

Nos. 22-1293, -1294, -1295, -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 FOR THE
ASSOCIATION FOR ACCESSIBLE MEDICINES
AS *AMICUS CURIAE*
IN SUPPORT OF THE DIRECTOR AND AFFIRMANCE**

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CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Association for Accessible Medicines certifies the following:

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

Association for Accessible Medicines.

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

N/A

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

N/A

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).

N/A

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). See also Fed. Cir. R. 47.5(b):

N/A

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).

N/A

September 23, 2022

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TABLE OF CONTENTS

	Page
GLOSSARY OF ABBREVIATIONS	vii
INTEREST OF <i>AMICUS CURIAE</i>	viii
INTRODUCTION	1
ARGUMENT	2
I. Serial patent applications concerning obvious variants of the same invention drive up prescription costs.....	2
II. Particularly in the pharmaceutical context, OTDP is an important tool to ensure a patentee receives only one period of exclusivity for an invention.	4
III. Allowing OTDP for PTA-adjusted patents is consistent with § 154(b) and the spirit of OTDP.....	8
A. Section 154(b) expressly limits PTA to patents without terminal disclaimers.....	8
B. Congress enacted § 154(b) to guarantee the patent term for an invention—not expand patent terms for serial applications.....	10
IV. Attaching PTA to obvious variants of the same invention unjustifiably extends patent terms and further inflates prescription drug costs.	11
A. Vascepa® Case Example.....	12
B. Otezla® Case Example	14
CONCLUSION.....	15

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Abbvie Inc. v. Mathilda & Terence Kennedy Inst.</i> , 764 F.3d 1366, 1373 (Fed. Cir. 2014)	7, 8
<i>AbbVie v. Boehringer Ingelheim Int’l GMBH</i> , No. 1:17-cv-01065-MSG-RL (D. Del. Aug. 2, 2017)	3
<i>Amarin Pharma, Inc. v. Hikma Pharm. USA, Inc.</i> , No. 1:20-cv-01630 (D. Del. Nov. 30, 2020).....	12
<i>Amarin Pharma, Inc. v. Hikma Pharm. USA, Inc.</i> , No. 2:16-cv-02525 (D. Nev. Oct. 31, 2016).....	12
<i>Amgen v. Sandoz</i> , No. 18-11026, 2021 WL 5366800 (D.N.J. Sept. 20, 2021).....	14, 15
<i>Application of Braithwaite</i> , 379 F.2d 594, 601 (C.C.P.A. 1967)	1, 8, 9, 11
<i>Gilead Scis., Inc. v. Natco Pharma Ltd.</i> , 753 F.3d 1208 (Fed. Cir. 2014)	4
<i>Kimble v. Marvel Ent., LLC.</i> , 576 U.S. 446 (2015).....	2
<i>Merck & Co. v. Hi-Tech Pharmacal Co.</i> , 482 F.3d 1317 (Fed. Cir. 2008)	2, 9, 10
<i>Miller v. Eagle Mfg. Co.</i> , 151 U.S. 186 (1894).....	2
<i>Novartis AG v. Ezra Ventura LLC</i> , 909 F.3d 1367 (Fed. Cir. 2018)	2, 9
<i>Perricone v. Medicis Pharm. Corp.</i> , 432 F.3d 1368 (Fed. Cir. 2005)	4
<i>Pfizer, Inc. v. Teva Pharm. USA, Inc.</i> , 518 F.3d 1353 (Fed. Cir. 2008)	7

TABLE OF AUTHORITIES (continued)

	Page(s)
<i>Proctor & Gamble Co. v. Teva Pharm. USA, Inc.</i> , 566 F.3d 989 (Fed. Cir. 2009)	4, 11
<i>Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.</i> , 611 F.3d 1381 (Fed. Cir. 2010)	7
Statutes	
35 U.S.C. § 154(b)	<i>passim</i>
35 U.S.C. § 154(b)(2).....	2, 10
35 U.S.C. § 154(b)(2)(B)	9
35 U.S.C. § 156.....	9, 10, 14
Other Authorities	
AAM, <i>Generic Drugs and Biosimilars Secure Big Savings for U.S. Patients</i> (2020), https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generic-Drug-Biosimilars-Savings-US-Fact-Sheet.pdf	7
American Inventors Protection Act of 1999, House Rpt. No. 106-287, 1999 WL 569140, at *29 (Aug. 3, 1999).....	10, 11
Barclays Bank PLC, <i>Biosimilars Monthly: Mar 2020 Edition</i> at 11 (Mar. 21, 2020)	7
<i>Biosimilar Cost Savings in the United States</i> , RAND Health Quarterly (2018), https://www.rand.org/pubs/periodicals/health-quarterly/issues/v7/n4/03.html	7
Biosimilar Council, <i>Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America’s Patients: Part I</i> (June 2019), available at https://biosimilarscouncil.org/wp-content/uploads/2019/10/Failure-to-Launch-Part-1.pdf	3

TABLE OF AUTHORITIES (continued)

Page(s)

Hikma confirms favourable ruling in generic Vascepa® patent suit,
<https://www.prnewswire.com/news-releases/hikma-confirms-favourable-ruling-in-generic-vascepa-patent-suit-301032237.html>..... 12

Nature Reviews: Drug Discovery, 21:251 (April 2022), *available at*
<https://media.nature.com/original/magazine-assets/d41573-022-00047-9/d41573-022-00047-9.pdf>..... 3

Orange Book, Vascepa®, *available at*
https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=205552&Appl_type=N..... 12

GLOSSARY OF ABBREVIATIONS

AAM	Association for Accessible Medicines
Br.	Principal Brief for Appellant
BIO Br.	Brief of <i>Amicus Curiae</i> Biotechnology Innovation Organization in Support of Appellant
FDA	U.S. Food and Drug Administration
IPO Br.	Brief for <i>Amicus Curiae</i> Intellectual Property Owners Association in Support of Neither Party Urging Reversal
Orange Book	FDA’s publication “Approved Drug Products with Therapeutic Equivalence Evaluations”
OTDP	Obviousness-Type Double Patenting
PTA	Patent Term Adjustment
PTE	Patent Term Extension
PTO	U.S. Patent and Trademark Office
PTO Br.	Principal Brief for Appellee (PTO)
PhRMA Br.	Brief of <i>Amicus Curiae</i> Pharmaceutical Research and Manufacturers of America (PhRMA)

INTEREST OF *AMICUS CURIAE*¹

The Association for Accessible Medicines (“AAM”) is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM’s members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM’s core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet account for only 22% of total drug spending. AAM regularly participates in litigation as *amicus curiae*.

Amicus and its members have a significant interest in the issues raised by this appeal: namely, ensuring that a patentee may not exploit formalisms to circumvent the basic rule that an inventor may obtain only one patent for an invention. *Amicus* urges this Court to affirm the decisions below to ensure that branded pharmaceutical companies cannot unlawfully extend their monopolies and deprive patients of lower cost generic and biosimilar alternatives.

¹ No counsel for any party authored this brief in any part, and no party, counsel, or person other than *Amicus*, its members, and its counsel contributed money to fund the preparation and submission of this brief, and all parties consent to the filing of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

INTRODUCTION

In the decisions below, the Patent Trial and Appeal Board correctly observed that patent-term adjustments (“PTA”) under 35 U.S.C. § 154(b) can result in different patent expiration dates for multiple patents reciting obvious variants of the same invention. The doctrine of obviousness-type double patenting (“OTDP”) has long been used to curb improper extensions of patent monopolies in circumstances such as these, preventing the patentee from “enjoying patent protection which would be continued beyond the expiration of his patent . . . on subject matter which does not differ from the subject matter of that patent in an unobvious, that is to say ‘patentable’ way.” *Application of Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967). Here, the Board properly held that OTDP supported invalidating obvious variants of already-issued patents.

In the pharmaceutical industry, OTDP is critically important to guard against patent gamesmanship and enable patient access to lower-cost alternatives to brand drugs and biologics. The context of PTA does not alter the analysis and holding otherwise would improperly extend drug monopolies and inflate prescription drug costs.

Critically, PTA is neither statutorily-mandated nor immune from OTDP. Instead, the statutory language embraces the doctrine of OTDP. Unlike patent term extensions (“PTE”) under section 156, section 154(b) “expressly excludes patents in

which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays.” *Novartis AG v. Ezra Ventura LLC*, 909 F.3d 1367, 1373 (Fed. Cir. 2018) (quoting *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1322 (Fed. Cir. 2008)); *see also* 35 U.S.C. § 154(b)(2) (“No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.”). As discussed further below, this difference in statutory language is material and—consistent with the legislative history—shows Congress never intended to insulate PTA from OTDP challenges.

The Board’s decisions should be affirmed.

ARGUMENT

I. Serial patent applications concerning obvious variants of the same invention drive up prescription costs.

The cost of prescription drugs remains high, in part due to patent holders improperly extending their patent rights over single inventions. For decades, drug manufacturers have engaged in a variety of patenting practices devised to obtain numerous overlapping patents. These practices can be used as an end run around the basic principle that “although the terms of the claims may differ,” “no patent can issue for an invention actually covered by a former patent, especially to the same patentee.” *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894); *see also Kimble v. Marvel Ent., LLC.*, 576 U.S. 446, 451 (2015) (“Patents endow their holders with superpowers, but only for a limited time.”).

Patent thickets are becoming increasingly prevalent, particularly in the context of biologics. A frequently cited example is Humira®, a biologic indicated for rheumatoid arthritis that resulted in 132 issued patents, almost twice as many patent applications, and a litigation with 74 asserted patents. *See, e.g.*, Complaint at ¶ 1, *AbbVie v. Boehringer Ingelheim Int’l GMBH*, No. 1:17-cv-01065-MSG-RL (D. Del. Aug. 2, 2017).

Critically, these patent thickets delay patients’ access to lower-cost drug alternatives. Many biologic and drug products with patent thickets are among the top-selling drugs, amounting to billions in annual sales. *See, e.g.*, Lisa Urquhart, “Top companies and drugs by sales in 2021,” *Nature Reviews: Drug Discovery*, 21:251 (April 2022), available at <https://media.nature.com/original/magazine-assets/d41573-022-00047-9/d41573-022-00047-9.pdf> (reporting Humira® was among the top 10 drugs with highest sales in 2021, with \$20.7 billion sales). Until biosimilar and generic alternatives enter the market, drug manufacturers often continue to increase their drug prices, costing Americans billions. *See, e.g.*, Biosimilar Council, *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America’s Patients: Part I* (June 2019), available at <https://biosimilarscouncil.org/wp-content/uploads/2019/10/Failure-to-Launch-Part-1.pdf> (estimating that between 2015-2019, “delayed entry of biosimilars due to

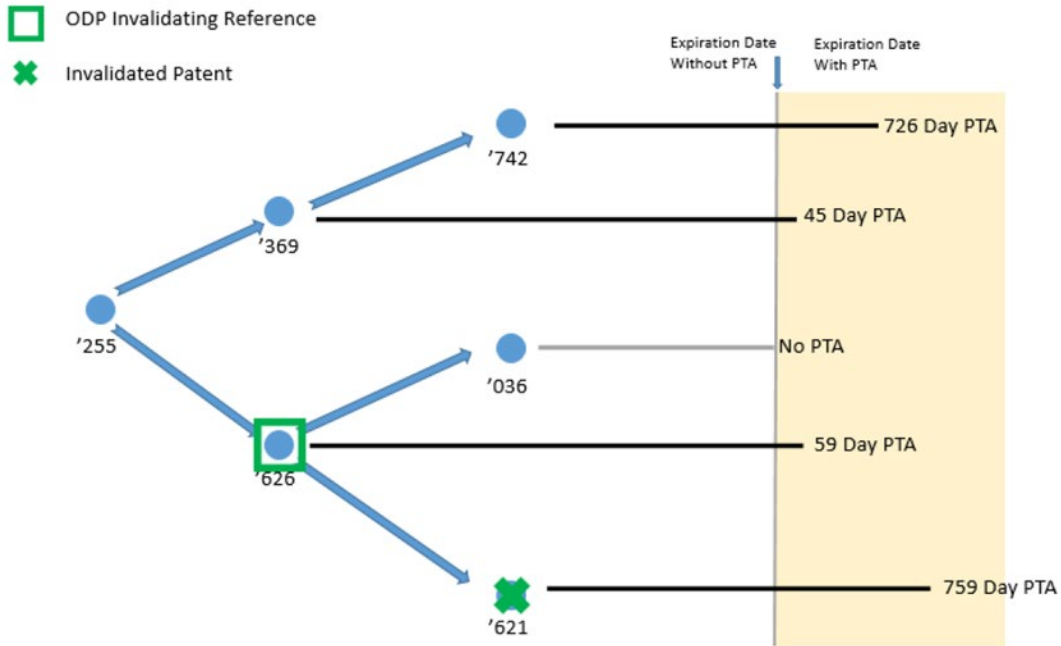
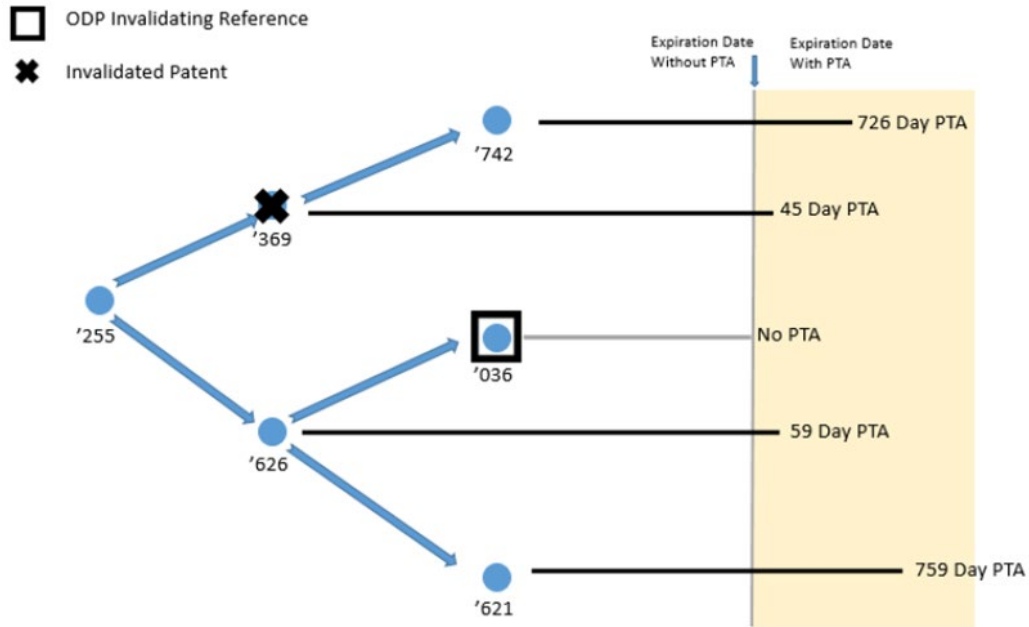
patenting has cost the U.S. health care system an astounding \$7.6 billion in lost savings”).

II. Particularly in the pharmaceutical context, OTDP is an important tool to ensure a patentee receives only one period of exclusivity for an invention.

OTDP is a powerful tool that “polices the proper application of the patent term for each invention.” *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005). The doctrine “is designed to prevent a patent owner from extending his exclusive rights to an invention through claims in a later-filed patent that are not patentably distinct from claims in the earlier filed patent.” *Proctor & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009). As a result, OTDP prevents drug manufacturers from extending their products’ monopolies by continually filing new continuation applications on minor variations of the same patent. *See, e.g., Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014) (“If an inventor could obtain several sequential patents on the same invention, he could retain for himself the exclusive right to exclude or control the public’s right to use the patented invention far beyond the term awarded to him under the patent laws.”).

Using this serial continuation strategy, drug manufacturers often obtain a family of patents in which one patent expires much later than others solely due to PTA, even if that patent lacks patentably distinct claims. In some cases that patent may be an earlier-filed, earlier-granted family member; in other cases that patent may be

a later-filed, later-granted family member. *See, e.g., infra* Section IV.A. As shown in the diagrams below, both of these fact patterns, which commonly occur in the pharmaceutical context, are at issue in this appeal:



Br. at 5-6. The PTO's brief distinguishes decisions cited by Appellant on multiple alternative grounds, including a passing argument that the patents at issue in those decisions were earlier-filed, earlier-issued patents while Appellant's patents were later-filed, later-issued patents. PTO Br. at 32, 34. While that is true for Appellant's patents subject of Reexamination Nos: 90/014,453, 90/014,455, and 90/014,457, it is not the case for the '369 patent in Reexamination No. 90/014,454.

Nevertheless, the Board correctly invalidated the '369 patent because that distinction does not matter—the purpose of OTDP is to prevent “an unjustified time-wise extension of the right to exclude as to [such] patentably indistinct subject matter.” PTO Br. at 39. Such an unwarranted extension occurs whenever one of the patents in the family already has enjoyed an entire patent term, regardless of which patent was filed and/or issued first. Neither the statute, nor precedent, nor logic would justify drawing a distinction based on filing and issuance order. And doing so would encourage gamesmanship, where a patent applicant would try to manipulate the order in which patentably indistinct applications are filed and issued so as to benefit from improper extensions of the patent monopoly through PTA. This Court should draw no such distinction. Nor does it need to do so to affirm. As the Board correctly recognized, Appellant's cited decisions are readily distinguishable on other grounds. *Id.* at 32, 34.

In view of the prevalence of patent thickets in the pharmaceutical context, OTDP is an important avenue for generic and biosimilar pharmaceutical companies to challenge improper patent extensions. *See, e.g., Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1389 (Fed. Cir. 2010) (in case concerning the drug Gemzar®, affirming summary judgment that claims reciting a method of treatment with gemcitabine were invalid for OTDP); *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008) (affirming holding that claims of one of the asserted patents were invalid for OTDP in a case concerning the drug Celebrex®); *accord Abbvie Inc. v. Mathilda & Terence Kennedy Inst.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014) (affirming declaratory judgment that patent reciting methods of treating rheumatoid arthritis was invalid for OTDP); *see also infra* Section IV. Successful OTDP challenges to drug patents translates to the earlier availability of lower-cost alternatives. *See, e.g.,* Barclays Bank PLC, *Biosimilars Monthly: Mar 2020 Edition* at 11 (Mar. 21, 2020) (biosimilar medicines reduce prescription prices by 20-60%); *Biosimilar Cost Savings in the United States*, RAND Health Quarterly (2018), <https://www.rand.org/pubs/periodicals/health-quarterly/issues/v7/n4/03.html> (summarizing biosimilars' reduction in direct spending); AAM, *Generic Drugs and Biosimilars Secure Big Savings for U.S. Patients* (2020), <https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generic-Drug-Biosimilars-Savings-US-Fact-Sheet.pdf> (over 10 years, generic medicines have

been responsible for nearly \$2.2 trillion in U.S. healthcare savings). The availability of OTDP is thus critically important to the pharmaceutical industry.

III. Allowing OTDP for PTA-adjusted patents is consistent with § 154(b) and the spirit of OTDP.

As former Chief Judge Rich explained, OTDP is “grounded in public policy and primarily intended to prevent prolongation of monopoly.” *Application of Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967). This Court has previously recognized that such a prolonged monopoly can occur if “[p]atents claiming overlapping subject matter that were filed at the same time . . . have different patent terms due to examination delays at the PTO”—i.e., due to the grant of PTA. *Abbvie*, 764 F.3d at 1373 (citing 35 U.S.C. § 154(b)) (explaining OTDP “is designed to prevent an inventor from securing a second, later expiring patent for the same invention” and the circumstances in which that can arise). Nothing in section 154(b) suggests that PTA-adjusted patents are immune from OTDP, and instead, the statute and its legislative history suggests that Congress contemplated OTDP *would* limit the grant of PTA.

A. Section 154(b) expressly limits PTA to patents without terminal disclaimers.

Section 154(b) provides a “[g]uarantee of prompt patent and trademark office responses,” such that if the PTO fails to comply with specified deadlines and other conditions are satisfied, the term “shall” be extended. *See* 35 U.S.C. § 154(b). But

the grant of PTA is not absolute, and critically, § 154(b) expressly excludes PTA for any patent “the term of which *has been disclaimed* beyond a specified date.” 35 U.S.C. § 154(b)(2)(B) (emphasis added).

Long before Congress enacted § 154, it was known that OTDP is easily remedied “by [a] terminal disclaimer[, which will] foreclose[] the possibility of such an extension of protection.” *Braithwaite*, 379 F.2d at 601. “[A] terminal disclaimer causes two patents to expire together, . . . which is tantamount for all practical purposes to having all the claims in one patent,” and thus is commonly used to overcome an OTDP rejection. *See id.* As evident from the plain language of § 154(b), Congress expressly limited the application of PTA by referencing terminal disclaimers—a tool primarily used to overcome OTDP rejections.

Against this background, Appellant and its *amici* repeatedly argue that PTA is “statutorily-mandated” (*see* Br. at 27; BIO Br. at 4; IPO Br. at 5; PhRMA Br. at 2-3), but this argument ignores that § 154(b) “expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays.” *Novartis AG v. Ezra Ventura LLC*, 909 F.3d 1367, 1373 (Fed. Cir. 2018) (quoting *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1322 (Fed. Cir. 2008)). PTA is in stark contrast to patent term extensions (“PTE”) under § 156, which contains “no similar provision that excludes patents in which a terminal disclaimer was filed from the benefits of Hatch-Waxman extensions.” *Novartis*, 909 F.3d at

1373-1374 (quoting *Merck*, 482 F.3d at 1322); *see also* 35 U.S.C. § 156. Unlike PTE, PTA is thus not “mandated”—PTA is warranted only in the absence of a terminal disclaimer (i.e., only if the patent claims are not obvious variants of another patent’s claims). While both §§ 154(b) and 156 recite conditions under which a term modification “shall” apply, there is simply no statutory basis to conflate PTA under § 154(b) with PTE under § 156. Doing so would ignore the remainder of §§ 154(b) and 156, which include materially different “[l]imitations” to when a term modification is allowed. 35 U.S.C. § 154(b)(2).

B. Congress enacted § 154(b) to guarantee the patent term for an invention—not expand patent terms for serial applications.

The legislative history further indicates Congress never intended PTA to enable patentees to circumvent OTDP and expand their patent rights. Congress enacted § 154(b) to help “solve current problems and inefficiencies in our patent system” to “guarantee[] [the full term] of patent protection to diligent applicants.” American Inventors Protection Act of 1999, House Rpt. No. 106–287, 1999 WL 569140, at *29 (Aug. 3, 1999). Congress explained that “[w]hile our foreign competitors are able to see the latest U.S. patent technology in their native languages barely six months after a U.S. inventor files a patent application in their country, the reverse is not true” due to delays and inefficiencies at the PTO. *Id.* at *32. Congress thus enacted § 154(b), the “Patent Term Guarantee Act” to address PTO delays and “protect patent terms.” *See id.* at *1, *8.

Permitting OTDP for PTA-adjusted patents is consistent with Congress' goal of guaranteeing an invention's patent term. Indeed, PTA was not intended to provide a bonus term adjustment to obvious variants of the same invention, it was simply intended to ensure that notwithstanding PTO delays, an invention is awarded a full patent term. *See id.* at *29. Applying OTDP to the PTA context would not shorten the guaranteed term of patent protection—the entire point of OTDP is that such patent protection *has already been awarded* to another patent claim. *See, e.g., Braithwaite*, 379 F.2d at 601. OTDP simply ensures that the appropriate term for patent protection is awarded only *once* for a single invention, a principle consistent with both the OTDP doctrine and § 154(b).

Permitting OTDP for PTA-adjusted patents is also consistent with Congress' goal of preventing delayed access to innovative technology. Again, the very purpose of OTDP is “to prevent a patent owner from extending his exclusive rights to an invention” that *already exists* in another patent. *See Proctor & Gamble Co.*, 566 F.3d at 999. Nowhere in the legislative history did Congress suggest there was a need to guarantee the patent terms for obvious variants of available inventions.

IV. Attaching PTA to obvious variants of the same invention unjustifiably extends patent terms and further inflates prescription drug costs.

This Court's decision is not merely hypothetical—it has real-world implications that would materially impact drug prices. The below case examples illustrate how, if left unchecked by OTDP, attaching PTA to obvious variants of the

same invention would unjustifiably extend patent terms and increase prescription drug costs.

A. Vascepa® Case Example

Vascepa® is a drug containing a form of purified fish oil and is covered by 69 patents in the Orange Book.² At its peak—before generic competition entered the market³—Vascepa® generated nearly \$1 billion in annual sales.⁴ An analysis of Vascepa®’s patent portfolio highlights the importance of OTDP in the context of PTA-adjusted patents.

The patentee filed several terminal disclaimers during prosecution to avoid OTDP rejections. But for the threat of OTDP and the patentee’s filing of terminal disclaimers, several of the patents listed in connection with Vascepa® would expire

² See Orange Book, Vascepa®, available at https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=205552&Appl_type=N (accessed on Aug. 25, 2022).

³ While generic competition is now available for Vascepa®, Vascepa® illustrates the hurdles patent thickets present to generic market entry. Lower-cost generic alternatives became available after the conclusion of a trial, *see infra* n.6, in which the patent holder for Vascepa® initially asserted 14 Orange Book-listed patents. See Complaint at ¶ 1, *Amarin Pharma, Inc. v. Hikma Pharm. USA, Inc.*, No. 2:16-cv-02525 (D. Nev. Oct. 31, 2016). After generic entry, the patent holder for Vascepa® initiated a second litigation asserting different Orange Book-listed patents. See Complaint at ¶ 1, *Amarin Pharma, Inc. v. Hikma Pharm. USA, Inc.*, No. 1:20-cv-01630 (D. Del. Nov. 30, 2020).

⁴ See, e.g., *Hikma confirms favourable ruling in generic Vascepa® patent suit*, <https://www.prnewswire.com/news-releases/hikma-confirms-favourable-ruling-in-generic-vascepa-patent-suit-301032237.html>.

later due to PTA. Indeed, the following nearly identical claims would be part of patents with different expiration dates due to PTA. Allowing this behavior undermines the entire purpose of OTDP.

	U.S. Patent No. 8,710,041	U.S. Patent No. 8,455,472
Claim	1. A method of lowering triglycerides in a subject on stable statin therapy having fasting triglycerides of about 200 mg/dl to less than 500 mg/dl comprising, administering orally to the subject on stable statin therapy daily for a period of at least about 4 weeks a pharmaceutical composition comprising about 4 g of ethyl-EPA and not more than about 4% DHA or its esters, by weight of all fatty acids present.	1. A method of lowering triglycerides in a subject on stable statin therapy having baseline fasting triglycerides of about 200 mg/dl to about 500 mg/dl, the method comprising administering to the subject about 4 capsules per day, each capsule comprising about 900 mg to about 1 g of ethyl [EPA] and not more than about 3% [DHA] or its esters, by weight of all fatty acids present, for a period of at least about 12 weeks.
Filed date	February 23, 2012	June 15, 2010
Issued date	April 29, 2014	June 4, 2013
Expiration date with terminal disclaimer	June 15, 2030	June 15, 2030
PTA expiration date (if no terminal disclaimer)	June 15, 2030	December 14, 2030

Moreover, over the past decade, the patentee has continued to seek patents related to the '472 patent and other Orange Book-listed patents. *See, e.g.*, U.S. Patent No. 11,439,618 (child of the '472 patent, which was filed over ten years after the '472 patent); *see also* U.S. Patent No. 11,154,526 (application filed in 2020 and related to Orange Book-listed patents that issued as early as 2012). But for OTDP, nothing would stop the patentee from seeking new patents covering substantially the same subject matter as the '472 patent—a decade after that patent issued—which could perpetually extend the patent term should those patents be awarded PTA.

B. Otezla® Case Example

Like Vascepa®, the Otezla® example illustrates how shielding PTA-adjusted patents from OTDP challenges delays patient access to more affordable medicines.

In *Amgen, Inc. v. Sandoz Inc.*, No. 18-11026, 2021 WL 5366800 (D.N.J. Sept. 20, 2021), the district court adopted the (incorrect) arguments urged by Appellant in this case, reasoning “[a] difference in expiration dates between two patents that arises solely from a statutorily authorized time extension, such as a patent-term adjustment pursuant to 35 U.S.C. § 154(b) or a patent-term extension pursuant to 35 U.S.C. § 156, cannot be the basis for an application of ODP.” *Amgen*, 2021 WL 5366800, at *26; *see also, e.g.*, Br. at 37-38 (discussing *Amgen*).

Had the district court invalidated the PTA-adjusted patent under OTDP, defendants could have marketed generic versions of Otezla® far earlier.

In invalidating that patent would have given the American public access to cost-effective alternatives of Otezla® nearly five years earlier in 2023, when the remainder of Otezla®'s patent portfolio expires. *See Amgen*, 2021 WL 5366800, at *1 (invalidating the later-expiring patent). And the mere threat of OTDP could have enabled earlier market competition. If the patentee filed a terminal disclaimer in view of an earlier-expiring and patentably indistinct patent, patent protection for Otezla® would expire on June 17, 2026—approximately 20 months earlier.

If this Court agrees with the district court's logic in *Amgen*, it is inevitable that PTA-adjusted patents will delay generic market entry, increasing health care costs and inappropriately expanding drug manufacturers' monopolies.

CONCLUSION

AAM respectfully requests that this Court affirm the Board's decisions, which correctly held that OTDP can apply to patents adjusted under 35 U.S.C. § 154(b).

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**CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION, TYPEFACE
REQUIREMENTS, AND TYPE STYLE REQUIREMENTS**

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) and Federal Circuit Rule 29(b) because it contains 3,442 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) because this brief has been prepared in 14-point Times New Roman, a proportionally spaced typeface, using Microsoft Word 2016.

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