No. 23-1231

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 U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF SANOFI, BEIGENE, LTD., MERCK SHARP & DOHME LLC, EMD SERONO, INC., AND PFIZER INC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the judge-made doctrine of non-statutory double patenting may be used to invalidate a patent based solely on a statutory grant of Patent Term Adjustment, which is intended to "guarantee" a patent's term when there is government delay in issuing a patent.

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INTEREST OF *AMICI CURIAE*[1]

Amici Sanofi, BeiGene, LTD., Merck Sharp & Dohme LLC, EMD Serono, Inc., and Pfizer Inc. are innovator biopharmaceutical companies engaged in the research and development of novel therapeutics for a wide variety of conditions. Amici recoup, and earn a return on, their enormous investments in biotechnology through the exclusivity afforded under U.S. patent laws. The period of lawful exclusivity—known as the "term" of an issued patent—is of great importance to Amici.

Through a variety of statutory provisions, Congress has provided certainty and predictability for patent terms, including extensions to fairly compensate patent owners for delays occasioned by the Patent Office. The decision below, however, disrupts this certainty and deprives patentees of their congressionally-authorized patent terms, through misapplication of an ever-expanding and mostly outdated judge-made doctrine called "non-statutory double patenting." The resulting uncertainty will adversely affect companies like Amici that develop life-saving and life-enhancing medicines and therapies. This Court should grant review to ensure that patents retain their full statutory terms.

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[1] Counsel of record for petitioner and respondent were notified on June 14, 2024 of Amici's intent to file this brief, and counsel for both parties responded that they did not object. No counsel for either party authored this brief in whole or in part, and no person other than Amici and their counsel made a monetary contribution to fund the submission or preparation of this brief.

STATEMENT

I. Legal Framework and History

Patent terms have been part of the intellectual property landscape since the first Congress. By providing a specific and reliable period of exclusivity, statutory patent terms encourage investment in innovation, and make the United States a technological world leader. Congress has repeatedly amended the statutory regime to ensure that patent terms are guaranteed—even in the face of administrative or regulatory delay.

Federal courts have occasionally acted to address perceived gaps in the statutory regime. Pertinent here, courts have endeavored to prevent inventors from obtaining unjustified extensions of patent term through multiple filings of substantially similar applications. As Congress has continued to refine the patent laws, however, this judicial intervention has become almost entirely obsolete and unnecessary. The instant petition presents a case study of this phenomenon.

A. The Patent Bargain

The Constitution gives Congress the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. This forms the basis for the patent "bargain," whereby a private property right in the form of a time-limited public franchise is exchanged for bringing new technologies to the public through disclosure. *Amgen Inc. v. Sanofi*, 598 U.S. 594, 604 (2023). Both the public and the inventor benefit

from this bargain. *See generally* James Madison, *The Federalist No. 43*, at 272 (Clinton Rossiter ed. 1961).

B. Reliable Patent Terms Are Essential to the Patent Bargain

The patent bargain only works if the patent system encourages investment in new inventions. *See Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1557 (Fed. Cir. 1983). Stimulation of investment, in turn, requires a clear and predictable patent term—that is, the length of time the inventor's public franchise will run.

Congress recognized this from the start, delineating a fourteen-year term—from the date of a patent's issuance—in the Patent Act of 1790. *See* Patent Act, §1, 1 Stat. 109 (1790). Since then, Congress has adjusted the patent term thrice, each time maintaining a predictable patent term. *See* Patent Act, §§ 5, 18, 5 Stat. 117 (1836) (fourteen years from issuance, with a possible seven-year extension); Patent Act, § 16, 12 Stat. 246 (1861) (seventeen years from issuance without extension); Uruguay Round Agreements Act ("URAA"), § 532(a), 108 Stat. 4809 (1994) (twenty years from filing).

Congress has also ensured inventors will not pay the price for administrative delay. When Congress enacted the URAA in 1995, the clock on patent term began running from the filing date, leaving inventors at the mercy of long application pendency periods at the Patent Office. Accordingly, Congress passed the Patent Term Guarantee Act of 1999 to "guarantee": (1) "prompt patent and trademark office responses," (2) "no more than 3-year application pendency," and (3) "adjustments for

delays due to interferences, secrecy orders, and appeals." 113 Stat. 1501, 1501A-557-560 (1999). In such cases, Congress guaranteed that the patent term "shall be extended 1 day for each day" of administrative delay. *See id.* The time added to meet these guarantees is called Patent Term Adjustment ("PTA").

Similarly, Congress created a drug and medical device-specific Patent Term Extension ("PTE") as part of the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"). *See generally* 98 Stat. 1585 (1984). PTE compensates patent owners for the Food and Drug Administration's lengthy approval process, by extending the term of a patent covering an approved product "by the time equal to the regulatory review period." 35 U.S.C. § 156(c).

Thus, Congress has ensured that patent owners are "guaranteed" their side of the patent bargain—and investors may rely on predictable patent terms that have not been eroded by government inefficiency.

C. The Rule Against "Double Patenting"

The other side of the patent bargain requires that when the patent term expires, "the monopoly created by it ceases to exist." *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896). At that point, the public receives "the advantage for which the privilege is allowed." *Grant v. Raymond*, 31 U.S. 218, 247 (1832). Thus, it is foundational that an inventor is allowed one patent per invention, and the patent term cannot be extended through serial applications. *See Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578, 579 (C.C.D. Mass. 1819) (Story, J.) ("It cannot be, that a patentee can have in use

at the same time two valid patents for the same invention; and if he can successively take out at different times new patents for the same invention, he may perpetuate his exclusive right.").

This basic rule against "double patenting" has a long history. *See* Edward C. Walterscheid, *Historical Development of the Law of Double Patenting up Through the 1952 Act*, 4 APLA Q.J. 243, 243 (1975). But courts have recognized there are two distinct doctrines: statutory double patenting ("SDP") and non-statutory double patenting ("NSDP"). *See generally In re Zickendraht*, 319 F.2d 225, 231 n.4 (CCPA 1963) (Rich, J., concurring). Both doctrines aim to prevent unjustified extensions of patent term through the practice of serial applications, but they apply to different situations and rely on different sources of law.

SDP is straightforward. It applies where one inventor files two patent applications that claim "identical subject matter." *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985). Because the Patent Act states an inventor "may obtain *a* patent" for a new invention, 35 U.S.C. § 101 (emphasis added), a second patent for the same invention will be denied. SDP is rare and not at issue here.

NSDP, in contrast, is continually evolving, confusing, and often litigated. NSDP has no statutory basis but is a judicial doctrine "grounded in public policy" to address a statutory loophole. *Id.* Specifically, NSDP is designed to prevent "unjustified extension[s]" of patent term, *In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir. 1998), "where an express statutory basis for the rejection is missing." *Longi*, 759 F.2d at 892. It applies where one inventor files two patent applications for separate inventions, but

one of those inventions "would have been obvious from the subject matter of the claims in the first patent." *Id.* at 893. NSDP is sometimes called "obviousness type" double patenting ("ODP"). *Id.* at 892.

NSDP is a doctrine of equity, developed by courts to address a specific statutory loophole. Historically, unjustified extensions of patent term were possible between original and continuing applications because—until the URAA was passed in 1995—patent term ran from the *date of issuance*. Thus, serially filed patent applications (which are not prior art to each other) with claims to obvious variations would end up with different patent terms running from different issue dates, functionally extending the term of patentably indistinct inventions.

NSDP plugged this hole. *See Promega Corp. v. Applied Biosystems, LLC*, 2013 WL 2898260, at *12 (N.D. Ill. June 12, 2013) ("[T]he doctrine is meant to prevent an inventor from extending the life of his patent by means of patents subject to different terms for different claims covering the same innovation."), *aff'd*, 557 F. App'x 1000 (Fed. Cir. 2014); *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1217 (Fed. Cir. 2014) (Rader, J., dissenting) (explaining that, before the URAA, a "patentee could file successive continuations … and perhaps do so *ad infinitum*," so courts "used obviousness-type double patenting to curtail that practice").

D. Congress Reins in the Courts

Congress has never explicitly endorsed NSDP. And, each time Congress has acted with implicit reference to

NSDP, it has been to prevent courts from taking it too far.

Congress's first implicit recognition came in the Patent Act of 1952. In preceding years, courts had used NSDP aggressively, even to invalidate divisional patents. *See* Walterscheid, *supra* at 259. A divisional application arises when an examiner decides that a "specific claimed matter is for different inventions" and directs the patentee to split one application into two or more. *Id.* at 259. Despite this direction, courts took the position that a divisional could still be subject to NSDP, because the "applicant could have litigated the division requirement, and his failure to do so was at his peril." *Id.* In response to this inequitable result, Congress passed section 121, creating a Safe Harbor against NSDP for divisionals so long as the requirements of the statute were met. *See* § 121, 66 Stat. 792, 800-01 (1952).

In the same Act, Congress passed section 253, which allows a patentee to "disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted." *Id.* at 809. These "terminal disclaimers" are used to, among other things, obviate charges of double patenting by aligning the patent terms of two separately filed applications. *See In re Robeson*, 331 F.2d 610, 614-15 (C.C.P.A. 1964) (discussing legislative history of section 253).

E. Congress Closes the Loophole

The current patent regime no longer has the loophole that NSDP was developed to address. Since 1995, patent terms run twenty years from the patent term filing date, rather than seventeen years from issuance. *See*

URAA, 108 Stat. at 4983–85. Applications claiming similar subject matter are usually filed as part of the same patent "family," so they share the same filing date for purposes of calculating patent term (the "patent term filing date"). *See* 35 U.S.C. § 154. Accordingly, within a family, no matter how many applications are filed or when the ensuing patents are issued, they share the same default patent term as the original application from which priority is claimed. The gamesmanship that NSDP was designed to address is therefore no longer a concern.

After the original application is filed, inventors may also file continuing applications[2] for claims of alternative scope or other aspects of the invention disclosed in the specification but not claimed in the original application. 37 C.F.R. § 1.78. Such continuing applications are treated as having the same patent term filing date as the original application. 35 U.S.C. § 120.

Continuing applications are an essential part of the patent landscape. They allow inventors to obtain issuance of the original application with claims that may be of primary importance and then pursue additional

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[2] Continuing applications include continuation and continuation-in-part applications. Continuation applications include the same information as the original application, and the expiration dates thereof are measured from the filing date of the original application (the patent term filing date). Continuation-in-part applications differ in that they can contain new information compared to the family's original application, but, like continuation applications, still share a common patent term filing date with the original application.

claims in continuing applications to protect other aspects of an invention. The availability of continuing applications prevents patentees from having to pursue every possible claim in the original application, which would overburden the PTO. Continuing applications are especially important when an invention has multiple applications, as in the pharmaceutical space. In 2018, more than 15% of patent applications filed in the United States were continuing applications. *See* Christopher A. Cotropia & Cecil D. Quillen, Jr., *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office as of FY 2018*, RICH. SCH. L., Res. Paper No. 2019-01, at 6–8 (May 20, 2019).

Because the terms of patents issuing from continuing applications are calculated from the filing date of the original application, *see* 35 U.S.C. § 154, patent families have the same default patent term, before adding either statutory PTA or PTE. There is no gamesmanship in the form of orchestrating patent filings to obtain unjust extensions. Indeed, expiration dates of the patents in a family will only differ if (i) administrative delay at the Patent Office results in a statutory grant of PTA pursuant to Congress's "guarantee" of full patent term, or (ii) the time consumed by the regulatory process reduces the useful life of the patent, resulting in compensation with PTE.

F. The Federal Circuit Expands NSDP Anyway

Even though Congress has plugged the statutory gap, the Federal Circuit has continued to apply judge-made NSDP in new and surprising ways. For example, in *In re Hubbell*, the Federal Circuit applied NSDP to

patent applications that did not share "inventive entities, were never commonly owned, and [were] not subject to a joint research agreement." 709 F.3d 1140, 1145 (Fed. Cir. 2013). *Hubbell*'s application of NSDP was completely detached from the doctrine's original purpose of preventing a *single inventor* from exploiting the prior loophole. *See id.* at 1151 (Newman, J., dissenting) ("In the entire body of precedent relating to rejection on the ground of double patenting, the rejected patents or applications were of common inventorship or common ownership."). Further, *Hubbell* involved the citation of a later-filed patent with a later patent term filing date against an earlier-filed patent application with an earlier patent term filing date.

Similarly, in *Gilead*, the Federal Circuit expanded NSDP again to hold "a later-issued, but earlier-expiring patent … invalidate[d] a first-issued, but later expiring patent." 753 F.3d at 1217 (Rader, J., dissenting). The facts of *Gilead* did "not raise the policy concern regarding subsequent extensions of patent term" because the later issued patent "unquestionably did *not* extend the term of the earlier-issuing" patent. *Id.* at 1218. Nevertheless, the Federal Circuit employed NSDP to address additional untethered policy concerns—acting as super legislator. *See id.* at 1220.

II. Decision Below

A. *Cellect* Expands NSDP Further Still

In *Cellect*, the Federal Circuit addressed for the first time whether NSDP could invalidate claims of patents within a family solely because of a statutory grant of PTA to some members of that family. At issue were a

series of continuing applications containing claims that shared the same default patent term as one original application. *See In re Cellect, LLC*, 81 F.4th 1216, 1219 (Fed. Cir. 2023). The challenged patent claims had earned different expiration dates solely because of PTA.

Arguing against NSDP, Cellect asserted that it had not sought an unjustified extension of a patent term. *Id.* at 1221. And NSDP would negate Cellect's statutory guarantee of PTA. *Id.* The application of NSDP to invalidate Cellect's claims put Cellect in a worse position than it would have been in had Congress not guaranteed compensation for administrative delay. Furthermore, the Federal Circuit had already held that NSDP does not apply where PTE causes expiration dates to differ. *See Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1369 (Fed. Cir. 2018).

The Federal Circuit rejected these arguments, concluding that NSDP applies to a member of a patent family which receives PTA due to administrative delays and therefore will expire later than other members of the same family. *Cellect*, 81 F.4th at 1219. The Federal Circuit then used NSDP to invalidate Cellect's claims in four separate patents. *Id.* The default patent term of Cellect's patents had already expired, so it was too late to file a terminal disclaimer to save them. *Id.* at 1226. In *Cellect*, no NSDP rejection was ever made during prosecution.

The Federal Circuit gave three primary reasons for again expanding NSDP. First, the court distinguished *Novartis* because "PTA and PTE are dealt with in different statutes and deal with differing circumstances." *Id.* Second, the court concluded that Cellect had "received

unjustified extensions of patent term" because the challenged patents received PTA and expired later than another, later-filed patent in the family. *Id.* at 1229-30. Third, the court concluded that the PTA statute required Cellect to file a terminal disclaimer to relinquish its PTA to obviate NSDP, which Cellect was no longer able to do. *Id.* at 1230.

B. *Cellect* Sows Confusion in the District Courts

Untethered from the origins of NSDP, *Cellect* and its predecessors are causing confusion in the lower courts. The confusion extends most dramatically to the District of Delaware, which hears a disproportionately high number of patent cases involving pharmaceuticals. For example, in *Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, 2023 WL 6295496 (D. Del. Sept. 27, 2023), and *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, 2023 WL 8803448 (D. Del. Dec. 13, 2023), two district judges disagreed whether, post-*Cellect*, NSDP can be used to invalidate an *earlier*-filed patent that expired later due to PTA. In *Acadia*, the judge was "unable to identify a case where, when challenged, a later-filed, later-issued, earlier-expiring patent was used as an [NSDP] reference to invalidate an earlier-filed, earlier-issued, later-expiring patent." 2023 WL 8803448, at *7. But, in *Allergan*, the judge invalidated an earlier-filed, earlier-issued patent solely because it received PTA and would expire after a later-filed patent that did not receive PTA, concluding that the reasoning of *Cellect* applied either

way, and "[t]he 'first-filed, first-issued' distinction is immaterial." *See* 2023 WL 6295496, at *22.[3]

Allergan is especially problematic because it discourages the filing of continuing applications, lest earlier-filed patents that received PTA be placed at risk merely because a continuing application may be examined more efficiently. But regardless of the outcome on appeal, *Allergan* is a symptom of the greater *Cellect* problem. When courts apply NSDP to patents with the same default patent term, there is no longer any equitable basis for the doctrine. Lacking the anti-gamesmanship rationale of the original NSDP, courts are using arbitrary public policy considerations to undermine the statutory scheme detailed by Congress.

SUMMARY OF ARGUMENT

The patent bargain stimulates investment of risk-capital in new technology. The cost of this investment, especially in the pharmaceutical industry, is enormous, and relies on definite and predictable patent terms, which Congress has recognized. *Cellect*, however, makes patent terms unpredictable and subject to administrative inefficiencies and judicial whim. Accordingly, *Cellect* will decrease investment, harming inventors and the public.

Cellect is also destabilizing. It undermines the use of continuing applications, an important and widespread practice which lightens the load for the Patent Office. It

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[3] *Allergan* and *Acadia* have been appealed to the Federal Circuit; oral argument in *Allergan* was held on May 9, 2024, while briefing in *Acadia* was completed on June 20, 2024.

puts inventors in a lose-lose situation, forcing them to disclaim a congressionally guaranteed period of exclusivity or risk invalidation. Under *Cellect*, NSDP is no longer based in the doctrine's equitable roots.

Cellect is legally incorrect. The Federal Circuit misconstrued 35 U.S.C. § 154(b)(2)(B). That provision is not meant to require terminal disclaimers for patents that have different patent terms solely because of PTA. The Federal Circuit applied a judge-made equitable doctrine in an inequitable way, contravening Congress's statutory guarantees in the process. *Cellect* punishes patentees for receiving congressionally-mandated compensation for patent term lost due solely to administrative delays by the Patent Office.

This Court should grant review because *Cellect* threatens the investment-backed expectations of inventors and undermines the patent bargain; because the Federal Circuit has supplanted Congress's judgment with its own; and because *Cellect* is unworkable for courts, inventors, and other stakeholders.

ARGUMENT

I. *Cellect* Undermines the Patent Bargain

A. Innovation Requires Investment

An important policy of the patent system "is to stimulate the investment of risk capital in the commercialization of useful patentable inventions so that the public gets some benefit from them." *Rohm*, 722 F.2d at 1571.

Investment is especially important in the pharmaceutical industry. The cost of research and development to bring a new drug to market is often in the billions. *See*

Emily May et al., *Unleash AI's Potential: Measuring the Return from Pharmaceutical Innovation*, DELOITTE, (2024), https://perma.cc/C4CS-ND4W ("[t]he average R&D cost to progress an asset from discovery to launch … for 2022–2023 [was] $2,284 million per asset"); Michael Schlander et al., *How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment*, 39 PHARMACOECONOMICS 1243, 1243 (2021) (cost estimates for developing a new drug range from $161 million to $4.54 billion); Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (Apr. 2021), https://www.cbo.gov/publication/57126 ("In 2019, the pharmaceutical industry spent $83 billion dollars on R&D.").

In turn, the public benefit of this investment is enormous. *See* Frank R. Lichtenberg, *New Drugs: Health and Economic Impacts*, NBER REPORTER (2002), https://perma.cc/5W6E-EWLG ("[T]he average new drug approval increases the life expectancy of people born in the year that the drug is approved by .016 years (5.8 days). …[S]ince there are approximately 4 million births per year in the United States, the average new drug approval increases the total expected life-years of the cohort by 63.7 thousand years."); Rena M. Conti & Frank S. David, *Public Research Funding and Pharmaceutical Prices: Do Americans Pay Twice for Drugs?*, F1000RES. (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7642989/ ("[B]iomedical research has generated enormous surplus economic value for the American public, far in excess of the sum of all public

and private investments in research and development.").

Pharmaceutical investment, however, is dependent on the exclusivity provided by patent term, which is how investors generate returns. A single day of patent term can be worth millions of dollars that can be re-invested in research and development of additional life-saving and life-enhancing therapies. Thus, if patent term decreases, investment decreases. *See* Eric Budish et al., *Patents and Research Investments: Assessing the Empirical Evidence*, 106 AM. ECON. REV. 183, 183–87 (2016) (estimating an increase in investment of 7-24% for every one-year of patent term). Likewise, if patent term is unpredictable, returns are riskier and investment and innovation will decrease.

B. Congress Has Enacted a Detailed and Predictable Patent Regime

There is always a balance between competition to lower drug prices and exclusivity to encourage investment in new drugs. This balance is a policy question for Congress—not courts—and Congress has addressed that policy question many times.

In 1984, Congress passed the Hatch-Waxman Act, creating a detailed regulatory regime to balance competition and exclusivity for drugs. The Hatch-Waxman Act grants marketing exclusivity to pioneer drugs, five years for new chemical entities and three years for previously approved active ingredients. *Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 761–62 (D.C. Cir. 2010). It also provides a framework for litigating relevant patents before commercial launch of generic products, so

that the parties do not have to wait until commercial marketing to resolve patent disputes. *See* 35 U.S.C. § 271(e)(2)(A).

In exchange, generic competitors are allowed to develop their products without threat of a patent infringement suit, under a safe harbor. *See* 35 U.S.C. § 271(e)(1); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 664 (1990). This carefully calibrated scheme balances competition and innovation.

Congress also realizes the importance of patent term, and the need for that term to be predictable. In the American Inventors Protection Act of 1999, which enacted PTA, Congress used the word "guarantee" four times. *See* 35 U.S.C. § 154. Likewise, for pharmaceuticals, Congress created PTE in the Patent Term Restoration Act, to ensure the lengthy FDA approval process would not reduce effective patent term. *See* 35 U.S.C. § 156(c).

C. *Cellect* Creates Unpredictability and Undercuts Congressionally Set Patent Terms

Many stakeholders—including inventors, investors, competitors, and regulators—rely on the predictable patent terms set by Congress. *Cellect* undermines this predictability and transparency.

Cellect puts a large number of patents that have received PTA at risk of invalidation, even when those patents would not otherwise be susceptible to NSDP. Since 2005, 63.6% of issued patents received an average of 411 days of PTA. Mark A. Lemley & Jason Reinecke, *Our More-than-Twenty-Year Patent Term*, (Stan. L. & Econ.

Olin Working Paper No. 586 at 1, 2023). A small but significant number of patents receive more than four years of PTA. *Id.* at 1–2. Many patents covering FDA-approved pharmaceuticals have received substantial PTA. *See, e.g.*, U.S. Patent No. 7,364,736 (covering Prolia/Xgeva, treating osteoporosis; 970 days of PTA); U.S. Patent No. 8,124,799 (covering Skyclarys, treating Friedreich's ataxia; 359 days of PTA); U.S. Patent No. 8,785,500 (covering Spravato, treating depression; 1,572 days of PTA); U.S. Patent No. 8,440,715 (covering Sunosi, improving wakefulness in adults with narcolepsy or sleep apnea; 444 days of PTA); U.S. Patent No. 8,088,378 (covering Polivy, treating lymphoma; 386 days of PTA); U.S. Patent No. 8,071,643 (covering Xenleta, treating pneumonia; 303 days of PTA).

The Federal Circuit's proposed solution—*i.e.*, "to file terminal disclaimers during prosecution, even in the absence of an [NSDP] rejection," *Cellect*, 81 F.4th at 1231—is no solution at all. The Federal Circuit would force patentees to file disclaimers of PTA due to administrative delay, in the absence of a Patent Office rejection based on NSDP and even when the applicant has a meritorious argument against it, for fear of losing on NSDP grounds later.

Terminal disclaimers come with serious disadvantages to the patent owner. For one, even if the NSDP concern applies only to a single claim in a patent application, the terminal disclaimer applies to the entire patent. *See* MPEP § 1490(VI)(A) ("A disclaimer of a terminal portion of the term of an individual claim, or individual claims will not be accepted."). For another, by

regulation, "when filed to obviate judicially created double patenting," a terminal disclaimer prevents that patent from being owned separately from the original. *See* 37 C.F.R. § 1.321(c)(3). This may be the tip of the iceberg. A recently proposed Patent Office rule would link patents with a terminal disclaimer together, such that if one claim in one patent is found invalid as anticipated or obvious, then all connected patents are unenforceable. *See Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting*, 89 Fed. Reg. 40439 (proposed May 10, 2024).

Most fundamentally, by forcing patentees to either preemptively disclaim PTA or risk the possibility of future invalidation based on NSDP, *Cellect* negates the very remedy Congress provided in the PTA statute to compensate inventors for administrative delay and the resulting loss of patent term. This undermines predictability and forces investors to again prognosticate about government efficiency. *Cellect* undermines the patent bargain that Congress has so carefully calibrated.

II. Legal Errors

Cellect is not just bad for inventors and the public; it is wrong as a matter of statutory interpretation, history, doctrine, and equity.

A. The Federal Circuit Misconstrued § 154(b)(2)(B)

The Federal Circuit's interpretation of section 154(b)(2)(B) was "critical" to the outcome in *Cellect*. *See Cellect*, 81 F.4th at 1228. That section states: "No patent the term of which has been disclaimed beyond a speci-

fied date may be adjusted [with PTA] beyond the expiration date specified in the disclaimer." 35 U.S.C. § 154(b)(2)(B). The Federal Circuit reasoned that because terminal disclaimers "are almost always filed to overcome" NSDP, then section 154(b)(2)(B) "is tantamount to a statutory acknowledgement that [NSDP] concerns can arise when PTA results in a later-expiring claim." *Cellect*, 81 F.4th at 1228. This reasoning is flawed for at least three separate reasons.

First, terminal disclaimers are not tied to NSDP the way the Federal Circuit presumed. Patent owners can file statutory disclaimers under 35 U.S.C. § 253 for any reason, including reasons that have nothing to do with NSDP. For instance, when an applicant has been awarded both PTA and PTE in excess of the fourteen-year statutory cap, *see* 35 U.S.C. § 156(c)(3), the applicant may disclaim any extra PTA to maximize the PTE award. Likewise, an applicant may wish to file a terminal disclaimer where the Patent Office improperly calculated PTA and awarded too many days. Further, a patentee may wish to dedicate patent term to the public, which is envisioned in 35 U.S.C. § 253(b).

Second, the Federal Circuit's interpretation relies on its newfangled formulation of NSDP, rather than the original NSDP that Congress likely had in mind with section 154(b)(2)(B). NSDP, as discussed above, closes the specific statutory loophole of serially filed applications with *different* default patent terms. But *Cellect* applied NSDP to patents within the same family that shared a default patent term.

If section 154(b)(2)(B) contemplates NSDP, it is likely for the limited situation where original patent applications containing patentably indistinct claims are filed separately on different dates, rather than as part of the same patent family, resulting in patents with different default terms. In that case, NSDP might apply to the later-filed, later-expiring patent because the patents would have different default patent terms—different start *and* end dates—which is controlled by the patentee. That, if anything, is what section 154(b)(2)(B) is aimed at—ensuring that PTA is disclaimed in instances where disclaimer of default patent term was already required. But it is far-fetched that Congress's intention was to create a de facto requirement for owners of patents in the same family—which are not subject to the same gamesmanship—to affirmatively and preemptively file terminal disclaimers, effectively denying statutorily guaranteed PTA.

Finally, if Congress intended section 154(b)(2)(B) to support NSDP challenges, it would have said so. That section means what it says and only applies if a terminal disclaimer has been filed. The Federal Circuit's approach is unpredictable and backwards, turning the guarantee of patent term in the PTA statute into a weakness.

B. Cellect Misapplied NSDP

The *Cellect* opinion is also contrary to history and doctrine. The Federal Circuit found that Cellect had "received an unjust timewise extension of term" simply because the expiration dates for patents in a family were

adjusted by PTA. *Cellect*, 81 F.4th at 1230. However, receiving the adjusted patent term explicitly granted by Congress is not "unjustified."

NSDP was crafted to "curtail" the practice of filing successive applications to "obtain additional patent term for obvious modifications of [an inventor's] earlier claims where [his] earlier patents and applications did not qualify as prior art, and perhaps do so *ad infinitum*." *Gilead*, 753 F.3d at 1217 (Rader, J., dissenting). Thus, the doctrine applies only to inequitable and *successive*—*i.e.*, later-filed—applications with a different default patent term. *See id.*

Statutory guarantees like PTA are not unjustified, nor are they even in the patentee's control. While PTA might affect a patent's *expiration* date, the start date—*i.e.*, the application filing date—remains the same. This makes all the difference because patentees cannot game the patent term filing date between members of a patent family—the same date applies to all patents in the family. Further, far from being "unjustified" or an "extension," PTA compensates patentees by "adjusting" patent term consumed by administrative delay by the Patent Office, which is beyond the control of the patentee, to the end of the default patent term date. This adjustment makes the patentee whole and realizes Congress's guarantee of statutorily-specified patent term. It is not extra. Whether the Federal Circuit approves of the patent regime or not, that is the balance Congress struck. *See U.S. 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.").

C. The Federal Circuit Misevaluated the Equities

The Federal Circuit also misapplied NSDP as a matter of equity—the root of NSDP. The Federal Circuit acknowledged there was no evidence of gamesmanship by Cellect. *See Cellect*, 81 F.4th 1216 at 1229. Cellect was not trying to obtain an unjustified extension of patent term by filing continuing applications. Whether continuing applications would be awarded more or less PTA due to administrative delays was outside of Cellect's control, but was within the control of the Patent Office.

On the other hand, there are significant harms from the application of NSDP. Because the default expiration date of Cellect's patent claims had already passed, it was too late to file a terminal disclaimer. Accordingly, Cellect's patents were held invalid, without recourse, solely due to a statutory *compensation of patent term* Cellect accrued based on Patent Office delay. No equitable reasons support the application of NSDP based on the presence of PTA.

III. Importance of this Court's Review

Cellect replaces Congress's carefully calibrated patent regime with one of judicial design. The negative consequences could impact virtually every patent-protected pharmaceutical product, harming pharmaceutical investment and innovation in the United States. *Cellect* is an ideal vehicle for this Court to step in and correct the Federal Circuit's expanding, ahistorical NSDP jurisprudence.

Innovation is expensive. Pharmaceutical companies develop life-saving and life-improving drugs, but at great expense—billions of dollars per drug. Congress has sought to encourage investment by ensuring that—when research and development is successful—the patentee is rewarded with a full patent term, not eroded by administrative delay. *Cellect* removes that assurance, and thereby threatens the reasonable, investment-backed expectations of investors.

This Court has frequently made clear that judge-made doctrines of equity cannot supersede statutory provisions. *See, e.g.*, *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 572 U.S. 663, 679 (2014) ("[I]n the face of a statute of limitations enacted by Congress, laches cannot be invoked to bar legal relief."); *SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC*, 580 U.S. 328, 331 (2017) (same as applied to the Patent Act); *INS v. Pangilinan*, 486 U.S. 875, 883 (1988) ("Court[s] of equity can no more disregard statutory and constitutional requirements and provisions than can courts of law." (quotation marks omitted)); *Off. of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 426 (1990) ("[J]udicial use of the equitable doctrine of estoppel cannot grant respondent a money remedy that Congress has not authorized."). The *Cellect* decision runs counter to this line of authority.

Finally, *Cellect* is unworkable and will lead to more confusion in the lower courts. The conflicting *Allergan* and *Acadia* decisions from the District of Delaware are just the beginning. Because NSDP is detached from its equitable roots—aimed at solving a specific statutory loophole—*Cellect* gives courts little guidance to navigate

the freestanding public policy concerns now guiding the doctrine.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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