Patent and Trademark Office (USPTO).

Because of the investment of its members, this case presents a question of substantial practical importance to IPO: namely, whether Congress's intent to extend the term of U.S. patents in which the Patent Office has delayed examination (as reflected in 35 U.S.C. § 154 of

<sup>1.</sup> No counsel of record for any party authored this brief in whole or in part, and no person or entity other than amicus curiae made a monetary contribution to the preparation or submission of this brief. As required by SCR 37.2, all parties were provided timely notice of intention to file.

<sup>2.</sup> IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting. The list of directors is attached to this brief.

the patent statute) takes precedence over the judge-made doctrine of obviousness-type double patenting (ODP). IPO believes that the unambiguous statutory language of Section 154 precludes any application of ODP. Therefore, IPO respectfully requests that this Court grant certiorari to correct the legally erroneous conclusion reached by the Federal Circuit, an error that will have significant negative effects on the value of many patents thereby reducing the incentive for future innovation.<sup>3</sup>

#### SUMMARY OF THE ARGUMENT

Section 154(b) of the Patent Act states that "if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office . . . the term of the patent shall be extended." 35 U.S.C. § 154(b)(1)(A) (emphasis added). The statute could not be clearer. If the issuance of a patent is delayed based on any of the reasons listed in the statute, "the term of the patent shall be extended." Id. Such patent term adjustments (PTAs) are premised on the recognition by Congress that delays by the Patent Office unfairly limit the effective term of a patent because patent term is measured from the earliest application filing date.

Importantly, Congress was very clear in defining in the statutory text itself the limited role played by terminal disclaimers. "No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer." 35 U.S.C. § 154(b)(2)(B). Indeed, the filing of a terminal disclaimer is the sole exception authorized by

<sup>3.</sup> IPO takes no position concerning the validity of the patents at issue on grounds other than ODP.

Congress to its mandatory "shall be extended" directive in Section 154. "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).

IPO believes that the Federal Circuit committed legal error by starting with and focusing its analysis on the judge-made doctrine of ODP rather than the language of the statute. The appellate court *assumed* that ODP always applies and only briefly referred to the language of Section 154 after concluding that ODP invalidated Appellant's claims. *In re: Cellect, LLC*, 81 F.4th 1216, 1228 (Fed. Cir. 2023). Instead, the Federal Circuit should have started (and ended) its analysis with the statute. Had the appellate court done so, it would have concluded that Appellant was entitled to the patent term adjustments it received because Appellant never filed a terminal disclaimer in any of the patents at issue.

IPO believes that if the Federal Circuit's misinterpretation of the law is allowed to stand, valuable patent rights will be unfairly invalidated, which in turn will reduce the incentive for future investment in critical research. Since 2016, approximately half of all granted patents have been awarded PTA based on USPTO delays in examination, more than a million U.S. patents in total. The Federal Circuit's legally erroneous application of ODP places many of these patents at risk for invalidation or loss of term, term that Congress explicitly granted. Patent owners are entitled to the entire patent term authorized by Congress, not a day less. But the Federal Circuit, in

effect, has reduced the term of the patents at issue to zero, the opposite of the result intended by Congress.

Accordingly, IPO believes that the extension of a patent's term under Section 154(b) should not, as a matter of law, invalidate the claims of that patent due to ODP. IPO respectfully requests that this Court grant certiorari to consider this important issue.

#### **ARGUMENT**

At issue are four patents owned by the Petitioner, Cellect, LLC, each of which had been granted a patent term adjustment under 35 U.S.C. § 154. Each of these patents was then rejected for ODP during reexamination based on an earlier Cellect patent that claimed the same effective filing date as the rejected patents. See Cellect, LLC, 81 F.4th at 1219–21. All of these patents would ordinarily have had the identical expiration date. But because the earlier Cellect patent had not had its term adjusted due to USPTO delay, its term ended before the terms of the rejected patents, all of which were given the benefit of some measure of patent term adjustment. Because none of the Cellect patents had been rejected on the basis of ODP during their original prosecution, no terminal disclaimers were ever filed.

The question presented here is whether the Federal Circuit improperly relied on the "judge-made" doctrine of ODP to invalidate Appellant's term-extended patents. The Patent Act states that "if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office . . . the term of the patent shall be extended." 35 U.S.C. § 154(b)(1)(A) (emphasis added).

Congress intended these patent term adjustments to be mandatory, not permissive. Indeed it is black letter law that "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)). In effect, the Federal Circuit has overruled the statute enacted by Congress based on a judge-made doctrine. This was legal error.

In 2019, this Court applied a traditional principle of statutory construction to the Federal Arbitration Act ("FAA") and determined that a judicially-created exception to an FAA provision could not stand: "[t]he short answer is that the [FAA] contains no [such] exception, and we may not engraft our own exceptions onto the statutory text." Henry Schein, Inc. v. Archer & White Sales, Inc, 139 S.Ct. 524, 530 (2019). See also id. at 531 ("Again, we may not rewrite the statute simply to accommodate [a recognized] policy concern."). The same result should apply here to ODP, a judicially-created exception to the patent statute. If Congress had wanted to apply ODP to PTA-extended patents, it would have said so in the statute. It did not.

The Federal Circuit itself had previously declined to hold "that a judge made doctrine [ODP] would cut off a statutorily-authorized time extension." *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1375 (Fed. Cir. 2018). And yet that is precisely what the Federal Circuit has done in this case, cut off a statutorily-authorized patent term adjustment based on a judge-made doctrine.

IPO believes that the Federal Circuit's reliance on the judge-made doctrine of ODP is legal error. The statute is

clear. When the USPTO delays the issuance of a patent as defined in the statute, "the term of the patent *shall* be extended." 35 U.S.C. § 154(b)(1)(A)(iv) (emphasis added). As it played out in this case, the Federal Circuit's ruling allowed a judge-made doctrine to negate the extension of patent term that Congress intended and then punished the patent owner for receiving that extra term by invalidating four entire patents.

IPO believes that if the Federal Circuit's interpretation of the law were allowed to stand, valuable patent rights would be unfairly invalidated or have their statutorilyauthorized terms reduced. This in turn would reduce the incentive of companies to invest money and time in innovative research. Patent owners are entitled to their patent rights for the entirety of the term authorized by Congress. Instead, the Federal Circuit's erroneous interpretation presents a dilemma for patent owners, a Catch-22 "gotcha". A patent owner may be entitled to a patent term adjustment under the statute, but according to the Federal Circuit's misinterpretation of the law, the patent term adjustment is a poison pill that can invalidate the patent in its entirety. At best, patentees entitled to extra term due to Patent Office delay must disclaim that extra term or run the risk of invalidation. That cannot be right!

In addition, IPO believes that the Federal Circuit's view of the law has already, and will continue to, cause unnecessary confusion in the courts below. Though the Federal Circuit's decision is less than one year old, it has already engendered conflicting interpretations in one of the leading patent trial courts, the District of Delaware, in strikingly similar fact patterns. *Cf. Allergan USA, Inc.* 

v. MSN Labs. Priv. Ltd., 2023 U.S. Dist. LEXIS 172641, at \*59–60 (D. Del. 2023) (Judge Andrews holding ODP applies) with Acadia Pharms. Inc. v. Aurobindo Pharma Ltd., 2023 U.S. Dist. LEXIS 221663, at \*21–24 (D. Del. 2023) (Judge Williams holding ODP does not apply).

Finally, IPO believes that the Federal Circuit's decision introduces uncertainty and instability into continuing application practice, a practice explicitly authorized by statute. 35 U.S.C. § 120. If allowed to stand, the Federal Circuit's decision risks the retroactive invalidation of many otherwise valid patents. This risk of invalidation potentially affects every patentee who files multiple applications and/or continuation applications that share the same priority date, a common and longstanding practice that allows inventors to protect the full scope of their inventions. The Federal Circuit's decision should not be allowed to upend the longstanding and statutorilysanctioned expectations of the patent community. To the contrary, "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).

#### **CONCLUSION**

IPO believes that the Federal Circuit's interpretation of the law is erroneous. Unless this Court grants certiorari, the lower court's erroneous interpretation will stand and do significant damage to the patent system and many otherwise valid patents. Therefore, IPO respectfully requests that this Court grant certiorari.

Respectfully submitted,

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# TABLE OF APPENDICES

	Page
APPENDIX — MEMBERS OF THE BOARD OF	
DIRECTORS INTELLECTUAL PROPERTY	
OWNERS ASSOCIATION	1a

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