No. 23-1231

IN THE

Supreme Court of the United States

CELLECT, LLC,

Petitioner,

v.

KATHERINE K. VIDAL, 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 PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies. Every day, PhRMA members strive to produce cutting-edge medicines, medical treatments, and vaccines that save, extend, and improve the lives of countless Americans. They make immense and risky investments to discover, develop, and deliver new life-changing medicines to patients. Over the last decade, they have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone. And those efforts and investments have yielded an unquestionable public benefit: thousands of safe and effective new medicines and treatments have been delivered by the biopharmaceutical industry to address the unmet medical needs of millions of patients.

The Biotechnology Innovation Organization ("BIO") is the principal trade association representing the biotechnology industry in all fifty states and abroad. BIO has more than 1,000 members, ranging from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. The majority of BIO's members are small companies that have yet to bring products to market or attain profitability. Approximately 90% of BIO's corporate members have annual revenues of under $25 million. These

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[1] Pursuant to Supreme Court Rule 37.6, *amici* states that no counsel for any party authored this brief in whole or in part, and that no entity or person other than *amici* and their counsel made any monetary contribution toward the preparation and submission of this brief. Both parties have confirmed adequate notice under Rule 37.2.

members rely heavily on venture capital and other private investment.

To protect those investments, members of PhRMA and BIO depend on a patent system that is robust, fair, and predictable. In particular, *amici* rely on the patent system to protect the diverse array of innovations they make in connection with developing a new medicine or treatment, including the unique compositions required to safely and effectively use new medicines in patients and novel manufacturing technologies needed to safely produce amounts of those medicines sufficient to meet an often immense patient demand.

Due to the nature of the patent examination process, securing comprehensive patent protection for these arrays of innovations typically requires filing a series of related patent applications derived from an original filing based on the inventive work. And because each of these applications receives an independent examination of varying duration, PhRMA and BIO members often secure a set of related patents, some of which expire later than others. The varying terms of these patents are dictated by the statutory scheme at issue here, which adjusts the term of individual patents if the Patent & Trademark Office ("PTO") fails to meet its statutory deadlines in conducting the examination of the associated application.

PhRMA and BIO members have a substantial interest in this case because the decision below threatens to retroactively cut short the terms of patents that were lawfully and properly obtained. More specifically, the Federal Circuit's decision raises the possibility that a judge-made doctrine of non-statutory double patenting could be used to override the statutorily-mandated terms of properly procured patents. That would con-

tradict Congress's explicit intent and disrupt the substantial investment-backed decisions of the members of PhRMA and BIO.

INTRODUCTION AND SUMMARY

The Federal Circuit's decision invalidated four patents for non-statutory double patenting because those patents had different terms due only to statutorily-mandated patent-term adjustments.[2] This Court's intervention is needed to revisit that now-final holding from the only court of appeals that can consider the question.

The issue at the heart of this case is the long-established, statutorily defined procedure that innovators must use to secure patents. Pursuant to that procedure, innovators, like PhRMA's and BIO's members, file patent applications that provide robust descriptions of a technological innovation and the various embodiments in which it may be put to productive application. Very commonly, the PTO will find certain proposed claims patentable, but not others. The patent applicant may (and usually is encouraged by the PTO to) accept the grant of a first patent on the "allowable" claims, and to then continue the effort to secure additional claims in a "continuing" application. Such applications have (at least) the information found in the original application, are measured as of the original application's filing date, but are independently examined. Patents may only issue from one of these continuing applications if a patent examiner finds that the claims in that application meet all the patentability requirements. Continuing application practice has

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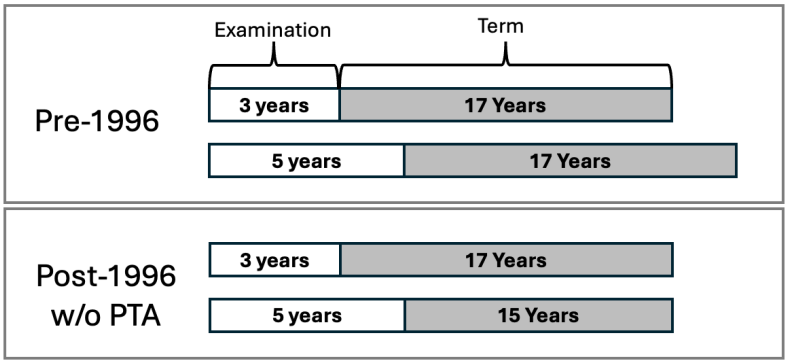
[2] "Statutory" double patenting is based on 35 U.S.C. § 101 and prohibits two patents from claiming the identical subject matter. *Application of Vogel*, 422 F.2d 438, 441 (C.C.P.A. 1970).

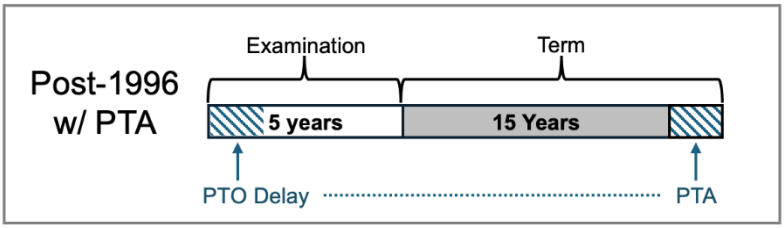
been around for more than 150 years, is explicitly authorized by statute, and is a fundamental part of the patent system.

Historically, PTO-caused delays in the examination of a patent application would not reduce the "effective" term of patent rights—the duration of exclusive rights enjoyed by the patent owner. That was because the term of each patent ran for a period of 17 years starting from when it was granted. On June 8, 1995 that system was changed: the new system provided a term of exclusive rights that again started when the patent was granted, but now expired 20 years after the application's original filing date, regardless of how long it took for the PTO to complete examination. In other words, in this post-1996 scheme, without patent term adjustments that compensate for PTO-caused delays in the grant of a patent, the period of exclusive rights that each patent provides would be shortened relative to the pre-1996 patent system (illustrated conceptually below).



Recognizing the prejudice this change caused to patent owners, Congress incorporated protections into the statute to prevent the reduction of effective patent term from PTO-caused examination delays. Using mandatory language, Congress "guaranteed" that diligent patent applicants would receive *at least* a 17-year

effective patent term if the PTO failed to meet statutorily-prescribed deadlines during the examination of any individual application. It implemented this "guarantee" via the statutory construct of a patent term adjustment, specifying that the term of a patent whose issuance was delayed by the PTO "shall be extended" proportionally to the period of that PTO delay (illustrated below).



Each and every patent whose grant was delayed by PTO actions thus was guaranteed term adjustments based on the unique circumstances of that patent's trip through the Patent Office.

The judge-made doctrine of non-statutory double patenting cannot displace these statutory requirements for patent-term adjustments. That is clear from the statutory text of 35 U.S.C. § 154(b), and it is equally clear from parallel statutory provisions in § 156 that grant back to patent holders any amounts of effective patent term lost to agency reviews. The decision below charts a solitary path that contravenes settled doctrine and conflicts with the governing statute. The Federal Circuit's new standard—in which non-statutory double patenting can extinguish statutorily-required patent terms—cannot stand.

Beyond its doctrinal errors, the decision below imperils settled expectations across innovative industries. That risk is particularly acute in the biotech and pharmaceutical industries where PhRMA's and BIO's members operate. On average, it takes more than a

decade of time and billions of dollars to deliver a new medicine to patients. A predictable patent system is foundational to those investments. Yet, under the Federal Circuit's decision, the Congressionally mandated terms of innovators' existing and future patents are now vulnerable to being cut off. The Federal Circuit's unjustified expansion of its non-statutory double patenting doctrine upends the investment-backed expectations of an untold number of patent owners who lawfully used continuation practices, were awarded statutorily mandated patent term adjustments, and made business decisions and investments based on possession of those patent rights.

This Court has often granted certiorari to realign the Federal Circuit's doctrines with governing statutes. See, *e.g.*, *SAS Inst. Inc.* v. *Iancu*, 138 S. Ct. 1348 (2018); *Halo Elecs., Inc.* v. *Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016); *Nautilus, Inc.* v. *Biosig Instruments, Inc.*, 572 U.S. 898 (2014). The Court should do so again here.

ARGUMENT

I. THE FEDERAL CIRCUIT ERRONEOUSLY APPLIED A NON-STATUTORY DOCTRINE TO CUT OFF STATUTORILY-MANDATED PATENT TERMS.

A. Patent Term Adjustments Are an Integral Part of the Statutorily Defined Patent Examination Process.

The patent term adjustment authority at issue here is an essential part of the PTO's application-by-application examination process.

1. Patent examination is a back-and-forth dialogue between the PTO and the inventor. It begins when an inventor (or her representative) files an application

with the PTO. "A patent examiner with expertise in the relevant field reviews an applicant's patent claims, considers the prior art, and determines whether each claim meets the applicable patent law requirements." *Cuozzo Speed Techs., LLC* v. *Lee*, 579 U.S. 261, 266 (2016). Those requirements include whether the invention is new, not obvious, and useful, and whether the application's description of the invention adequately supports its claims. 35 U.S.C. §§ 101, 102, 103, 112.

Life sciences innovators commonly file robust applications reflecting the broad array of innovations that come with developing a new medicine. They typically describe, for example, not only the most promising active ingredient discovered but other promising candidates as well. These applications also typically describe different formulations necessary to use the new medicines in human patients, diseases that doctors can treat using these medicines, and ways of manufacturing the medicine. Such robust disclosures ensure that, among other things, the innovator can secure patent rights that provide commercially viable protection—preventing competitors from circumventing narrow claims with just minor changes. These robust patent applications also benefit the public because their contents are published 18 months after the application is first filed, regardless whether patents are ever granted on the various inventions each describes.

Unsurprisingly, claims that protect the full array of innovations resulting from development of new medicines also take more time to secure. There can be many rounds of examination: the examiner at first "accepts a claim or rejects it and explains why. If the examiner rejects a claim, the applicant can resubmit a narrowed (or otherwise modified) claim, which the examiner will consider anew, measuring the new claim against the

same patent law requirements. If the examiner rejects the new claim, the inventor typically has yet another chance to respond with yet another amended claim." *Cuozzo*, 579 U.S. at 266–67 (citation omitted). Throughout, "the patent examiner and the applicant, in the give and take of rejection and response, work toward defining the metes and bounds of the invention to be patented." *In re Buszard*, 504 F.3d 1364, 1366–67 (Fed. Cir. 2007). The dialogue often reaches a point where the applicant has to make a choice. If the examiner finds some claims patentable, but not others, applicants may accept the allowable claims and file an additional application to "continue" the examination process on the remainder, rather than delaying the issuance of the already-allowed claims through further back-and-forth with the examiner.

2. This practice is referred to as "continuation" practice, and it has been part of the patent system for a very long time. The Patent Act of 1952 "was the first to put continuation practice fully into statutory text," through 35 U.S.C. §§ 120 and 121. *Immersion Corp.* v. *HTC Corp.*, 826 F.3d 1357, 1363 (Fed. Cir. 2016).

But "[l]ong before Congress enacted section 120," this Court recognized the existence and legitimacy of continuation practice. *Id.* at 1362. That started at least as early as *Godfrey* v. *Eames*, where the Court held that "two petitions [we]re to be considered as parts of the same transaction, and both as constituting one continuous application, within the meaning of the law." 68 U.S. (1 Wall.) 317, 325–26 (1863). And it continued through the decades that followed. See, *e.g.*, *Smith* v. *Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 500 (1876) ("the effort to obtain a new patent in 1864" was "but one stage in a continuous effort," not "a new and independent application, disconnected from the

application made in 1855"); *Birdsell* v. *Shaliol*, 112 U.S. 485, 488 (1884) ("The patent is a continuing patent"); *Gen. Talking Pictures Corp.* v. *W. Elec. Co.*, 304 U.S. 175, 183 (1938) ("The subjects matter of the claims of the other two patents were disclosed in the original applications and were claimed in the continuation applications upon which they issued.").

"Every industry, and inventors from large corporations or small startups to sole inventors currently benefit from, and regularly utilize[,] continuing patent application practice." Stephen T. Schreiner & Patrick A. Doody, *Patent Continuation Applications: How the PTO's Proposed New Rules Undermine an Important Part of the U.S. Patent System with Hundreds of Years of History*, 88 J. Pat. & Trademark Off. Soc'y 556, 557 (2006). Prominent inventors like Thomas Edison have filed continuation applications, as have most of the world's largest innovator companies. *Id.* at 560. PhRMA and BIO members are no different: continuation practice is critical to protecting their innovations and inventions.

3. The deep-rooted continuation practice has significant practical benefits as well. When independent inventions share an application, inventors get distinct protection by breaking those inventions up into so-called divisional applications. 35 U.S.C. § 121; MPEP § 201.06 (9th ed., Rev. 7.2022, Feb. 2023). But much of the time, an innovator may "file[] a patent application disclosing and claiming one invention and later realize[] that the specification discloses a second or broader invention," at which point "he may seek coverage of those additional claims pursuant to 35 U.S.C. §120." *Antares Pharma, Inc.* v. *Medac Pharma Inc.*, 772 F.3d 1354, 1358 (Fed. Cir. 2014).

Before 1996, the length of time consumed in examination of an application had no consequence on the duration of an inventor's exclusive rights, because patents enjoyed a 17-year term that began when the patent *issued*. No matter how long the examination process took, therefore, the patent would provide the same duration of exclusive rights. But in the mid-1990s, Congress changed the method of calculation to one that ran 20 years from the date that the first patent application was *filed*. Uruguay Round Agreements Act (URAA), Pub. L. No. 103-465, § 532(a)(1), 108 Stat. 4809, 4983-85 (1994). With this change, the clock started immediately upon filing, with the effect that any Patent-Office-caused delays during examination "consumed the effective term of a patent." *Wyeth* v. *Kappos*, 591 F.3d 1364, 1366 (Fed. Cir. 2010). So, for example, if the Patent Office imposed improper rejections requiring an appeal to a court to reverse, that Patent-Office-caused delay would reduce the period of exclusive rights conferred by the patent when it was eventually granted, potentially by years.

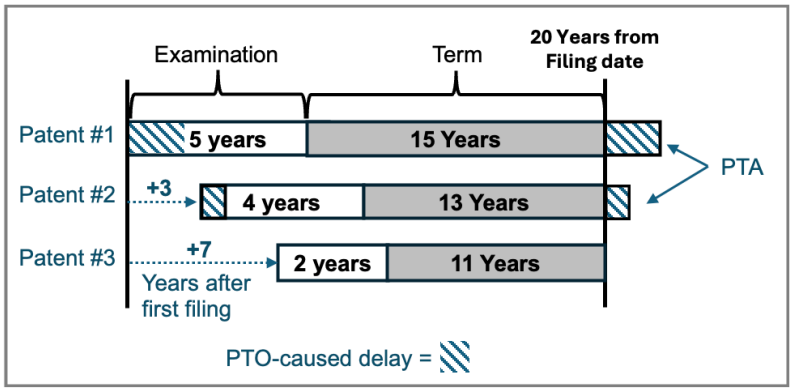
Recognizing this problem, Congress enacted a remedy that would protect patentees against loss of the patent term due to delays caused by the Patent Office in the examination process: mandatory patent-term adjustments (PTAs). In doing so, Congress intended to "guarantee[] diligent applicants at least a 17-year term" by adjusting the patent term to compensate for examination delays attributable solely to the Patent Office. H.R. Rep. No. 106-287, pt. 1, at 50 (1999). The first iteration gave back to inventors the time it took to successfully appeal an examiner's rejection. Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (requiring term extension for interference delay, secrecy orders, or appellate review resulting in reversal of an adverse patentability determination).

The second iteration was even more granular. Codified at 35 U.S.C. § 154(b), Congress prescribed mandatory patent term adjustments for specific types of PTO-caused delays during examination. See Pub. L. No. 106-113, § 1000(a)(9), 113 Stat. 1501, 1536 (1999). "Section 154(b)(1) outlines three types of delays caused by the USPTO." *Supernus Pharms., Inc.* v. *Iancu*, 913 F.3d 1351, 1353 (Fed. Cir. 2019). They include, for example, failing to issue a first action within 14 months of the application, or "fail[ing] to issue a patent after three years have passed between the filing date of the application and the date of allowance." *Id.* Congress thus set deadlines within which it expected the PTO to perform its various examining functions, such as starting examination promptly after an application is filed, promptly responding to applicant communications during examination, and otherwise conducting examination in an expeditious manner.

In each iteration, the statute has employed a design that makes precise adjustments to the term of patents based on what occurred during the examination of the specific application that resulted in the patent whose term is being extended. Examination delays in related patent applications derived from the same original application, for example, do not influence the PTA adjustments provided for another patent. Instead, the statute mandates term adjustments that are patent-specific and compensate an inventor for Patent Office delays that occurred in securing *that* patent—and that patent only.

Importantly, in the post-1996 scheme, the term of a patent issuing from an original application or from a continuation of that application will be measured from the same filing date of the original application. So, for

example, if three patents emanate from an original filing, all three of the patents will have their term measured from the date the original application was filed (illustrated below). If PTO-caused examination delays occur in two of the three patents, patent term adjustments mandated by § 154 will cause the term of those patents to expire after the 20 years from filing date term of the third patent, whose examination was not delayed.[3]



In other words, the statutory design of the PTA authority only applies to patents whose grant is delayed by the PTO and does so under a carefully prescribed formula based on specific types of PTO-caused delays.

The post-1996 patent system that maintains continuing practice and provides precisely calculated patent

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[3] Certain patents that concern pharmaceutical products are eligible to have their term extended pursuant to 35 U.S.C. § 156 to compensate for periods of time consumed during regulatory review by the Food & Drug Administration (FDA) of the pharmaceutical product. Extensions granted pursuant the § 156 authority are added to the term of the patent, which may be adjusted due to a PTA, but are also subject to an overall limit on the duration of exclusive rights following approval of the pharmaceutical product.

term adjustment to account for Patent-Office-caused delays bears no resemblance to the system that gave rise to the equitable doctrine of non-statutory double patenting. In the pre-1996 system, non-statutory double patenting was justified by courts because it was possible that a patent applicant could secure an extended term of exclusive rights by delaying the filing of a second application or by engaging in conduct during examination that delayed the grant of the patent. When multiple related patents issued, the courts thus focused on the source of the extended term of rights, and found double patenting only when an unjustified extension of patent rights was attributable to delays caused by the applicant. Congress's conversion of the patent term to run from filing of the application rather than from the grant of the patent eliminated the possibility of applicants securing additional term by manipulating the timing of when they filed their patent applications. And § 154 directly accounts for any applicant-caused delays during the examination of a single application by reducing the length of a patent term adjustment for such applicant-caused delays.[4] In other words, Congress has eliminated or accounted for the original judicial concerns motivating the non-statutory double patenting doctrine, and the resulting PTA system cannot be forced into that rationale.

PTA is thus an integral part of the broader patent application and continuation system that Congress has created and on which U.S. innovators have long relied. Indeed, nearly "[h]alf of all US patents receive

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[4] *See* 35 U.S.C. § 154(b)(2)(C)(i) ("The period of adjustment of the term of a patent … shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.")

PTA." Brief of the NYIPLA as Amicus Curiae in Support of Certiorari at 2, *Cellect, LLC* v. *Vidal*, No. 23-1231 (2024). PTA provided due to Patent Office delays is simply not a basis for finding non-statutory double patenting.

B. Judge-Made Law Cannot Negate the Statutory Mandate.

The Patent Term Guarantee Act's text is clear and mandatory: when the Patent Office fails to meet certain statutory deadlines in examination, the "term of the patent *shall be extended* 1 day for each day" that the Patent Office delays. 35 U.S.C. § 154(b)(1)(A)(iv) (emphasis added). Congress made that a "guarantee," as the statute's name itself states and as the statutory provisions reiterate many times. This mandate is independent of—and is not limited by—the judge-made non-statutory double patenting doctrine.

Before this case, the Federal Circuit had recognized as much. In *Novartis Pharmaceuticals Corp.* v. *Breckenridge Pharmaceutical Inc.*, the court acknowledged that "Congress intended patent owners who filed patent applications before the transition date to the new patent term law to enjoy the maximum possible term available," and that applying non-statutory double patenting to cut off that statutory term "would be inconsistent with the [statute]." 909 F.3d 1355, 1366 (Fed. Cir. 2018). And again in *Novartis AG* v. *Ezra Ventures LLC*, the Federal Circuit did not allow the judge-made, non-statutory double patenting doctrine to supersede a statutory term-rule—specifically, a patent-term extension granted pursuant to 35 U.S.C. § 156. 909 F.3d 1367, 1369 (Fed. Cir. 2018). Section 156 uses the same mandatory language as § 154(b) and is designed to "restore the value of the patent term that a patent owner loses" due to administrative agency review. *Id.*

Breaking from these rulings, the decision below purports to find congressional support for using the judge-made non-statutory double patenting doctrine to override statutory PTA commands by looking to a provision related to so-called terminal disclaimers. Pet. App. 20a–23a. According to the Federal Circuit, because terminal disclaimers are often filed to overcome a non-statutory double patenting rejection, the statutory provision about terminal disclaimers was "tantamount to a statutory acknowledgement that ODP concerns can arise when PTA results in a later-expiring claim that is patentably indistinct." *Id.* at 22a. And because the patentee had not sought a terminal disclaimer here, the Federal Circuit thought, it would "frustrate the clear intent of Congress" not to apply non-statutory double patenting. *Id.* at 23a.

The Federal Circuit's reasoning is wrong. The terminal disclaimer language in §154(b)(2)(B) is simply one of the rules for *calculating the length* of a patent-term adjustment. It provides that if an applicant has *already* limited the term of a patent that might issue from an application by providing a voluntary "terminal disclaimer" during examination of that application, that applicant cannot (logically) extend the term of that patent beyond the already agreed-to expiration date. Section 154(b)(2)(B) thus has nothing to do with *whether* a properly awarded patent term adjustment should be cut short by non-statutory double patenting.[5] This provision certainly is not a reason to find

[5] Terminal disclaimers are used in a variety of situations, often unrelated to double patenting. For example, a patent applicant or patent owner may use it to dedicate a portion of the term of a patent to the public or to disclaim some amount of an earned patent term adjustment in favor of securing a longer patent term extension under § 156 based on FDA regulatory review periods. A terminal disclaimer also can be used by applicants to expedite

that *any* term adjustment mandated by §154(b) is an *unjustified* timewise extension of rights.

* * *

In the end, "'even the most formidable' policy arguments cannot 'overcome' a clear statutory directive." *BP p.l.c.* v. *Mayor of Baltimore*, 141 S. Ct. 1532, 1542 (2021) (citation omitted). Yet that is the consequence of the decision below. The Federal Circuit has woven its own convoluted web of judge-made law and equitable doctrine under the non-statutory double patenting umbrella. The simple path to cut through that web is the one that Congress provided: the statute speaks in mandatory terms, and the statute controls. This Court should grant certiorari and reject the Federal Circuit's anti-statutory approach.

II. THE FEDERAL CIRCUIT'S DECISION DISRUPTS SETTLED EXPECTATIONS OF INNOVATORS.

The Court also should grant certiorari because the Federal Circuit's decision harms innovators, including PhRMA's and BIO's members, and thereby undermines the patent system as an engine of innovation.

As this Court has explained, "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). But that is exactly what the Federal Circuit's decision does. It unsettles investment-backed expectations *after* those investments have been made—indeed, patents that were valid when issued may suddenly become threatened if the patentee gets

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allowance of claims the patent examiner has rejected for non-statutory double patenting, in lieu of pursuing a time-consuming appeal to rebut a defective double patenting rejection.

a subsequent patent with a shorter term. And these are critical investments to deliver new medicines and therapies to patients. To "change so substantially the rules of the game now" necessarily "subvert[s] the various balances" struck by Congress, the PTO, and innovators who prosecuted their patents without any knowledge that this new judge-made rule would someday arise. *Id.*

The Federal Circuit's decision also risks unique consequences for pharmaceutical and biotechnology innovators like PhRMA's and BIO's members. Life sciences-related patent applications often require a long gestation period and significant investment: PhRMA members, for example, spend, on average, 10 to 15 years to develop and bring a drug to market. PhRMA, *The Dynamic U.S. Research and Development Ecosystem* 1 (2021), https://tinyurl.com/2rm3z76h. Regulatory protocols are only becoming more complex. To take just one example, the number of procedures per patient in Phase II and III protocols has increased 44% since 2009. See *Rising Protocol Design Complexity is Driving Rapid Growth in Clinical Trial Data Volume, According to Tufts Center for the Study of Drug Development*, GlobalNewswire (Jan. 12, 2021). Today, Phase III clinical trials generate an average of 3.6 million data points—three times the amount collected 10 years ago. *Id.*

Research and development costs are rising too. For the past decade, costs have gone up by approximately 8.5% every year. Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* 16 (Apr. 2021). Economists estimate that, on average, every new drug that makes it to market has cost about *$2.6 billion* to get there. Joseph A. DiMasi, Henry G. Grabowski, & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of*

R&D Costs, 47 J. Health Econ. 20, 20 (2016).[6] And that estimate does not account for often significant FDA post-approval requirements or for new indications, new forms of administration, and novel combination products. *Id.*

On top of increasing costs, the risks are significant: more than 90% of clinical drug candidates fail to obtain FDA approval. Helen Dowden & Jamie Munro, *Trends in Clinical Success Rates and Therapeutic Focus*, 18 Nat. Revs. Drug Discovery 495, 495-96 figs. 1 & 2 (2019). And approvals are getting harder to obtain. In the 1980s and 1990s, 20% of developed drugs received FDA approval and reached market; by 2016, fewer than 12 percent of drugs reached the market.[7]

The decision below puts this whole ecosystem—and the investments that fuel it—in jeopardy. Retroactively, it creates an unwarranted and unanticipated risk that proper statutorily mandated term adjustments could be used as a basis for invalidating a patent, long after all of the patents in a family were prosecuted—and long after the enormous investments needed to deliver new medicines and therapies to patients. That would "destroy[] the legitimate expectations of inventors in their property." *Festo*, 535 U.S. at 739. Proactively, too, PhRMA and BIO members need stability to maintain the pace of innovation in the discovery, development, and delivery of cutting-edge medicines to patients. The decision below destabilizes the system that is so critical to incentivizing innovators to innovate.

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[6] These figures reflect both the expenses incurred in discovering, developing, and clinically testing a drug that is approved, as well as the many products that fail to reach the market.

[7] Congressional Budget Office, *supra*, at 16-17.

The Court should grant certiorari and reaffirm the primacy of Congress's legislative directive over the judge-made doctrine of obviousness-type double patenting.

CONCLUSION

The Court should grant certiorari and vacate the Federal Circuit's decision.

Respectfully submitted,

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