Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

In re: CELLECT, LLC,
Appellant.

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in *Ex Parte* Reexamination Nos. 90/014,453, 90/014,454, 90/014,455, 90/014,457

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) IN SUPPORT OF PETITION FOR REHEARING *EN BANC*

JEFFREY P. KUSHAN
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

STEVEN J. HOROWITZ
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000

DAVID E. KORN
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street, N.W.,
Suite 300
Washington, DC 20004
(202) 835-3400

November 27, 2023

Counsel for Pharmaceutical Research and Manufacturers of America

CERTIFICATE OF INTEREST

I, Jeffrey P. Kushan, counsel for Pharmaceutical Research and Manufacturers of America, certify the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

   Pharmaceutical Research and Manufacturers of America.

2. **Real Party in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

   None.

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

   PhRMA has no parent corporation and no publicly held corporation owns 10% or more of its stock. However, its membership includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at www.phrma.org/about#members.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

   None.

5. **Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency

that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

Cellect, LLC v. Samsung Electronics Co., No. 1:19-cv-438 (D. Colo.).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not Applicable.

November 27, 2023

/s/ *Jeffrey P. Kushan*

JEFFREY P. KUSHAN
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

Counsel for Pharmaceutical Research and Manufacturers of America

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTEREST OF *AMICUS 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.[2] PhRMA member companies are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives, and PhRMA advocates for public policies encouraging innovation in life-saving and live-enhancing new medicines.

PhRMA members make significant contributions to serve these goals and have led the way in the search for new cures. Over the last decade, they more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022. PhRMA members rely on patent protection for their innovations when they make these investments and their product development decisions.

PhRMA members have a substantial interest in this case. They make immense and risky investments to discover, develop, and deliver

---

[1] No counsel for any party authored this brief in any part, and no party, counsel, or person other than amicus contributed money to fund the preparation and submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

[2] *See* www.phrma.org/about#members.

new medicines to patients. Their efforts yield not only groundbreaking medicines, but a host of related inventions, including new ways of delivering treatment and advanced manufacturing technologies. PhRMA members often must file multiple applications to secure patents on their inventions, in full compliance with the Patent Office's continuing application procedures authorized by 35 U.S.C. § 120. But because examination of each invention raises unique issues, the length of examination of each application varies, resulting in multiple patents issuing with varying terms due to statutorily-mandated term adjustments reflecting the Patent Office's failure to meet its statutory examination deadlines.

The panel's decision is of concern to PhRMA because it raises the possibility that patents lawfully and properly procured and having statutorily-mandated term adjustments could be invalidated under theories of non-statutory double patenting contrary to the explicit intent of Congress, which would retroactively disrupt the substantial investment-backed decisions of PhRMA members.

INTRODUCTION

In a precedential opinion addressing a question of first impression, the panel invalidated patents for non-statutory double patenting having different terms due to statutorily-mandated patent-term adjustments under 35 U.S.C. § 154(b). But this Court has previously held that a statutorily-mandated term extension *cannot* give rise to double patenting, *see Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018), and declined to permit this judge-made doctrine to cut short a statutory term mandated by another provision in § 154, *see Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355 (Fed. Cir. 2018). The panel's decision conflicts with this Court's precedent—including *Ezra*, which it cites, and *Breckenridge*, which it does not—and risks being improperly extended beyond its facts in ways that could upset settled expectations across innovative industries.

The panel decision should be vacated and rehearing granted.

ARGUMENT

I. The Panel Improperly Applied Non-Statutory Double Patenting to Cut Off a Statutorily-Mandated Term, in Conflict with *Ezra* and *Breckenridge*.

The judicially-created doctrine of non-statutory double patenting is implicated only when claims in different patents with different

expiration dates define patentably *indistinct* inventions—by definition, it does not apply when the claims define patentably distinct inventions. *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012). But when patents claim indistinct inventions, there remains the separate question whether a difference in term is *justified*. *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001) (doctrine prevents "*unjustified* timewise extension" (emphasis added)).

Here, the term differences are justified because they are due solely to a considered legislative determination that additional patent terms are warranted: that legislative determination should not be superseded by a judge-made doctrine. The panel's contrary determination conflicts with *Ezra* and *Breckenridge* and warrants *en banc* review.

A. Judge-Made Law Cannot Negate the Patent Term Guarantee Act of 1999.

Ezra confirms that the "judge-made doctrine" of non-statutory double patenting should not "cut off a statutorily-authorized time extension," 909 F.3d at 1375, but that is precisely what the panel decision does, enabling judicial policy to supersede the policy views of Congress reflected in the Patent Term Guarantee Act of 1999. *Cf. BP*

p.l.c. v. Mayor & City Council, 141 S. Ct. 1532, 1542 (2021) ("even the most formidable policy arguments cannot overcome a clear statutory directive" (internal quotation marks omitted)).

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" of Patent-Office delay. 35 U.S.C. § 154(b)(1)(A)(iv) (emphasis added). That mandate addressed a problem that first arose when Congress changed the rules for calculating a patent's term in 1994. Uruguay Round Agreements Act (URAA), Pub. Law 103-465, § 532(a)(1). Prior to the URAA, examination delays did not affect the duration of exclusive rights conferred by a patent, which commenced at grant and ran for 17 years thereafter. The switch to a term measured 20 years from the patent application filing date, however, meant that any Patent Office delays in issuing the patent "consumed the effective term of a patent." *Wyeth v. Kappos*, 591 F.3d 1364, 1366 (Fed. Cir. 2010).

Recognizing this problem, Congress enacted a remedy for diligent patent applicants in § 154(b)(1): mandatory patent-term adjustments

when the Patent Office fails to meet defined statutory deadlines for performing its examination responsibilities, such as issuing a first office action within 14 months of filing or concluding examination within three years. *See Wyeth*, 591 F.3d at 1367. The statute thus reflects Congress's intent to "guarantee[] diligent applicants at least a 17-year term" by extending term to compensate for examination delays attributable solely to the Patent Office. H.R. Rep. No. 106-287, pt. 1, at 50 (1999). Applying double patenting *because of* patent-term adjustments awarded to compensate the patent owner for Patent-Office delays would, for many patents, result in effective patent terms far shorter than 17 years, contrary to the very purpose of the statute.

The panel's decision cannot be reconciled with *Breckenridge*, which it does not cite. *Breckenridge* involved a non-statutory double-patenting challenge that would cut off a legislatively-mandated rule designed to preserve features of pre-URAA patent term. This Court refused to allow judge-made doctrine to supersede Congress's intent: "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 applying double patenting to cut off that

statutory term "would be inconsistent with the URAA." 909 F.3d at 1366.

Importantly, *Breckenridge* and this case involve legislative mandates codified *in the same section* of the Patent Act: § 154—there, preserving at least a 17-year term for patents issuing from "transitional" applications, and here, preserving an *effective* 17-year term for patents issuing from post-URAA applications. The legislative choice to shift the expiration date of a patent by granting a patent-term adjustment under § 154(b) should be given the same force as the post-URAA shift in expiration date of patents this Court addressed in *Breckenridge*.

The panel's decision also conflicts with *Ezra*. Like *Breckenridge* (but unlike this panel decision), *Ezra* declined to allow the judge-made doctrine of non-statutory double patenting to supersede a statutory term rule—specifically, a patent-term extension granted pursuant to 35 U.S.C. § 156. Critically, § 156 uses the same mandatory language as § 154(b), providing that "[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." (emphasis added). Both forms of statutorily-

mandated extension—patent-term adjustment under § 154(b) and patent-term extension under § 156—are designed to "restore the value of the patent term that a patent owner loses" due to review by an administrative agency. *Ezra*, 909 F.3d at 1369. And both reflect carefully tailored legislative decisions to adjust a patent's term due to agency delays (the FDA under § 156 and the Patent Office under § 154(b)) beyond the patentee's control. *Cf. O'Melveny & Myers v. FDIC*, 512 U.S. 79, 85 (1994) (courts should not "adopt a court-made rule to supplement federal statutory regulation that is comprehensive and detailed").

As explained further below, the reference to disclaimers of patent term in § 154 does not distinguish *Ezra*, and it cannot possibly distinguish *Breckenridge*, which involved another portion of the same statute with a similar explicit reference to such disclaimers.[3]

[3] So-called "terminal disclaimers" may be provided for reasons unrelated to double patenting, as reflected in the language of the rule that governs them. *Compare* 37 C.F.R. § 1.321(b) (applicant "may disclaim or dedicate … any terminal part of the term of a patent"), *with* § 1.321(c) ("a terminal disclaimer, *when filed to obviate* judicially created double patenting" (emphasis added)).

B. Section 154's Reference to Disclaimers Reflects a Term-Calculation Rule, Not an Invitation to Apply Double Patenting.

The panel justified its decision in part based on language in § 154 that refers to terminal disclaimers: "[n]o 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). But this language is not *a reason* to apply double patenting to patents with terms extended by § 154(b); it simply precludes a patent-term adjustment from extending a patent's term past the date specified in a terminal disclaimer for that patent. By the same token, once the Patent Office has granted a statutorily-mandated extension to compensate for examination delays in an application, it cannot use *that additional term as the reason*, via double patenting, to revoke the *entire* adjustment, much less the entire patent (*e.g.*, because the Office examined a later application in the same family faster).

The terminal disclaimer language in § 154(b)(2)(B) is simply one of the rules for *calculating the length* of a patent-term adjustment. For example, the statute directs the Patent Office to adjust the term of a patent by the number of days beyond 14 months that the Office failed to

issue a first office action, *see* 35 U.S.C. § 154(b)(1)(A)(i). It then specifies reduction of that period by the number of days of applicant-caused delay, *see id.*, § 154(b)(2)(C). And ultimately, it provides that the adjustment cannot extend the term of a patent beyond the date specified in any terminal disclaimer the applicant provided for that patent, *see id.*, § 154(b)(2)(B). In other words, § 154(b)(2)(B) simply caps *the length* of the adjustment dictated by § 154(b)(1), based on any terminal disclaimer.

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—it certainly is not a reason to find that *any* term adjustment mandated by § 154(b) is an *unjustified* timewise extension of rights. To the contrary, § 154(b)(2)(B) explicitly requires the term of a patent to be extended even if the patent has term that has been limited by a terminal disclaimer provided for that patent. If Congress had intended double patenting to entirely vitiate patent term adjustments in § 154(b), it would have said so.

Notably, the statute at issue in *Breckenridge*—also part of § 154—contains a similar reference to terminal disclaimers, but this Court did

not read that reference as an invitation to apply double patenting to find patent claims to what were concededly indistinct inventions invalid. Specifically, the statute provided that transitional patents are entitled to the greater of a 20-year term from filing or 17-year term from issuance, "*subject to any terminal disclaimers*." 35 U.S.C. § 154(c). The *Breckenridge* challenger, like the panel here, reasoned that the reference to terminal disclaimers suggested that double patenting should apply to cut off the statutorily-mandated term. This Court disagreed, holding that the reference did *not* "command[] how to assess whether a given patent's term should be terminally disclaimed;" instead, the provision merely suggested "that a patent's term … may be subject to a terminal disclaimer depending on the relevant facts, as is true for the term of any patent." 909 F.3d at 1366 n.4. So, too, here. The reference to disclaimers does not mean that double patenting negates any patent-term adjustment; the statute merely addresses how the patent-term adjustment is to be calculated to account for a previously provided terminal disclaimer.

Importantly, the panel in this case did not even attempt to reconcile its treatment of the reference to disclaimers in § 154(b)(2) with

Breckenridge's analysis of a similar reference elsewhere in the same statute. The conflict in this Court's decisions warrants *en banc* review.

II. The Panel's Erroneous Decision Disrupts Settled Expectations of Innovators.

The general rule that courts should not use judge-made law to supersede a legislative mandate applies with special force when doing so would retroactively disrupt investment-backed decisions based on statutorily-mandated rights. Indeed, as the Supreme 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 panel decision does here.

The potential for the panel's decision to cause unanticipated consequences can be seen by considering an approach to patent prosecution frequently taken by pharmaceutical innovators. Such innovators typically file an initial application comprehensively disclosing many related inventions. Claims to all those inventions rarely issue from that initial application. Instead, innovators typically must file additional applications pursuant to the Patent Office's continuing application practice under 35 U.S.C. § 120. If the Patent

Office examines all of the related applications within the statutorily-guaranteed timeframes, all the patents will expire on the same day. Only when the Patent Office fails to do so will one (or more) expire later.

Ironically, under the panel's reasoning, the Patent Office's own failure to meet its statutory deadlines (and the term extension that failure compels) justifies double patenting. But the clear mandates of the Act, coupled with *Ezra* and *Breckenridge*, gave innovators no reason to expect these fully anticipated patent-term adjustments could give rise to double patenting.

The panel's decision thus creates an unwarranted and unanticipated risk that proper statutory term adjustments could be used as a basis for invalidating a patent, long after all of the patents in a family were prosecuted, thereby "destroying the legitimate expectations of inventors in their property." *Festo,* 535 U.S. at 739. For example, the panel's decision has already been erroneously and rigidly extended in a recent case, despite materially different facts. *See Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, No. 19-cv-1727, 2023 WL 6295496, at *21–22 (D. Del. Sept. 27, 2023), *appeal docketed*, No. 24-

1061 (Fed. Cir.). That erroneous extension provides further reason for *en banc* review, to protect against the risk of even more extreme outcomes than in *Cellect* itself.

The panel's decision creates the potential for retroactive disruption of settled, investment-backed decisions of PhRMA members, long after they have made the enormous investments needed to deliver new medicines and therapies to patients embodying their patented innovations. 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. *Festo*, 535 U.S. at 739.

The full Court should grant the petition for rehearing, vacate the decision, and reaffirm the primacy of Congress's legislative directive over the judge-made doctrine of obviousness-type double patenting.

CONCLUSION

En banc review is warranted.

November 27, 2023

Respectfully submitted,

/s/ *Jeffrey P. Kushan*

JEFFREY P. KUSHAN
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

STEVEN J. HOROWITZ
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000

DAVID E. KORN
PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA
950 F Street, N.W.,
Suite 300
Washington, DC 20004
(202) 835-3400

Counsel for Pharmaceutical Research and Manufacturers of America

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 35(g)(3). The brief contains 2,575 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Century Schoolbook font.

November 27, 2023

/s/ *Jeffrey P. Kushan*

JEFFREY P. KUSHAN
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

Counsel for Pharmaceutical Research and Manufacturers of America