

No. 14-647

IN THE
Supreme Court of the United States

GILEAD SCIENCES, INC., *et al.*,

Petitioners,

v.

NATCO PHARMA LIMITED
and NATCO PHARMA, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED
STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

JEREMY LOWE

Counsel of Record

THOMAS K. HEDEMANN

AXINN, VELTROP & HARKRIDER LLP

90 State House Square

Hartford, CT 06103

(860) 275-8100

jlowe@axinn.com

Counsel for Respondents

Natco Pharma Limited

and Natco Pharma, Inc.

256966

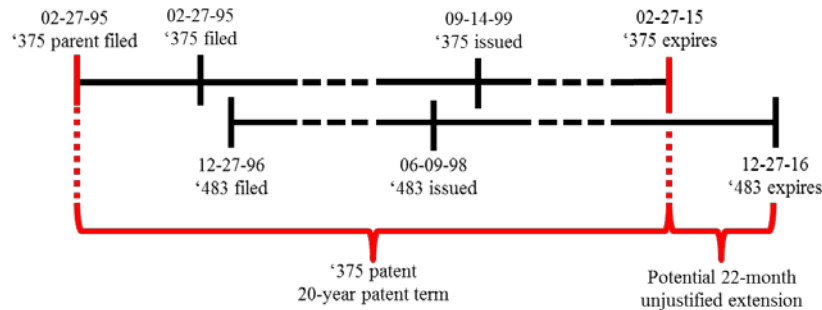


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QUESTION PRESENTED

The patent laws have never permitted a single party to own two patents claiming the same invention or obvious modifications thereof with different expiration dates. Such double patenting extends the patent term for a single invention beyond the statutory grant. In this case, Petitioners' U.S. Patent No. 5,763,483 ("the '483 patent") expires after and extends the term of Petitioners' U.S. Patent No. 5,952,375 ("the '375 patent") by almost two years:



Against this backdrop, the question presented is whether the Federal Circuit correctly held that the first-expiring '375 patent is a double-patenting reference against the later-expiring '483 patent, where both patents are subject to the modern patent term of 20 years from filing?

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondents state as follows:

Natco Pharma Limited is a publicly-traded Indian company, it has no parent company and no other publicly-traded Indian company owns 10% or more of Natco Pharma Limited stock.

Natco Pharma, Inc. is a wholly-owned subsidiary of Natco Pharma Limited.

TABLE OF CONTENTS

QUESTION PRESENTED.....	i
CORPORATE DISCLOSURE STATEMENT	ii
TABLE OF AUTHORITIES.....	v
INTRODUCTION.....	1
STATEMENT OF THE CASE	4
A. Legal Background	4
1. The Double-Patenting Doctrine	4
2. The Creation of the Terminal Disclaimer Permits Ownership of Duplicative Patents By Guaranteeing Simultaneous Expiration.....	6
3. The Passage of the URAA Changes the Statutory Patent Term.	7
4. The PTO Adjusts Its Application of the Obviousness-Type Double-Patenting Doctrine in Response to the Change in Patent Term.	8
B. Factual Background.....	10
C. District Court Proceedings.....	11
D. Appellate Court Proceedings	12
REASONS FOR DENYING THE PETITION	16
I. THE OPINION FOLLOWS APPLICABLE DOUBLE-PATENTING PRECEDENT.	16
A. The Opinion Follows This Court’s Precedent.	16

B. The Opinion Follows Lower Courts’ Precedent.	19
II. THE OPINION IS FIRMLY GROUNDED IN DOUBLE-PATENTING LAW AND POLICY.....	21
A. The Opinion Implements Congressional Intent.	21
B. The Opinion Safeguards the Public’s Expectations.	23
C. The Opinion Prevents Gamesmanship In Patent Prosecution.	24
D. The Opinion Is On All Fours With PTO’s Longstanding Application of the Doctrine.	25
III. THE OPINION DOES NOT PRESENT AN IMPORTANT ISSUE OF FEDERAL LAW.....	27
CONCLUSION	32

TABLE OF AUTHORITIES

	Page(s)
Federal Cases	
<i>Abbott Labs. v. Lupin Ltd.</i> , 2011 WL 1897322 (D. Del. May 19, 2011).....	11
<i>Abbvie Inc. v. Kennedy Trust for Rheumatology Research</i> , 2014 WL 2977299 (S.D.N.Y. June 2, 2014)	28
<i>Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust</i> , 764 F.3d 1366 (Fed. Cir. 2014)	3, 21, 28
<i>Alice Corp. Pty. Ltd. v. CLS Bank Int’l</i> , 134 S. Ct. 2347 (2014).....	27
<i>Amgen Inc. v. F. Hoffmann-La Roche Ltd.</i> , 580 F.3d 1340 (Fed. Cir. 2009)	21
<i>Application of Braithwaite</i> , 379 F.2d 594 (C.C.P.A. 1967).....	7
<i>Application of Robeson</i> , 331 F.2d 610 (C.C.P.A. 1964).....	2, 5
<i>Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.</i> , 98 F.3d 1563 (Fed. Cir. 1996)	24
<i>Ass’n for Molecular Pathology v. Myriad Genetics, Inc.</i> , 133 S. Ct. 2107 (2013).....	27
<i>In re Berg</i> , 140 F.3d 1428 (Fed. Cir. 1998)	23
<i>Boehringer Ingelheim Int’l GmbH v. Barr Labs., Inc.</i> , 592 F.3d 1340 (Fed. Cir. 2010)	7
<i>Brigham and Women’s Hosp. Inc. v. Teva Pharms. USA, Inc.</i> , 761 F. Supp. 2d 210 (D. Del. 2011).....	11

<i>In re Copeman</i> , 135 F.2d 349 (C.C.P.A. 1943).....	20
<i>Eli Lilly & Co. v. Barr Labs., Inc.</i> , 251 F.3d 955 (Fed. Cir. 2001)	7, 30
<i>In re Emert</i> , 124 F.3d 1458 (Fed. Cir. 1997)	24
<i>In re Fallaux</i> , 564 F.3d 1313 (Fed. Cir. 2009)	6, 7, 8
<i>Geneva Pharms., Inc. v. GlaxoSmithKline PLC</i> , 349 F.3d 1373 (Fed. Cir. 2003)	23
<i>In re Hubbell</i> , 709 F.3d 1140 (Fed. Cir. 2013)	6, 23
<i>Koninklijke Philips N.V. v. Zoll Med. Corp.</i> , 2014 WL 2810206 (D. Mass. June 20, 2014).....	28
<i>In re Laughlin</i> , 48 F.2d 921 (C.C.P.A. 1931).....	20
<i>Litton Sys., Inc. v. Whirlpool Corp.</i> , 728 F.2d 1423 (Fed. Cir. 1984)	8
<i>In re Longi</i> , 759 F.2d 887 (Fed. Cir. 1985)	5, 23
<i>Mayo Collaborative Servs. v.</i> <i>Prometheus Labs., Inc.</i> , 132 S. Ct. 1289 (2012).....	27
<i>McCreary v. Pa. Canal Co.</i> , 141 U.S. 459 (1891).....	17
<i>Merck & Co. v. Hi-Tech Pharmacal Co.</i> , 482 F.3d 1317 (Fed. Cir. 2007)	30
<i>Miller v. Eagle Mfg. Co.</i> , 151 U.S. 186 (1894).....	1, 16, 17, 18
<i>Odiorne v. Amesbury Nail Factory</i> , 18 F. Cas. 578 (C.C.D. Mass. 1819).....	5, 18, 23, 24
<i>Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.</i> , 678 F.3d 1280 (Fed. Cir. 2012)	23

<i>Perricone v. Medicis Pharm. Corp.</i> , 432 F.3d 1368 (Fed. Cir. 2005)	23
<i>Suffolk Co. v. Hayden</i> , 70 U.S. 315 (1865).....	16, 17
<i>Teva Pharms. USA, Inc. v. Sandoz, Inc.</i> , 2015 WL 232131 (U.S. Jan. 20, 2015).....	27
<i>In re Van Ornum</i> , 686 F.2d 937 (C.C.P.A. 1982).....	6, 17
<i>In re Woodsome</i> , 10 F.2d 1003 (D.C. Cir. 1926)	19
Federal Statutes	
35 U.S.C.	
§ 101 (2012)	5
§ 154(b)(1)(A) (2012).....	29
§ 156 (2012)	29, 30
§ 253 (2012)	6
Cooperative Research and Technology Enhancement (CREATE) Act of 2004	22
Patent Act of 1952	2, 5, 6, 17
Patent Law Amendments Act of 1984.....	4, 22, 28
Uruguay Round Agreements Act of 1994.....	<i>passim</i>
Rules	
Fed. R. Civ. P. 54(b).....	12
Sup. Ct. R. 10.....	1, 16
Regulations	
37 C.F.R. § 1.321(c) (2014)	6
37 C.F.R. § 1.321(c)(3) (2014).....	6
Constitutional Provisions	
U.S. Const., Article I, § 8.....	5

Other Authorities

130 Cong. Rec. H10,527 (1984) 4, 23, 28
Manual of Patent Examining Procedure
 (5th ed., rev. 16, 1994) 8
Manual of Patent Examining Procedure
 (6th ed. 1995)..... 9
Manual of Patent Examining Procedure
 (8th ed., rev. 3, 2005) 9, 26
Manual of Patent Examining Procedure
 (9th ed. 2014)..... 25, 26, 28, 31

INTRODUCTION

Petitioners have presented no “compelling reasons” for their Petition for a Writ of Certiorari (“Petition”) to be granted. *See* Sup. Ct. R. 10.

As an initial matter, the Federal Circuit’s April 22, 2014 majority opinion (“Opinion”) did not “fundamentally recast” the doctrine of obviousness-type double patenting as Petitioners allege. The patent laws have never permitted a single party to own duplicative patents with different expiration dates because that “would operate to extend or prolong the monopoly beyond the period allowed by law.” *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894). The double-patenting doctrine has always prevented that outcome by restricting the last-expiring patent, either by invalidation or, in modern times, by requiring that it be terminally disclaimed so that the two patents expire at the same time. Thus, in holding that the first-expiring ‘375 patent can serve as a double-patenting reference against the later-expiring ‘483 patent, the Federal Circuit applied the doctrine in the same way it has always been applied.¹

There is no dispute that Petitioners are entitled to a single, 20-year statutory term for the invention claimed in the ‘375 patent. As Petitioners’ would have it, however, they should receive an *additional* 22 months of exclusivity merely because the later-filed and duplicative ‘483 patent issued before the

¹ It was assumed for the purposes of the appeal that the ‘375 and ‘483 patents claim near-identical or duplicative subject matter.

'375 patent. Such extension of the statutory patent term granted to a single invention has never been permitted. Thus, it is Petitioners who would alter the double-patenting doctrine, for the first time, to permit single ownership of duplicative patents with different expiration dates.

Petitioners fail to demonstrate that the Opinion conflicts with this Court's 19th century double-patenting precedent. They contend that because the Court then said that "the power to create a monopoly is exhausted by the first patent," the Federal Circuit erred by not giving primacy to the first-issued '483 patent, which was filed later than the '375 patent and which will thus expire later. (Pet. at 17, quoting *Miller*, 151 U.S. at 198.) Petitioners ignore, however, that these opinions predate the Patent Act of 1952, wherein Congress created the terminal disclaimer, the mechanism that *permits* the single ownership of duplicative patents by ensuring that such patents expire simultaneously. See *Application of Robeson*, 331 F.2d 610, 614 n.4 (C.C.P.A. 1964). Thus, the exhaustion rationale cited by Petitioners is no longer applicable in the context of obviousness-type double patenting and does not conflict with the Opinion.

Petitioners further ignore that the Uruguay Round Agreements Act of 1994 ("URAA") tied patent expiration to the *filing* date instead of the *issue* date. A focus on issuance can therefore no longer reliably safeguard the purposes of the double-patenting doctrine. In this case, both the '375 and '483 patents are governed by the post-URAA patent laws, and the Federal Circuit therefore looked directly to the

expirations of the patents. The Opinion is entirely consistent with this Court's double-patenting precedent.

Petitioners' reliance on the linguistic convention of discussing the doctrine in terms of issuance in the Court's early double-patenting precedent is thus mistaken. As the Federal Circuit recognized, the patent laws at the time inextricably tied expiration to issuance. (Pet. App. at 12a.) Focusing on controlling the term of "the last" or "the later" of the patents to issue therefore meant the same as controlling the term of the last patent to expire. (*Id.*) In fact, the last-expiring patent was held invalid in every Supreme Court opinion cited by Petitioners—precisely the same result as the Federal Circuit reached in the Opinion.

Petitioners also contend that the Opinion conflicts with the Federal Circuit's own obviousness-type double-patenting precedent. (Pet. at 19-21.) Petitioners' argument is, however, based on the same superficial and flawed reading of opinions dealing with patents subject to the pre-URAA patent term. Furthermore, although former Chief Judge Rader dissented from the Opinion, the Federal Circuit as a whole denied Petitioners' request for rehearing *en banc*. (Pet. App. 33a-34a.) The only subsequent Federal Circuit case to reference the Opinion endorsed it in full. *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1374 (Fed. Cir. 2014). Thus, there is no conflict within Federal Circuit decisions or between circuits.

Finally, Petitioners assert that the Opinion is contrary to congressional intent and will upset the settled expectations of patent holders. (Pet. at 30-33.) The opposite is true. In passing the Patent Law Amendments Act of 1984, Congress stated that it expected the United States Patent and Trademark Office (“PTO”) to continue “the practice of rejecting claims in commonly owned applications of different inventive entities on the ground of double patenting . . . in order to prevent an organization from obtaining two or more patents with different expiration dates covering nearly identical subject matter.” 130 Cong. Rec. H10,527 (1984). The Opinion implements that expressed intent. Furthermore, Petitioners do not deny that the patent laws have always barred a single patentee from owning duplicative patents with different expiration dates. Nor do they deny that, for commonly-owned and duplicative patent applications subject to the post-URAA patent term, the PTO requires a terminal disclaimer in the second-filed, and therefore last-expiring, of the two applications.

In sum, Petitioners have failed to carry their burden of demonstrating that there are compelling reasons for this Court to grant the Petition.

STATEMENT OF THE CASE

A. Legal Background

1. The Double-Patenting Doctrine

The doctrine of double patenting is rooted in the constitutional authority to secure for inventors exclusive rights in their discoveries “for limited

Times,” U.S. Const., art. I, § 8, and in the provision of the Patent Act that an inventor may obtain “a patent,” i.e., a single patent, for an invention, 35 U.S.C. § 101 (2012). As Justice Story put it, “[i]t 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 during a century” *Odiorne v. Amesbury Nail Factory*, 18 F. Cas. 578, 579 (C.C.D. Mass. 1819).

The prohibition on double patenting has two forms: statutory double patenting and obviousness-type double patenting. The former applies when two patents claim identical subject matter and derives from the patent statute’s limitation that an inventor “may obtain *a* patent” for a new and useful invention. 35 U.S.C. § 101 (2012) (emphasis added). The latter has correspondingly developed over time in the courts to prevent multiple patents by the same inventor for merely “obvious modifications” of the same subject matter. *Robeson*, 331 F.2d at 614.

The “fundamental” policy underlying the obviousness-type double-patenting doctrine is that “[t]he public should . . . be able to act on the assumption that upon the *expiration* of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been *obvious* to those of ordinary skill in the art at the time the invention was made” *In re Longi*, 759 F.2d 887, 892-93 (Fed. Cir. 1985) (quoting *In re Zickendraht*, 319 F.2d 225, 232 (C.C.P.A. 1963)). In addition, the doctrine serves the

important purpose of preventing “multiple infringement suits by different assignees asserting essentially the same patented invention.” *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013); *see also In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009) (stating that the doctrine is intended to prevent “harassment by multiple assignees”).

2. The Creation of the Terminal Disclaimer Permits Ownership of Duplicative Patents By Guaranteeing Simultaneous Expiration.

Prior to Congress’s creation of the terminal disclaimer in the Patent Act of 1952, ch. 950, 66 Stat. 809 (1952), the consequence of double patenting was always the invalidity of the last-expiring patent. Through a terminal disclaimer, a patent owner may “disclaim” the portion of the patent term in the last-expiring patent that extends beyond the term of the first-expiring patent. 35 U.S.C. § 253 (2012); 37 C.F.R. § 1.321(c) (2014). The terminal disclaimer also requires the patent owner to retain ownership over both patents. *See* 37 C.F.R. § 1.321(c)(3) (2014). Thus, a valid terminal disclaimer resolves both the main problems posed by duplicative patents owned by a single entity, i.e., unjustified extension of the statutory patent term and multiple infringement suits by different assignees of duplicative patents. In essence, a valid terminal disclaimer creates a situation “which is tantamount for all practical purposes to having all the claims in one patent.” *In re Van Ornum*, 686 F.2d 937, 948 (C.C.P.A. 1982) (quoting *Application of Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967)).

To be effective, a disclaimer must be filed prior to the expiration of the earlier patent. *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1347-50 (Fed. Cir. 2010). Furthermore, “[a] patent owner cannot avoid double patenting by disclaiming the earlier patent.” *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 n.5 (Fed. Cir. 2001). In this case, Gilead filed a terminal disclaimer in the earlier-expiring ‘375 patent, and did not file a disclaimer in the later-expiring ‘483 patent.

3. The Passage of the URAA Changes the Statutory Patent Term.

The passage of the URAA on December 8, 1994 harmonized the patent term in the United States with that of most other nations by changing the term from 17 years from the date of issuance to 20 years from the earliest effective filing date in the United States. Pub. L. No. 103-465 § 532, 108 Stat. 4809 (1994) (codified as amended at 35 U.S.C. § 154(a)(2)). This change in the statutory patent term had the effect of eliminating the opportunity for extending the effective patent term for an invention by using continuation applications to obtain both the early priority date of the original application and a late expiration date of a later-issuing continuation application. *See Fallaux*, 564 F.3d at 1318. While its scope might have diminished somewhat, the doctrine remains an important, congressionally-mandated requirement in the situations in which it does apply. *Id.* at 1319.

4. The PTO Adjusts Its Application of the Obviousness-Type Double-Patenting Doctrine in Response to the Change in Patent Term.

The Manual of Patent Examining Procedure (“MPEP”) is published by the PTO and sets out rules for both patent examiners and patent practitioners regarding the prosecution of patent applications. The MPEP does not have the force of law, but reflects the PTO’s interpretation and implementation of the patent laws as set out in statutes, regulations and case law. *Litton Sys., Inc. v. Whirlpool Corp.*, 728 F.2d 1423, 1439 (Fed. Cir. 1984).

Prior to the URAA, the MPEP instructed that, when there were provisional double-patenting rejections in two applications, the examiner should withdraw the rejection in either one of the applications and permit it to issue as a patent. (MPEP § 804, (5th ed., rev. 16, 1994).) This policy reflects the pre-URAA patent term of 17 years from issuance because the application with the withdrawn rejection would then be the first to issue and the first to expire. The other application would then issue only upon the filing of a terminal disclaimer.

Shortly after the URAA was signed into law, the instruction was changed to provide that the examiner should withdraw the rejection “in one of the applications (*e.g., the application with the earlier filing date*) and permit the application to issue as a patent.” (MPEP § 804.I.B (6th ed. 1995) (emphasis added).) This change recognized that, going forward, patent examiners would be receiving applications for

which the filing date rather than issuance would determine expiration. In those cases, the application with the earlier filing date would expire first and should thus be permitted to issue. The other application, which would expire later, would again only be permitted to issue with a terminal disclaimer.

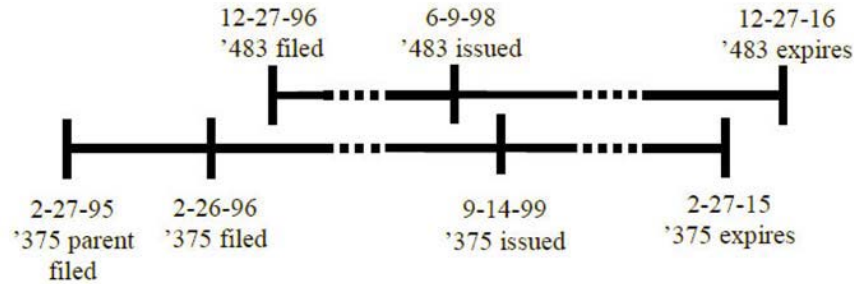
Finally, in 2005 the instruction changed to provide that the examiner withdraw the double patenting rejection “in the *earlier filed* application thereby permitting that application to issue without need of a terminal disclaimer.” (MPEP § 804.I.B.1 (8th ed., rev. 3, 2005) (emphasis added).)² By this time, there could be exceedingly few applications remaining eligible for the pre-URAA patent term of 17 years from issuance and the expiration of all applications under consideration would therefore be determined by their filing date. Thus, patent examiners were categorically instructed to let the earlier-filed and, therefore, earlier-expiring application issue (here the ‘375 patent), and to require a terminal disclaimer in the later-filed and, therefore, later-expiring patent (here the ‘483 patent).

² Petitioners incorrectly describe the MPEP as instructing that a terminal disclaimer is “required for the earlier-filed application.” (Pet. at 29.) Petitioners also incorrectly contend that this rule “was in effect prior to the URAA’s changes in the patent terms on June 8, 1995,” citing the sixth edition of the MPEP published in January 1995. (*Id.*) In fact, that rule was instituted in 2005. *Supra*, p. 8.

B. Factual Background

This litigation exists because Petitioners failed to inform the patent examiner for the application leading to the '483 patent of their co-pending and duplicative application leading to the '375 patent. Had Petitioners done so, the patent examiner would have required a terminal disclaimer in the '483 patent before allowing it to issue, *see supra*, pp. 8-9, and no double-patenting issue would have materialized.

The '375 and '483 patents relate to the inhibition of viruses through selective interference with certain enzymes. (Pet. App. at 2a.) The two patents are commonly owned by Gilead Sciences, Inc., and list the same inventors. (*Id.*) Although the “written descriptions of the patents are very similar and, in substantial parts, identical,” they are part of different patent families and do not claim priority to a common patent application and have different expiration dates. (*Id.* at 2a-3a.) The applications leading to the '375 and '483 patents were also before different examiners. (*Id.* at 3a.) Gilead crafted a separate chain of applications with a later priority date for the '483 patent and it therefore expires after the '375 patent even though it issued earlier:



(*Id.* at 3a-4a.)

After the '483 patent issued, Gilead spontaneously filed a terminal disclaimer in the application that led to the '375 patent and disclaimed any portion of the '375 patent term that extended beyond the expiration date of the '483 patent. (*Id.* at 3a.) Thus, it was only after the '483 patent issued that Gilead informed either the examiner of the '375 patent or of the '483 patent about the existence of the other patent application. (*Id.* at 3a-4a.) No terminal disclaimer was filed for the '483 patent. (*Id.* at 4a.)

C. District Court Proceedings

In December 2012, the district court granted Gilead's motion for summary judgment that, as a matter of law, the '375 patent could not serve as a double-patenting reference to the '483 patent because it was issued after the '483 patent. (*Id.* at 31a-32a.) The district court relied on *Abbott Laboratories v. Lupin Ltd.*, No. 09-152, 2011 WL 1897322 (D. Del. May 19, 2011) and *Brigham and Women's Hospital Inc. v. Teva Pharmaceuticals USA, Inc.*, 761 F. Supp. 2d 210 (D. Del. 2011). (*Id.* at 30a-31a.) In both cases, one of the patents was subject to the pre-

URAA patent term, and the other was subject to the post-URAA term. The Delaware district court therefore held that the obviousness-type double-patenting doctrine did not apply because the issue was caused by a change in the patent laws. (*Id.* at 31a.) In May 2013, the district court entered final judgment under Fed. R. Civ. P. 54(b), and Natco appealed to the Federal Circuit. (*Id.* at 5a.)

D. Appellate Court Proceedings

On appeal, in a 2-1 opinion, the Federal Circuit Court of Appeals held that, “under the circumstances of this case,” “a patent that issues after but expires before another patent [can] qualify as a double patenting reference for that other patent,” and that “the district court erred in excluding the ‘375 patent as a potential double patenting reference for the ‘483 patent.” (*Id.* at 6a.)

The majority explained that the “bedrock” principle of the patent system is the ability for the public to freely use the invention claimed in the patent as well as obvious or patentably indistinct modifications of that invention once the patent expires. (*Id.* at 10a.) Assuming that the ‘483 patent covers obvious modifications of the invention in the ‘375 patent, the majority determined that this principle is violated here because upon the expiration of the ‘375 patent, the public is not able to freely use the invention and all obvious variants of the invention claimed in the ‘375 patent. (*Id.* at 11a.)

The majority was not persuaded by Gilead’s argument that the focus should be on the potential

patent term extension of the first issued '483 patent and that the '375 patent “in no way extends the term of exclusivity for the '483 patent.” (*Id.* at 11a-12a.) It rejected Gilead’s characterization of double patenting as applicable only to the “second” or “later” issuing patent. (*Id.* at 12a.) The majority reasoned that before the URAA, patent issuance was tied to expiration and thus “looking to patent issue dates had [] served as a reliable stand-in for the date that really mattered – patent expiration.” (*Id.*) After the URAA, however, patent issue dates are no longer a “reliable stand-in” for expiration dates because “there are now instances, like here, in which a patent that issues first does not expire first.” (*Id.*) Thus, “it is the comparison of Gilead’s patent expiration dates that should control, not merely the issuance dates.” (*Id.* at 13a.)

The majority stated that relying on issuance dates, as Gilead advocates, would encourage gamesmanship during prosecution because inventors could “routinely orchestrate” patent term extensions by filing serial applications on obvious modifications, claim priority to different applications in each, and then arrange for the application claiming the latest filing date to issue first. (*Id.*) This tactic would permit the applicant to obtain additional patent term exclusivity for obvious variants of the inventions while also exploring the value of an earlier priority date during prosecution. The majority further observed that relying on issuance also would permit the period of exclusivity for a patent to vary significantly based on just a few days’ difference in issuance of the applicant’s patents. (*Id.* at 14a.) “Such significant vacillations in an inventor’s period

of exclusivity over his invention and its obvious variations is simply too arbitrary, uncertain, and prone to gamesmanship.” (*Id.*)

Instead, the majority concluded that looking at the earliest expiration date of all the patents “best fits and serves the purpose of the doctrine of double patenting.” (*Id.* at 14a-15a.) Using the expiration date for post-URAA obviousness-type double-patenting cases also preserves the use of terminal disclaimers for later-expiring patents to create one expiration date for their term of exclusivity and is consistent with the MPEP. (*Id.* at 15a.) Thus, the court concluded that a patent’s expiration date also should control, not “merely” the issuance date. (*Id.* at 12a-13a.)

The dissent explained that, in his view, there was “no reason to apply double patenting under our two accepted justifications for the doctrine.” (*Id.* at 19a.) According to the dissent, “Gilead’s subsequent ‘375 patent unquestionably did not extend the term of the earlier-issuing ‘483 patent. The ‘375 patent claims priority to an earlier filing date and consequently expires first.” (*Id.*) Nor, according to the dissent, does the case “involve the potential for harassment by multiple assignees asserting essentially the same patented invention.” (*Id.* at 20a.) “The risk of separate parties suing on the two patents is . . . *adequately* mitigated” because “the ‘375 patent is subject to a terminal disclaimer with respect to the ‘483 patent” (*Id.* (emphasis added).) The dissent could not say that this risk was *wholly* mitigated because, upon the expiration of the ‘375 patent, the terminal disclaimer will also expire,

and Gilead will be free to assign the still-existing '483 patent. Thus, the potential for a subsequent suit by a different assignee persists.

Acknowledging Gilead's failure to inform the examiners of its other application, the dissent stated that the "question becomes whether Gilead's conduct warrants the creation of a new rule proscribing its patent rights." (*Id.*) The dissent answered this question in the negative, in large part because of disagreement with what the dissent characterized as the majority's reliance "on the flawed assumption that upon the expiration of a patent, the public obtains an absolute right to use the previously-claimed subject matter." (*Id.* at 21a.) In the dissent's view, other patents, as well as other legal and regulatory bars, may prohibit the public from practicing the invention. (*Id.*) Thus, while explaining that he was not "disparag[ing] the doctrine of obviousness-type double patenting," the dissent explained that he would "proceed more cautiously" than the majority. (*Id.* at 17a, 19a.)

After the Federal Circuit issued its opinion, Petitioners petitioned for rehearing *en banc*. (*Id.* at 33a-34a.) Biotechnology Industry Organization ("BIO") and the Pharmaceutical Research and Manufacturers of America ("PhARMA") filed a brief of *amicus curiae* in support of the petition. The petition was denied on July 29, 2014. (*Id.*) BIO and

PhARMA have also filed an amicus brief in support of this Petition.³

REASONS FOR DENYING THE PETITION

The Opinion does not conflict with a decision of this Court or a prior decision of the Federal Circuit. Nor does it implicate an important issue of federal law. Accordingly, Petitioners have not carried their burden of demonstrating any “compelling reasons” for the Petition to be granted. *See* Sup. Ct. R. 10.

I. THE OPINION FOLLOWS APPLICABLE DOUBLE-PATENTING PRECEDENT.

A. The Opinion Follows This Court’s Precedent.

Petitioners contend that the Opinion “directly conflicts” with this Court’s decisions in *Suffolk* and *Miller*, two 19th century cases, and their progeny. (Pet. at 15-18.) These decisions, Petitioners assert, establish that “the power to create a monopoly is exhausted by the first patent.” (*Id.* at 17 (quoting *Miller*, 151 U.S. at 198).) Under this rule, apparently, only the first patent to *issue* can serve as a double-patenting reference and, consequently, only the second patent to *issue* can be void for double patenting. (*Id.* at 16.) Petitioners are wrong.

³ Petitioners unsuccessfully sought amicus support from a number of organizations that represent a broader spectrum of interested parties, including the Federal Circuit Bar Association, the American Intellectual Property Law Association, the Intellectual Property Owners Association and the New York Intellectual Property Law Association.

First, Petitioners fail to acknowledge that these cases pre-date Congress's creation of the terminal disclaimer in the Patent Act of 1952. Prior to the introduction of the terminal disclaimer, the patent system did not permit a patentee to own duplicative patents. *See, e.g., Miller*, 151 U.S. at 197 (“[T]wo valid patents for the same invention cannot be granted []to the same . . . party.”). Thus, the unavoidable consequence of double patenting was the invalidity of the last-expiring, and hence first-issued, patent. With the creation of the terminal disclaimer, however, single ownership of duplicative patents became possible. *See Van Ornum*, 686 F.2d at 948. As the Federal Circuit has explained, because a valid terminal disclaimer ensures that duplicative patents expire at the same time, “a situation is created which is tantamount for all practical purposes to having all the claims in one patent.” *Id.* The rationale relied upon by Gilead is thus no longer a valid rationale in the context of obviousness-type double patenting.

Second, in both *Suffolk* and *Miller*, and indeed in every other double-patenting case decided by this Court, the *last-expiring* patent is held invalid. *See Suffolk Co. v. Hayden*, 70 U.S. 315, 319 (1865); *Miller*, 151 U.S. at 197-98 (listing cases); *McCreary v. Pa. Canal Co.*, 141 U.S. 459 (1891). That, of course, is exactly the same result the Federal Circuit reached in the Opinion, where it held that, under the circumstances presented in this case, a terminal disclaimer was required in the later-expiring ‘483 patent to preserve its validity. (Pet. App. at 15a-16a.) Thus, the Opinion’s conclusion is fully

consistent with the conclusions reached in this Court's precedent.

Third, the Federal Circuit's reasoning also follows this Court's precedent. In addition to the inapplicable exhaustion rationale, *Miller* also identified "the further reason that a new and later patent for the same invention would operate to extend or prolong the monopoly beyond the period allowed by law." 151 U.S. at 198 (citing *Odiorne*, 18 F. Cas. at 579). As Justice Story had explained 75 years earlier, an unjustified extension of a patent term "would completely destroy the whole consideration derived by the public for the grant of the patent, viz. the right to use the invention at the expiration of the term specified in the original grant." *Odiorne*, 18 F. Cas. at 579.

Here, the '375 patent expires on February 27, 2015. On that date, the public should have the right to use the invention claimed in the '375 patent and any obvious variations. Following the dissent, Petitioners object that there may be other legal and practical barriers preventing the public's use of an invention upon the expiration of the patent. (Pet. at 18 n.2.) The point, of course, is that *barring* other such barriers, the public is entitled to use the claimed invention upon patent expiration. Absent the application of the double-patenting doctrine, however, the public will *not* be free to do so until the '483 patent expires some 22 months later. In effect, the statutory term of the '375 patent would be unjustly extended by 22 months, in contradiction of this Court's precedent. Thus, the Federal Circuit's conclusion that the doctrine of obviousness-type

double patenting applies to the '375 patent is fully consistent with this Court's precedent.

Finally, Petitioners emphasize that the Court's older double-patenting opinions are phrased in terms of issuance rather than expiration. (Pet. at 15-18.) As discussed, however, this is merely a linguistic artifact of the then-operative patent laws, where a patent's expiration was determined by its issuance. At the time, the first patent to issue would always be the first patent to expire, and thus the objective of preventing unjustified extensions of a patent term could be expressed as giving priority to the first-issued patent. With the URAA, however, patent expiration is now tied to the filing date, and issuance is consequently no longer a reliable stand-in for expiration. In this case, both the '375 and '483 patents are governed by the post-URAA patent laws.

B. The Opinion Follows Lower Courts' Precedent.

Petitioners' contention that the Opinion conflicts with lower court decisions is based on the same mistakes as discussed above. (*Id.* at 19-21.) For example, Petitioners point to the statement in a 1926 opinion from the D.C. Circuit that, if two duplicate patents are granted to the same applicant, "the latter is invalid." *In re Woodsome*, 10 F.2d 1003, 1004 (D.C. Cir. 1926). Again, however, Petitioners ignore: (1) that Congress did not create the terminal disclaimer permitting a single patentee to own duplicative patents until 1952; and (2) that the

invalidation of the last-expiring patent is entirely consistent with the Opinion.

Petitioners similarly and incorrectly find a conflict between the Opinion and two older opinions by the U.S. Court of Customs and Patent Appeals (“CCPA”), *In re Copeman*, 135 F.2d 349 (C.C.P.A. 1943) and *In re Laughlin*, 48 F.2d 921 (C.C.P.A. 1931), that predate the creation of the terminal disclaimer. (Pet. at 19-20.) In both cases, the CCPA agreed with the patent office’s rejection of a patent application that was duplicative over an already-issued patent owned by the same applicant, and in both cases the court reasoned that a second patent could not be allowed for a single invention. In *Copeman*, for example, the CCPA explained that a reason for the prohibition on double patenting “is that under the system of granting patents, the monopoly of a single invention might be — as in the present case if the appealed claims were allowed — greatly extended.” *Copeman*, 135 F.2d at 351. By definition, only the last-expiring patent can *extend* the monopoly for single invention; the last-expiring patent is therefore the cause of the potential problem that the double-patenting doctrine combats. Here, the last-expiring patent is the ‘483 patent. Just as the CCPA concluded in *Copeman* and *Laughlin*, therefore, the Federal Circuit held in the Opinion that the ‘483 patent may be held invalid for double patenting in the absence of a valid terminal disclaimer.

Petitioners also cite a number of CCPA and Federal Circuit opinions that post-date the introduction of the terminal disclaimer. (Pet. at 20-

21.) In every case, however, the patents at issue were subject to the pre-URAA patent term of 17 years from issuance, and the term “last to issue” and its equivalents can be exchanged with “last to expire” with the exact same result.⁴ Furthermore, the absence of any conflict with the Federal Circuit’s prior opinions is evidenced by the denial of Gilead’s petition for rehearing *en banc* and the appellate court’s recent explicit affirmation of the Opinion in *Abbvie*, 764 F.3d at 1374.

II. THE OPINION IS FIRMLY GROUNDED IN DOUBLE-PATENTING LAW AND POLICY.

Petitioners assign a considerable portion of the Petition to arguments that the majority’s rationale in the Opinion is without merit. (Pet. at 22-29.) Not only are Petitioners’ arguments incorrect, but disagreement with the rationale for a holding is not a cognizable reason for certiorari to be granted.

A. The Opinion Implements Congressional Intent.

Petitioners’ argue that the Opinion missteps because “there is no indication that Congress has ever attempted to alter [the double-patenting doctrine], much less fundamentally change it the

⁴ Petitioners cite dicta from a footnote in *Amgen Inc. v. F. Hoffmann-La Roche Ltd.* stating that the later-issued patent “presumably cannot be used as an obviousness-type double patenting reference” to the first-issued patent. 580 F.3d 1340, 1354 n.5 (Fed. Cir. 2009). That statement is correct because there was a terminal disclaimer in the later-issued patent, presumably removing the danger that it could unjustifiably extend the term of the first-issued patent.

way the Federal Circuit has.” (Pet. at 22-23.) This argument is based on the incorrect assumption that the Opinion somehow changed the doctrine of obviousness-type double patenting. It did not. As discussed above, the Opinion continued the longstanding and established application of the doctrine to police the prohibition on unjustified extensions of a patent term. Thus, Gilead’s contention that “Congress could have easily changed the obviousness-type double-patenting doctrine” in the CREATE Act is a non sequitur.⁵ (*Id.* at 24.)

Furthermore, the Opinion is fully consistent with congressional intent as expressed in the legislative history surrounding the Patent Law Amendments Act of 1984:

The Committee expects that the Patent and Trademark Office will reinstitute in appropriate circumstances the practice of rejecting claims in commonly owned applications of different inventive entities on the ground of double patenting. This will be necessary in order to prevent an organization from obtaining two or more patents with different expiration dates covering nearly

⁵ The CREATE Act allowed for the filing of terminal disclaimers to save patents subject to obviousness rejections from patents owned by others within a joint research agreement. Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, § 2, 118 Stat. 3596 (2004) (codified as amended at 35 U.S.C. § 103(c) (2012)). This illustrates Congress’s intention to maintain the prohibition on duplicative patents with differing expiration dates. The Opinion accomplishes this goal.

identical subject matter. In accordance with established patent law doctrines, double patenting rejections can be overcome in certain circumstances by disclaiming the terminal portion of the term of the later patent, thereby eliminating the problem of extending patent life.

130 Cong. Rec. H10,527 (1984); *see also* *Hubbell*, 709 F.3d at 1153 (discussing the legislative history). This legislative history affirms both that a main purpose of the doctrine is to prevent a patentee from owning duplicative patents with different expiration dates, and that a terminal disclaimer in the last-expiring patent can cure the problem. Thus, the Opinion effectuates congressional intent.

B. The Opinion Safeguards the Public’s Expectations.

A fundamental policy underlying the obviousness-type double-patenting doctrine is that “[t]he public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made” *Longi*, 759 F.2d at 892-93 (quoting *Zickendraht*, 319 F.2d at 232); *see also* *Odiorne*, 18 F. Cas. at 579; *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1373 (Fed. Cir. 2005); *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 (Fed. Cir. 2003); *In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir.

1998); *In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997); *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1577 (Fed. Cir. 1996). The public thus expects that it will be free to use the invention claimed in the '375 patent and any obvious variations upon the expiration of that patent. As discussed, that expectation is safeguarded when a terminal disclaimer is required in the last-expiring patent, in this case the '483 patent.

Petitioners contend that the public's expectation formed upon the issuance of the '483 patent and was not changed upon the later issuance of the earlier-expiring '375 patent. (Pet. at 25.) This argument misses the mark. The salient point is that the public, *when it looks at a patent*, should be able to act on the assumption that when *that patent* expires, it is free to use the claimed invention. That was the fundamental bargain that was struck when the patent issued. *See Odiorne*, 18 F. Cas. at 579. As Petitioners would have it, the public is not entitled to form that expectation until it investigates whether another later-expiring, duplicative patent exists that would further block its use of the invention. There is no basis in the case law for Petitioners' position.

C. The Opinion Prevents Gamesmanship In Patent Prosecution.

The Federal Circuit explained in the Opinion that Petitioners' proposed approach would permit gamesmanship during prosecution:

But if the double patenting inquiry was limited by issuance date, inventors could routinely orchestrate patent term extensions by (1) filing serial applications on obvious modifications of an invention, (2) claiming priority to different applications in each, and then (3) arranging for the application claiming the latest filing date to issue first. If that were to occur, inventors could potentially obtain additional patent term exclusivity for obvious variants of their inventions while also exploring the value of an earlier priority date during prosecution.

(Pet. App. at 13a.) Petitioners now argue that eliminating such loopholes should be left to Congress. (Pet. at 25-26.) Petitioners do not deny, however, that the gamesmanship the Federal Circuit described would in fact be rendered possible by their approach. Nor can it deny that it is appropriate for a court to consider whether the Petitioners' proposed new rule is consistent with congressional intent.

D. The Opinion Is On All Fours With PTO's Longstanding Application of the Doctrine.

As discussed above, *supra* pp. 7-8, the Opinion is on all fours with how the PTO handles obviousness-type double-patenting issues during prosecution. *See* MPEP § 804.I.B.1 (9th ed. 2014). As also discussed, the PTO's application has evolved after the URAA's passage to account for the dwindling of applications subject to the old patent term of 17 years from issuance. *See supra* pp. 7-8.

Petitioners contend that the majority overlooked that MPEP § 804.I.B.1 applies to pending applications whereas the situation here involves two issued patents. (Pet. at 29.) The point, however, is that the MPEP is a public document that informs both patent examiners and practitioners, i.e., patentees, about how the PTO implements the patent laws. Thus, the MPEP shows that patentees could not have expected to be entitled to own duplicative patents with different expiration dates. Furthermore, Section 804.I.B.1 *is* applicable here because the patent examiner would have followed it and required a terminal disclaimer in the application that resulted in the ‘483 patent if he had been informed of the co-pending application leading to the ‘375 patent. Thus, the ‘483 patent was permitted to issue without a terminal disclaimer only because the patent examiner was not aware of the co-pending application leading to the ‘375 patent.⁶

⁶ PhARMA and BIO, the two special-interest organizations that have filed a joint amicus brief in support of the Petition, contend that the Opinion creates uncertainty because “the actual term of the first patent to issue remains unknown as long as any application that might give rise to an allegation of double patenting remains pending because at any point a second patent that cuts short the term of the first patent could issue.” (Amicus Br. at 9.) Any such uncertainty can only arise, however, if the applicant fails to inform the patent examiner about duplicative, co-pending applications. *See* MPEP § 2001.05(b) (9th ed. 2014) (requiring applicants to bring co-pending applications that are material to patentability to the attention of the examiner).

III. THE OPINION DOES NOT PRESENT AN IMPORTANT ISSUE OF FEDERAL LAW.

As a general matter, this case does not rise to the level of importance that customarily attaches to patent cases reviewed by the Supreme Court. In its most recent patent opinion, for example, the Court determined the appropriate standard of review for claim constructions, an issue that has relevance to nearly every patent litigation. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, No. 13-854, 2015 WL 232131 (U.S. Jan. 20, 2015). Other recently granted petitions involve broadly significant questions of subject-matter eligibility. See *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014) (addressing whether claims to computer-implemented inventions are patent-eligible subject matter); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (addressing whether isolated but naturally occurring DNA is patentable); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (addressing whether methods of determining an increase or decrease in dosage amounts are patent eligible).

By contrast, the doctrine of obviousness-type double patenting, although still a relevant defense, is only infrequently asserted and lacks the general importance of the patent cases where the Court grants certiorari. Furthermore, the specific issue presented here, where the last-expiring of two commonly-owned patents was the first to issue, is unusual and fact-specific in its own right because it requires that the same patentee file duplicative patents in *different families* rather than employ the

far more common practice of filing continuations within the same patent family.⁷

Petitioners assert that the Federal Circuit’s decision “upsets . . . settled expectations” of innovators. (Pet. at 30; *see also id.* at 14.) But the law has *never* permitted patentees to own duplicative patents with different expiration dates. As stated above, *supra* pp. 3, 20, the legislative history surrounding the Patent Law Amendments Act of 1984 demonstrates that Congress expected the PTO to continue “the practice of rejecting claims in commonly owned applications of different inventive entities on the ground of double patenting . . . in order to prevent an organization from obtaining two or more patents with different expiration dates covering nearly identical subject matter.” 130 Cong. Rec. H10,527 (1984). Furthermore, the PTO has a long-standing practice of requiring a terminal disclaimer in the second-filed, and therefore last-expiring, of two co-owned and duplicative patent applications subject to the post-URAA patent term. MPEP § 804.I.B.1 (9th ed. 2014). Petitioners’ assertion that patentees could have had any reasonable expectation to the contrary is not credible.

⁷ To date, the Opinion has only been cited three times, and none of those cases present the same issue as here. *See Abbvie Inc. v. Kennedy Trust for Rheumatology Research*, No. 13-1358, 2014 WL 2977299 (S.D.N.Y. June 2, 2014); *Abbvie*, 764 F.3d 1366; *Koninklijke Philips N.V. v. Zoll Med. Corp.*, No. 10-11041, 2014 WL 2810206 (D. Mass. June 20, 2014). The paucity of citations illustrates the infrequency with which this issue arises.

Petitioners next contend that “the panel majority’s decision upsets congressional intent and renders numerous other aspects of patent law moot.” None of the purported examples Petitioners provide have any merit.

Petitioners first argue that the Opinion’s rationale will upset congressional intent in a situation where one of two co-owned and duplicative patents is subjected to the pre-URAA patent term of 17 years from issuance and the other is subject to the post-URAA term of 20 years from filing. (Pet. at 31.) This suggestion ignores that the patents in *this* case are both subject to the same post-GATT term of 20 years from filing, and that the Opinion is explicitly limited thereto. (See Pet. App. at 6a, 12a n.6, 16a.) Thus, Petitioners’ hypothetical, which is unlikely to ever come up again because the URAA transition occurred almost 20 years ago, is not an issue presented by this case.

Petitioners next postulate that the Opinion “could deprive patent owners” of term adjustments provided for prosecution delays by the PTO under 35 U.S.C. § 154(b)(1)(A). (Pet. at 31.) Similarly, the authors of the amicus brief further hypothesize that the Opinion “has the potential to interfere with” patent term adjustments and extensions under 35 U.S.C. §§ 154, 156. (Amicus Br. at 11-12.) Again, however, neither patent in this case is subject to a patent term extension or adjustment and this hypothetical was not considered by the Federal Circuit. On the contrary, the majority explicitly said that cases involving patent term extensions “are [not] relevant to the facts or our discussion here.” (Pet. App. at 12a

n.6.) If this issue should be realized in practice, therefore, it will have to be ruled on by at least one lower court before it is ripe for appellate review.⁸

Petitioners also assert that the Opinion is “irreconcilable” with the “one-way” or “two-way” test for double patenting. (Pet. at 31-32.) The “two-way” test is applied in very rare instances to determine whether two sets of claims are in fact duplicative, i.e., whether the *substance* of one claim is merely an obvious variation of another claim. The Opinion, by contrast, dealt with whether the ‘375 patent can *in principle* be a double-patenting reference to the ‘483 patent. It said nothing about whether the ‘483 patent is in fact invalid for double patenting over the ‘375 patent. Thus, the Opinion has no bearing on the “two-way” test or its future applicability.

Finally, Petitioners contend that the Opinion “disrupts the PTO’s operations” because it “would

⁸ The hypotheticals presented in the amicus brief are even further removed from the facts upon which the Opinion was decided because they assume that the two duplicative patents are part of the *same family*. (Amicus Br. at 13.) Furthermore, the Federal Circuit has held “that a patent term extension under § 156 may be applied to a patent subject to a terminal disclaimer.” *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1324 (Fed. Cir. 2007). The Opinion does not disrupt this holding. On the contrary, should the question be presented in the future, a court may conclude that a statutory extension or adjustment of a patent term is not “unjustified” and thus does not present a double-patenting issue. See *Eli Lilly*, 251 F.3d at 968 (stating that the “fundamental reason for the rule [of obviousness-type double patenting] is to prevent unjustified timewise extension of the right to exclude”) (citing cases)).

require the PTO to establish a new set of procedures and standards.” (Pet. at 32.) But as already discussed, the PTO long ago adapted its double-patenting review to account for the change in patent term with the URAA. *Supra*, pp. 7-8. The only way the PTO would have to establish a new set of procedures would be if the Opinion was set aside by this Court and Petitioners’ proposed double-patenting scheme were adopted.

In sum, Petitioners have not demonstrated that the Opinion implicates an important question of federal law.

CONCLUSION

Petitioners have not established any compelling reasons for this Court to grant the Petition. Therefore, Respondents respectfully request that the Court deny the Petition.

Respectfully Submitted,

JEREMY LOWE

Counsel of Record

THOMAS K. HEDEMANN

AXINN, VELTROP & HARKRIDER LLP

90 State House Square

Hartford, Connecticut 06103

(860) 275-8100

jlowe@axinn.com

Counsel for Respondents

Natco Pharma Limited

and Natco Pharma, Inc.