No. 14-

IN THE

Supreme Court of the United States

GILEAD SCIENCES, INC., HOFFMANN–LA ROCHE, INC., F. HOFFMANN–LA ROCHE, LTD., AND GENENTECH, INC., *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

PETITION FOR A WRIT OF CERTIORARI

M. PATRICIA THAYER
SIDLEY AUSTIN LLP
555 California Street
Suite 2000
San Francisco, CA 94104
(415) 772-1200

CARTER G. PHILLIPS*
JEFFREY P. KUSHAN
RYAN C. MORRIS
JAMES A. HIGH
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
cphillips@sidley.com

Counsel for Petitioners

* Counsel of Record

November 26, 2014

QUESTION PRESENTED

This Court's double-patenting doctrine establishes the "well-settled rule that two valid patents for the same invention," or obvious modifications of that invention, "cannot be granted" to a single party. *Miller* v. *Eagle Mfg. Co.*, 151 U.S. 186, 196–97 (1894). The Court has repeatedly held that when two such patents are granted to a single party, "the later one [i]s void." *Id.* at 197 (discussing *Suffolk Co.* v. *Hayden*, 70 U.S. (3 Wall.) 315 (1865)). In the decision below, the Federal Circuit inverted this century-old doctrine, holding a first-issued patent invalid based on the issuance of the second patent.

The question presented is:

Whether, contrary to this Court's consistent and longstanding precedent and Congress's intent, the double-patenting doctrine can be used to invalidate a properly issued patent before its statutory term has expired using a second, later-issuing patent whose term of exclusivity is entirely subsumed within that first patent's term?

PARTIES TO THE PROCEEDING AND RULE 29.6 CORPORATE DISCLOSURE STATEMENT

The parties to the proceeding are listed in the caption.

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

Gilead Sciences, Inc. has no parent company, and no publicly held company owns 10 percent or more of the stock of Gilead Sciences, Inc.

Hoffmann-La Roche Inc.'s ultimate parent, Roche Holding Ltd., is publicly traded on the Swiss Stock Exchange. Upon information and belief, more than 10 percent of Roche Holding Ltd.'s voting shares are held either directly or indirectly by Novartis AG, a publicly held Swiss corporation. Apart from Roche Holding Ltd. (and indirectly, Novartis AG), there is no publicly held company with a 10 percent or greater ownership of Hoffmann-La Roche, Inc.

F. Hoffmann-La Roche Ltd. is a wholly-owned subsidiary of Roche Holding Ltd., a publicly held Swiss corporation. Upon information and belief, more than 10 percent of Roche Holding Ltd.'s voting shares are held either directly or indirectly by Novartis AG, a publicly held Swiss corporation.

Genentech, Inc.'s parent companies are: Roche Holdings, Inc., Roche Finance Ltd., and Roche Holding Ltd. Roche Holding Ltd. is a publicly traded company indirectly owning 10% or more of Genentech, Inc.'s stock. Upon information and belief, more than 10 percent of Roche Holding Ltd.'s voting shares are held either directly or indirectly by Novartis AG, a publicly held Swiss corporation.

TABLE OF CONTENTS

TABLE OF CONTENTS—continued

TABLE OF AUTHORITIES

CASES Page

TABLE OF AUTHORITIES—continued

TABLE OF AUTHORITIES—continued

STATUTES

TABLE OF AUTHORITIES—continued

TABLE OF AUTHORITIES—continued

PETITION FOR A WRIT OF CERTIORARI

Petitioners Gilead Sciences, Inc., Hoffman-La Roche, Inc., F. Hoffmann-La Roche, Ltd., and Genentech, Inc. (collectively, Gilead) respectfully petition for a writ of certiorari to review the decision and judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The court of appeals' opinion is reported at 753 F.3d 1208 and is reproduced at Pet. App. 1a–23a. The court's order denying rehearing or rehearing en banc is unreported and reprinted at Pet. App. 33a–34a. The district court's opinion is available at 2012 WL 6697411 and reproduced at Pet. App. 24a–32a.

JURISDICTION

The court of appeals entered judgment on April 22, 2014, Pet. App. 1a, and denied a timely petition for rehearing en banc on July 29, 2014, *id.* at 34a. On October 15, 2014, the Chief Justice extended the time for filing this petition to and including November 26, 2014. This Court has jurisdiction under 28 U.S.C. § 1254.

STATUTORY PROVISIONS INVOLVED

The appendix to this petition contains relevant statutory provisions.

INTRODUCTION

In the decision below, a divided panel of the Federal Circuit fundamentally recast the judicially created doctrine of obviousness-type double patenting in a way that directly conflicts with this Court's

longstanding precedent on "double patenting." The panel majority concluded that the relevant question is not whether a second patent extends the exclusivity period of a first patent, but whether the second patent expires before the first patent's statutorily decreed term. To do this, the majority determined that the relevant inquiry is the expiration date of the second patent, not which patent issued first. And it held that a second, later-issuing patent can invalidate an earlier-issued patent even if the later-issuing patent expires before that first-issued patent. This Court, however, has squarely held that, for double patenting, "[t]he last [patent], not the first, is void," *Suffolk Co.* v. *Hayden*, 70 U.S. (3 Wall.) 315, 319 (1865), and that "the issue date … determines priority," *Miller* v. *Eagle Mfg. Co.*, 151 U.S. 186, 197 (1894).

The majority tried to justify its break from this Court's established case law by referencing Congress's change in how the term of patent exclusivity is measured. But a court of appeals does not have the freedom to jettison this Court's well-established common law doctrines whenever Congress adjusts patent laws. When Congress legislates against the backdrop of a well-established common law doctrine—as it has with this Court's double-patenting doctrine—Congress must speak directly to the question addressed by the common law in order to alter it. See, *e.g.*, *United States* v. *Texas*, 507 U.S. 529, 534 (1993). The panel majority identified nothing to suggest that Congress even addressed the double-patenting doctrine, much less sought to fundamentally alter it. Nor is there any evidence in the legislative record to indicate that Congress intended to reject this Court's prior holdings. In fact, Congress has consistently expressed its approval of the well-

established double-patenting doctrine as it existed before the decision in this case.

This Court's intervention is needed now. The Federal Circuit's new expansion of the double-patenting doctrine upsets the settled expectations of many thousands of innovators who have relied on the stable, century-old double-patenting doctrine. Numerous patents prosecuted and granted under well-established standards and expectations now risk being invalidated. Indeed, the Federal Circuit's decision in this case invalidated a properly issued patent concerning an indisputably novel invention for safely and effectively treating the flu (TAMIFLU®). Moreover, the Federal Circuit's decision upsets congressional intent and renders numerous other aspects of patent law moot. And the decision will disrupt the operations of the Patent & Trademark Office (PTO), which has established a stable set of double-patenting standards based on this Court's clear statement of the law. The Federal Circuit's rejection of this Court's longstanding doctrine is an important issue of federal law that warrants this Court's immediate review.

STATEMENT OF THE CASE

A. Legal Background

1. The longstanding double-patenting doctrine

a. The double-patenting doctrine has long "preclude[d] one person from obtaining more than one valid patent for the same invention or obvious modifications of the same invention." 3A Donald S. Chisum, *Chisum on Patents* § 9.01 (2014). By 1893, this Court described "well-settled" the common law "rule that two valid patents for the same invention" or varia-

tions of it "cannot be granted … to the same" entity and, when this situation arises, "the later" issuing of the two patents "must be declared void." *Miller*, 151 U.S. at 196–97. According to the Court, "the issue date and not the filing date [of the patent application] determines priority to patents." *Id.* at 197 (discussing *Suffolk*, 70 U.S. (3 Wall.) at 315). The "reason for the rule" is "that the power to create a monopoly is exhausted by the first patent" and that "a new and later patent for the same invention would operate to extend or prolong the monopoly beyond the period allowed by law." *Id.* at 198 (discussing *Odiorne* v. *Amesbury Nail Factory*, 18 F. Cas. 578 (C.C.D. Mass. 1819) (No. 10,430)).

Throughout the 20th Century, courts of appeals faithfully applied this common law double-patenting doctrine. See *In re Woodsome*, 10 F.2d 1003, 1004 (D.C. Cir. 1926) (rule "well settled"); *In re Copeman*, 135 F.2d 349, 351 (CCPA 1943).

After Congress passed the Patent Act of 1952, the Court of Customs and Patent Appeals (CCPA), which was a predecessor to the Federal Circuit, rationalized the double-patenting doctrine by dividing it into two species: statutory double patenting and obviousness-type double patenting. See *In re Van Ornum*, 686 F.2d 937, 942 (CCPA 1982). The key distinction between the two was the relationship between the later claims and the first-issued claims. If the later claims were *identical*, they were void under 35 U.S.C. § 101, which prohibits issuance of two patents on the *same* invention (i.e., statutory double patenting). 686 F.2d at 942. If the later claims were different from the first-issued claims, but only as "mere obvious modifications of, or improvements on, inventions defined in the claims of patents already issued to the same inventors," this was obviousness-type double patenting,

and the later claims could survive, provided they were limited by the expiration of the first-issued patent. *Id.* This was done by providing a "terminal disclaimer" in the later patent to make its term expire on the same date as the first-issued patent. *Id.* at 942–43.

The Federal Circuit adopted the "obviousness-type" double-patenting doctrine as it had existed for over a century. Like its predecessors, the Federal Circuit explained that the doctrine "prevent[s] an inventor from effectively extending the term[s] of exclusivity by the subsequent patenting of variations that are not patentably distinct from the first-patented invention." *Applied Materials, Inc.* v. *Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1568 (Fed. Cir. 1996).

b. Congress has addressed topics that implicate double patenting many times over the past 50 years, but it has never disturbed this common law doctrine. For instance, in the Patent Law Amendments Act of 1984, Pub. L. No. 98-622, 98 Stat. 3383, Congress focused on issues of joint inventorship in situations where multiple related patents are owned by one entity, see 129 Cong. Rec. E5777, E57778 (daily ed. Nov. 18, 1983), but expected that the PTO would "in appropriate circumstances … rejec[t] claims in commonly owned applications of different inventive entities on the ground of double patenting," 130 Cong. Rec. H10525, H10527 (daily ed. Oct. 1, 1984).

More recently, in the Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, 118 Stat. 3596, Congress sought to remedy the limitations in the Patent Law Amendments Act of 1984 that had resulted in patents on inventions from joint research projects being improperly invalidated. As part of the CREATE Act, Congress

indicated that the double-patenting doctrine as it then existed should continue to be a viable doctrine: "The doctrine of 'obviousness-type double patenting,' a judicial doctrine used by courts to prevent patentees from obtaining an unjustifiable extension of the amount of time to exercise a patent's right to exclude, shall apply to" these jointly held patents. H.R. Rep. No. 108-425, at 6 (2004).

2. Patent term changes in response to the General Agreement on Tariffs and Trade

The United States has long measured a patent's term of exclusivity based on the date that the patent issued. By 1861, Congress had established that the term for all patents would be 17 years from issuance of the patent. See An Act in Addition to an Act to Promote the Progress of the Useful Arts, ch. 88, § 16, 12 Stat. 246, 249 (1861); *Siemens's Adm'r* v. *Sellers*, 123 U.S. 276, 285 (1887). This basic term remained unchanged for over a century. See Rev. Stat. § 4884 (1874); An Act to Revise and Codify the Laws Relating to Patents and the Patent Office, and to Enact into Law Title 35 of the United States Code Entitled "Patents," Pub. L. No. 93-593, § 154, 66 Stat. 792, 804 (1952).

By the 1990s, a majority of other nations had adopted the practice of measuring patent terms from the date the patent application leading to the patent was filed, rather than the date that the patent was issued. See Robert Patrick Merges & John Fitzgerald Duffy, *Patent Law and Policy* 59 (3d ed. 2002). In April 1994, the United States entered into a series of multilateral trade agreements that amended the framework of the General Agreement on Tariffs and Trade (GATT). One of those agreements—the Agreement on Trade-Related Aspects of Intellectual Prop-

erty Rights (TRIPS)—sought to encourage international uniformity in how patent terms are measured, providing that each signatory must ensure that a patent's term shall not expire less than 20 years after the application leading to the patent was filed. See U.S. Dep't of State, *Treaties in Force* 490–91 (Jan. 2014); see also TRIPS art. 33.

Congress implemented its TRIPS obligation through the Uruguay Round Agreements Act (URAA), Pub. L. No. 103-465, 108 Stat. 4809 (1994), by making a change to the provision of U.S. law that defines the term of U.S. patents. Under the change, a patent issued from an application filed on or after June 8, 1995, enjoys a term of exclusivity that starts when the patent issues and ends 20 years from the date on which the application was filed. See *id.* § 532(a)(2), 108 Stat. at 4984 (codified as 35 U.S.C. § 154(a)(2)). Congress also addressed the transition from the old system to the new by providing that any patent that had already issued or would issue from an application filed before June 8, 1995, would enjoy a term expiring either 17 years after the issuance date, or 20 years after the application resulting in the patent was filed, whichever date was later. *Id.* § 532(c)(1), 108 Stat. at 4984-85 (codified as 35 U.S.C. § 154(c)); *Bristol-Myers Squibb Co.* v. *Royce Labs., Inc.*, 69 F.3d 1130, 1132 (Fed. Cir. 1995). In some instances, this automatically extended the term of previously issued patents. See *Bristol-Myers Squibb*, 69 F.3d at 1132.

B. Proceedings Below

1. This case concerns a patent covering TAMIFLU®, one of the most successful influenza treatments currently on the market. Pet. App. 25a.

In the early 1990s, researchers at Gilead recognized the limited options for treating the flu and started a program to discover a safer and more effective treatment. Pet. App. 25a. In particular, the researchers sought a potent and safe anti-influenza agent that could be administered orally and that would treat numerous influenza strains. *Id.*

On February 27, 1995, Gilead filed a patent application related to this research, identifying certain compounds that could be used to treat the flu. Pet. App. 26a; CAFC JA358–65, 508, 529. As this research continued to yield additional discoveries, Gilead disclosed them in a series of continuation-in-part applications to the initial February 1995 application, filing these additional applications on June 6, 1995, December 29, 1995, and February 26, 1996. Pet. App. 26a; CAFC JA151, 368–82, 508–09, 529. Each application added scientific detail regarding discoveries about targeted compounds. CAFC JA509.

In mid-1995, after synthesizing and testing hundreds of possible compounds, Gilead's research team discovered oseltamivir. Pet. App. 25a. Studies showed that oseltamivir is highly potent extremely effective against a range of influenza strains, and that it can be administered orally. *Id.*; CAFC JA507.

Seeking to quickly obtain protection for its discovery, Gilead used the provisional patent application process, filing a provisional application for oseltamivir on December 29, 1995. Pet. App. 26a.[1] On

---

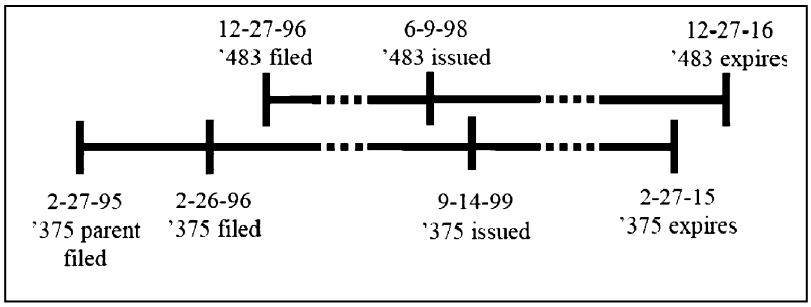
[1] The provisional application process permits an inventor to file an application quickly and establish an early effective date, without some of the formality required by a non-provisional application. *See* 35 U.S.C. § 111(b). In order to use this provisional procedure, Gilead could not file its provisional application in the

December 27, 1996, Gilead filed the required non-provisional application with specific claims covering oseltamivir. Pet. App. 3a; see 35 U.S.C. § 119(e)(1). Based on this non-provisional application, the PTO issued U.S. Patent No. 5,763,483 (the '483 patent) on June 9, 1998. CAFC JA510. The '483 patent covers TAMIFLU® (oseltamivir), its metabolite, its formulation, and its methods of use to treat the flu. Pet. App. 25a–26a. Under the URAA, the '483 patent will expire on December 27, 2016, 20 years after the December 27, 1996 filing date of Gilead's non-provisional application. See 35 U.S.C. § 154(a)(2).

After the '483 patent issued, Gilead filed a terminal disclaimer in the family of applications related to its influenza research, disclaiming any portion of a patent term that extended beyond the expiration date of the '483 patent. Pet. App. 3a. On September 14, 1999—almost a year and a half after the '483 patent issued—the PTO issued U.S. Patent No. 5,952,375 (the '375 patent) based on the continuation-in-part application that Gilead previously had filed on February 26, 1996. Pet. App. 26a; CAFC JA507. Because the continuation-in-part application that ultimately led to the '375 patent was filed after enactment of the URAA, the '375 patent's term is measured from the earliest application to which the patent claims priority, namely the initial February 27, 1995 application. Pet. App. 26a; CAFC JA508. Accordingly, the '375 patent is scheduled to expire on February 27, 2015. CAFC JA508. The following diagram shows the timelines for the '375 and '483 patents:

---

same family of applications that it had previously filed and thus potentially exposed the patent to additional prior art. *See id.*



Pet. App. 4a.

In June 1999, the Food & Drug Administration (FDA) approved oseltamivir for treating the flu. CAFC JA109, 138–39, 507.

2. In February 2011, and again in August 2011, Natco informed Gilead by letter that it had filed Abbreviated New Drug Applications (ANDAs) with the FDA, seeking approval to market generic versions of TAMIFLU® before the expiration of the '483 patent. Pet. App. 27a; see also 21 U.S.C. § 355(j)(2)(vii)(IV). After each letter, Gilead filed a complaint against Natco, alleging that Natco's ANDAs infringed the '483 patent. Pet. App. 27a; see 35 U.S.C. § 271(e)(2)(A); CAFC JA505. Natco in turn answered and counterclaimed, alleging only that the claims of the '483 patent are invalid under the obviousness-type double-patenting doctrine, not that they are not novel or truly inventive. Pet. App. 5a, 27a. According to Natco, the '375 patent rendered the '483 patent invalid for double patenting, even though the '375 patent issued after the '483 patent and expires before it and therefore could not conceivably have extended the term of the first-issued patent.

3. Gilead and Natco cross-moved for summary judgment on Natco's double-patenting defense, and the district court granted summary judgment to Gilead. The court viewed the motions as presenting a

"narrow issue" of "whether the '375 patent can be used as a reference patent for purposes of determining if the '483 patent is an unlawful extension of the '375 patent." Pet. App. 29a. Without addressing whether one patent was obvious in light of the other, the court concluded simply that because the '483 patent issued before and expires after the '375 patent, the '483 patent could not "unlawfully exten[d] the terms of the '375 patent." *Id.* at 30a–31a. The court also determined that "the lifespan of Gilead's patents seem to be a result of changes in patent law." *Id.* at 32a. Natco conditionally stipulated to infringement of two claims of the '483 patent and appealed the district court's summary judgment ruling. *Id.* at 5a.

4. On appeal, a divided panel of the Federal Circuit determined that "the district court erred in concluding that the '483 patent could not be invalid for double patenting" based on the '375 patent. Pet. App. 16a. The majority held that "a patent that issues after but expires before another patent" can "qualify as a double patenting reference for that other patent," *id.* at 6a.

In reaching that conclusion, the majority saw "little import here in the fact that the '483 patent issued first." Pet. App. 12a. It recognized the century's worth of consistent case law measuring double patenting based on which patent issued first, and invalidating only the second-issuing patent, but rejected that authority in a single sentence, stating simply that "those cases dealt with patents to which the URAA did not apply." *Id.* Critically, the judges did not identify anything in the URAA that changed the double-patenting doctrine, or that even suggested Congress intended such a change. Instead, the majority stated that earlier cases looked to "issue dates" because they supposedly "previously served as a reliable stand-in

for the date that really mattered—patent expiration." *Id.* And, rather than identify any congressional intent, the majority looked to "policy concerns" that, it asserted, warranted this change to the double-patenting doctrine, suggesting that use of issuance dates to establish a double-patenting reference allows for "gamesmanship during prosecution" and potential arbitrariness. *Id.* at 13a. The majority further asserted that "using the expiration date as a benchmark in post-URAA cases of obviousness-type double patenting preserves the ability of inventors to use a terminal disclaimer of later-expiring patents." *Id.* at 15a.

Ultimately, the majority reasoned "that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention." Pet. App. 10a. And it concluded that this "principle is violated when a patent expires and the public is nevertheless barred from practicing obvious modifications of the invention claimed in that patent because the inventor holds another later-expiring patent with claims for obvious modifications of the invention." *Id.* at 11a. Regardless of which patent issued first, the '483 patent expires later and would, in the majority's view, prevent the public from practicing obvious modifications of the '375 patent, which "violates the public's right to use the invention claimed in the '375 patent … after the '375 patent expires." *Id.*

According to the dissent, the majority's "expansion" of the obviousness-type double-patenting doctrine "is unwarranted." Pet. App. 17a. The dissent correctly explained that the double-patenting doctrine served a particular policy—it was used "to curtail [the] practice" of patentees filing successive continuations to obtain *additional* patent terms for obvious modifica-

tions where earlier patents and applications did not qualify as prior art. *Id.* As the dissent stated, after the URAA, "successive continuations generally do not result in any additional patent term" and thus "a primary motivation behind the doctrine … is largely no longer applicable." *Id.* at 18a.

Although the dissenting judge would retain the doctrine, he would "proceed more cautiously" here because "courts should be reluctant to create or expand judge-made exceptions to statutory grants." Pet. App. 19a. According to the dissent, neither of the two justifications for the obviousness-type double-patenting doctrine justified expanding the doctrine. *Id.* This "case does not raise the policy concern regarding subsequent extensions of patent term." *Id.* If "the '375 patent had never issued, Gilead would certainly be entitled to the '483 patent's 2016 expiration date." *Id.* at 19a–20a. And "this case does not involve the potential for harassment by multiple assignees" because "the '375 patent is subject to a terminal disclaimer … and thus is only enforceable so long as it and the '483 patent are commonly owned." *Id.* at 20a.

The dissenting judge also found nothing in Gilead's conduct that could warrant the majority's expansion of the double-patenting doctrine. Pet. App. 20a. He explained that under 35 U.S.C. § 154(b), a patentee desiring the longest expiration date "must forfeit its earlier claim to priority and subject any new patent to intervening prior art." *Id.* "Gilead followed that precise approved course" in obtaining the '483 patent and "gave up roughly 10 months of priority." *Id.*

The dissenting judge also debunked the majority's core rationale for expanding the double-patenting doctrine, namely "the flawed assumption that upon expiration of a patent, the public obtains an absolute right to use the previously-claimed subject matter."

Pet. App. 21a. He reasoned that not even a patentee, much less the public, has an unmitigated right to "use" the claimed subject matter of the patent. *Id.* at 21a–22a. Moreover, he expressed "a number of concerns" that "counsel for a more restrained approach." *Id.* at 23a. In particular, the dissent identified the interplay between the majority's new rule and "the new 'first-inventor-to-file' provision of the Leahy-Smith American Invents Act" (AIA), which will produce unwarranted and "unforeseen consequences." *Id.*

REASONS FOR GRANTING THE PETITION

This Court should grant the petition to rectify the Federal Circuit's erroneous refashioning of the double-patenting doctrine. The panel majority's decision below directly conflicts with this Court's double-patenting decisions, as well as the precedent of the lower courts that have faithfully followed this Court's case law for more than a century. The majority identified nothing to suggest that Congress intended to fundamentally alter this well-established law. If anything, Congress has left it undisturbed while enacting laws that directly implicate this doctrine, such as the appropriate term of patents or the validity of commonly owned or controlled patents on related inventions.

This Court should intervene immediately because of the important federal question presented. The majority's decision here will upset the well-settled expectations of innovators who have prosecuted and obtained patents that are valid under this Court's longstanding precedent, but who now face the prospect that many of their patents may be invalidated by the sudden revision of a well-established doctrine by the court with exclusive jurisdiction over all patent appeals. Moreover, the majority's decision upsets

congressional intent and renders numerous other aspects of patent law moot. A court of appeals does not have the authority to fundamentally undermine this Court's well-established case law and Congress's intent based on its own policy concerns.

In sum, the Court should grant the petition.

I. CERTIORARI IS WARRANTED TO RESOLVE THE CONFLICTS CREATED BY THE DECISION BELOW.

A. The Decision Below Directly Conflicts With This Court's Double-Patenting Precedent And Well-Established Lower Court Precedent.

1. In the decision below, the majority held that a second-issuing, but earlier-expiring patent could be used to invalidate a patent that was granted first and that expires later. Pet. App. 16a. The majority reasoned that, because the second patent to issue claimed an earlier application date and therefore expired earlier, it could be used to invalidate the first patent. The majority's holding directly conflicts with this Court's decision in *Suffolk Co.* v. *Hayden*, 70 U.S. (3 Wall.) 315 (1865), and its progeny.

In *Suffolk*, this Court established that the relevant inquiry for double patenting is which patent issues first and that only the second patent to issue—not the first—should be invalidated. There, the patentee had filed an initial patent application with the patent office in December 1854. *Id.* at 316. The patentee filed a second patent application in June 1857, and in December 1857, the patent office issued a patent to him on this second application. *Id.* In September 1860, the patent office finally granted the patentee a patent on the first application that was filed in December 1854. *Id.* In an infringement suit involving only the Decem-

ber 1857 patent, which had issued first, the defendant argued that the second-issuing patent consisted of "the same improvement embraced in the patent of the 1st December, 1857" and "insisted that, for this reason, this prior patent"—namely, the December 1857 patent—"is void." *Id.* at 319. The Court rejected this argument, characterizing it as an "obviou[s] … misapprehension" of the law. *Id.* Of the two patents, the Court held, "[t]he last, not the first, is void." *Id.*

In *Miller* v. *Eagle Manufacturing Co.*, 151 U.S. 186 (1894), the Court summarized its precedent on double patenting, reconfirming the holding in *Suffolk* that the date a patent *issues* is the point of departure and that the second, not the first, patent is invalidated. According to the *Miller* Court, *Suffolk* held that when a patentee holds two patents for the same invention, "the later one [i]s void, although the application for it was filed first, thereby deciding that it is the *issue date* … which determines priority to patents issued to the same inventor on the same machine." *Id.* at 197 (emphasis added). Indeed, in *Miller*, the Court considered it a "well-settled rule" that when a patentee holds two patents for the same invention, "the *later* must be declared void." *Id.* at 196–97 (emphasis added). And the *Miller* Court discussed other cases reaching the same conclusion. The Court explained that in *McCreary* v. *Pennsylvania Canal Co.*, 141 U.S. 459 (1891), for example, it had held that "where a party owned two patents, showing substantially the same improvement, the *second* was void." *Miller*, 151 U.S. at 197 (emphasis added).

The *Miller* Court traced "the reason for the rule" that the second patent, not the first, is invalid back to Justice Story's decision in *Ordiorne* v. *Amesbury Nail Factory*, 18 F. Cas. 578 (C.C.D. Mass. 1819) (No. 10,430), which, in the Court's view, established "that

the power to create a monopoly is exhausted by the first patent." *Miller*, 151 U.S. at 198. Justice Story reasoned that an "inventor can have but a single valid patent for his invention" and that "the *first* he obtains, while it remains unrepealed, is an estoppel to any future patent for the same invention." 18 F. Cas. at 579. Justice Story explained further that the "public have by the *first patent* acquired an inchoate interest" in the invention that cannot be upset by a later-issuing patent. *Id.* (emphasis added). And the Court has echoed this same rationale in later cases, explaining that the prohibition against double-patenting arises "because the *first patent* exhausts the statutory right secured by the act of Congress." *Caliga* v. *Inter Ocean Newspaper Co.*, 215 U.S. 182, 189 (1909) (emphasis added).

The majority's decision below that the first patent to issue can be invalidated by a later-issuing second patent thus not only directly contravenes the holdings of this Court, but it conflicts with the fundamental reasoning underlying those decisions. The majority's reasoning—that the public has a right to use a patented invention as soon as any patent covering it expires, and that any patent that could be viewed as extending the exclusive rights to that invention, or obvious variations of it, violates the double-patenting doctrine, Pet. App. 10a–11a—contradicts two central tenets of this Court's double-patenting decisions.

First, it ignores the principle that the first-issued patent, not the second, establishes the public's expectations for when the period of exclusivity in the "invention" will end. Contrary to the majority's rationale, the public's expectations cannot be set until exclusive rights are actually granted—at issuance of a patent. As Justice Story explained, the "public have by the *first patent* acquired an inchoate interest" in

the invention. *Odiorne*, 18 F. Cas. at 579. The expectation at that point is that the public cannot use the invention without authorization for the period defined in § 154. Pet. App. 10a–11a. By the time the second patent issues, the public's interests and expectations in the "invention" and obvious variations of it have already been established. Here, the fact that the '375 patent expires *before* the '483 patent means that the '375 patent is incapable of affecting the public's interest in the "invention." Simply put, the public, due to the earlier issuance of the '483 patent, could have no expectation of being able to use the invention before the exclusive rights conveyed by that patent expired in 2016.[2]

Second, the majority's reasoning contravenes the principle that the first patent to issue "exhausts the statutory right secured by the act of Congress." *Caliga*, 215 U.S. at 189; *Miller*, 151 U.S. at 198 ("the power to create a monopoly is exhausted by the first patent"). Contrary to the majority's rationale, a second patent to issue cannot affect the first patent because, without a terminal disclaimer, it is a nullity and should not have issued. See *Miller*, 151 U.S. at 198 ("no patent can issue for an invention actually

---

[2] The decision below proceeds from the false premise that the public has an unfettered right to use a patented invention when the patent expires. As the dissent explains, the majority's erroneous assumption "ignores the possible existence of overlapping patents." Pet. App. 21a. For instance, one patent may encompass another (termed "domination") without running afoul of the double-patenting doctrine. *See In re Kaplan*, 789 F.2d 1574, 1577–78 (Fed. Cir. 1986); *Gen. Foods Corp.* v. *Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278–79 (Fed. Cir. 1992) (finding domination but no double patenting). Moreover, there are "[s]till other legal and regulatory bars [that] may prohibit the public from practicing the claimed subject matter." Pet. App. 21a.

covered by a former patent"). According to Justice Story, issuance of the second patent was "merely [a] ministerial ac[t] of the officers of the government" that cannot upset the rights established by the first patent. *Odiorne*, 18 F. Cas. at 579. A later-issuing second patent cannot retroactively invalidate an earlier-issued first patent.

2. Because the decision below conflicts with this Court's well-established precedent, it also creates a conflict with lower court decisions that have faithfully followed the Court's double-patenting law. For instance, the panel's holding conflicts with the decisions of the D.C. Circuit, which has made clear that it was "well settled" in that Circuit "that an applicant may not have two patents for the same invention, and, if two such patents are granted, *the latter is invalid*." *Woodsome*, 10 F.2d at 1004 (emphasis added).

Likewise, the decision below conflicts with the decisions of the CCPA, as well as the Federal Circuit's own case law. According to the CCPA, the double-patenting doctrine provides that the claims in a patent application "may not be allowed *over the patent already granted* to the applicant, since he has already obtained in his patent all the protection to which he is entitled." *Copeman*, 135 F.2d at 351 (emphasis added). Indeed, because the CCPA reviewed decisions from the PTO, the fundamental question for double-patenting was whether "an applicant's *issued patent* may be used in rejecting the claims" before the PTO in a separate application. *Id.* (emphasis added); see *In re Vogel*, 422 F.2d 438, 441 (CCPA 1970) (same); *In re Zickendraht*, 319 F.2d 225, 227 (CCPA 1963) (same). The panel majority's conclusion that the second patent to issue can invalidate the first-issued patent is fundamentally inconsistent with these decisions.

The conflict between the decision below and the CCPA's decision in *In re Laughlin*, 48 F.2d 921 (CCPA 1931), is illustrative. In *Laughlin*, the applicant filed a second application over a year and a half after its first application, but the second application issued first on February 14, 1925. *Id.* at 922. The applicant amended his first patent application in February 1928, and the patent office rejected the application on double-patenting grounds. *Id.* The CCPA affirmed, reasoning that granting a patent on the first application "would result in double patenting, or a *second patent* for precisely the same principle of the *first* in no way claimed to be improved or altered in any patentable regard." *Id.* at 925 (emphases added). The conclusion and analysis adopted by the majority below is completely inconsistent with *Laughlin*.[3] Under modern practice, the PTO would not grant the second patent with a term that extended past the one set by the first-issued patent.[4]

The majority's decision also conflicts with the Federal Circuit's own prior case law. In *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985), for instance, the Federal Circuit stated that the purpose of the double-patenting doctrine is to stop "the issuance of the claims in a *second patent* [that are] not patentably distinct from the claims of the *first patent*." *Id.* at 892 (emphases added). Indeed, prior to the decision below, the Federal Circuit had consistently held that the double-patenting doctrine invalidates a second,

---

[3] CCPA case law is "binding as precedent" on the Federal Circuit. *S. Corp.* v. *United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982) (en banc).

[4] Terminal disclaimers were not used to avoid obviousness-type double-patenting rejections until the 1960s. *See, e.g.*, *Van Ornum*, 686 F.2d at 942 (discussing evolution of doctrine).

subsequent patent that is not patentably distinct from a first, earlier-issued patent. See *Eli Lilly & Co.* v. *Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012) (doctrine prohibits "issuance of the claims in a *second patent* not patentably distinct from the claims of the *first patent*" (emphases added)); *Ga.-Pac. Corp.* v. *U.S. Gypsum Co.*, 195 F.3d 1322, 1326 (Fed. Cir. 1999) (per curiam) (same), *amended on other grounds*, 204 F.3d 1359 (Fed. Cir. 2000); *Applied Materials*, 98 F.3d at 1568 (same). The Federal Circuit had even stated plainly that all "'double patenting rejections … rest on the fact that a patent has been issued and later issuance of a second patent will continue protection, beyond the date of expiration of the first patent.'" *Sun Pharm. Indus. Ltd.* v. *Eli Lilly & Co.*, 611 F.3d 1381, 1389 (Fed. Cir. 2010) (emphasis omitted) (quoting *Kaplan*, 789 F.2d at 1579–80).

Further, contrary to the majority's sole focus on the expiration date of patents, the Federal Circuit has previously stated that the double-patenting doctrine prevents the issuance of a patent that would "'effectively extend the life of the patent that would have the *earlier of the two issue dates*.'" *Symbol Techs., Inc.* v. *Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991) (quoting *Gerber Garment Tech., Inc.* v. *Lectra Sys., Inc.*, 916 F.2d 683, 686 (Fed. Cir. 1990)) (emphasis added). And the court has even recognized that the second patent to issue "cannot be used as an obviousness-type double patenting reference against" the first patent to issue. *Amgen Inc.* v. *F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1354 n.5 (Fed. Cir. 2009); *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (recognizing post URAA that obviousness-type double patenting "prohibits the issuance of claims in a second patent that are 'not patentably distinct from the claims of the first patent'").

B. The Panel Majority's Rationale For Its Decision Is Meritless.

The majority below acknowledged the long line of double-patenting cases that it refused to follow. Pet. App. 12a (citing, among others, *Miller* and *Suffolk*). It simply dismissed those cases in a single sentence as cases that "dealt with patents to which the URAA did not apply." *Id.* Of course, it is not the province of a court of appeals to reject decisions of this Court, even when there is an intervening Act of Congress. See, *e.g.*, *Rodriguez de Quijas* v. *Shearson/Am. Express, Inc.*, 490 U.S. 477, 484 (1989) ("Court of Appeals should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions."). The court of appeals' cavalier dismissal of this Court's prior decisions, by itself, warrants this Court's review. But what makes the issue particularly worthy of further review is that the panel's analysis is both incorrect and illogical.

1. Congress has embraced, not altered, the longstanding double-patenting doctrine.

Congress is presumed to legislate against the backdrop of the common law. *Astoria Fed. Sav. & Loan Ass'n* v. *Solimino*, 501 U.S. 104, 108 (1991) ("where a common-law principle is well established … the courts may take it as given that Congress has legislated with an expectation that the principle will apply except 'when a statutory purpose to the contrary is evident'") (citations omitted). And "[i]n order to abrogate a common-law principle, the statute must 'speak directly' to the question addressed by the common law." *United States* v. *Texas*, 507 U.S. at 534. Obviousness-type double patenting has been a part of the common law for over a century and a half, and there is no indication that Congress has ever attempted to

alter it, much less fundamentally change it the way the Federal Circuit has.

Contrary to the majority's understanding, Congress has done nothing to disturb this doctrine while nonetheless addressing the appropriate term of a patent. For example, in the URAA, Congress said nothing about double patenting despite the fact that it specifically determined what the appropriate term of a U.S. patent should be. Nor is there anything in the law or in the legislative history of the URAA that suggests Congress intended to measure "post-URAA" patents differently under the double-patenting doctrine than pre-URAA patents.

In fact, Congress' actions establish the contrary—its decision reflected in § 154(b) to give "transitional" patents the "longer" of the two types of patent terms reflects a clear congressional intent not to disturb the pre-existing expectations of patent owners and the public in pre-URAA patents, and to provide any benefits the new standard might bestow on these older patents.

Ultimately, if anything can be drawn from congressional activity over the century-plus existence of the common law double-patenting doctrine, it is that Congress has endorsed the form of that doctrine as it existed before the panel majority's decision in this case. For instance, in the CREATE Act, which was passed after the URAA, Congress directly addressed the situation of commonly held and closely related patents in the context of parties engaged in joint research activities. Pub. L. No. 108-453, § 2, 118 Stat. at 3596 (amending 35 U.S.C. § 103(c)). Instead of placing additional constraints on the terms of these related patents, Congress allowed parties to a joint research agreement to overcome obviousness rejections over earlier-issued patents owned by their re-

search partners by using the same double-patenting law that governs patents and applications that are owned by one entity. *Hubbell*, 709 F.3d at 1148–49. Congress could have easily changed the obviousness-type double-patenting doctrine to specify that the term of all patents invoking the CREATE Act would revert to the earliest-expiring patent. It did not. Instead, Congress provided that applicants could overcome rejections based on previously issued patents owned by joint research partners by filing a terminal disclaimer—the same mechanism that has been used for decades at the PTO to resolve double-patenting issues that arise for *later issuing* patents. 35 U.S.C. § 103(c) (2004) (expanding the parties who can use a terminal disclaimer); see also *id.* § 253(b) (allowing terminal disclaimers); *Manual of Patent Examining Procedure* § 1490 (9th ed. 2014) (MPEP) (setting forth procedures for terminal disclaimers). Thus, when it enacted the CREATE Act, Congress expressly stated that the double-patenting doctrine as it then existed would apply to these patents:

> Patents issued under this Act shall be enforceable in the same manner, to the same extent, and for the same term as when patents are issued to a common owner or are subject to common assignment. The doctrine of 'obviousness-type double patenting,' a judicial doctrine used by courts to prevent patentees from obtaining an unjustifiable extension of the amount of time to exercise a patent's right to exclude, shall apply to such patents.

H.R. Rep. No. 108-425, at 6 (collecting cases).

2. Policy concerns cannot justify the decision below.

Lacking any indication that Congress intended to disturb (rather than embrace) the longstanding double-patenting doctrine either via the URAA or elsewhere, the majority retreated to "policy" reasons for recasting the foundational principles of the doctrine. The majority first reasoned that its new rule is consistent with the pre-existing doctrine because patent issuance dates were merely a proxy for what "really matter[s]—patent expiration." Pet. App. 12a. There is, however, no need for a "proxy" to determine the expiration of a patent—it has been legislatively defined in § 154. Moreover, under this Court's precedent, the relevant factor defining the public's expectations is the expiration of the first patent to issue—"the first patent exhausts the statutory right secured by the act of Congress," *Caliga*, 215 U.S. at 189; *Miller*, 151 U.S. at 198 ("the power to create a monopoly is exhausted by the first patent"), and sets the public's expectation to an "inchoate interest" in the patent. *Odiorne*, 18 F. Cas. at 579. That principle is especially pertinent in this case where the first-issued '483 patent established the public's interest in a 2016 expiration date. The later issuance of the '375 patent, which has an earlier expiration date, could do nothing to upset the public's (and the patentees') expectation of a 2016 expiration date. The panel majority's approach to double patenting is simply inconsistent with this Court's double-patenting decisions. And its other policy concerns are similarly unavailing.

a. The majority's "gamesmanship" concerns are unfounded.

The majority asserted that focusing on the date a patent issued could lead to "gamesmanship during prosecution." Pet. App. 13a. But this policy concern

can be eliminated by Congress "any time it chooses," and such "policy arguments … are thus best addressed to Congress," not courts. *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997). Indeed, in the URAA, Congress sought to eliminate the gamesmanship of "submarine" patents—intentionally delaying issuance of patents—*not* by altering the double-patenting doctrine, but by changing to a system that measures patent terms from the filing of the application, rather than issuance of the patent. Karen Tripp & Linda Stokley, *Changes in U.S. Patent Law Effected by the Uruguay Round Agreements Act—The GATT Implementation Legislation*, 3 Tex. Intell. Prop. L.J. 315, 318 (1995). Any remaining opportunity for gamesmanship is slight and does not warrant deviating from this Court's longstanding precedent.[5]

---

[5] Indeed, the majority's hypothetical gamesmanship scenario relies on an applicant "arranging for the application claiming the latest filing date to issue first." Pet. App. 13a. But the timing of a patent's issuance depends at least as much on the PTO as it does on individual applicants. And Congress has already structured the patent system to limit such a strategy. First, later applications become subject to additional prior art with later filing dates (as noted by the dissent below, *id.* at 20a). Second, this strategy likely cannot produce an extension of more than 18 months because all applications are published 18 months after filing, 35 U.S.C. § 122(b)(1)(A), making an earlier application prior art to a later application. Moreover, now that, under the AIA, patents are awarded based on a first-to-file standard rather than a first-to-invent basis, delays in filing could deprive the first inventor of a patent if a later inventor files an application first. *Id.* § 102(a)(2). Given Congress's policy choices to make these changes while leaving double patenting untouched, there is no room for the Federal Circuit to make its own policy choice to expand the scope of obviousness-type double patenting.

b. The majority's "changed circumstances" are makeweight.

The panel majority asserted further that changed circumstances justify a changed rule, stating that under the URAA "there are now instances, like here, in which a patent that issues first does not expire first." Pet. App. 12a. This reasoning is unavailing.

As an initial matter, this reasoning ignores that Congress actually engaged that question in the URAA, and concluded it was appropriate to give patents longer, rather than shorter, terms. Under § 154(c)(1), Congress decreed that transitional patents shall enjoy the longer of either the old term (17 years from issuance) or the new term (20 years from filing date).

The situation framed by the majority also is not new—before the URAA, a patent could issue after, but expire before a related patent. For instance, as part of the Hatch-Waxman Act in 1984, Congress provided for patent term extensions to compensate for regulatory delays caused by the FDA that effectively prohibited patentees from marketing their inventions. Pub. L. No. 98-417, § 201(a), 98 Stat. 1585, 1598-99 (1984) (codified at 35 U.S.C. § 156); see also *Pfizer Inc.* v. *Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361, 1364 (Fed. Cir. 2004). But in doing so Congress provided that at most one patent could receive this term extension for a given FDA application. 35 U.S.C. § 156(c)(4). Thus, under this scheme, a first-issuing patent could receive a term extension, and a continuation could receive none, meaning that the first-issuing patent would expire later.[6]

---

[6] *See Patent Term Extensions*, http://www.uspto.gov/patents/resources/terms/156.jsp (last modified Apr. 4, 2012) (listing several hundred patents that received term extensions and pro-

c. The majority's new rule leads to more, not less, instability.

The panel majority also asserted that basing the double-patenting doctrine on the issuance date could lead to "vacillations in an inventor's period of exclusivity" based on which patent issues first and that this is "too arbitrary" and "uncertain" to allow. Pet. App. 13a–14a. Not so. The date that the first patent issues has consistently dictated the period of exclusivity. Which patent issues first may depend on a variety of factors, not the least of which is the PTO's workload. But that has always been true. In *Suffolk*, for instance, the Court remarked that the reason the applicant's first application was not granted first was not because the applicant "was guilty of any laches, or was in any default in reference to the delay of the commissioner to act on his first application." 70 U.S. (3 Wall.) at 316. Yet, "the issue date and not the filing date … determines priority to patents." *Miller*, 151 U.S. at 197.

The majority claimed that its new rule—allowing a later-issuing patent to cut short the term of an earlier-issued patent—"guarantees a stable benchmark that preserves the public's right to use the invention." Pet. App. 15a. But truncating existing patent rights *in medias res* does not promote stability, and the majority's assertion to the contrary is illogical. Even if the Federal Circuit had the latitude to favor "a stable benchmark" as a policy matter (which it does not), stability is better served by following well-established precedent on double patenting, rather than disturb-

---

duced this situation, such as U.S. Patent No. 5,451,233, which issued Sept. 19, 1995 and expired Dec. 15, 2010. A continuation of the '233 patent, U.S. Patent No. 5,749,888, descended from an application filed April 15, 1986, was issued May 12, 1998, and expired Aug. 20, 2008, two years before the '233 patent.).

ing settled expectations by shortening patent terms based on the issuance of later patents.[7]

d. The MPEP is inapplicable and irrelevant.

Finally, the majority purported to support its decision with MPEP § 804.I.B.1, which states that if two pending patent applications are subject to a provisional double-patenting rejection, a terminal disclaimer should be required for the earlier-filed application. Pet. App. 15a-16a. That rule, however, was in effect prior to the URAA's changes in patent terms on June 8, 1995, see MPEP § 804.I.B (6th ed. Jan. 1995); *Manual of Patent Office Procedure* § 9-9 (1948), and thus cannot justify the majority's reasoning in light of the URAA's passage.

The majority also overlooked the fact that this rule is entirely inapplicable to the facts the PTO faced here since the rule applies only to pending *applications* and does not address the situation in which there is an already issued patent. MPEP § 804.I.B.1 (9th ed. Mar. 2014). In any event, the MPEP is not law—nor even a regulation—and, as the Federal Circuit routinely states, it "is not binding on th[e] court." *Hubbell*, 709 F.3d at 1146. MPEP § 801.I.B.1 cannot justify the majority's departure from this Court's well-established precedent.

---

[7] Congress made a policy choice to allow inventors to obtain multiple related patents. As Natco explained below, "Section 102 includes provisions that exclude the inventor's own work as qualifying prior art." Natco CAFC Br. 20 n.8. This policy applied before the AIA, 35 U.S.C. § 102(e) (2012) (certain patents and public applications "by another" qualify as prior art), and Congress has continued it in the AIA, *id.* § 102(a)(2) (2013) (patent or application must name "another inventor" to be prior art).

II. THE DECISION BELOW PRESENTS AN IMPORTANT ISSUE OF FEDERAL LAW.

The question presented raises in an important issue of federal law that warrants this Court's immediate review. The Federal Circuit's expansion of the obviousness-type double-patenting doctrine will have far-reaching and harmful effects beyond this case.

For decades, innovators have relied upon what they previously understood to be a stable set of rules for obviousness-type double patenting, and have accordingly conformed their patent prosecution activities to comply with those rules. See, *e.g.*, Charles L. Gholz, *The Law of Double Patenting in the CCPA*, 4 APLA Q.J. 261, 261 (1976) ("[T]he CCPA has established an integrated body of case law which … has the indisputable virtues (particularly when compared to prior case law) of being easy to apply and relatively predictable of result."). The Federal Circuit's new rule for obviousness-type double patenting upsets those settled expectations and will cause turmoil for companies that now face the prospect that their patents may be invalidated because they relied on rules that have now been cast aside. The new rule will also serve as the basis for further erosions of both the public's and patentees' settled expectations.[8]

Moreover, the panel majority's decision upsets congressional intent and renders numerous other aspects of patent law moot. As explained, Congress implemented the URAA by providing that the term of a patent that issues from an application filed before June

---

[8] The Federal Circuit has already indicated that it will build upon its recasting of the obviousness-type double-patenting doctrine, despite congressional approval of the prior form of the doctrine. *See AbbVie Inc.* v. *Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1381 (Fed. Cir. 2014).

7, 1995 is the longer of 17 years from issuance or 20 years from the earliest filing date for the application. The same law provides that a patent issuing from an application filed on or after June 7, 1995 enjoys a term of 20 years from its earliest filing date. Congress did not attach additional conditions to these term provisions. Under the majority's rationale, however, a patent issuing from an application filed after June 7, 1995 will necessarily truncate the statutorily prescribed 17- or 20-year term of a patent issuing from an application filed before this date—in direct conflict with Congress's explicit statutory design. This arises despite the fact that the patent owner was in no way responsible for the different patent terms—those different terms are provided as a consequence of the statutory scheme Congress enacted. The Federal Circuit's new rule will upset this congressional intent based on the court's *current* policy preferences.

Additionally, when Congress passed the American Inventors Protection Act of 1999, it provided a granular mechanism to compensate patent applicants for delays by the PTO. See 35 U.S.C. § 154(b)(1)(A) (extending patent terms for delays during prosecution). This authority reflected Congress's intent to vary the term of each patent based on the individual circumstances encountered during examination of the application resulting in the patent. Congress could have exempted related patents from these standards, or adopted a blanket rule specifying a single term for every patent that might relate to an invention in any of these family members. It did not. Now, however, the decision below could deprive patent owners of these congressionally granted term adjustments.

The holding is also irreconcilable with the body of law governing the "one-way" or "two-way" test for double patenting. Under that body of law, a later-

issuing patent is subjected to a more stringent test to establish double patenting if the reason its issuance was delayed is not the fault of the patent applicant. See, *e.g.*, *In re Emert*, 124 F.3d 1458, 1461 (Fed. Cir. 1997). Specifically, if the challenged patent issued later because of PTO delays, the challenged claims must not only be shown to be obvious over the earlier-issued claims, but the converse must also be proven—the later-issuing claims must make the earlier-issued claims obvious. *Id.* The Federal Circuit grounded this doctrine on this Court's longstanding precedents. *In re Goodman*, 11 F.3d 1046, 1053 (Fed. Cir. 1993) (citing *Miller*, 151 U.S. at 197). The Federal Circuit had consistently applied this doctrine for two decades. See *id.* at 1046, 1053; *Hubbell*, 709 F.3d at 1140, 1149–50. And the doctrine was a stable part of the double-patenting law that Congress approved in connection with 2004's CREATE Act. See, *supra*, Section I.B. The majority's new rule renders this entire body of law moot by making the predicate inquiry of the two-way test—which patent issued later and why—irrelevant. The only inquiry under the majority's rule is which patent expires first.

The majority's expansion of the double-patenting doctrine not only upsets the expectations of patent holders, the public, and Congress, but also disrupts the PTO's operations. To this point, the PTO has issued patents under a stable set of standards, guarding the patent protection bestowed on the first-issued patent but rejecting the claims of a potentially second-issuing patent (unless there is a terminal disclaimer in the second patent). Now, the Federal Circuit has thrown that system out and would require the PTO to establish a new set of procedures and standards. Indeed, unless the PTO derives procedures for trying to claw back already issued patents

that have a longer exclusivity period than a second-issuing patent, the Federal Circuit's new standard would make courts—rather than the PTO—the primary arbiters of which patents should have been granted.

CONCLUSION

For the foregoing reasons, the petition for certiorari should be granted.

Respectfully submitted,

M. PATRICIA THAYER
SIDLEY AUSTIN LLP
555 California Street
Suite 2000
San Francisco, CA 94104
(415) 772-1200

CARTER G. PHILLIPS*
JEFFREY P. KUSHAN
RYAN C. MORRIS
JAMES A. HIGH
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
cphillips@sidley.com

Counsel for Petitioners

November 26, 2014

* Counsel of Record

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS,
FEDERAL CIRCUIT

No. 2013-1418

GILEAD SCIENCES, INC., HOFFMANN-LA ROCHE, INC., F. HOFFMANN-LA ROCHE, LTD., AND GENENTECH, INC.,
Plaintiffs-Appellees,

v.

NATCO PHARMA LIMITED AND NATCO PHARMA, INC.,
Defendants-Appellants.

April 22, 2014

Opinion

Before RADER, *Chief Judge*, PROST and CHEN, *Circuit Judges*.

Opinion for the court filed by Circuit Judge CHEN. Dissenting opinion filed by Chief Judge RADER.

CHEN, *Circuit Judge*.

Gilead Sciences, Inc. ("Gilead") owns United States Patent Nos. 5,763,483 and 5,952,375, which are directed to antiviral compounds and methods for their use. While the patents list the same inventors and the written descriptions disclose similar content, they do not claim priority to a common patent application and have different expiration dates. Gilead sued Natco Pharma Limited ("Natco") for infringement of the '483 patent after Natco filed a request with the Food and

Drug Administration seeking approval to market a generic version of one of Gilead's drugs that is allegedly covered by the '483 patent. In response, Natco asserted that the '483 patent was invalid for obviousness-type double patenting over Gilead's '375 patent. In Gilead's view, the '375 patent cannot serve as a double patenting reference against the '483 patent because, even though the '483 patent's expiration date is twenty-two months after the '375 patent's expiration date, the '375 patent issued after the '483 patent.

The United States District Court for the District of New Jersey agreed with Gilead and, pursuant to a stipulation, granted it final judgment on infringement. Natco appeals that judgment and argues that the '375 patent should qualify as an obviousness-type double patenting reference for the '483 patent because it expires before the '483 patent. Because the obviousness-type double patenting doctrine prohibits an inventor from extending his right to exclude through claims in a later-expiring patent that are not patentably distinct from the claims of the inventor's earlier-expiring patent, we agree with Natco that the '375 patent qualifies as an obviousness-type double patenting reference for the '483 patent. We therefore vacate the district court's decision and remand.

I

The '375 and '483 patents were issued to the same inventors and are commonly owned by Gilead. The inventions disclosed in both patents are related to the inhibition of viruses through selective interference with certain enzymes. The written descriptions of the patents are very similar and, in substantial parts, identical.

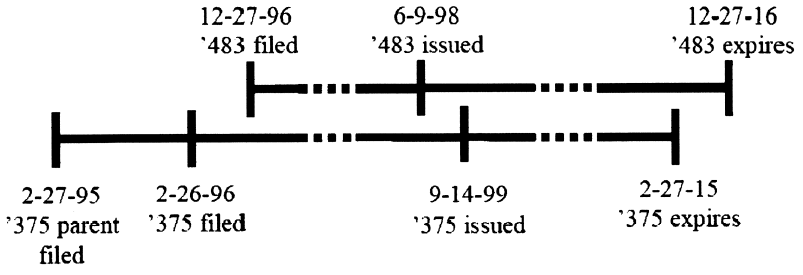
Despite their similarities in content, however, the '375 and '483 patents are not part of the same family of patents and were not before the same patent examiner. Instead, Gilead crafted a separate "chain" of applications, having a later priority date than the '375 patent family. That separate chain resulted in the issuance of the '483 patent. Because the patents do not claim priority to any common application, they will expire at different times as governed by the provisions of the Uruguay Rounds Agreement Act. The '375 patent was filed on February 26, 1996, and claims priority to a regular utility patent application filed on February 27, 1995. It expires twenty years later on February 27, 2015, and issued on September 14, 1999. The '483 patent was filed on December 27, 1996, and claims priority to a provisional utility patent application filed on December 29, 1995. Though filed after the application for the '375 patent, it issued first, on June 9, 1998, and expires last, on December 27, 2016.[1]

After the '483 patent issued, Gilead filed a terminal disclaimer in the application that led to the '375 patent. Through it, Gilead disclaimed any portion of the '375 patent term that extended beyond the expiration date of the '483 patent—which, absent abandonment, would not occur since, as explained above, the '375 patent's expiration date is before the '483 patent's expiration date. From the prosecution history records, that appears to be the first time Gilead informed either the examiner of the '375 patent or of the '483 patent about the existence of the other

[1] Although the '483 patent's priority date is based on the filing date of a provisional application (December 29, 1995), it expires twenty years from the patent's earliest non-provisional filing date (December 27, 1996). *See* 35 U.S.C. § 154.

patent application. No terminal disclaimer was filed for the '483 patent.

The following diagram illustrates the relevant dates for each patent, and how, because of different priority dates, the two patents have different expiration dates.



II

In March 2011, Gilead filed the current suit against Natco, alleging that Natco's Abbreviated New Drug Application No. 202-595 infringed the '483 patent. Among other defenses, Natco asserted that the '483 patent was invalid for obviousness-type double patenting in light of claim 8 of the '375 patent. In December 2012, the district court granted summary judgment in favor of Gilead on Natco's double patenting defense.

Relying on two district court cases, the court concluded that "a later-issued but earlier-expiring patent" cannot "serve as a double-patenting reference against an earlier-issued but later-expiring patent." J.A. 7 (citing *Abbott Labs. v. Lupin Ltd.*, 2011 WL 1897322 (D.Del. May 19, 2011) and *Brigham & Women's Hosp. Inc. v. Teva Pharm. USA, Inc.*, 761 F.Supp.2d 210 (D.Del.2011)).[2] It explained that "[t]he

[2] The district court did not cite *Ex Parte Pfizer, Inc., Patent Owner & Appellant*, 2010 WL 532133 (Bd.Pat.App. & Interf. Feb.12, 2010). In that case, the Board of Patent Appeals and

Uruguay Round Agreements Act of 1994, which became effective on June 8, 1995, changed the term for a U.S. patent from seventeen years from the patent issue date to twenty years from the earliest effective filing date." J.A. 6 (citing Uruguay Round Agreements Act ("URAA"), Pub.L. No. 103-465, § 532(a), 108 Stat. 4809, 4983–85 (1994)). In the district court's view, any "extensions of the patent terms at issue were not unlawful because the extensions were not a result of gamesmanship, but instead were a result of changes to patent laws." J.A. 7.

In May 2013, after Natco conditionally stipulated to infringement of two claims of the '483 patent, the district court certified its summary judgment ruling for appeal under Rule 54(b) because Natco's "only invalidity defense on the '483 patent" was obviousness-type double patenting. J.A. 10.

Natco filed a timely appeal. We have jurisdiction under 28 U.S.C. § 1295(a). For purposes of this appeal, we assume that the '483 patent claims a mere obvious variant of the invention claimed in the '375 patent.

Interferences held that an earlier-expiring patent could qualify as an obviousness-type double patenting reference regardless of whether it issues prior to or after another patent. *Id*. at *21. According to the Board, it was the "patent term and not the patent issue date that determines if a claim . . . qualifies as a double patenting reference." *Id*. The later-expiring patent, in the Board's opinion, would impermissibly block the public from practicing the invention (and obvious derivations thereof) disclosed in the patents that expired first—which was "precisely what obviousness-type double patenting was intended to prevent"—an extension of a patentee's "right to exclude the public from practicing" the invention in an expired patent. *Id*.

III

This appeal presents a narrow question: Can a patent that issues after but expires before another patent qualify as a double patenting reference for that other patent? We conclude under the circumstances of this case that it can and, therefore, that the district court erred in excluding the '375 patent as a potential double patenting reference for the '483 patent.

A

The prohibition against double patenting is a longstanding doctrine of patent law. It is based on the core principle that, in exchange for a patent, an inventor must fully disclose his invention and promise to permit free use of it at the end of his patent term. As the Supreme Court has explained, "[i]t is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property. It is upon this condition that the patent is granted." *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185, 16 S.Ct. 1002, 41 L.Ed. 118 (1896).[3] The bar against double patenting was created

[3] *See also*, *e.g.*, *Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 33–34, 123 S.Ct. 2041, 156 L.Ed.2d 18 (2003) ("The rights of a patentee . . . are part of a carefully crafted bargain . . . under which, once the patent . . . monopoly has expired, the public may use the invention . . . at will and without attribution." (internal quotation marks and citations omitted)); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230, 84 S.Ct. 784, 11 L.Ed.2d 661 (1964) ("[W]hen the patent expires the monopoly created by it expires, too, and the right to make the article . . . passes to the public."); *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197–98, 14 S.Ct. 310, 38 L.Ed. 121 (1894) (explaining history of and collecting cases on double patenting); *In re Hubbell*, 709 F.3d 1140, 1145 (Fed.Cir.2013); *In re Longi*, 759 F.2d 887,

to preserve that bargained-for right held by the public. *See*, *e.g.*, *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197-98, 202, 14 S.Ct. 310, 38 L.Ed. 121 (1894); *Suffolk Co. v. Hayden*, 70 U.S. 315, 317, 3 Wall. 315, 18 L.Ed. 76 (1865); *Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1346 (Fed.Cir.2010); *In re Longi*, 759 F.2d 887, 892 (Fed.Cir.1985); *Application of Robeson*, 51 C.C.P.A. 1271, 331 F.2d 610, 614 (1964); *Odiorne v. Amesbury Nail Factory*, 18 F.Cas. 578, 579 (C.C.D.Mass.1819). 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. As Justice Story explained in 1819, "[i]t cannot be" that a patentee can obtain two patents in sequence "substantially for the same invention[ ] and improvements"; "it 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." *Odiorne*, 18 F.Cas. at 579. Thus, the doctrine of double patenting was primarily designed to prevent such harm by limiting a patentee to one patent term per invention or improvement.

The scope of the bar against double patenting has also been well-established in patent law jurisprudence. Federal courts for over a century have applied the principles of the doctrine as a means to preserve the public's right to use not only the exact invention claimed by an inventor when his patent expires, but also obvious modifications of that invention that are not patentably distinct improvements. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967

---

892 (Fed.Cir.1985); *Odiorne v. Amesbury Nail Factory*, 18 Fed. Cas. 578, 579 (C.C.D.Mass.1819) (Story, J.).

(Fed.Cir.2001) ("The judicially-created doctrine of obviousness-type double patenting . . . prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.").[4] With the addition of § 253 in 1952, however, Congress slightly altered the effect of the bar on double patenting.

In *Application of Robeson*, our predecessor court first addressed the impact of that statutory provision, which in part permits a patentee to disclaim any terminal part of the term of his patent without a disclaimer of claim scope. 331 F.2d at 614. It explained that 35 U.S.C. § 253's terminal disclaimer provision

---

[4] *See also*, *e.g.*, *In re Hubbell*, 709 F.3d at 1145; *In re Longi*, 759 F.2d at 892; *In re Peiler*, 19 C.C.P.A. 1051, 56 F.2d 878, 878 (1932) (affirming double patenting rejection where claim "covered the same inventive idea" as "obvious to any one skilled in the art on inspection and examination of the disclosures of the parent application"); *In re Swan*, 18 C.C.P.A. 935, 46 F.2d 572, 573 (1931) (affirming double patenting rejection of specific use for prior invention where there was not "a patentable distinction between [the] former patent and th[e] further and more specific claim [in the new patent application]"); *Kirsch Mfg. Co. v. Gould Mersereau Co*., 6 F.2d 793, 794 (2d Cir.1925) (Hand, J.) (affirming invalidity of patent on double patenting grounds after concluding that the later claims were "an obvious modification" that "accomplishes substantially the same result" by "difference in means [that] did not require invention" that was "a new display of ingenuity beyond the compass of the routineer" or "the limited imagination of the journeyman"); *In re Isherwood*, 46 App.D.C. 507, 511 (D.C.Cir.1917); *Otis Elevator Co. v. Portland Co*., 127 F. 557, 561–63 (1st Cir.1903); *Palmer Pneumatic Tire Co. v. Lozier*, 90 F. 732, 740–45 (6th Cir.1898); *Swift v. Jenks*, 29 F. 642, 643 (C.C.N.D.N.Y.1887); *Wheeler v. McCormick*, 29 F. Cas. 905, 909 (C.C.S.D.N.Y.1873); *Smith v. Ely*, 22 F. Cas. 533, 537 (C.C.D.Ohio 1849) *remanded on other grounds*, 56 U.S. 137, 15 How. 137, 14 L.Ed. 634 (1853).

provided patent owners a remedy against a double patenting charge by "permit[ting] the patentee to cut back the term of a later issued patent so as to expire at the same time as the earlier issued patent." *Robeson*, 331 F.2d at 614 n. 4 (citing commentary of P.J. Federico). Relying on that understanding of the purpose of terminal disclaimers permitted by the new § 253, the court concluded that a terminal disclaimer could negate a double patenting rejection in some instances.

> Where, as here, the claimed subject matter is an obvious modification of what has already been claimed, a second patent is contrary to one of the fundamental principles underlying the patent system, namely, that when the right to exclude granted by a patent expires at the end of the patent term, the public shall be free to use the invention as well as obvious modifications thereof or obvious improvements thereon. Thus, to grant a second patent for an obvious variation deprives the public of those rights. If, however, the second patent expires simultaneously with the first, the right to fully utilize the patented discovery at the expiration date remains unimpaired. . . . [H]ere, the only real objection to granting appellant's application is an extension of the monopoly. The terminal disclaimer, which Congress had expressly provided, removes any danger of such result.

Id. at 614-15.

Thus, the *Robeson* court reasoned that a terminal disclaimer should be a permissible means to overcome the prohibition on double patenting when it aligns the expiration dates of an inventor's several patents that claim mere obvious variations of the same invention

to create a single term of limited exclusivity. *Id*.; *see Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1280 (Fed.Cir.1992) (explaining that "obviousness-type double patenting . . . could be overcome by filing a terminal disclaimer, which had been provided for in section 253 of the 1952 Patent Act for that very purpose"). Indeed, as our predecessor court later explained, a terminal disclaimer "causes [such] . . . patents to expire together, a situation . . . which is tantamount for all practical purposes to having all the claims in one patent." *Application of Braithwaite*, 54 C.C.P.A. 1589, 379 F.2d 594, 601 (1967).

B

With those principles of double patenting in mind, we now turn to the question presented by this appeal: whether a later-issued patent can serve as a double patenting reference for an earlier-issued patent if the later one expires first.

As discussed, it is a bedrock principle of our patent system that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention. *See* discussion *supra*; *In re Longi*, 759 F.2d at 892 ("The public should . . . be able to act on the assumption that upon the *expiration* of [a] patent it will be free to use not only the invention claimed in the patent but also [any] modifications or variants [thereof] which would have been *obvious* to those of ordinary skill in the art at the time the invention was made."). The double patenting doctrine has always been implemented to effectively uphold that principle. *Perricone v. Medicis Pharm. Corp*., 432 F.3d 1368, 1372 (Fed.Cir.2005).

And that principle is violated when a patent expires and the public is nevertheless barred from practicing obvious modifications of the invention claimed in that patent because the inventor holds another later-expiring patent with claims for obvious modifications of the invention.[5] Such is the case here. The '375 patent expires on February 27, 2015. Thus, come February 28, 2015, the public should have the right to use the invention claimed in the patent and all obvious variants of that invention. *See* discussion *supra*. That was the condition upon which the '375 patent was issued to the inventors. *See* discussion *supra*. But the public will not be free to do so. The '483 patent does not expire until December 27, 2016, and it (we assume for this appeal) covers obvious modifications of the invention claimed in the '375 patent. The '483 patent, therefore, extends the inventors' term of exclusivity on obvious variants of the invention claimed in the '375 patent for an additional twenty-two months past the expiration of the '375 patent. That plainly violates the public's right to use the invention claimed in the '375 patent and all obvious variants of it after the '375 patent expires.

Gilead's response is simply that the "'*375 patent* in no way extends the term of the exclusivity *for the '483 patent*." Respondent's Br. at 14 (emphasis added). Gilead argues that we should focus on the potential

---

[5] Note that we address only obvious variants of an invention, not separately patentable improvements. The public's ability to practice an invention claimed in an expired patent may be further restricted by, for example, an overlapping patent covering patentably *distinct* subject matter. But the point of the double patenting doctrine is to protect the public from attempts by inventors to effectively extend their patent term through a later-expiring patent claiming patentably *indistinct* subject matter.

term extension for the '483 patent instead of the '375 patent because the '483 patent issued first. However, we see little import here in the fact that the '483 patent issued first. Gilead cites cases that describe the double patenting bar as applicable to the "second" or "later" issuing patent. *See* Respondent's Br. at 21-27. But those cases dealt with patents to which the URAA did not apply and, critical to a double patenting analysis, to patents for which the expiration date was inextricably intertwined with the issuance date. *See*, *e.g.*, *Miller*, 151 U.S. at 197, 14 S.Ct. 310; *Suffolk Co.*, 70 U.S. at 315-19; *In re Hubbell*, 709 F.3d at 1145; *Perricone*, 432 F.3d at 1372; *Eli Lilly*, 251 F.3d at 967; *In re Longi*, 759 F.2d at 892; *Application of Vogel*, 57 C.C.P.A. 920, 422 F.2d 438, 441 (1970); *Robeson*, 331 F.2d at 614. As discussed above, the primary ill avoided by enforcement of the double patenting doctrine is restriction on the public's freedom to use the invention claimed in a patent and all obvious modifications of it after that patent *expired*. Thus, the focus on controlling the patent term of later *issued* patents in those cases makes perfect sense: before the URAA, later issued patents *expired* later.[6]

In other words, for double patenting inquiries, looking to patent issue dates had previously served as a reliable stand-in for the date that really mattered—patent expiration. But as this case illustrates, that tool does not necessarily work properly for patents to which the URAA applies, because there are now instances, like here, in which a patent that issues first does not expire first. Therefore, in light of the principles reflected in our prior case law as explained

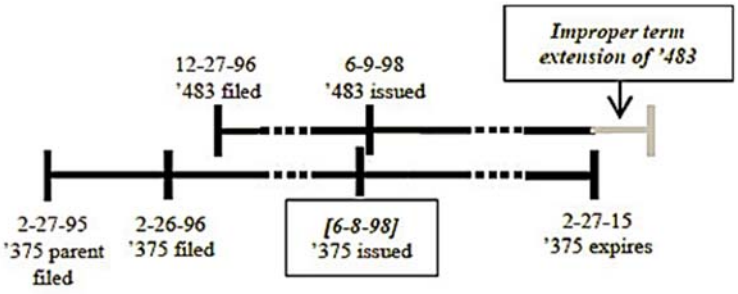
[6] There are exceptions to that rule of course, such as patents that qualify for term extensions, but none are relevant to the facts or our discussion here.

above, it is the comparison of Gilead's patent expiration dates that should control, not merely the issuance dates.

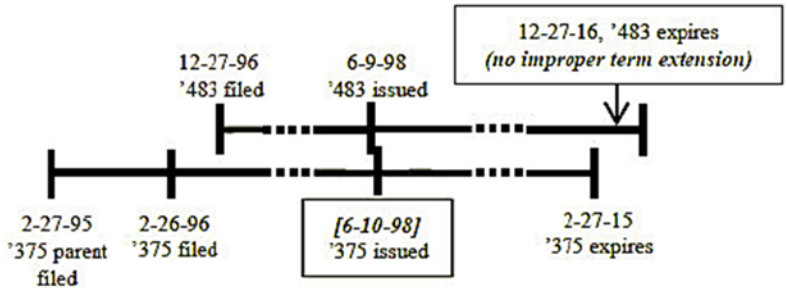
Relying on issuance date only as Gilead prefers would also have several shortcomings. First, if we were to hold that issuance date is the determining factor for double patenting inquiries for post-URAA patents, the terms of such patents could be subject to significant gamesmanship during prosecution. In the URAA, Congress clearly limited the one period of exclusivity an inventor can obtain for each of his inventions to twenty years from the filing date of the earliest application to which the inventor claims priority—with some limited exceptions. *See* 35 U.S.C. § 154(a) (2013); URAA, 108 Stat 4809 § 532(a)(1). 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.

Second, if the double patenting inquiry was determined by issuance date for post-URAA patents, there could be a significant difference in an inventor's period of exclusivity over his invention (and its obvious variants) based on mere days' difference in the issuance of several patents to the inventor. Here, for example, if the '375 patent issued *the day before* the '483 patent, in Gilead's view, the last twenty-two

months of the term of the '483 patent would be an improper extension of patent term.



Now if the '375 patent issued *the day after* the '483 patent, those last twenty-two months of the term of the '483 patent would not be an improper extension of patent term.



Such significant vacillations in an inventor's period of exclusivity over his invention and its obvious variants is simply too arbitrary, uncertain, and prone to gamesmanship. Congress could not have intended to inject the potential to disturb the consistent application of the doctrine of double patenting by passing the URAA.

Looking instead to the earliest expiration date of all the patents an inventor has on his invention and its obvious variants best fits and serves the purpose of the

doctrine of double patenting. Permitting any earlier expiring patent to serve as a double patenting reference for a patent subject to the URAA guarantees a stable benchmark that preserves the public's right to use the invention (and its obvious variants) that are claimed in a patent when that patent expires.

Furthermore, using the expiration date as a benchmark in post-URAA cases of obviousness-type double patenting preserves the ability of inventors to use a terminal disclaimer of later-expiring patents to create one expiration date for their term of exclusivity over their inventions and obvious variants, "which is tantamount for all practical purposes to having all the claims in one patent." *Braithwaite*, 379 F.2d at 601. Such disclaimers would preserve the public's right to use a patented invention and obvious modifications of it when the earliest patent expires and would effectively overcome any objection to improper term extension.

Indeed, looking to the expiration date instead of issuance date is consistent with the PTO's guidance in the Manual of Patent Examining and Procedure ("MPEP"). The MPEP presents a hypothetical where two pending patent applications filed by the same inventor are subject to provisional obviousness-type double patenting rejections over each other. *See* MPEP § 804.I.B.1. In such a situation, the MPEP instructs that a terminal disclaimer is required for the later of the two applications (which the hypothetical anticipates to have the later expiration date) before that application can issue. *See id*. Applied to the facts here, a terminal disclaimer would have been required for the '483 patent.

We therefore hold that an earlier-expiring patent can qualify as an obviousness-type double patenting

reference for a later-expiring patent under the circumstances here. In cases where such obviousness-type double patenting is present, a terminal disclaimer can preserve the validity of the later-expiring patent by aligning its expiration date with that of the earlier-expiring patent. That disclaimer will most effectively enforce the fundamental right of the public to use the invention claimed in the earlier-expiring patent and all obvious modifications of it after that patent's term expires.

IV

Gilead currently enjoys the benefits of the '375 patent, including an earlier priority date and the specific exclusivity provided by the scope of its claims. The expiration of the '375 patent triggers the public's right to use the invention claimed in it and all obvious modifications of that invention. When the '375 patent expires, however, the public will not be free to do so because (as we assume) the '483 patent claims some of those obvious variants of the invention in the '375 patent and expires twenty-two months later. Therefore, if it does indeed claim obvious variants of the invention claimed in the '375 patent, the '483 patent would violate the doctrine against double patenting.

Accordingly, the district court erred in concluding that the '483 patent could not be invalid for double patenting because the '375 patent could not qualify as an obviousness-type double patenting reference. We therefore vacate the judgment of the district court and remand for further proceedings consistent with this opinion.

VACATED AND REMANDED

COSTS

Each party shall bear its own costs.

RADER, *Chief Judge*, dissenting.

Today the court expands the judicially-created doctrine of obviousness-type double patenting. The court holds that a later-issued, but earlier-expiring patent can invalidate a first-issued, but later expiring patent—even where the patents are subject to a requirement of common ownership. Because this expansion is unwarranted, I respectfully dissent.

I.

To be clear, my dissent today is not meant to disparage the doctrine of obviousness-type double patenting. Undoubtedly, the doctrine has served a useful purpose over the years. Immediately prior to the Uruguay Round Agreements Act (URAA) and the General Agreement on Tariffs and Trade (GATT), a U.S. patent enjoyed a term of 17 years from its issue date. A patentee could file successive continuations and obtain additional patent term for obvious modifications of its earlier claims where its earlier patents and applications did not qualify as prior art, and perhaps do so *ad infinitum*. Courts used obviousness-type double patenting to curtail that practice. *See*, *e.g.*, *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed.Cir.2001) ("The judicially-created doctrine of obviousness-type double patenting cements that legislative limitation [on the duration of the patentee's right to exclude] by prohibiting a party from obtaining an extension of the right to exclude

through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." (citation omitted)).

However, based on changes implemented as part of the GATT and URAA, the term of a patent is now generally limited to 20 years from its filing date or the earliest claimed filing date under 35 U.S.C. §§ 120, 121 or 365(c). 35 U.S.C. § 154(a)(2). With this change, successive continuations generally do not result in any additional patent term. Rather, the filing date of the earliest member of a patent family limits the rest of the related patents. *Id*. Thus a primary motivation behind the doctrine—preventing the effective extension of patent term—is largely no longer applicable. *Cf. In re Fallaux*, 564 F.3d 1313, 1319 (Fed.Cir.2009) (noting that under post-GATT patent terms a double patenting issue may arise in limited instances based on changes to patent terms under 35 U.S.C. §§ 154, 156).

That being said, the doctrine of obviousness-type double patenting is also predicated on a second underlying policy concern—preventing multiple infringement suits by different assignees asserting essentially the same patented invention. *Id*. This secondary and far less prevalent concern receives some notice in this court's case law. *See*, *e.g*., *In re Griswold*, 53 C.C.P.A. 1565, 365 F.2d 834, 840 n. 5 (1966). However, in this case, neither policy concern justifies an extension of double patenting.

II.

The court correctly frames the narrow question presented in this appeal: "Can a patent that issues after but expires before another patent qualify as a double patenting reference for that other patent?"

Maj. Op. at 1211-12. But the court then proceeds to craft a new rule to answer the question in the affirmative. According to the court, the expiration dates of the patents govern the inquiry irrespective of filing or issue dates. Maj. Op. at 1215.

As an initial matter, I would proceed more cautiously before articulating a new rule to address this novel situation. In my opinion, courts should be reluctant to create or expand judge-made exceptions to statutory grants. *See*, *e.g.*, *W. Union Tel. Co. v. Lenroot*, 323 U.S. 490, 514, 65 S.Ct. 335, 89 L.Ed. 414 (1945) (Murphy, J., dissenting) ("[T]he judicial function does not allow us to disregard that which Congress has plainly and constitutionally decreed and to formulate exceptions which we think, for practical reasons, Congress might have made had it thought more about the problem."); *United States v. Rutherford*, 442 U.S. 544, 559, 99 S.Ct. 2470, 61 L.Ed.2d 68 (1979) ("Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference."). Thus, I would view the question through the lens of judicial restraint.

With this view, I see no reason to apply double patenting under our two accepted justifications for the doctrine. First, this case does not raise the policy concern regarding subsequent extensions of patent term. 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. Notably, if the '375 patent had never issued, Gilead would certainly be entitled to the '483 patent's 2016 expiration date.

Second, this case does not involve the potential for harassment by multiple assignees asserting essentially the same patented invention. *E.g.*, *Fallaux*, 564 F.3d at 1319. Here, the '375 patent is subject to a terminal disclaimer with respect to the '483 patent and thus is only enforceable so long as it and the '483 patent are commonly owned. J.A. 546-47. The risk of separate parties suing on the two patents is therefore adequately mitigated.

Against this backdrop, the question becomes whether Gilead's conduct warrants the creation of a new rule proscribing its patent rights. Because both of the accepted justifications for the obviousness-type double patent doctrine are not implicated, I would find Gilead's conduct does not rise to that level.

III.

Respectfully, I find the court's reasoning to the contrary unpersuasive. Under 35 U.S.C. § 154(b) a patentee may not maintain its earliest possible priority date while seeking to extend the expiration date of subsequent patent claims. Rather, to obtain a longer patent term, a patentee must forfeit its earlier claim to priority and subject any new patent to intervening prior art. Gilead followed that precise approved course. Instead of claiming priority to the '375 patent family, Gilead filed the application that ultimately issued as the '483 patent as a separate family. In the process, Gilead gave up roughly 10 months of priority. Consequently, the '483 patent is subject to roughly 10 months of intervening prior art.

Nevertheless, despite sacrificing almost a year of priority, the court contends that Gilead acted improperly by continuing to pursue claims in the application that issued as the '375 patent. To support

this conclusion, the court holds that in the case of competing patents, a patentee is stuck with the earliest expiration date irrespective of filing or issue dates. Maj. Op. at 1215. To justify this new rule, the court relies on the flawed assumption that upon the expiration of a patent, the public obtains an absolute right to use the previously-claimed subject matter. Maj. Op. at 1214. I think the issue is more nuanced than the court acknowledges.

To begin with, not even a patentee has the affirmative right to use its claimed subject matter. *Spindelfabrik Suessen-Schurr, Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft*, 829 F.2d 1075, 1081 (Fed.Cir.1987); *see also* 35 U.S.C. § 154(a)(1). Thus, when a patent expires, this court cannot assume that such a right (which never existed) transfers to the public. Additionally, the court's assumption ignores the possible existence of overlapping patents. For example, where a first patent claims a genus, upon expiration of that patent, the public may still be excluded from practicing the full scope of the expired claim due to subsequent patents on various species contained within the prior genus claim. Still other legal and regulatory bars may prohibit the public from practicing the claimed subject matter as well. For example, certain claims in the '483 patent refer to methods of treating influenza using a drug compound. Consequently, certain uses of that method are subject to prior approval from the Food and Drug Administration. I believe this demonstrates that upon expiration of a patent, the public does not *necessarily* obtain an unfettered, affirmative right to practice the claims.

At the same time a patentee may not continue to claim the exclusive right to particular subject matter

beyond the expiration of its patent. Such a proposition is the antithesis of the quid pro quo of the patent system. Instead, it is more accurate to say that upon expiration of a patent, that particular expired patent is no longer a bar to the public's use of the claimed subject matter. Further, any subsequent attempts to prolong the initial patent term using obvious variants should not bar the public from practicing the initially claimed subject matter. However, it is important to note that subsequent improvements, if satisfying the criteria for patentability, *could* bar the public from practicing some subject matter encompassed by expired patents. Finally, consistent with our precedent, I would find that efforts to obtain patentably indistinct claims in a patent having common inventorship but owned by a different entity should also not bar the public. These narrow limitations on patentability and validity are consistent with established case law. This case does not compel the court to go any further.

Accordingly, I differ with the court on the effect this court should give to subsequent attempts by a patent owner to seek exclusive rights to obvious variants that do *not* extend the term of its earlier patent. Because this court is not presented with same-invention double patenting, I am aware of no argument that the Patent Act precludes such conduct. And because the patents in this case are subject to a common ownership requirement, that concern provides no basis for complaining of Gilead's conduct. Simply put, the only relevant question is whether this court should extend our case law to encompass this new behavior exhibited by Gilead.

As I began at the outset, I view that question through the lens of judicial restraint. To be sure,

condoning Gilead's conduct may lead to some strategizing during prosecution to maximize patent term and obtain varying priority dates to hedge against intervening prior art. But I do not perceive Gilead's conduct as so manifestly unreasonable to warrant a new judicially-created exception to invalidate patents. *Cf. Rutherford*, 442 U.S. at 555, 99 S.Ct. 2470 ("[F]ederal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy. . . . Only when a literal construction of a statute yields results so manifestly unreasonable that they could not fairly be attributed to congressional design will an exception to statutory language be judicially implied.") (citations omitted).

As a final point, I think a number of concerns counsel for a more restrained approach. Chief among those is the interplay between today's decision and the new "first-inventor-to-file" provision of the Leahy-Smith America Invents Act, Pub.L. No. 112-29 § 3, 125 Stat. 285-86 (2011) ("the AIA"). Under the AIA's new "first-inventor-to-file" framework, prospective patentees are under tremendous pressure to file their applications early. I am concerned that today's opinion will have unforeseen consequences in this new race to the Patent Office.

Accordingly, for the foregoing reasons, I respectfully dissent.

APPENDIX B

UNITED STATES DISTRICT COURT,
D. NEW JERSEY

Nos. 11-CV-1455 (SDW-MCA),
11-CV-4969 (SDW-MCA)

GILEAD SCIENCES, INC., HOFFMANN-LA ROCHE, INC., F. HOFFMANN-LA ROCHE, LTD., AND GENENTECH, INC.,
Plaintiffs,

v.

NATCO PHARMA LIMITED AND NATCO PHARMA, INC.,
Defendants.

Dec. 21, 2012

OPINION

WIGENTON, *District Judge*.

Before this Court is Plaintiffs Gilead Sciences, Inc., Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd. and Genentech, Inc.'s motion for summary judgment pursuant to Federal Rule of Civil Procedure 56 and Defendants Natco Pharma Limited and Natco Pharma Inc.'s cross-motion for summary judgment also pursuant to Federal Rule of Civil Procedure 56. This Court, having considered the parties' submissions, decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons stated below, this Court *GRANTS* Plaintiffs' motion and *DENIES* Defendants' motion.

I. BACKGROUND

This case concerns a dispute between Plaintiffs Gilead Sciences, Inc., Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd. and Genentech, Inc. ("Gilead") and Natco Pharma Limited and Natco Pharma Inc. ("Natco") over access to a patented pharmaceutical product. Gilead owns the patent at issue and seeks to prevent Natco from marketing a generic version of Gilead's patented product. The narrow issue before this Court concerns whether, between two closely related patents, the later-issued but earlier-expiring patent can be used as a reference patent to invalidate the earlier-issued and later-expiring patent.

II. FACTS

Researchers at Gilead Sciences Inc., led by Dr. Choung Kim, developed Oseltamivir, a highly potent neuraminidase inhibitor. (*See* Pls.' Statement of Uncontested Material Facts ("Pls.' Facts") ¶ 9.) Oseltamivir was developed in response to the "need for a potent and safe anti-influenza agent that could be used to treat a wide range of influenza strains, and be administered orally." (Pls.' Opening Mem. in Supp. of Motion for Summ. J. ("Pls.' Br. in Supp.") 2.) Oseltamivir is "the first of its kind to be orally bioavailable; having [an] excellent safety profile; and [is] broadly effective against various flu types." (*Id*.) In June 1999, the United States Food and Drug Administration ("FDA") approved Oseltamivir, which is currently marketed as TAMIFLU®. (*See* Pls.' Facts ¶ 9.) U.S. Patent No. 5,763,483 (the " '483 patent"), titled Carbocylic Compounds, is assigned to Gilead Sciences, Inc. (*See* Pls.' Facts ¶ 24.) The '483 patent "covers TAMIFLU® (oseltamivir phosphate), its metabolite (oseltamivir carboxylate), oseltamivir-

based formulations, methods of inhibiting neuraminidase and treatment or prophylaxis of influenza infection." (Pls.' Br. in Supp. 3-4) (citing Pls.' Facts ¶ 5-6). The '483 patent issued from non-provisional application 08/774,345 (the " '345 application"), which claimed the benefit of priority to provisional application 60/009,306 (the " '306 application"), which was filed on December 29, 1995. (*See* Pls.' Facts ¶ 26.) The '483 patent issued on June 9, 1998, which is before any other patent in the Oseltamivir patent family was issued. (*See id*.)

U.S. Patent No. 5,952,375 (the '[?]'375 patent") and U.S. patent No. 5,866,601 (the " '601 patent") issued on September 14, 1999 from a series of continuation-in-part ("CIP") applications (collectively the " '245 CIP family"). (*See* Pls.' Facts ¶ 13.) The earliest of the '245 CIP family was application 08/395,245 (the " '245 application"), which was filed on February 27, 1995. (*See id*.) The '375 patent and the '601 patent both claim priority to: (1) the '245 application; (2) CIP application 08/476,946 (the " '946 application"), which was filed on June 6, 1995, and issued as the '601 patent; (3) and CIP application 08/580,567 (the " '567 application"), which was filed on December 29, 1995. (*See id*. at ¶ 14.) Application 08/606,624 (the " '624 application") was filed on February 26, 1996 as a CIP of the '567 application. (*See id*. at ¶ 21.) The '624 application eventually issued as the '375 patent. (*See id*.) The '375 patent is also assigned to Gilead Sciences, Inc. (*See id*. at ¶ 11.) The '483 patent, '375 patent, and '601 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book") as patents for TAMIFLU®. (*See* Pls.' Facts ¶ 27.) Only the '375 and '483 patents are relevant to this opinion.

On February 2, 2011, Natco sent a letter to Gilead, pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV), making Defendants aware that Natco filed Abbreviated New Drug Application ("ANDA") No. 202-595 with the FDA seeking approval to market a generic version of TAMIFLU® 75 mg oseltamivir phosphate prior to the expiration of the '483 patent. (*See* Pls.' Facts ¶ 2.) On March, 15, 2011, Gilead filed a complaint in this Court against Natco, alleging, *inter alia*, that Natco's filing of an ANDA infringed on the '483 patent. (*See id*. at ¶ 3; Dkt. no. 1.) On August 5, 2011, Natco notified Gilead that it submitted an amended ANDA seeking a generic version of TAMIFLU® but for dosages of 30mg and 45 mg instead of 75mg. (*See id*. at ¶ 4.) On August 29, 2011, Gilead filed another complaint against Natco alleging that Natco's amended ANDA also infringed on the '483 patent. (*See id*.) On September 30, 2011, Natco filed its answer and counterclaims, alleging, *inter alia*, that the claims of the '483 patent are invalid due to obviousness-type double-patenting, thereby negating Gilead's claim of patent infringement. (*See id*. at ¶ 5.) Also, Natco alleged that the '375 is the reference patent for its claim of double-patenting. (*See id*.) On January 20, 2012, Natco provided Gilead with its Invalidity and Non-Infringement Contentions, wherein Natco asserted that the claims of the '483 patent are invalid due to obviousness-type double-patenting of claim eight of the '375 patent. (*See id*. at ¶ 6.)

III. LEGAL STANDARD

Summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). A factual dispute is genuine if a reasonable jury could return a

verdict for the nonmovant, and it is material if, under the substantive law, it would affect the outcome of the suit. *See Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The moving party must show that if the evidentiary material of record were reduced to admissible evidence in court, it would be insufficient to permit the nonmoving party to carry its burden of proof. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

Once the moving party meets the initial burden, the burden then shifts to the nonmovant who must set forth specific facts showing a genuine issue for trial and may not rest upon the mere allegations or denials of its pleadings. *See Shields v. Zuccarini*, 254 F.3d 476, 481 (3d Cir.2001). The court may not weigh the evidence and determine the truth of the matter but rather should determine whether there is a genuine issue as to a material fact. *See Anderson*, 477 U.S. at 249. In doing so, the court must construe the facts and inferences in "a light most favorable" to the nonmoving party. *Masson v. New Yorker Magazine, Inc*., 501 U.S. 496, 521, 111 S.Ct. 2419, 115 L.Ed.2d 447 (1991). The nonmoving party "must present more than just 'bare assertions, conclusory allegations or suspicions' to show the existence of a genuine issue." *Podobnik v. United States Postal Serv*., 409 F.3d 584, 594 (3d Cir.2005) (quoting *Celotex Corp*., 477 U.S. at 325). If the nonmoving party "fail[s] to make a sufficient showing on an essential element of [its] case with respect to which [it] has the burden of proof," then the moving party is entitled to judgment as a matter of law. *Celotex Corp*., 477 U.S. at 323.

IV. DISCUSSION

Obviousness-type double-patenting is a judicially created doctrine that seeks to preclude an inventor from unjustifiably extending patent protection past the statutory limit. *See In re Berg*, 140 F.3d 1428, 1431-32 (Fed.Cir.1998). "It requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in the commonly owned patent." *See id*. (citing *In re Braat*, 937 F.2d 589, 592 (Fed.Cir.1991). The obviousness-type double-patenting inquiry requires a two-step analysis: "[f]irst, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences." *Eli Lilly & Co. v. Barr Labs., Inc*., 251 F.3d 955, 968 (Fed.Cir.2001). Second, a court must decide if the differences between the two claims demonstrate patentable distinction. *See id*. Regarding the second step, a later claim is "not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." *Eli Lilly*, 251 F.3d at 968. The party asserting the defense of obviousness-type double-patenting must prove it by clear and convincing evidence. *See Symbol Tech., Inc. v. Opticon, Inc*., 935 F.2d 1569, 1580 (Fed.Cir.1991). While, on a macro level, the dispute between the parties concerns the issue of double-patenting, the narrow issue before this Court is whether the '375 patent can be used as a reference patent for purposes of determining if the '483 patent is an unlawful extension of the '375 patent.

Important to this Court's consideration of the present issue is a brief discussion of the change in patent law concerning patent terms. The Uruguay Round Agreements Act of 1994, which became effective on June 8, 1995, changed the term for a U.S.

patent from seventeen years from the patent issue date to twenty years from the earliest effective filing date. *See* Uruguay Round Agreements Act, Pub.L. No. 103-465, § 532(a), 108 Stat. 4809, 4983-85 (1994). Patents that issued prior to June 8, 1995 expire on the later of two dates: either (1) seventeen years from the issue date or (2) twenty years from the effective filing date. Patents issued after June 8, 1995 have a twenty year term set from the earliest effective filing date.

Here, Natco argues that the '375 patent can serve as a double-patenting reference for the '483 patent. (*See* Defs.' Opp'n to Pls.' Summ. J. Mot. And Br. in Supp. of Defs.' Cross-Mot. for Partial Summ. J. ("Defs.' Opp'n" 6-7.) Following that premise, Natco also argues that the '483 patent unlawfully extends the terms of the '375 patent. (*See id*. 4-5.) Gilead contends that Natco's positions are untenable given the existing case law regarding obviousness-type double-patenting. (*See* Pls.' Opening Mem. In Supp. 2.) More specifically, Gilead argues that the '375 patent cannot serve as a reference for double-patenting because it issued after the '483 patent and terminates before the '483; thereby not making the '483 patent an unlawful extension of the '375 patent. (*See id*. at 10-12.)

Gilead relies on two district court decisions to support its contention that the '375 patent cannot serve as double-patenting reference for the '483 patent: (1) *Abbott Labs. v. Lupin Ltd*., Civ. A. No. 09-152,-LPS, 2011 WL 1897322 (D.Del. May 19, 2011) and (2) *Brigham & Women's Hosp. Inc. v. Teva Pharm. USA, Inc*., 761 F.Supp.2d 210 (D.Del.2011). In both cases the district court in the district of Delaware had to address whether a later-issued but earlier-expiring patent can serve as a double-patenting reference against an earlier-issued but later-expiring patent.

Both times, the Delaware district court held that a later-issued but earlier-expiring patent cannot be used as an invalidating reference against an earlier-issued but later-expiring patent because logically a later-issued patent cannot be extended by a patent that was already in existence. *See Abbott Labs*., 2011 WL 1897322 at *8; *Brigham & Women's Hosp. Inc*., 761 F.Supp.2d at 226. Similarly here, the '375 patent cannot serve as a reference patent as it issued after and terminates before the '483 patent. Therefore the '483 does not unlawfully extend Gilead's right to exclusivity.

In both cases, the district court also found that the extensions of the patent terms at issue were not unlawful because the extensions were not a result of gamesmanship, but instead were a result of changes to patent laws. *See Abbott Labs*., 2011 WL 1897322 at *10; *Brigham & Women's Hosp. Inc*., 761 F.Supp.2d at 225. Natco argues that Gilead obtained the '483 patent in part because Gilead failed to disclose the '624 application, which ultimately issued as the '375 patent, to the United States Patent and Trademark Office ("PTO"). (*See* Natco Opp. Br./Br. in Supp. of Cross-Motion ("Natco Opp. Br.") 5.) Natco highlights this nondisclosure because the '567 application, the parent application to the '624 application, contained a similar disclosure to the '306 provisional application, which is the parent application for the '483 patent. (*See* Natco's L.R. 56.1 Statement of Uncontested Facts ("NSOF") ¶ 4; Decl. of Diane C. Ragosa ("Ragosa Decl.") 11.) Natco contends that had the PTO known about the '375 patent application, the patent examiner "would have conditioned the allowance of the '483 patent on Gilead terminally disclaiming any term of the '483 patent that extended beyond twenty years

after the filing date of the '375 patent. (Defs.' Opp'n 5.) Natco's argument, however, is ineffective.

Gilead notified the PTO of the '375 patent family of applications, including the '567 application, which contained a similar disclosure to the '306 provisional application. (*See* Gilead's Reply Br. 8.) Therefore, the nondisclosure of the '624 application, though it also contained a similar disclosure to the '306 provisional application, is not detrimental to Gilead's case because of Gilead's disclosure of the '567 application. Similar to *Abbott Labs*. and *Brigham*, the lifespan of Gilead's patents seem to be a result of changes in patent law, and not any gamesmanship from Gilead. Since the issuance of the '483 patent is not the result of any strategic abuse of the patent system by Gilead, the '375 patent cannot serve as a reference patent to invalidate the '483 patent because of obviousness-type double-patenting.

V. CONCLUSION

For the reasons set forth above, Plaintiffs' motion for summary judgment is *GRANTED* and Defendants' cross-motion is *DENIED*.

APPENDIX C

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

[Filed July 29, 2014]

2013-1418

GILEAD SCIENCES, INC., HOFFMANN-LA ROCHE,INC., F. HOFFMANN-LA ROCHE, LTD., and GENENTECH, INC.,

Plaintiffs-Appellees,

v.

NATCO PHARMA LIMITED and NATCO PHARMA, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the District of New Jersey in Nos. 11-CV-1455 and 11-CV-4969, Judge Susan D. Wigenton.

ON PETITION FOR REHEARING EN BANC

Before Prost,[*] *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, and HUGHES, *Circuit Judge*.[**]

---

[*] Sharon Prost assumed the position of Chief Judge on May 31, 2014.

[**] Randall R. Rader, who retired from the position of Circuit Judge on June 30, 2014, did not participate in this decision.

PER CURIAM.

ORDER

Appellees Gilead Sciences, Inc., et al. filed a petition for rehearing en banc. The petition was first referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on August 5, 2014.

FOR THE COURT

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

July 29, 2014
Date

APPENDIX D

FEDERAL STATUTES

35 U.S.C. § 101. Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 111. Application

(a) In general.—

(1) Written application.—An application for patent shall be made, or authorized to be made, by the inventor, except as otherwise provided in this title, in writing to the Director.

(2) Contents.—Such application shall include—

(A) a specification as prescribed by section 112;

(B) a drawing as prescribed by section 113; and

(C) an oath or declaration as prescribed by section 115.

(3) Fee, oath or declaration, and claims.—The application shall be accompanied by the fee required by law. The fee, oath or declaration, and 1 or more claims may be submitted after the filing date of the application, within such period and under such conditions, including the payment of a surcharge, as may be prescribed by the Director. Upon failure to submit the fee, oath or declaration, and 1 or more claims within such prescribed period, the application shall be regarded as abandoned.

(4) Filing date.—The filing date of an application shall be the date on which a specification, with or without claims, is received in the United States Patent and Trademark Office.

(b) Provisional application.—

(1) Authorization.—A provisional application for patent shall be made or authorized to be made by the inventor, except as otherwise provided in this title, in writing to the Director. Such application shall include—

(A) a specification as prescribed by section 112(a); and

(B) a drawing as prescribed by section 113.

(2) Claim.—A claim, as required by subsections (b) through (e) of section 112, shall not be required in a provisional application.

(3) Fee.—The application shall be accompanied by the fee required by law. The fee may be submitted after the filing date of the application, within such period and under such conditions, including the payment of a surcharge, as may be prescribed by the Director. Upon failure to submit the fee within such prescribed period, the application shall be regarded as abandoned.

(4) Filing date.—The filing date of a provisional application shall be the date on which a specification, with or without claims, is received in the United States Patent and Trademark Office.

(5) Abandonment.—Notwithstanding the absence of a claim, upon timely request and as prescribed by the Director, a provisional application may be treated as an application filed under subsection (a). Subject to section 119(e)(3), if no such request is made, the provisional application shall be regarded as abandoned 12

months after the filing date of such application and shall not be subject to revival after such 12-month period.

(6) Other basis for provisional application.—Subject to all the conditions in this subsection and section 119(e), and as prescribed by the Director, an application for patent filed under subsection (a) may be treated as a provisional application for patent.

(7) No right of priority or benefit of earliest filing date.—A provisional application shall not be entitled to the right of priority of any other application under section 119 or 365(a) or to the benefit of an earlier filing date in the United States under section 120, 121, or 365(c).

(8) Applicable provisions.—The provisions of this title relating to applications for patent shall apply to provisional applications for patent, except as otherwise provided, and except that provisional applications for patent shall not be subject to sections 131 and 135.

(c) Prior filed application.—Notwithstanding the provisions of subsection (a), the Director may prescribe the conditions, including the payment of a surcharge, under which a reference made upon the filing of an application under subsection (a) to a previously filed application, specifying the previously filed application by application number and the intellectual property authority or country in which the application was filed, shall constitute the specification and any drawings of the subsequent application for purposes of a filing date. A copy of the specification and any drawings of the previously filed application shall be submitted within such period and under such conditions as may be prescribed by the Director. A failure to submit the

copy of the specification and any drawings of the previously filed application within the prescribed period shall result in the application being regarded as abandoned. Such application shall be treated as having never been filed, unless—

(1) the application is revived under section 27; and

(2) a copy of the specification and any drawings of the previously filed application are submitted to the Director.

35 U.S.C. § 154. Contents and term of patent; provisional rights

(a) In general.—

(1) Contents.—Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

(2) Term.—Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications under section 120, 121, or 365(c), from the date on which the earliest such application was filed.

(3) Priority.—Priority under section 119, 365(a), or 365(b) shall not be taken into account in determining the term of a patent.

(4) Specification and drawing.—A copy of the specification and drawing shall be annexed to the patent and be a part of such patent.

(b) Adjustment of patent term.—

(1) Patent term guarantees.—

(A) Guarantee of prompt Patent and Trademark Office responses.--Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—

(i) provide at least one of the notifications under section 132 or a notice of allowance under section 151 not later than 14 months after—

(I) the date on which an application was filed under section 111(a); or

(II) the date of commencement of the national stage under section 371 in an international application;

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;

(iii) act on an application within 4 months after the date of a decision by the Patent Trial and Appeal Board under section 134 or 135 or a decision by a Federal court under section 141, 145, or 146 in a case in which allowable claims remain in the application; or

(iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied,

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) Guarantee of no more than 3-year application pendency.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application, not including—

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

(ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Patent Trial and Appeal Board or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C),

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) Guarantee of adjustments for delays due to derivation proceedings, secrecy orders, and appeals.—Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to—

(i) a proceeding under section 135(a);

(ii) the imposition of an order under section 181; or

(iii) appellate review by the Patent Trial and Appeal Board or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability,

the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

(2) Limitations.—

(A) In general.—To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

(B) Disclaimed term.—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.

(C) Reduction of period of adjustment.—

(i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.

(ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.

(iii) The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

(3) Procedures for patent term adjustment determination.—

(A) The Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.

(B) Under the procedures established under subparagraph (A), the Director shall—

(i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination no later than the date of issuance of the patent; and

(ii) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director.

(C) The Director shall reinstate all or part of the cumulative period of time of an adjustment under paragraph (2)(C) if the applicant, prior to the issuance of the patent, makes a showing that, in spite of all due care, the applicant was unable to respond within the 3-month period, but in no case shall more than three additional months for each such response beyond the original 3-month period be reinstated.

(D) The Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.

(4) Appeal of patent term adjustment determination.—

(A) An applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the appli-

cant's request for reconsideration. Chapter 7 of title 5 shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

(B) The determination of a patent term adjustment under this subsection shall not be subject to appeal or challenge by a third party prior to the grant of the patent.

(c) Continuation.—

(1) Determination.—The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

(2) Remedies.—The remedies of sections 283, 284, and 285 shall not apply to acts which—

(A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of paragraph (1).

(3) Remuneration.—The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)).

(d) Provisional rights.—

(1) In general.—In addition to other rights provided by this section, a patent shall include the right to obtain a reasonable royalty from any person who, during the period beginning on the date of publication of the application for such patent under section 122(b), or in the case of an international application filed under the treaty defined in section 351(a) designating the United States under Article 21(2)(a) of such treaty, the date of publication of the application, and ending on the date the patent is issued—

(A)(i) makes, uses, offers for sale, or sells in the United States the invention as claimed in the published patent application or imports such an invention into the United States; or

(ii) if the invention as claimed in the published patent application is a process, uses, offers for sale, or sells in the United States or imports into the United States products made by that process as claimed in the published patent application; and

(B) had actual notice of the published patent application and, in a case in which the right arising under this paragraph is based upon an international application designating the United States that is published in a language other than English, had a translation of the international application into the English language.

(2) Right based on substantially identical inventions.—The right under paragraph (1) to obtain a reasonable royalty shall not be available under this subsection unless the invention as claimed in the patent is substantially identical to the invention as claimed in the published patent application.

(3) Time limitation on obtaining a reasonable royalty.—The right under paragraph (1) to obtain a reasonable royalty shall be available only in an action brought not later than 6 years after the patent is issued. The right under paragraph (1) to obtain a reasonable royalty shall not be affected by the duration of the period described in paragraph (1).

(4) Requirements for international applications.—

(A) Effective date.—The right under paragraph (1) to obtain a reasonable royalty based upon the publication under the treaty defined in section 351(a) of an international application designating the United States shall commence on the date of publication under the treaty of the international application, or, if the publication under the treaty of the international application is in a language other than English, on the date on which the Patent and Trademark Office receives a translation of the publication in the English language.

(B) Copies.—The Director may require the applicant to provide a copy of the international application and a translation thereof.

35 U.S.C. § 253. Disclaimer

(a) In general.—Whenever a claim of a patent is invalid the remaining claims shall not thereby be rendered invalid. A patentee, whether of the whole or any sectional interest therein, may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent. Such disclaimer shall be in writing, and recorded in the Patent and Trademark Office; and it shall thereafter be considered as part of the original patent to the

extent of the interest possessed by the disclaimant and by those claiming under him.

(b) Additional disclaimer or dedication.—In the manner set forth in subsection (a), any patentee or applicant may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted or to be granted.

35 U.S.C. § 271. Infringement of patent

* * * *

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma

technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date

which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section

505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy

that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

* * * *