United States Court of Appeals for the Federal Circuit

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG.

Plaintiffs-Appellants

 \mathbf{v} .

BRECKENRIDGE PHARMACEUTICAL INC., PAR PHARMACEUTICAL, INC., WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED,

Defendants-Appellees

2017-2173, 2017-2175, 2017-2176, 2017-2178, 2017-2179, 2017-2180, 2017-2182, 2017-2183, 2017-2184

Appeals from the United States District Court for the District of Delaware in Nos. 1:14-cv-01043-RGA, 1:14-cv-01196-RGA, 1:14-cv-01289-RGA, 1:14-cv-01494-RGA, 1:14-cv-01508-RGA, 1:15-cv-00078-RGA, 1:15-cv-00128-RGA, 1:16-cv-00431-RGA, 1:17-cv-00389-RGA, 1:17-cv-00420-RGA, Judge Richard G. Andrews.

Decided: December 7, 2018

CHRISTINA A. L. SCHWARZ, Venable LLP, New York, NY, argued for plaintiffs-appellants. Also represented by NICHOLAS NICK KALLAS, LAURA KATHERINE FISHWICK, CHRISTOPHER EARL LOH.

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, argued for all defendants-appellees. Defendant-appellee West-Ward Pharmaceuticals International Limited also represented by KEITH A. ZULLOW, STEVEN J. BERNSTEIN, NAOMI BIRBACH, MICHAEL B. COTTLER, New York, NY.

RACHEL C. HUGHEY, Merchant & Gould P.C., Minneapolis, MN, for defendant-appellee Breckenridge Pharmaceutical Inc. Also represented by Christopher J. Sorenson; B. Jefferson Boggs, Jr., Alexandria, VA; Daniel Evans, Atlanta, GA.

DANIEL BROWN, Latham & Watkins LLP, New York, NY, for defendant-appellee Par Pharmaceutical, Inc. Also represented by Brenda L. Danek, Marc Nathan Zubick, Chicago, IL; Gabriel Bell, Robert J. Gajarsa, Washington, DC.

Before PROST, Chief Judge, WALLACH and CHEN, Circuit Judges.

CHEN, Circuit Judge.

This case involves the complicated, potential double-patenting situation in which the later-filed of two related patents, which share a common specification and effective filing date, expires before the term of the earlier-filed patent due to an intervening change in law by Congress defining a patent's term. When the patent owner filed for the first patent, the governing law defined the patent term as 17 years from the date the patent issued. When the patent owner filed for its second, related patent, the governing law was amended to define the patent term as expiring 20 years from the patent's earliest effective filing date. Because of the two patents' relatively early effective filing date, the change in patent term law caused the second patent to expire earlier than the first patent. The

patent owner here concedes that the claimed inventions in the two related patents are obvious variants of each other. The legal question we confront in this appeal is whether the law of obviousness-type double patenting requires a patent owner to cut down the earlier-filed, but later expiring, patent's statutorily-granted 17-year term so that it expires at the same time as the later-filed, but earlier-expiring patent, whose patent term is governed under an intervening statutory scheme of 20 years from that patent's earliest effective filing date. See 35 U.S.C. § 154(a)(2) (2012).

Novartis Pharmaceuticals Corporation and Novartis AG (collectively, Novartis) appeal the district court's decision to invalidate U.S. Patent No. 5,665,772 based on obviousness-type double patenting. The invalidating reference, Novartis's U.S. Patent No. 6,440,990, was filed after, and issued after, but expired before the '772 patent. Both patents claimed the same priority date. The '990 patent expired before the '772 patent because the '990 patent was filed after the June 8, 1995 effective date of the Uruguay Round Agreements Act of 1994 (URAA), § 532, Pub. L. No. 103-465, 108 Stat. 4809, 4983, and thus expired on September 23, 2013, 20 years from its earliest effective filing date. The '772 patent, on the other hand, was filed before the effective date of the URAA and pursuant to the URAA transition statute 35 U.S.C. § 154(c)(1)—expired 17 years from its issuance, on September 9, 2014. Due to a five-year patent term extension Novartis was subsequently granted 35 U.S.C. § 156, the '772 patent's term expires on September 9, 2019. And due to the intervening change in law through the implementation of the URAA, the lifespan of the '772 patent encompasses that of the '990 patent (even without considering the § 156 five-year term extension).

Applying our decision in *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014), which held that a later-filed but earlier-expiring patent can

serve as a double patenting reference for an earlier-filed but later-expiring patent, the district court found the '990 patent to be a proper double patenting reference for the '772 patent. Because the parties stipulated to invalidity if the court concluded that the '990 patent is a double patenting reference to the '772 patent, the district court found claims 1–3, 7, and 10 of the '772 patent invalid. We disagree that the '990 patent is an invalidating reference.

The patents at issue in Gilead were both filed after the effective date of the URAA and claimed different priority dates. 753 F.3d at 1210. Because Gilead's earlier-filed patent claimed an earlier priority date, despite issuing after the later-filed patent, that earlier-filed patent expired before the later-filed patent. Id. As the district court correctly summarized, we held in Gilead that the expiration date is the benchmark of obviousnesstype double patenting. But our opinion was limited to the context of when both patents in question are post-URAA patents. Id. at 1216. Here we have one pre-URAA patent (the '772 patent) and one post-URAA patent (the '990 patent), governed by different patent term statutory regimes. Our decision in *Gilead* thus does not control the present situation. Instead, the correct framework here is to apply the traditional obviousness-type double patenting practices extant in the pre-URAA era to the pre-URAA '772 patent and look to the '772 patent's issuance date as the reference point for obviousness-type double patenting. Under this framework, and because a change in patent term law should not truncate the term statutorily assigned to the pre-URAA '772 patent, we hold that the '990 patent is not a proper double patenting reference for the '772 patent. Accordingly, we reverse.

BACKGROUND

Novartis owns the '772 patent, which claims the compound everolimus, and the '990 patent, which is directed to certain methods of treatment using everolimus and

specific pharmaceutical compositions comprising everolimus. Everolimus is the active ingredient in Zortress® and Afinitor®, which can be used to treat certain cancers and prevent rejection in kidney and liver transplantations. Novartis sued Breckenridge Pharmaceutical Inc., Par Pharmaceutical, Inc., and West-ward Pharmaceuticals International Ltd. (collectively, Defendants/Appellees) for infringing claims 1–3, 7, and 10 of the '772 patent after Defendants sought FDA approval to market generic versions of Zortress® and Afinitor®.

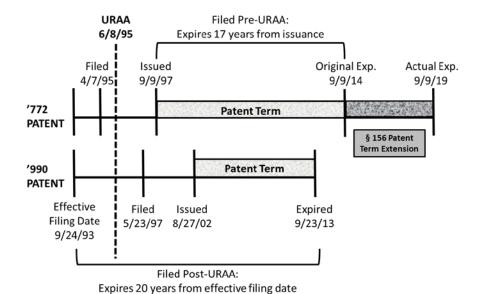
In the district court, Defendants conceded that their proposed products infringe the '772 patent's asserted claims. The parties stipulated that the '772 patent and the '990 patent are assigned to the same entity, and both patents share the same named inventors. The parties further stipulated that if the district court found the '990 patent to be a proper double patenting reference to the '772 patent, then the claims of the '990 patent would render the asserted claims of the '772 patent invalid for obviousness-type double patenting. J.A. 135. Thus, the only question before the district court was whether the '990 patent could serve as an obviousness-type double patenting reference against the '772 patent.

The '990 patent issued later, but expired earlier, than the '772 patent due solely to a change in patent term law. On June 8, 1995, the passage of the URAA changed the term of a U.S. patent from 17 years from the issuance date to 20 years from the filing date of the earliest U.S. or Patent Cooperation Treaty (PCT) application to which priority is claimed, excluding provisional applications. Pub. L. No. 36-38, 12 Stat. 246, 246 (§ 16) (1861–1994); Pub. L. No. 103-465, § 532(a), 108 Stat. 4809, 4983–85 (1994). The URAA transition statute expressly provides that the term of a patent issuing from an application filed before June 8, 1995 "shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant,

subject to any terminal disclaimers." 35 U.S.C. § 154(c)(1).

The '772 patent was filed on April 7, 1995, and issued on September 9, 1997. Because it was filed before June 8, 1995, the expiration date of the '772 patent is September 9, 2014 (17 years from the September 9, 1997 issuance date). After the '772 patent issued, Novartis obtained a five-year patent term extension under 35 U.S.C. § 156.1 The '990 patent was filed on May 23, 1997 and issued on August 27, 2002. Because it was filed after the URAA's effective date and claimed priority from a September 24, 1993 PCT filing date, the same effective filing date as the '772 patent, the '990 patent expired on September 24, The following diagram illustrates the relevant 2013. dates for each patent, and how, because of the URAA, the '990 patent has an earlier expiration date than the '772 patent.

³⁵ U.S.C. § 156 authorizes patent term extensions, if certain requirements are met, and is one of the statutes that codifies the Drug Price Competition and Patent Term Restoration Act of 1984. Public Law 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355(b), (j), (l); 35 U.S.C. §§ 156, 271, 282) (Hatch-Waxman Act). provision of this law seeks to restore the term of patents covering certain products that must receive premarket regulatory approval. See Eli Lilly & Co. v. Medtronic Inc., 496 U.S. 661, 669 (1990). For these products, the patent owner loses the value of the patent term during the early years of the patent because the product cannot be commercially marketed without approval from a regulatory agency. Novartis was granted a five-year extension on the '772 patent (the maximum extension authorized by § 156) because the '772 patent, among others, lost at least five years of commercialization due to the lengthy FDA regulatory review approval process.



Relying on our decision in *Gilead*, which holds that a later-filed but earlier-expiring patent can serve as a double-patenting reference for an earlier-filed but later-expiring patent in the post-URAA context, *see* 753 F.3d at 1212, the district court found here that the post-URAA '990 patent is a proper double patenting reference against

the pre-URAA '772 patent. Thus, the asserted claims of the '772 patent were invalid for obviousness-type double patenting because they concededly were not patentably distinct from the claims of the '990 patent. The district court acknowledged that there was no binding precedent that addressed the precise issue of whether a post-URAA patent may serve as a double patenting reference against a pre-URAA patent; however, it concluded that this court's rationale regarding the public's right to practice an invention after a patent expires, underlined in *Gilead*, applied. 753 F.3d at 1214 ("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.") (citations omitted). The district court was particularly persuaded by the fact that *Gilead* included a footnote that cited to *Ex parte Pfizer*, *Inc.*, 2010 WL 532133 (Bd. Pat. App. & Interf. Feb. 12, 2010), a case with substantially similar facts to the instant case. *Gilead*, 753 F.3d at 1211 n.2. In *Pfizer*, the Board found that a later-filed, post-URAA patent with an expiration date in 2015 could serve as a double patenting reference for an earlier-filed, pre-URAA patent with an expiration date in 2019. 2010 WL 532133 at *20–21. The Board in *Pfizer* reasoned that the later-expiring, pre-URAA patent would otherwise impermissibly extend the patent owner's right to exclude the public from practicing the invention. *Id.* at *21.

The district court also cited other post-Gilead district court decisions reaching the same conclusion in cases with similar fact patterns, including Janssen Biotech Inc. v. Celltrion Healthcare Co., 210 F. Supp. 3d 278 (D. Mass. 2016), MLC Intellectual Property, LLC v. Micron Technology, Inc., 2016 WL 4192009 (N.D. Cal. Aug. 9, 2016), and DDB Technologies, LLC v. Fox Sports Interactive Media, LLC, 2014 WL 12167628 (W.D. Tex. May 15, 2014). And it rejected Novartis's efforts to distinguish the present case from Gilead.

First, the district court rejected Novartis's argument that there is no unjustified extension of patent rights or public harm because the '772 patent's expiration date is the same as it would have been had the '990 patent never issued. The district court emphasized that it was Novartis's choice to file the '990 patent, and the harm to the public lies in the inability to practice the invention claimed in the '990 patent once it expired.

Second, the district court dismissed Novartis's argument that, unlike the patent owners in *Gilead* and *AbbVie, Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust*, 764 F.3d 1366 (Fed. Cir. 2014), Novartis did not engage in any gamesmanship such as the structuring of priority claims among related patents to

obtain the benefit of one patent gaining a later expiration date. The district court held that a patentee need not engage in gamesmanship in order to violate the principles of double patenting because neither *Gilead* nor *AbbVie* held that gamesmanship is required.

Third, the district court was unpersuaded by Novartis's argument that allowing an earlier-expiring post-URAA patent to serve as a double patenting reference for a later-expiring, pre-URAA patent would effectively shorten the statutorily mandated 17-year term of the pre-URAA patent. The district court found that Novartis ran this risk by seeking a second patent on an obvious variant of its invention claimed in its first issued patent.

Finally, the district court addressed Novartis's argument that the § 156 patent term extension it received for its '772 patent is not an unjustified extension of patent rights and effectively immunized its patent from a double patenting challenge. While the district court acknowledged that this is true in the abstract, it noted that Novartis's § 156 patent term extension grant is not at issue here and that there is no case law supporting Novartis's proposition that a term extension immunizes a patent from a double patenting challenge.² Thus, the district

This extension does not affect the obviousness-type double patenting analysis here because the '772 patent's original expiration date of September 9, 2014 (without its patent term extension under § 156) is still later than the '990 patent's expiration date of September 24, 2013. Thus, we need not address the interplay of § 156 PTEs and obviousness-type double patenting in this opinion. We address that issue in a concurrently issued opinion finding that obviousness-type double patenting does not invalidate an otherwise validly obtained PTE under § 156. See Novartis AG v. Ezra Ventures LLC, No. 2017-2284 (Fed. Cir. Dec. 7, 2018).

court held that the '990 patent is a proper double patenting reference for the '772 patent and that the '990 patent renders the '772 patent invalid for obviousness-type double patenting.

Novartis appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

"While the ultimate conclusion that a patent is invalid under the doctrine of obviousness-type double patenting is reviewed de novo, the underlying factual determinations—including the existence of secondary factors such as unexpected results—are reviewed for clear error." AbbVie, 764 F.3d at 1372 (citing Eli Lilly & Co. v. Teva Parenteral Meds., Inc., 689 F.3d 1368, 1376 (Fed. Cir. 2012)). This appeal presents a narrow legal question: can a post-URAA patent that issues after and expires before a pre-URAA patent qualify as a double patenting reference against the pre-URAA patent? We conclude under the circumstances of this case that it cannot. Therefore, the district court erred in using the '990 patent as a double patenting reference for the '772 patent.

A.

"Non-statutory, or obviousness-type, double patenting is a judicially created doctrine designed to foreclose 'claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." *Takeda Pharm. Co. v. Doll*, 561 F.3d 1372, 1375 (Fed. Cir. 2009) (quoting *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1373 (Fed. Cir. 2005)). In *Gilead*, we laid out the principles underlying the prohibition against double patenting. *See* 753 F.3d 1212–14. The core principle is 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." *Id.* at 1212. Prohibiting double patenting prevents a patentee from obtaining sequential patents on the same invention and obvious variants, to thereby effectively manufacture a timewise extension of its patent exclusivity through a later-expiring patent. *Id.* The key purpose of obviousness-type double patenting is thus to prevent a patent owner from controlling the public's right to use the patented invention beyond the statutorily allowed patent term of that invention.

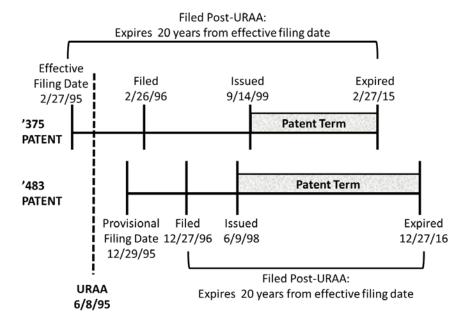
Federal courts have applied the principles of obviousness-type double patenting for over a century to restrict a patent owner's patents on an invention and obvious variants to one 17-year patent term. See, e.g., Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 967 (Fed. Cir. 2001). Traditionally, courts looked at the issuance dates of the respective patents, because, under the law pre-URAA, the expiration date of the patent was inextricably intertwined with the issuance date, and used the earlier-issued patent to limit the patent term(s) of the later issued patent(s). See Miller v. Eagle Mfg. Co., 151 U.S. 186, 196–97 (1894) (citing Suffolk in finding that a first issued patent claiming the same invention invalidates a second issued patent); Suffolk Co. v. Hayden, 70 U.S. 315, 319 (1865) (finding that where two patents covering the same invention or device were issued to the same party, the later one issued was void, even though the application for it was filed first, and holding that it is the issuance date, not the filing date, which determines which patent issued to the same inventor on the same invention is void); In re Longi, 759 F.2d 887, 895–897 (Fed. Cir. 1985); Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1372 (Fed. Cir. 2005); *Eli Lilly*, 251 F.3d at 967.

For example, for the traditional scenario of two pre-URAA patents, if a first patent issued in, say, 1990, then that first patent would expire 17 years later in 2007. If the patent owner secured a second, patentably indistinct patent in 1992, then the patent owner would be required to file a terminal disclaimer with the second patent so that it would expire at the same time as the first patent in 2007, rather than two years later in 2009. Without the terminal disclaimer, the second patent would be invalid for obviousness-type double patenting because otherwise the first and second patents collectively would give the patent owner a 19-year period of exclusivity.

In Gilead, we recognized that the change in patent term law under the URAA altered the analytical inquiry for double patenting; issuance dates of post-URAA patents did not serve as reliable stand-ins for the expiration date of the patent as is true for pre-URAA patents, and the proper reference point for an obviousness-type double patenting inquiry is the expiration date of the patent in question. 753 F.3d at 1215. On appeal, Appellees argue that Gilead controls here and urge us to apply the same expiration date-based analysis applied in *Gilead*, which would find the earlier-expiring '990 patent a proper obviousness-type double patenting reference against the '772 patent. We disagree. Gilead addressed a question that is not applicable here. In Gilead, we concluded that, under the circumstance where both patents were post-URAA, a patent that issues after but expires before another patent can qualify as a double patenting reference against the earlier-issuing, but later-expiring patent. Id. at 1211–12, 1217. Here, however, Novartis owns one pre-URAA patent (the '772 patent) and one post-URAA patent (the '990 patent), and the 17-year term granted to the '772 patent does not pose the unjustified time extension problem that was the case for the invalidated patent in Gilead.

Gilead involved U.S. Patent Nos. 5,763,483 and 5,952,375. *Id.* at 1209. When Gilead Sciences, Inc. (Gilead) sued Natco Pharma Limited (Natco) for infringement of its '483 patent, Natco asserted that the '483 patent was invalid for obviousness-type double patenting over Gile-

ad's '375 patent. *Id*. The '375 and '483 patents were issued to the same inventors, commonly owned by Gilead, and contained very similar specification disclosures. *Id*. at 1210. The post-URAA '375 patent was filed on February 26, 1996, claimed priority from a patent application filed on February 27, 1995, and expired on February 27, 2015. *Id*. The post-URAA '483 patent was filed on December 27, 1996, claimed priority from a provisional application filed on December 29, 1995, and expired on December 27, 2016. *Id*. The following diagram illustrates the relevant dates for the two patents at issue in *Gilead*:



While we found that the '375 patent could serve as a double patenting reference against the '483 patent, even though the '483 patent issued first and expired 22 months after the '375 patent, our holding was limited to the post-URAA context.

Throughout *Gilead*, we repeatedly noted that our analysis was rooted in the consequences that flow from the implementation of the URAA's new patent term rule

under which a patent expires 20 years from the effective filing date:

[F]or 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.

Id. at 1215.

And we discussed several shortcomings of relying on issuance dates for patents in the post-URAA context where the patent term is 20 years from the earliest effective filing date, but none are applicable to this case. One such shortcoming is that patent terms could be subject to significant gamesmanship during prosecution. Id. If the double patenting inquiry post-URAA was limited to focusing on patent issuance dates, inventors could orchestrate patent term extensions by filing serial applications on obvious variants of the same invention, claiming priority from different applications in each, and arranging for the application with the latest filing date to issue first. Id. We noted in our opinion that Gilead had "crafted a separate 'chain' of applications, having a later priority date than the '375 patent family" such that the later-filed but earlier-issued '483 patent expired second. *Id.* at 1210.

Another shortcoming of using the issuance date for post-URAA patents is that a mere day's difference in the issuance of multiple patents could result in a significant difference in an inventor's period of exclusivity. *Id.* at 1215. To illustrate this, in *Gilead* we noted that if the '375 patent had issued the day before the '483 patent, the last 22 months of the term of the '483 patent would have been an improper extension of patent term. *Id.* at 1215–16.

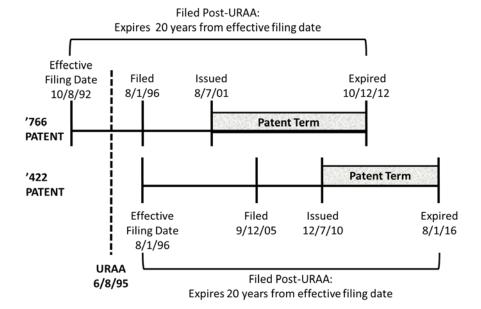
Here, the present facts do not give rise to similar patent prosecution gamesmanship because the '772 patent expires after the '990 patent only due to happenstance of an intervening change in patent term law. Both the '772 and the '990 patents share the same effective filing date of September 24, 1993. If they had been both pre-URAA patents, the '990 patent would have expired on the same day as the '772 patent by operation of the terminal disclaimer Novartis filed on the '990 patent, tying its expiration date to that of the '772 patent. And if they had been both post-URAA patents, then they would have also both expired on the same day. Thus, the current situation does not raise any of the problems identified in our prior obviousness-type double patenting cases. At the time the '772 patent issued, it cannot be said that Novartis improperly captured unjustified patent term. The '990 patent had not yet issued, and the '772 patent, as a pre-URAA patent, was confined to a 17-year patent term. Moreover, unlike *Gilead*, Novartis here did not structure the priority claim of its '990 patent to capture additional patent term beyond the term it was granted for its '772 patent. In fact, the '990 patent's term expired before the '772 patent's original 17-year term. Given the different circumstances in this case, our holding in Gilead does not resolve the narrow question on appeal here.

В.

Following *Gilead*, we confirmed in *AbbVie* that obviousness-type double patenting continues to apply post-URAA. 764 F.3d at 1368. While Appellees are correct on appeal that the URAA does not abrogate the doctrine of obviousness-type double patenting, we disagree with Appellees that *AbbVie* controls here. Like *Gilead*, *AbbVie* is inapposite because it also involved two post-URAA patents. *Id.* at 1369–70. In *AbbVie*, appellant Kennedy argued that the URAA and its implementation of a 20-year period of protection running from a patent's earliest claimed priority date eliminated the need for the obvious-

ness-type double patenting doctrine. *Id.* at 1373. We disagreed. While we recognized "that the unjustified patent term extension justification for obviousness-type double patenting' may have 'limited force in . . . many double patenting rejections today, in no small part because of the change in the Patent Act from a patent term of seventeen years from issuance to a term of twenty years from filing," we also reaffirmed its continued importance. *Id.* at 1373–74 (citing *In re Fallaux*, 564 F.3d 1313, 1318 (Fed. Cir. 2009)).

AbbVie is a prime example of the post-URAA scenario we contemplated in *Gilead* where an inventor, seeking to prolong his exclusivity rights over his invention, applies for a second patent on an obvious variant of his invention protected by a first patent but chooses a different, later priority date than the one relied on for the first patent so that the second patent expires later than the first patent. The following diagram illustrates the relevant dates for the two patents at issue in *AbbVie*, U.S. Patent Nos. 7,846,442 and 6,270,766. *Id.* at 1369–70.



The first-issued '766 patent was filed on August 1, 1996, claimed priority from October 8, 1992, and expired October 12, 2012. Id. at 1369. The second-issued '422 patent was filed on September 12, 2005, claimed priority from August 1, 1996 (rather than October 8, 1992), and expired on August 21, 2018. *Id.* at 1370. AbbVie sought a declaratory judgment that claims of the '422 patent (second-issued, second-expiring) were invalid over the '766 patent (first-issued, first-expiring) for obviousnesstype double patenting. Id. at 1370. We agreed with the district court's double patenting invalidity ruling, explaining that the patent owner had impermissibly sought an undue patent term extension for its later-expiring, patentably indistinct claims by choosing to claim different priority dates for its patent applications, thereby ensuring that the resulting patents would have different expiration dates. AbbVie is distinguishable from the situation here because it not only involved two post-URAA patents, but also because the earlier-filed patent had an earlier issuance date and earlier expiration date.

C.

In this particular situation where we have an earlier-filed, earlier-issued, pre-URAA patent that expires after the later-filed, later-issued, post-URAA patent due to a change in statutory patent term law, we decline to invalidate the challenged pre-URAA patent by finding the post-URAA patent to be a proper obviousness-type double patenting reference.³ Instead, we apply our traditional, pre-URAA obviousness-type double patenting practice, *see supra*, to Novartis's challenged pre-URAA patent. That

³ We recognize that there are other fact patterns that could arise from hybrid situations in which one patent is pre-URAA and the other is post-URAA. We decline to address those other fact patterns in this opinion and limit our opinion to the specific facts of this case.

is, we use the '772 patent's issuance date as the reference point for our obviousness-type double patenting analysis. As we recognized in *Gilead*, looking to the patent issuance dates pre-URAA serves as a reliable guide for assessing whether a patent may serve as a double patenting reference against another patent. *See* 753 F.3d at 1215. Under this analysis, the '990 patent is not a proper obviousness-type double patenting reference for the '772 patent. When the '772 patent issued, the '990 patent had not yet issued and thus did not exist as a double patenting reference against the '772 patent.

This approach is most consistent with the URAA transition statute, which ensures that patent owners, like Novartis with its pre-URAA '772 patent, enjoy the greater of a 20-year from earliest effective filing date or 17-year from issuance patent term. The statute reads: "The term of a patent that is in force on or that results from an application filed before [June 8, 1995] shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaim-35 U.S.C. § 154(c)(1) (emphasis added). Congress could have written the transition statute to strictly give any patents filed before the transition date a 17-year-from-issuance term and any patents filed after the transition date a 20-year-from-the-earliest-priority date term, by using the language "shall be the greater of," Congress intended patent owners who filed patent applications before the transition date to the new patent term law to enjoy the maximum possible term available for their resulting patents under either patent term regime. Thus, to require patent holders to truncate any portion of the statutorily-assigned term of a pre-URAA patent that

extends beyond the term of a post-URAA patent would be inconsistent with the URAA transition statute.⁴

Moreover, this approach is consistent with the core principle underlying the double patenting doctrine: giving one invention and nonobvious variants of that invention the same patent term. See infra. The key purpose of obviousness-type double patenting is to prevent a patent owner from extending the exclusivity rights over his invention beyond a full patent term. We saw this impermissible practice in Gilead and in AbbVie, where the patent owners claimed different effective filing dates for different patents to extend the life of patent exclusivity. Gilead, 753 F.3d at 1210–11; AbbVie, 764 F.3d at 1369– 71. Here, critically, Novartis did not seek to extend its patent rights over its everolimus invention beyond one patent term, in this case, 17 years from issuance of the Had the law not changed, regardless of '772 patent. whether Novartis obtained the '990 patent, the '772 patent would have expired on September 9, 2014 (September 9, 2019 with the patent term extension). The fact that the law for the term of a patent changed, resulting in

⁴ Appellees point to the "subject to any terminal disclaimers" language in the statute to argue that the '772 patent was subject to a terminal disclaimer once the '990 patent subsequently issued. But that argument lacks merit because it assumes this statutory language commands how to assess whether a given patent's term should be terminally disclaimed; we instead read "subject to any terminal disclaimers" in its ordinary sense that a patent's term provided for in this transition provision may be subject to a terminal disclaimer depending on the relevant facts, as is true for the term of any patent. But as explained *supra*, no terminal disclaimer was necessary for the '772 patent because the '990 patent is not a proper double patenting reference.

the later-issued '990 patent having an earlier expiration date than it would have pre-URAA should not affect the '772 patent's statutorily-granted 17-year patent term. Rather than Novartis receiving a windfall with a 17-year term for its '772 patent, its '990 patent's term was truncated by the intervening change in law. To find that obviousness-type double patenting applies here because a post-URAA patent expires earlier would abrogate Novartis's right to enjoy one full patent term on its invention.

CONCLUSION

The district court erred in finding that the post-URAA '990 patent is a proper obviousness-type double patenting reference for the pre-URAA '772 patent. We have considered Appellees' other arguments and find them unpersuasive. Therefore, we reverse the district court's decision.

REVERSED

Costs

No Costs.