

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

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**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

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In re: CELLECT, LLC,  
*Appellant.*

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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

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**BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH  
AND MANUFACTURERS OF AMERICA (PhRMA)**

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## 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](http://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).

None.

- 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.

May 23, 2022

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## **INTEREST OF THE *AMICUS CURIAE*<sup>1</sup>**

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is a voluntary, nonprofit association representing the country’s leading research-based pharmaceutical and biotechnology companies.<sup>2</sup> PhRMA’s mission is to advocate for public policies encouraging innovation in life-saving and live-enhancing new medicines. PhRMA’s member companies are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.

PhRMA’s members make significant contributions to serve these goals and have led the way in the search for new cures. Since 2000, PhRMA members have invested more than \$1 trillion in the search for new treatments and cures, including \$91.1 billion in 2020 alone.

PhRMA members rely on the assurance of patent exclusivity for their

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<sup>1</sup> PhRMA submits this brief with the consent of all parties pursuant to Fed. R. App. P. 29(a)(2). 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).

<sup>2</sup> PhRMA’s members are listed at [www.phrma.org/about#members](http://www.phrma.org/about#members) (last visited May 22, 2022).



innovations when they make these investments and their product development decisions.

PhRMA members have a substantial interest in this case. Their ability to innovate depends directly on effective and reliable patents to protect the immense and risky investments required to discover, develop, and deliver new medicines to patients. The patent examination process, however, requires an iterative approach, where the Patent Office and the applicant reach agreement over time as to how the patentable inventions in an application can be claimed. That reality often results in multiple patents with varying terms reflecting the circumstances of each examination, including mandatory statutory term adjustments when the Patent Office does not meet its statutory examination deadlines.

## **INTRODUCTION**

These consolidated appeals challenge the Board's decision, across four separate cases, to apply obviousness-type double patenting to invalidate patents based on differences in term that are attributable *solely* to statutorily-mandated patent-term adjustments under 35 U.S.C. § 154(b). This Court has previously held that a statutorily-

mandated term extension *cannot* give rise to obviousness-type double patenting, *see Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018), and it has also declined to permit this judge-made doctrine to cut short a statutory term mandated by another legislative choice reflected in § 154, *see Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355 (Fed. Cir. 2018). The Board's decisions are inconsistent with this Court's precedent.

Here, the Board used the mere difference in patent term, without any finding of gamesmanship or other impropriety on the part of the patent applicant, as the factual predicate to deploy the judge-made doctrine of obviousness-type double patenting to invalidate a series of patents. Central to the Board's reasoning in each decision was that any difference in the term of these related patents represents an *unjustified* extension of term that warrants invocation of the doctrine of obviousness-type double patenting. But patent-term adjustments under § 154(b) are *not* unjustified; they are statutorily-mandated, reflecting the legislature's decision to adjust patent term to compensate for delays by the Patent Office during the examination of patents—the very opposite of an unjustified extension.

The Board also justified its finding of obviousness-type double patenting based on its speculative concern that the related patents might be separately enforced by different assignees. But none of the patents at issue was separately owned, and this Court has never found obviousness-type double patenting based solely on a *theoretical* risk of harassment if the patents might someday become separately owned and enforced.

If left undisturbed, the Board's decisions would invite double-patenting challenges to many existing patents procured by unquestionably diligent conduct of the patent applicant, and for which no reasonable basis existed for questioning entitlement to their statutorily-dictated patent-term adjustments. The retroactive effects of this change to the judge-made law of double patenting would cause grossly inequitable results, particularly to companies in the pharmaceutical sector who have relied on those existing patents to justify their significant efforts and expenses associated with bringing new therapeutic products to market.

The decisions should be reversed.

## ARGUMENT

### **I. The Board’s Decisions Are Inconsistent With the Fundamental Purpose of Obviousness-Type Double Patenting, Which is to Protect Against *Unjustified* Extensions of Patent Term.**

This Court’s predecessor court long ago recognized that “[t]he fundamental reason” for obviousness-type double patenting is “to prevent *unjustified* extension of the right to exclude granted by a patent.” *In re Schneller*, 397 F.2d 350, 354 (CCPA 1968) (emphasis modified). Not every extension of patent term is “unjustified.” Consistent with the doctrine’s “equitable” foundations, *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020), this Court has assessed patent policies, statutory schemes, as well as the facts and circumstances of the cases brought before it, applying double patenting to prevent unjustified extensions while declining to apply double patenting where a challenged difference in patent term is justified—or mandated by statute. *See, e.g., Breckenridge*, 909 F.3d at 1363–64 (distinguishing *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014)). In short, the *reasons* for a difference in patent term matter. Under the Board’s test, however, the mere difference in term is reason enough to invalidate a patent—whether that difference

in term was justified or even statutorily-mandated becomes irrelevant. The Board's approach should be rejected.

**A. Obviousness-Type Double Patenting Requires a Determination That a Challenged Extension of Term is *Unjustified*.**

This Court has not invalidated every later-expiring patent claiming an obvious variant of an invention claimed in an earlier-expiring patent. To the contrary, the Court's approach has been responsive to the facts and circumstances giving rise to a difference in patent term, permitting an assessment of whether a challenged extension of patent term was justified or unjustified.

For example, the Court saw no basis to conclude that the patentee in *Breckenridge* “improperly captured unjustified patent term.” 909 F.3d at 1363–64. In that case, the challenged extension was caused by a choice by Congress, reflected in the change in patent term law under the Uruguay Round Agreements Act of 1994 “transition statute,” 35 U.S.C. § 154(c)(1). *Id.* at 1358. As the Court explained, the reference patent expired earlier than the challenged patent “only due to the happenstance of an intervening change in patent term law,” which changed the patent term from 17 years from issuance to 20 years from

the effective filing date. *Id.* at 1357–58. The Court thus distinguished *Breckenridge*, in which the challenged extension was *not* “unjustified,” from cases involving “prosecution gamesmanship.” *Id.* at 1364; *see also Immunex Corp. v. Sandoz Inc.*, 395 F. Supp. 3d 366, 422 (D.N.J. 2019) (concluding that, when a patent’s challenged term results from “an act of Congress, rather than improper gamesmanship by the patentee,” the “statutory term . . . may not be cut short” (internal quotation marks omitted)), *aff’d* 964 F.3d 1049, 1059 (Fed. Cir. 2020).

This Court followed a similar course in *Ezra*. 909 F.3d at 1374–75. There, as in *Breckenridge*, the Court found no evidence that the challenged difference in patent term resulted from “gamesmanship” that would push expiration “beyond a statutory time limit.” *Id.* at 1375 (internal quotation marks omitted). Indeed, the challenger failed to identify any “tactics” on the part of the patentee designed to “orchestrate” a “longer patent-exclusivity period[.]” *Id.* Instead, the challenged extension of term again resulted from choice by Congress: “a statutorily-allowed term extension under § 156,” *i.e.*, a patent-term extension. *Id.* at 1374.

This Court’s application of the “two-way test” for obviousness-type double patenting reflects a similar sensitivity to the *reasons* why two related and otherwise-valid patents might not have the identical patent term. The two-way test protects patents that might be invalid for double patenting if the one-way test were to apply, based on this Court’s recognition that the additional term of a patent that results from delays caused by the Patent Office during examination is not an “unjustified” extension of term. *See In re Janssen Biotech, Inc.*, 880 F.3d 1315, 1325 (Fed. Cir. 2018) (discussing requirements for two-way test). The two-way test is based on the principle that an applicant “who files applications for basic and improvement patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the applicant does not have complete control.” *In re Braat*, 937 F.2d 589, 593 (Fed. Cir. 1991). Thus, under this Court’s precedent, at least when the Patent Office is solely responsible for delays in examination that cause one of the patents to have a longer term, an otherwise-viable double-patenting challenge may be rejected. *See Janssen Biotech*, 880 F.3d at 1325. The rationale for finding no obviousness-type double patenting deficiency in patents governed by

“two-way test” situations is particularly relevant in this case, which concerns extensions that correspond to a period of delay in granting the patent that the statute defines to be attributable to the Patent Office, not the patent applicant. Again, the reasons for the difference in patent term matter.

In other situations, the Court has assessed the conduct of the applicant during examination to determine if the extended term of a patent was “unjustified” and double patenting applied. For example, the Court distinguished the “structuring of priority claims” found to constitute gamesmanship in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), from the statutorily mandated extension in *Ezra*, which involved no such gamesmanship. *See Ezra*, 909 F.3d at 1374–75. Unlike the Court’s view in *Gilead*, the statutory extension of patent term in *Ezra* was not *unjustified*.

**B. The Board’s Approach Cannot Be Squared With This Court’s Assessment of the Reasons for a Challenged Difference in Patent Term.**

Contrary to this Court’s approach, the Board focused on the perceived “inequity” of “a second patent’s term beyond the expiration of the first patent.” (Appx22.) But a later expiration is a feature present



in almost every case involving supposed double patenting; that fact alone cannot distinguish between *justified* and *unjustified* differences in term. In short, the Board’s reasoning fails to consider the “fundamental reason” for the judge-made doctrine’s existence. *Schneller*, 397 F.2d at 354.

The challenged extensions of term here are attributable *solely* to statutorily-mandated patent-term adjustments under § 154(b). Every challenged day of extension was granted, pursuant to that statute, to compensate for lost term due to the delays in issuance of the patent that the statute defines to be solely due to the Patent Office’s conduct in examination of the patent. There is no suggestion in the Board’s decision that Collect orchestrated an improper extension of term through the kind of gamesmanship this Court has associated with the *Gilead* case. Indeed, the statutory design of § 154(b) accounts for any applicant-caused delays during examination—any such periods of delay *automatically reduce* the length of the patent-term adjustment provided under § 154(b). Consequently, the only reason why a patent issuing from an application subjected to protracted examination has an

extended term is the Patent Office's failure to meet Congressionally defined deadlines set forth in § 154(b)(1).

The Board's decisions, if left undisturbed, threaten to inject uncertainty into routine practices in procurement of patents and to undermine the incentive structure that is central to pharmaceutical innovation. Conventional and lawful patenting practices reveal the inequity of the Board's rule. For example, pharmaceutical innovators commonly file an initial application that comprehensively discloses a novel compound and therapeutic applications thereof. This initial application discloses to the public the compound and related discoveries, including methods of making and using the compound. Given the breadth of this public disclosure, the prosecution of this first application can lead to prolonged consideration by the Patent Office, thus extending the examination process beyond the guarantees in the Patent Term Guarantee Act of 1999, codified in 35 U.S.C. § 154(b). Later-filed continuation applications—which are a normal and important part of prosecution practice—covering methods of making and using the compound typically proceed on a faster examination timeline. Consequently, the Board's decision may cause the first patent

that is granted—unquestionably *valid* when it issued—to be spontaneously rendered invalid for obviousness-type double patenting over a later-issuing continuation patent because the examination of the continuation application took less time. A patent-term adjustment mandated by § 154(b) in such a case ensures that the innovator receives an effective 17-year term for the invention.

In short, if the Patent Office promptly examines one patent in a family, then *every* other patent in that family could be invalidated for obviousness-type double patenting based on a retroactive challenge targeting a mandatory patent-term adjustment, even years after the first patent issued. The Board's rule thus condemns the common practice of filing continuation applications, *see* 35 U.S.C. § 120, even when that practice does not confer an *unjustified* timewise extension of exclusivity relative to a patent already awarded to the innovator.

To be sure, these consolidated appeals do not present this common fact pattern from the pharmaceutical context—and, for that reason, the Court need not address that context in particular. But the pharmaceutical fact pattern further underscores the need to assess the

reasons for a difference in patent term, and thus to reject the Board’s incorrect rule.

**II. The Board Erred in Applying the Judge-Made Doctrine of Obviousness-Type Double Patenting to Cut Off a Statutorily-Mandated Term Extension.**

The Board’s decisions are also wrong for another reason: the judge-made doctrine of obviousness-type double patenting cannot cut short a statutorily mandated term extension under § 154(b).

**A. Judge-Made Law Cannot Trump the Mandates of the Patent Term Guarantee Act of 1999.**

As the Court stated in *Ezra*, “obviousness-type double patenting [i]s a ‘judge-made doctrine’ that is intended to prevent extension of a patent beyond a ‘statutory time limit.’” 909 F.3d at 1375. Agreeing with the Board here, however, “would mean that a judge-made doctrine would cut off a statutorily-authorized time extension.” *Id.* Indeed, the Board’s decisions effectively substitute the Board’s policy views for those of the Congress, which are reflected in the text of the Patent Term Guarantee Act of 1999. *Cf. BP p.l.c. v. Mayor & City Council of Baltimore*, 141 S. Ct. 1532, 1542 (2021) (explaining that “even the most formidable policy arguments cannot overcome a clear statutory directive” (internal quotation marks omitted)). The text of the Act 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).

The Patent Term Guarantee Act of 1999 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). Specifically, examination delays did not affect the duration of exclusive rights conferred by a patent under the earlier, 17-years-from-issuance regime—patent exclusivity would commence at grant and run for 17 years thereafter. But the switch to a term of 20 years measured from the filing date of a patent application meant that any delays in grant by the Patent Office “consumed the effective term of a patent.” *Wyeth v. Kappos*, 591 F.3d 1364, 1366 (Fed. Cir. 2010).

Recognizing the problem created by the switch, Congress enacted a remedy for diligent patent applicants in § 154(b)(1): mandatory patent-term adjustment whenever the Patent Office fails to meet statutory deadlines for performing its responsibilities in examination of a patent application, such as issuing a first office action within 14 months of

filing or concluding examination within three years.<sup>3</sup> *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 obviousness-type double patenting based on the patent-term adjustment awarded to compensate the patent owner for Patent-Office delay in examination would, for many patents, result in patent terms shorter than 17 years, which contravenes the very purpose of § 154(b).

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*. Both this case and that one involved changes designed to preserve features of pre-URAA patent term—there, preserving the 17-year period of exclusive rights for patents issuing from “transitional” applications, and here, preserving the availability of

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<sup>3</sup> The original extensions provided by the URAA (*i.e.*, due to appeals, secrecy orders or interference proceedings) were found insufficient by Congress, which led to modification of bases of extensions provided by §154(b) through the Patent Term Guarantee Act of 1999. *See* 35 U.S.C. § 154(b)(1), (2) (1994).

an *effective* 17-year term for patents issued from applications filed after the URAA’s effective date—each of which is codified in the same section (§ 154) of the Patent Act.

The legislative choice to extend patent terms under the Patent Term Guarantee Act is likewise entitled to the same weight as the patent-term extension regime addressed in *Ezra*. The Court’s decision there was based on a statutory provision, 35 U.S.C. § 156, that uses the same mandatory language as § 154(b). 35 U.S.C. § 156 (“The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product *shall be* extended”) (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 the statutory term of a patent due to agency delays (whether the FDA under § 156 or the Patent Office under § 154(b)) beyond the patent owner’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”). *Ezra* controls the outcome here.

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

The Board justified its decision to eliminate a statutorily-mandated extension 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). (Appx14.) But this language is *not* an invitation to apply obviousness-type double patenting to invalidate issued patents based on terms extended by § 154(b). Rather, the language merely precludes the use of patent-term adjustment to regain the portion of a term that has *already* been expressly disclaimed by the patentee during examination. By the same token, once the Patent Office has granted a statutorily-mandated extension to compensate for examination delays in one application, it cannot use double patenting to take away that extension just because it examined a later application in the same family faster.



In other words, the provision on which the Board relies (referring to disclaimers) merely articulates one of the rules for *calculating* patent-term adjustment. For example, the statute directs the Patent Office to add days for Patent-Office delays beyond 14 months for a first office action, *see* 35 U.S.C. § 154(b)(1)(A)(i), and to subtract days for applicant-caused delay, *see id.*, § 154(b)(2)(C), and, in the end, the statute provides that the total number of days cannot extend the term of a patent beyond the date specified in any terminal disclaimer the applicant may have filed, *see id.*, § 154(b)(2)(B). These rules for calculating patent-term adjustment have nothing to do with whether a properly awarded patent-term adjustment can later be cut short by obviousness-type double patenting. If Congress had wanted to permit double patenting to cut short an extension mandated by § 154(b), it could have said so.

Notably, the statute at issue in *Breckenridge*—a different provision of § 154—contains a similar reference to terminal disclaimers, but this Court did *not* read that reference as an invitation to apply double patenting. 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 challenger in *Breckenridge*, like the Board here, argued that the reference to terminal disclaimers suggested that double patenting should apply to cut off the statutorily mandated term. This Court disagreed. It held 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.

### **III. The Board Erred in Holding that a Speculative Concern Regarding Harassment by Multiple Assignees Can Serve as a Freestanding Basis for Obviousness-Type Double Patenting.**

#### **A. This Court Has Never Allowed a Speculative Concern Regarding Harassment to Serve as a Freestanding Basis for Obviousness-Type Double Patenting.**

Preventing unjustified extensions of patent term is the “fundamental” purpose for obviousness-type double patenting.

*Schneller*, 397 F.2d at 354. Although this Court has recognized that obviousness-type double patenting also addresses a concern about “harassment by multiple assignees,” see *In re Van Ornum*, 686 F.2d 937, 945 (Fed. Cir. 1982), it has *never* applied the doctrine to invalidate a patent based on a freestanding, speculative concern about such harassment. To the contrary, every case of obviousness-type double patenting has either involved an unjustified extension of term or an actual risk of harassment, based on actual separate ownership of the patents.

In this case, however, the Board took an unprecedented and unwarranted approach—it cited a speculative concern about potential harassment by multiple assignees if the patents were to become separately owned and asserted in the future to serve as a freestanding basis to apply obviousness-type double patenting. (*See* Appx18–20.) Such a rule would drastically expand the judge-made doctrine.

To be sure, this Court has on rare occasions invoked the concern over “harassment by multiple assignees” as a rationale for applying obviousness-type double patenting. See, e.g., *In re Fallaux*, 564 F.3d 1313, 1318–19 (Fed. Cir. 2009). But in every case where the Court has

done so as an independent basis for applying double patenting, it found an actual risk of harassment on the facts of the case. In particular, the relevant patents in each such case were owned by separate entities at the time the obviousness-type double patenting was asserted, which provided a concrete reason to be concerned about separate enforcement. *See id.* at 1319 (“The harassment justification for obviousness-type double patenting is particularly pertinent here because the Fallaux application and the Vogels patents are not commonly owned.”); *see also In re Hubbell*, 709 F.3d 1140, 1147 (Fed. Cir. 2013).

By contrast, this Court has never relied on mere speculation of potential separate ownership and enforcement of patents that were actually owned by one entity. Indeed, this Court’s predecessor court dismissed concerns regarding the “mere possibility of harassment,” particularly where “ownership remains in the same person.” *See, e.g., In re Jentoft*, 392 F.2d 633, 641 (CCPA 1968). If, as here, the patents in question are owned by the same entity, then the hypothetical concern that they may one day be separately owned and separately enforced is not—and should not be—sufficient to give rise to double patenting.

To the extent the unusual scenario of a party being harassed by multiple assignees later arises, that issue is best remedied by a district court at the time it occurs or becomes manifest, based on the facts and circumstances of the particular case. There may be facts (such as contractual restrictions on assignment) that make the “separate enforcement” concern especially remote in particular cases, and the courts should remain open to assessing the impact of such facts, and to considering procedures that mitigate concerns about separate enforcement. For example, a district court has procedures available to address any concern about harassment by multiple assignees by requiring joinder of parties under the Federal Rules of Civil Procedure. By contrast, the Board is ill-equipped to address in the abstract the equities associated with concrete separate enforcement concerns, which by definition arise *after* patent issuance in the context of concrete infringement disputes.

**B. Applying a Freestanding, Speculative Anti-Harassment Policy Would Conflict With This Court’s Precedent.**

The Board’s interpretation of this concern as a freestanding, black-letter basis for obviousness-type double patenting also conflicts

with a long line of cases declining to apply obviousness-type double patenting where a difference in term was justified.

For example, if the concern surrounding harassment by multiple assignees were sufficient, by itself, to give rise to double patenting, then the Federal Circuit's predecessor court would not have accepted terminal disclaimers lacking the current "no separate enforcement" provision as a basis for obviating a double-patenting rejection. *Contra, e.g., In re Robeson*, 331 F.2d 610, 615 (CCPA 1964) (acknowledging potential concern regarding "harassment by multiple assignees," but finding "on the facts" that there was no "abuse of the terminal disclaimer," and the removal of the "extension of the monopoly" justified reversing the double-patenting rejection).<sup>4</sup>

Similarly, the application of double patenting based solely on the future *possibility* of divided ownership and "harassment by multiple assignees" is inconsistent with *Breckenridge* and *Ezra*. As discussed at

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<sup>4</sup> Since the 1970s, the Patent Office has required by rule that terminal disclaimers include a provision barring separate enforcement. The Federal Circuit's predecessor court held that that rule was within the Patent Office's power to promulgate, *see Van Ornum*, 686 F.2d 937, but neither it nor this Court has ever held that the statute authorizing terminal disclaimers, 35 U.S.C. § 253, *requires* such a common-ownership rule.

length above, each of those cases involved an assessment of whether the challenged extension of term was *justified*, and in each case, the Court held that the extension was in fact justified—indeed, statutorily mandated. But in *neither* case did the Court go on to apply a freestanding, speculative anti-harassment theory of double patenting. Under a broad reading of the Board’s decisions here, however, that might have been required: absent a terminal disclaimer, a freestanding concern that the patents might one day be separately owned and enforced is enough (in the Board’s view) to justify applying double patenting.

More broadly, if the mere theoretical possibility of harassment based on the patents becoming independently owned and enforced in the future, standing alone, were a legitimate concern to justify the application of double patenting, there would be no reason to consider issuance or expiration dates at all, which would render much of the reasoning employed by the Federal Circuit in its major decisions on double patenting meaningless. *See, e.g., AbbVie Inc. v. Mathilda & Terence Kennedy Inst. Rheumatology Tr.*, 764 F.3d 1366, 1374 (Fed. Cir. 2014) (emphasizing the importance of double patenting “where two

patents have different expiration dates”); *Gilead*, 753 F.3d 1214–17 (Fed. Cir. 2014) (similar).

**C. The Board’s Own Decisions Are Internally Inconsistent in the Application of Its Unprecedented Freestanding Rule.**

Notably, not even the Board fully endorses its own apparent view that concerns about harassment alone can justify applying obviousness-type double patenting. In at least one of its decisions, the Board held that a later-expiring patent could not be used as a double-patenting reference against the challenged, earlier-expiring patent, thereby permitting these two patents to coexist despite having no terminal disclaimers linking them for common-ownership purposes. *E.g.*, (Appx41 (“For two patents with different expiration dates, double patenting only invalidates the later patent, whereas here the challenged patent is the *earlier* patent and the ’626 patent is the *later* patent.”).) If harassment by multiple assignees were a freestanding, independent concern that justified invalidating a patent, then *either* patent claiming an indistinct invention, on its own, should be invalid in the absence of a terminal disclaimer tying the two together, irrespective of differences in term. But not even the Board adopted that view.



The Board's internally inconsistent decisions reflect an implicit recognition that the anti-harassment policy cannot bear the weight of the Board's double-patenting determinations.

### CONCLUSION

The Court should reverse the Board's erroneous decisions.

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## CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 35(g)(3). The brief contains 4,760 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

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