



PATENT HAPPENINGS

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Obviousness-Type Double Patenting Should Not Nullify A Patent Term Adjustment

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Long and arduous, the path of prosecution began with the filing of a parent patent application. Several years later, the applicant files a first continuation application. A few more years pass. The applicant then files a second continuation application. More time passes until the first continuation finally issues. A few months later, the second continuation issues. Because both patents claim priority back to the parent application, they both ordinarily would expire 20 years from the parent's application filing date. For the first patent, however, the Patent Office (PTO) awards a significant amount of "Patent Term Adjustment" (PTA).¹ The PTO does not award any PTA for the second patent. As a result, the second patent, a later-filed and later-issued patent, will expire before the first patent, an earlier-filed and earlier-issued patent.

The patent owner asserts the patents against a competitor. The competitor argues that the doctrine of obviousness-type double patenting (ODP) invalidates the claims of the first patent because the claims of the early-expiring second patent, even though later-filed and later-issued, allegedly render obvious

¹ Under 35 U.S.C. § 154(b)(1), "the term of the patent shall be extended 1 day for each day" that the PTO failed to act within a certain time frame as specified in various provisions within the statute, and subject to limitations and adjustments set forth in the statute to account for the applicant's prosecution delays. *See generally*, Robert A. Matthews, Jr., ANNOTATED PATENT DIGEST § 9:24 – Extensions for PTO Delays [*hereinafter* "APD"]. The statute calls the time frames in which the PTO must act as "Patent Term Guarantees." Patent parlance refers to this type of patent term extension as a Patent Term Adjustment (PTA). This terminology serves to distinguish this type of term extension from a Patent Term Extension (PTE) awarded pursuant to 35 U.S.C. § 156 for products that have undergone FDA regulatory review. *See generally*, APD § 9:23 Extensions for FDA Delays under § 156.



the challenged claims of the first patent.² The competitor argues that unless the patentee files a terminal disclaimer³ and effectively surrenders all of the PTA awarded by the PTO for the first patent, the court should invalidate the challenged claims of the first patent. The competitor moves for summary judgment on the defense. What should the court do: uphold the PTA, expressly provided for by statute as a “guarantee” of patent term; or apply a judge-made doctrine to undo the “guarantee” of PTA if the applicant refuses to file, or can’t file, a terminal disclaimer?

In 2015, the district court in *Magna Elecs., Inc. v. TRW Automotive Holdings Corp.*,⁴ had to resolve this issue on a similar fact pattern. Sending a wave of trepidation to patent owners counting on the ability to enjoy PTA awarded to their patents,⁵ the district court granted summary judgment that obviousness-type double patenting applied in this scenario. Having done nothing more than filing a second continuation application which issued as a patent, the patentee in *Magna* lost the PTA for its earlier-filed patent.

Whether ODP can nullify PTA where the award of PTA provides the only reason for the patents differing expiration dates presents an economically important issue for patent owners. Yet the *Magna*

² Generally, ODP applies to invalidate claims of a later-expiring patent if those claims are merely an obvious variant of the claims of an earlier-expiring patent and the patents are commonly owned or have a common inventive entity. See APD § 19:8 Overview of Obviousness-Type Double Patenting. Typically, a court applies a “one-way test” and looks to see if the challenged claims of the later-expiring patent are obvious in view of a claim of the earlier-expiring patent. See APD § 19:20 One-Way Test Generally Applies. In rare circumstances, a “two-way” test, used in analyzing *statutory* double patenting, can apply in analyzing ODP where the claims of the later-expiring patent must additionally render the claims of the earlier-expiring patent obvious. See APD § 19:21 Two-Way Test Applicable in Limited Circumstances. In all instances, the test for ODP focuses on a comparison of the patent claims, not a comparison of the disclosure in the specifications of the two patents. See APD § 19:16 Analysis Must Compare the Claims, Not the Disclosure.

³ A patentee can moot an ODP challenge by filing a terminal disclaimer in which the patentee surrenders the portion of the patent term of the later-expiring patent that extends beyond the expiration date of the earlier-expiring patent. See *generally*, APD § 19:11 Terminal Disclaimer Can Overcome Obviousness-Type Double Patenting. Additionally, by PTO regulation, the terminal disclaimer must also ensure that the two patents remain commonly owned or else the terminally disclaimed patent loses its enforceability during any period of time in which common ownership did not exist. 37 C.F.R. § 1.321(c)(3). See *In re Van Ornum*, 686 F.2d 937, 948 (CCPA 1982) (upholding the regulation); see e.g., *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009) (applicant could not file a terminal disclaimer to overcome an ODP challenge since he permitted the earlier patent and the rejected application to be assigned to different entities).

⁴ No. 1:12-cv-654; 1:13-cv-324, 2015 WL 11430786, *3-*6 (W.D. Mich. Dec. 10, 2015).

⁵ Surprisingly, the authors have not found any other judicial opinions that have cited or relied on *Magna* to address whether ODP can nullify a PTA. Indeed, in researching the issue for this article, the authors located only one other case that raised the issue of whether ODP can negate a PTA. See *XY, LLC v. Trans Ova Genetics, LC*, No. 17-cv-00944-WJM-NYW, 2018 WL 11000694, *2 (D. Colo. May 14, 2018) (noting that the accused infringer asserted that the “newly-identified ’367 and ’541 Patents each constitute invalidating obviousness-type double patenting (‘ODP’) prior art against the ’559 Patent, which (due to patent term adjustment) expires more than five years after the ’367 and ’541 Patents”), *related appeal*, 968 F.3d 1323, 1330-32 (Fed. Cir. 2020) (reversing a judgment on the pleadings that the claims of the ’559 Patent were invalid under § 101 and remanding). However, at the time the authors wrote this article, the district court had not yet issued any published opinions addressing the substance of the ODP defense. Further, from examining the case docket, it appears that the accused infringer has opted to drop the ODP defense and pursue other defenses.



court did not directly address this issue when it struck down the patent for ODP. Instead, it appears that the patentee merely argued that ODP could not apply because the patent forming the basis for the ODP challenge issued after the challenged patent.⁶ Relying on *Gilead*,⁷ the district court rejected this argument:

Magna's expert provides a rebuttal on double patenting, but the Court finds Mr. Nranian's rebuttal largely unpersuasive. For example, Mr. Nranian opined that a later issued patent (but still earlier-expiring one) cannot be used for double patenting. This is a clear misstatement of the law, as TRW notes. See *Gilead*, 753 F.3d at 1217. Regardless, however, it's the Court's duty to interpret and apply the law.

* * *

Gilead is indistinguishable from this case for purposes of deciding whether the doctrine can apply here.

TRW correctly notes that *Gilead* stands for the simple proposition that a court should look to the expiration dates not the issuance dates to determine if a patent can be used as the prior art patent under the doctrine.⁸

In reaching its holding, the district did not expressly address that the patents had differing expiration dates only because the PTO awarded the specified amount of PTA based on the PTO's delay in completing its examination, something not caused by the patent applicant. But one cannot fault the district court for not explicitly addressing this point since the patentee arguably conceded the point when it stated to the court “double patenting is to prevent unjustified timewise extension of the right to exclude granted by a patent *no matter how the extension is brought about.*”⁹

For the reasons that follow, and in view of later issuing Federal Circuit precedent, the authors believe that the Federal Circuit would not uphold the district court's judgment if confronted with the issue today.

⁶ The saga of the *Magna* litigation involved three infringement actions, which the court consolidated for pretrial purposes, and over 20 asserted patents from three different patent families. See generally, *Magna Elecs., Inc. v. TRW Automotive Holdings Corp.*, No. 1:12-cv-654; 1:13-cv-324, 1:13-cv-687, 2013 WL 12086667, *1 (W.D. Mich. Sep. 25, 2013) (describing the three suits and how the court would administer them). Hence, the practical circumstances of the case may have influenced the patentee not attacking the ODP defense as strongly as it attacked other defenses in the suit.

⁷ *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1214-17 (Fed. Cir. 2014) (over the dissent of Judge Rader, vacating a summary judgment dismissing an obviousness-type double patenting challenge and remanding because district court erred in ruling that a later-issued but earlier-expiring patent could not be used as a double patenting reference to an earlier-issued and later-expiring patent, the Federal Circuit noting that later-expiring patent improperly impeded the public's right to practice the earlier-expiring patent, and therefore obviousness-type double patenting could apply).

⁸ *Magna*, 2015 WL 11430786, at *3-*4.

⁹ *Id.* at *4 (emphasis in original and added by district court judge to the patentee's statement). The “no matter how the extension is brought about” language used by the accused infringer does appear in quotes from the Federal Circuit that summarily describe the justification for having ODP. *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (“There are two justifications for obviousness-type double patenting. The first is ‘to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about.’”) (quoting *In re Van Ornum*, 686 F.2d 937, 943-44 (C.C.P.A. 1982).) Arguably, the district court may have read too much into the patentee's concession based on the patentee repeating a statement of dicta from the Federal Circuit that long preceded the introduction of PTA into U.S. patent law.



We believe that the Federal Circuit would find that by merely enjoying a PTA on one patent that originally would have expired with the patent asserted to create the ODP violation, the patentee has not engaged in conduct that amounts to an “*unjust* time-wise extension” of the patent’s term that permits applying ODP. Accordingly, the judge-made doctrine of ODP should not overcome a statutorily granted extension of a patent’s term with a PTA.

The *Magna* court faced an issue of first impression with little guidance available from the Federal Circuit. Several years earlier, the Federal Circuit instructed in *In re Fallaux*¹⁰ that changes made in measuring patent term based on the patent’s effective filing date, rather than its issue date,¹¹ did not necessarily obviate the need for the doctrine of obviousness-type double patenting. In so doing, the court stated “in some cases there may still be the possibility of an unjust time-wise extension of a patent arising from patent term adjustment under § 154 [i.e., PTA] or patent term extension under § 156 [i.e., PTE].”¹² Unfortunately, while suggesting that ODP may apply to patents having PTA or PTE, the Federal Circuit did not offer any examples of what might constitute an “*unjust* time-wise extension” of a patent’s term based on awarded PTA.

A year after handing down *Fallaux*, the Federal Circuit, in *Boehringer Ingelheim Intern. GMBH v. Barr Labs., Inc.*,¹³ addressed an example of a patentee’s conduct in using awarded PTE that rose to the level of an “unjust time-wise extension” of the patent’s term. There, the asserted patent had received 1,564 days of PTE. The accused infringer argued that based on the claims of a sibling patent, ODP should apply to invalidate the claims of the asserted patent. During the infringement action, the patentee sought to negate the ODP defense by filing a terminal disclaimer. The patentee argued that it could terminally disclaim the original term of its patent so that its original expiration date coincided with the expiration date of the sibling patent and then add all of the PTE to that adjusted expiration date.¹⁴

¹⁰ 564 F.3d 1313, 1318-19 (Fed. Cir. 2009).

¹¹ See *Golan v. Pingel Enterprise, Inc.*, 310 F.3d 1360, 1364 n.1 (Fed. Cir. 2002) (“Effective June 8, 1995, the patent laws were amended to change the term of a patent from seventeen years measured from the date the patent issued to twenty years measured from the filing date of the earliest U.S. application for which priority benefit is claimed. ...”); see generally APD § 9:17 Patents in Force or Applications Filed Before June 8, 1995. Patents subject to a term of 17 years measured from issue dates are often referred to as pre-URAA patents. URAA refers to the Uruguay Rounds Agreement Act that led to Congress changing the patent term.

¹² *Fallaux*, 564 F.3d at 1319.

¹³ 592 F.3d 1340, 1347-49 (Fed. Cir. 2010).

¹⁴ The law permits applying PTE to a patent subject to a terminal disclaimer. *Merck & Co., Inc.*, 482 F.3d 1317, 1322-23 (FDA extension properly applied to extend the life of a terminally disclaimed patent for 1233 days as measured from the expiration of the patent applying the terminal disclaimer and rejecting accused infringer’s argument that the terminal disclaimer totally barred applying the FDA extension since the underlying patent was not also extended, the court instructing “[t]he computation of a Hatch-Waxman patent term extension is from the expiration date resulting from the terminal disclaimer and not from the date the patent would have expired in the absence of the terminal disclaimer. Any waiver of the term is thus not ignored or nullified because the terminal disclaimer provides the date from which the patent term extension begins.”). In contrast, PTA may not extend the term of a patent subject to a terminal disclaimer past the expiration date



However, at the time it filed the terminal disclaimer the sibling patent had already expired. According to the Federal Circuit, this gave the patentee an “unjust” advantage that the ODP doctrine seeks to prohibit. The Federal Circuit explained:

By failing to terminally disclaim a later patent prior to the expiration of an earlier related patent, a patentee enjoys an *unjustified* advantage—a purported time extension of the right to exclude from the date of the expiration of the earlier patent. The patentee cannot undo this *unjustified timewise extension* by retroactively disclaiming the term of the later patent because it has *already* enjoyed rights that it seeks to disclaim.¹⁵

The patentee further argued that because its patent enjoyed a PTE, it had not unjustly enjoyed any timewise extension of its patent term, but had simply benefited from an extension expressly granted by the statute. The Federal Circuit rejected this argument. It noted that under a PTE, a patentee does not enjoy as broad a scope of exclusionary rights as during the original term.¹⁶ Consequently, by not filing the terminal disclaimer until after the sibling patent had expired the patentee had engaged in “precisely the type of ‘unjustified timewise extension of the right to exclude’ that the doctrine of obviousness-type double patenting is designed to prevent.”¹⁷ Thus, *Boehringer* teaches that in analyzing whether ODP should apply to negate a patent term extension, the patentee must have engaged in conduct that unjustly allowed it to enjoy greater rights than what a proper application of the law allows.¹⁸

Arguably, the Federal Circuit muddied the water as to what conduct counts as an “*unjust* time-wise extension” of patent term sufficient to apply ODP in *Gilead*. In *Gilead*, the patentee filed a first patent application claiming priority to a parent application filed a year earlier. Ten months later (22 months after the filing of the parent application), the patentee filed a second patent application having a written description “very similar and, in substantial parts, identical” to the first patent application.¹⁹ However,

imposed by the terminal disclaimer. 35 U.S.C. § 154(b)(2)(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.”).

¹⁵ *Boehringer Ingelheim*, 592 at 1347-48 (emphases added).

¹⁶ *Id.* at 1349. See also 35 U.S.C. § 156(b); *Biogen Intern. GmbH v. Banner Life Sciences LLC*, 956 F.3d 1351, 1356-58 (Fed. Cir. 2020) (“Subsection (b) limits the scope of the patent extension to ‘any use approved for the product,’ and further, for method of treatment patents, to uses also ‘claimed by the patent.’ § 156(b)(2).”); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996) (“[T]he restoration period of the patent does not extend to all products protected by the patent but only to the product on which the extension was based. *Id.* at § 156(b)(1).”).

¹⁷ *Boehringer Ingelheim*, 592 at 1349.

¹⁸ Later in the opinion, the Federal Circuit ruled that the safe harbor provision of § 121 applied to the underlying patent asserted as the ODP reference, and therefore, the ODP defense failed on that ground. *Id.* at 1354. See generally, APD § 19:10 Divisional Applications Based on PTO Restriction Requirements (discussing § 121’s safe harbor). Accordingly, while instructive and persuasive, as *dicta*, the Federal Circuit’s discussion in this opinion of the need to find acts showing an unjust timewise extension of term to support applying ODP carries no precedential weight. See generally, APD § 2:13 Dictum Limits Scope of What is Binding & § 2:16— Dictum of Prior Federal Circuit Decisions.

¹⁹ 753 F.3d at 1210.



in the second patent application the patentee did not claim priority to the first patent application and its parent. Consequently, applying the 20-year term measured from the later priority date, the patent maturing from the second application expired 22 months later than the patent maturing from the first patent application. Additionally, one should also note, that by having the later priority date, the patentee had subjected itself to the risk that prior art arising during that 22-month intervening period could apply against the application's claims in the second patent (not only during prosecution, but also in any future litigation). For reasons not disclosed in the opinion, and thus apparently unrelated to any acts taken by the patentee during prosecution of the two sets of applications, the second-filed patent application issued as a patent before the first-filed patent had issued. Other than describing the patentee as having "crafted" the second and separate chain of applications to have a later priority date,²⁰ and thereby to expire later, the majority did not identify any "unjust" action taken by the patentee or a benefit unfairly enjoyed by the patentee.

Over the dissent of Judge Rader, the majority in *Gilead* ultimately held that the although the first-filed patent issued after the second-filed patent, it was proper to use the first-filed patent as an ODP reference against the second-filed patent since the second patent expired 22 months later.²¹ While not identifying any unjust or improper acts taken by the patentee,²² the majority instructed that if it did not apply ODP in this circumstance "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."²³ Again, the court pointed to no evidence that the patentee had "arranged" for the second-filed application to issue first.²⁴

²⁰ *Id.*

²¹ *Id.* at 1214-17.

²² The majority did characterize the patentee as "enjoy[ing] the benefits of the '375 patent, including an earlier priority date and the specific exclusivity provided by the scope of its claims." But that appears to have no bearing on the patentee prosecuting and obtaining a second patent, with differing claim scope, for which 22 additional months of possible prior art could apply to defeat its validity.

²³ *Id.* at 1215.

²⁴ The Federal Circuit's apparent hostility to an applicant filing two patent applications having different priority dates, with resulting differing expiration dates, may find root in the court's treatment of the two-way test for ODP for pre-URAA patents. For pre-URAA patents, in the rare circumstance that the PTO, through no fault of the applicant, issued a later-filed patent application before it issued an earlier-filed application, the court, as an exception to the general rule of only applying a one-way test, would apply a two-way test in analyzing ODP. See note 2, *supra*. The Federal Circuit, however, has held that "if an applicant can file all of its claims in one application, but elects not to, it is not entitled to the exception of the two-way test." *In re Berg*, 140 F.3d 1428, 1434 (Fed. Cir. 1998). *E.g. In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1375-76 (Fed. Cir. 2008) (PTO properly applied a one-way test for ODP, where the court concluded the applicant could have filed the claims at issue earlier but instead through provoking interference and filing continuation applications it delayed in presenting the claim to the PTO, and therefore the circumstances did not justify applying the "narrow exception" of using a two-way



In his dissent Judge Rader disagreed with the majority's assessment. In his view, the patentee's "conduct" in filing a second application claiming a later priority date "does not rise to [a] level" justifying "the creation of a new rule proscribing its patent rights."²⁵ He noted that "to obtain a longer patent term, a patentee must forfeit its earlier claim to priority and subject any new patent to intervening prior art." And here, the patentee had "followed that precise approved course."²⁶

Despite Judge Rader's cogent comments, the Federal Circuit, in *AbbVie Inc. v. Kennedy Institute of Rheumatology Trust*,²⁷ again affirmed that the mere filing of two separate patent applications claiming different priority dates justifies applying ODP if the patents have different expiration dates. The court emphatically stating:

We now make explicit what was implicit in *Gilead*: the doctrine of obviousness-type double patenting continues to apply where two patents that claim the same invention have different expiration dates. ... [The patentee] is not entitled to an extra six years of monopoly solely because it filed a separate application unless the two inventions are patentably distinct.²⁸

Against this backdrop, in 2018, the Federal Circuit explicitly addressed whether ODP can nullify a PTE in *Novartis AG v. Ezra Ventures, LLC*.²⁹ There the patentee had two patents related to a drug product. The first patent, a pre-URAA patent that expired 17 years after its issue date, covered the drug product. The second patent, a post-URAA patent, that expired 20 years from its filing date, covered a method of administering the drug product claimed in the first patent. The PTO issued the first patent several months before the patentee had filed the patent application that led to the second patent. Based on the 17-year term, the first patent would have expired approximately three and half years before the second patent would expire. But the patentee had obtained a PTE for the claims of the first patent, thereby extending its term for five more years, with the first patent thereby expiring approximately a year and half after the second patent.³⁰

During an infringement suit, the accused infringer argued that in view of the extended expiration date of the first patent from the awarded PTE, ODP should apply to invalidate the claims of the first patent in view of the earlier-expiring second patent. The Federal Circuit disagreed. The court held that

test). Thus, judicial history may support the majority's view in *Gilead* showing displeasure when an applicant appears to have spread claims across multiple applications.

²⁵ *Id.* at 1219 (Rader, C.J., *dissenting*).

²⁶ *Id.*

²⁷ 764 F.3d 1366, 1373-74 (Fed. Cir. 2014) (claims in a species patent were invalid for obviousness-type double patenting over claims in an expired patent directed to a genus because the genus was sufficiently small enough that its disclosure made the species an obvious variant).

²⁸ *Id.* at 1374.

²⁹ 909 F.3d 1367, 1373-75 (Fed. Cir. 2018).

³⁰ *Id.* at 1370.



when a term extension causes a patent, which would have otherwise expired before the double patenting reference expires, to expire after the double patenting reference expires, ODP does not apply. In short, “obviousness-type double patenting does not invalidate a validly obtained PTE in such a scenario.”³¹

Writing for the court, Judge Chen, who also authored the majority opinion in *Gilead*, instructed that where a statutorily provided term extension results in an earlier-filed and earlier-issued patent having a later expiration date than a second patent that term extension does not trigger ODP concerns.

This case does not raise the traditional concern with obviousness-type double patenting of a patent owner ‘extending his exclusive rights to an invention through claims in a later-filed patent that are not patentably distinct from claims in the earlier filed patent.’ Here, it is the earlier-filed, earlier-issued ’229 patent, not the later-filed, later-issued ’565 patent, that has the later expiration date, due to a statutorily-allowed term extension under § 156.³²

Judge Chen distinguished the PTE scenario from *Gilead* and *AbbVie* by noting that here the applicant had not attempted to engage in “gamesmanship” by “structuring priority claims” that would result in the first patent expiring later than the second patent despite having patentably indistinct claims from the second patent.³³ Indeed, the court noted that “[b]ut for the § 156 PTE, the ’229 patent would have expired before the ’565 patent. So there is also no concern that Novartis, once its ’229 patent issued, sought to subsequently ‘secur[e] a second, later-expiring patent for the same invention’ as in *AbbVie Inc.*...”³⁴

Rejecting the accused infringer’s argument that the PTO should not award PTE if the resulting term extension will violate ODP, Judge Chen explained that the PTO should examine ODP issues based on the patent’s validity *without* the extension.

Finally, Ezra argues that a PTE must not be granted if such an extension violates other provisions of law, such as invalidity under ... obviousness-type double patenting. We agree to the extent of considering a patent’s validity *without* a § 156 extension. For example, if a patent, under its original expiration date without a PTE, should have been (but was not) terminally disclaimed because of obviousness-type double patenting, then this court’s obviousness-type double patenting case law would

³¹ *Id.* at 1373. Viewed in isolation, the phrase “in this scenario” might suggest that the court’s ruling depends on the unique characteristics of PTE, and as such its ruling would not apply to other forms of extensions, such as a PTA. As previously discussed, in *Boehringer Ingelheim*, the Federal Circuit expressly relied on some of the unique characteristics of PTE to rule that the patentee had obtained an unjust timewise extension of its patent such that ODP applied. Unlike *Boehringer Ingelheim*, however, and as explained, *infra*, in *Ezra* the Federal Circuit did *not* rely on any of the unique characteristics of PTE in reaching its conclusion that ODP should not apply to negate a validly obtained statutory extension of a patent term. Thus, in the authors’ view, the “in this scenario” phrase merely refers to the situation where the statutory grant of a term extension for the challenged patent provides the sole cause for the challenged patent to expire later than the ODP reference.

³² *Id.* at 1374.

³³ *Id.*

³⁴ *Id.* at 1375.



apply, and the patent could be invalidated. However, *if a patent, under its pre-PTE expiration date, is valid under all other provisions of law, then it is entitled to the full term of its PTE.*³⁵

As a final reason for not applying ODP, Judge Chen remarked that if the court applied ODP to nullify the PTE, that “would mean that a judge-made doctrine would cut off a statutorily-authorized time extension,” something the Federal Circuit would not do.³⁶ This aspect of the opinion has support in Judge Rader’s dissent in *Gilead* where, in speaking against what he viewed as an improper expansion of the ODP doctrine, he cautioned that “courts should be reluctant to create or expand judge-made exceptions to statutory grants.”³⁷ This view has good company as the Supreme Court has refused to permit a judge-made doctrine to eliminate a temporal right granted by a statute to enforce a patent, overruling years of prior Federal Circuit precedent.³⁸

On the same day as it handed down *Ezra*, in a second opinion written by Judge Chen, the Federal Circuit refused to permit ODP to shorten the 17-year term of a pre-URAA patent, also subject to PTE, in view of a post-URAA patent that, although later-filed, and claimed the same priority date as the pre-URAA patent, expired earlier.³⁹ The court held that “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.”⁴⁰ The court further instructed that if it found “that obviousness-type double patenting applies here because a post-URAA patent expires earlier [that] would abrogate Novartis’s right to enjoy one full patent term on its invention.”⁴¹ Accordingly, the Federal Circuit reversed the judgment of invalidity for ODP thereby allowing the patentee to enjoy the full 17-year term measured from the issue date *plus* the additional 5-year extension provided by the PTE.

The Federal Circuit has yet to address whether ODP can apply to nullify a PTA. Under the facts of the *Magna*-type hypothetical set out at the beginning of this article, and the rationale of *Ezra*, ODP

³⁵ *Id.* at 1374 (first emphasis in original, second emphasis added).

³⁶ *Id.*

³⁷ *Gilead*, 753 at 1215 (Rader, C.J., *dissenting*) (citing *W. Union Tel. Co. v. Lenroot*, 323 U.S. 490, 514, 65 S.Ct. 335 (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 (1979) (“Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference.”)).

³⁸ See, e.g., *SCA Hygiene Products Aktiebolag v. First Quality Baby Products, LLC*, 137 S. Ct. 954, 961 & 967 (2017) (overruling Federal Circuit precedent that allowed laches, a judge-made doctrine of equity, to bar all pre-suit damages since that ran contrary to the Court’s assessment that in § 286 Congress provided that “a patentee may recover damages for any infringement committed within six years of the filing” its infringement suit). See also *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 134 S. Ct. 1962, 1977 (2014) (reversing judgment that when laches applies it bars all pre-suit damages under the Copyright Act given that by statute the copyright holder may sue for damages going back three years).

³⁹ *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical, Inc.*, 909 F.3d 1355, 1362-67 (Fed. Cir. 2018)

⁴⁰ *Id.* at 1366.

⁴¹ *Id.* at 1367.



should not negate the PTA. When patents subject to a 20-year term measured from their priority date have the same priority date, as in *Magna*, they expire at the same time. ODP does not come into play.⁴² If the PTO awards PTA to one patent, and that patent thereby expires later solely because of the PTA, then, just like the patent at issue in *Ezra*, no concern arises that the patentee has somehow gamed the system to enjoy extra patent term.⁴³ The PTA does not give the patentee an “unjust time-wise extension” of the patent’s term. Thus, ODP should not apply and the patentee gets to exercise the full extent of the PTA. This conclusion comports with the legislative history of § 154 regarding PTA where Congress explained that under its amendments to § 154

no patent applicant diligently seeking to obtain a patent will receive a term of less than the 17 years as provided under the pre-GATT standard; in fact, most will receive considerably more. Only those who *purposely manipulate* the system to delay the issuance of their patents will be penalized under Title III, a result that the Committee believes entirely appropriate.⁴⁴

⁴² *Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp.3d 466, 484-85 (D. Del. Mar. 7, 2019) (granting patentee summary judgment of no ODP where both patents had “the same priority date and have no patent term extension,” and “[t]herefore, obviousness-type double patenting does not apply as a matter of law”); *Koninklijke Philips N.V. v. Zoll Med. Corp.*, No. 10-11041-NMG, 2014 WL 2810206, *1-3 (D. Mass. Jun. 20, 2014) (rejecting an ODP defense because all of the challenged patents expired the same day or before the patents asserted to give rise to the obviousness-type double patenting and thus there was no time-wise extension of the patents).

While courts often identify “prevent[ing] multiple infringement suits by different assignees asserting essentially the same patented invention,” as a second policy goal of ODP, see *Hubbell*, 709 F.3d at 1145, the authors have found no published judicial decisions where a court has applied ODP to patents expiring at the same time. The PTO appears to hold a different view. See MPEP 804.02 VI. Terminal Disclaimers Required to Overcome Nonstatutory Double Patenting Rejections In Applications Filed on or After June 8, 1995 (instructing examiners to issue provisional ODP rejections for applications on patents that, if issued, will expire at the same time and justifying the ODP rejections on the basis of promoting the filing of terminal disclaimers to insure common ownership and to allow the terminal disclaimer to impact whether PTA gets awarded).

Concerns about multiple infringement suits of patents having the same expiration date could be addressed under the doctrine of statutory double patenting the doctrine specifically aimed at a patentee having more than one patent covering the same subject matter. See *In re Boylan*, 392 F.2d 1017, 1045-46 (CCPA 1968) (“We agree that if the appellant claims the same subject matter (i.e., the same invention) that he claimed in his copending, but earlier-issued patent, 35 U.S.C. § 101 bars the issuance of a second patent, and a terminal disclaimer is of no avail[.]”)

⁴³ Cf. *Merck Sharp & Dohme Corp. v. Teva Pharmaceuticals USA, Inc.*, 217 F. Supp.3d 782, 787-88 (D. Del. Nov. 16, 2016), *appeal dismissed*, (Fed. Cir. Apr. 6, 2017) (in a post-*Gilead* case, ruling that claims of a parent patent, a pre-URAA patent, were not invalid for ODP in view of the claims of a continuation patent, also a pre-URAA patent, which expired before the parent patent due to a terminal disclaimer filed as part of reviving the continuation application from a period of abandonment, the court ruling that “the oddity” of the child patent expiring before the parent patent, as a result of its terminal disclaimer, was “not an instance of a patentee seeking to extend the patent term with ‘sequential’ applications,” and therefore, obviousness-type double patenting did not apply). While the patents at issue in *Merck* did not have PTA, the scenario of the parent patent having a later expiring date than the child continuation patent presents a similar scenario of a parent patent subject to a PTA expiring later than a child continuation patent having no PTA. Indeed, the terminal disclaimer in *Merck* acted as a “negative PTA” to the child patent as a price for reviving that application.

⁴⁴ H.R. Rep. No. 106-287, at 49-50, 1999 WL 569140, *48-49 (1999) (emphasis added)



Accounting for this policy goal, the Federal Circuit’s statement in *Breckenridge* has applicability in the context of PTAs since allowing ODP to apply to defeat a PTA awarded to an earlier-filed and earlier-issuing patent “would abrogate [the patentee]’s right to *enjoy one full patent term on its invention*.”⁴⁵

During the final stages of drafting this article, a district court reached the same conclusion as we state above. In *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*,⁴⁶ the court held that ODP does not apply where a later-filed, later-issued patent expires before the earlier-filed, earlier-issued patent due to a statutorily allowed term extension under § 154(b). Following the rationale of *Ezra*, the district court instructed that “[u]nlike in *Gilead*, the granting of a PTA does not present the potential for gamesmanship by inventors to secure a second, later expiring patent for the same invention.”⁴⁷ The district court also found as an “important” factor to its decision that it was “swayed by the Federal Circuit’s observation that ‘a judge made doctrine’ should not be used to ‘cut off a statutorily-authorized time extension.’”⁴⁸

A more challenging question arises if two patents do not share the same priority date, with the later-expiring patent having a PTA. But *Ezra* arguably supplies the answer to this question too — consider the patent’s validity without the PTA. As noted above, the Federal Circuit instructed in *Ezra* that “if a patent, under its pre-PTE expiration date, is valid under all other provisions of law [including ODP], then it is entitled to the full term of its PTE.” This should apply with equal force to a patent having a PTA. Accordingly, even under the rule of *Gilead*, when faced with an ODP issue of patents having different priority dates a court should analyze the ODP issue with the patents in their pre-PTA form.

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⁴⁵ *Breckenridge*, 909 F.3d at 1367 (emphasis added).

⁴⁶ ___ F.Supp.3d ___, ___, 2021 WL 1845499, *29-*30 (D.N.J. Apr. 7, 2021)

⁴⁷ *Id.* 2021 WL 1845499, at *29.

⁴⁸ *Id.* (citing *Ezra*, 909 F.3d at 1375)