

## Gilead And Potential Unforeseen Consequences: Part 1

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Many in the patent community, particularly in the pharmaceutical industry, were surprised when the Federal Circuit issued its April opinion in *Gilead Sciences Inc. v. Natco Pharma Ltd.*, No. 2013-1418 (Fed. Cir. Apr. 22, 2014). The decision vacated and remanded that of the district court and held that plaintiff Gilead's earlier-issued (but later-expiring) '483 patent could be invalidated for obviousness-type double-patenting in view of Gilead's later-issued (but earlier-expiring) '375 patent. Slip Op. at 2-3.

The finding that an earlier-issued patent could be invalidated for ODP by a later-issued patent led former Chief Judge Randall Rader to dissent strongly and conclude that the majority's decision was an unwarranted expansion of the doctrine of ODP that would have "unforeseen consequences." Dissent, Slip Op. at 1, 7.



Carl Morales

When Gilead filed a petition for en banc rehearing in June,[1] followed by an amicus brief in support of en banc rehearing by the Biotechnology Industry Organization and the Pharmaceutical Research and Manufacturers of America in July,[2] Gilead looked like it could be headed for review by the full Federal Circuit. However, on July 29, 2014, Gilead's petition for en banc rehearing was denied,[3] and now the patent community must confront the potential long-term implications of the Gilead holding.[4]

ODP is an important mechanism for invalidating patents and rejecting patent applications, particularly in the pharmaceutical industry, where the cure for ODP, a terminal disclaimer, is often an impractical option because it would disclaim the valuable terminal portion of a patent's term.

In this first article of a two-part series, we explore the ODP rationale from Gilead, whether Gilead altered settled criteria for establishing ODP, and the public policy behind the majority opinion. In the second article, we take the Gilead majority's revised ODP criteria and public policy concerns and note the conflict with two recent Federal Circuit decisions on ODP (*In re Hubbell* and *In re Fallaux*), and we consider potential "unforeseen consequences" that may result from application of the Gilead holding to common situations involving patent term adjustment and continuation applications.

We hope that a more thorough understanding of Gilead and its potential impact can assist patent practitioners and their clients in identifying current and future ODP situations not previously envisioned.

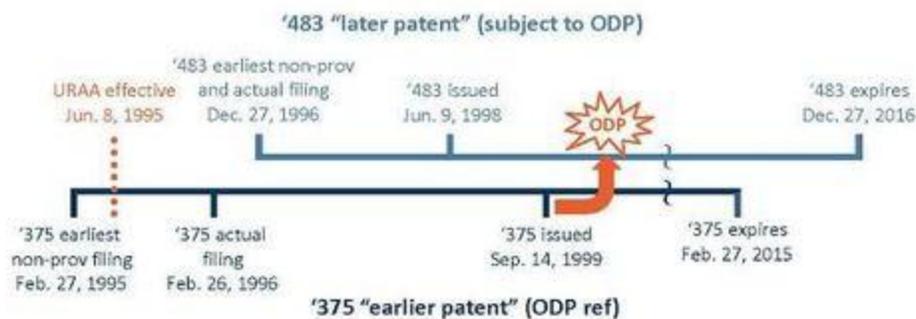
## Gilead: Expansion of ODP or Redefinition of ODP Post-URAA?

ODP “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.”[5] Prior to Gilead, the exercise of determining which of two qualifying patents is the ODP reference patent, and which is the patent that is subject to ODP in view of the other, seemed straightforward[6]: The ODP reference patent is the “earlier patent” (i.e., the earlier-issued patent), and this patent can be used to invalidate for ODP a “later patent” (i.e., a later-issued patent). The classic public policy rationale is that the “later patent” could potentially be (1) an “unjustified timewise extension of the right to exclude granted by [the earlier] patent”[7] or (2) used with the “earlier patent” to harass potential infringers through multiple infringement suits by different assignees of the two patents.[8]

However, the Gilead majority suggests that the definitions of “earlier patent” (the ODP reference patent) and “later patent” (the patent subject to ODP in view of the earlier patent) have changed with the now-essentially complete transition from a pre- to post-Uruguay Round Agreements Act[9] framework for determining U.S. patent term. In particular, the majority distinguishes between pre-URAA patents in cases cited by Gilead, where “the expiration date was inextricably intertwined with the issuance date,” and post-URAA patents, such as those at issue in Gilead, for which the expiration dates are “intertwined” not with the issue date but instead with “the patent’s earliest non-provisional filing date.”[10] Slip Op. at 12-13.

In short, according to the Gilead majority, in determining which patent is the ODP reference patent and which patent is subject to ODP, it is the expiration dates that have always been the deciding criteria, and not necessarily the issue dates. Slip Op. at 11, 13. Hence, for pre-URAA patents, the ODP reference patent (the “earlier patent”) is the earlier-issued patent because the earlier issuance is predictive of that patent’s earlier expiration. But for post-URAA patents, the ODP reference patent (again, still the “earlier patent”) is the patent with the earliest nonprovisional filing date because it is the earliest nonprovisional filing date that is predictive of that patent’s earlier expiration.[11]

With this redefinition of “earlier patent” and “later patent” for post-URAA patents, the Gilead majority analyzes the relationship between Gilead’s ‘483 and ‘375 patents to determine which is the ODP reference patent and which is subject to ODP:



First, because both the ‘483 and ‘375 patents were actually filed after the URAA effective date of June 8, 1995, both are post-URAA patents subject to terms expiring 20 years from their earliest nonprovisional filing dates. The expiration dates are therefore Dec. 27, 2016 (for the ‘483 patent) and Feb. 27, 2015 (for the ‘375 patent). Hence, according to the Gilead majority, the ‘483 patent is the “later patent,” and thus

subject to ODP in view of the “earlier” ‘375 patent (the ODP reference patent), because the ‘483 patent expires later even though the ‘483 patent issued earlier.

In contrast, Gilead argued that the “‘375 patent in no way extends the term of the exclusivity for the ‘483 patent.” Slip op. at 12. While undoubtedly correct, Gilead’s assertion operates under what the majority considers to be the false presumption that the ‘375 patent is the “later patent” because the ‘375 patent issued later, when instead the majority considers the ‘375 patent to be the “earlier patent” because it expires earlier. The “later patent” (the ‘483 patent, not the ‘375 patent), because of its later expiration date, is the patent that can potentially extend the term of exclusivity of the “earlier patent” and is therefore subject to ODP.

The majority’s reclassification of Gilead’s ‘483 patent from “earlier patent” (not subject to ODP) to “later patent” (subject to ODP) raises the question of whether similarly situated patents could likewise be reclassified and thus exposed for the first time to invalidity under ODP. Is the majority’s holding (1) a fact-specific redefinition of ODP that tracks the current method of determining the term of U.S. patents or (2) a general expansion of ODP that can invalidate patents previously thought immune from ODP? As noted above, the dissent cautions against the latter, and the answer to this question will reflect Gilead’s future impact on patent law.

### **Gilead’s Public Policy Rationale for Unsettling Settled Expectations**

The Gilead majority emphasizes that the ‘483 patent is an unjustifiable extension of the right to exclude provided by the ‘375 patent because “the public should have the right to use the invention claimed in the [‘375] patent and all obvious variants of that invention” upon the ‘375 patent’s expiration. Slip Op. at 11. Many might question how, at the time of its issuance, the ‘483 patent was ostensibly not an unjustifiable extension of the not-yet-existing ‘375 patent, but nonetheless could instantly become an unjustifiable extension the very moment the ‘375 patent issued by Gilead’s own actions.[12] Dissent, Slip Op. at 4 (“Notably, if the ‘375 patent had never issued, Gilead would certainly be entitled to the ‘483 patent’s 2016 expiration date.”).

The majority’s closest response to its apparent disturbance of the public’s expectation of the ‘483 patent’s expiration is that Gilead should have known that the ‘483 patent would be potentially invalid for ODP in view of the ‘375 patent upon the issuance of the latter because a terminal disclaimer should have been filed in the application that became the ‘483 patent.

In particular, the majority cites to Manual of Patent Examining Procedure § 804(I)(B)(1) to assert that, in “a hypothetical where two pending patent applications filed by the same inventor are subject to provisional obviousness-type double patenting rejections over each other,”[13] “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,” and, therefore, “[a]ppplied to the facts here, a terminal disclaimer would have been required for the ‘483 patent.”[14] Slip Op. at 15-16.

Overlooking Gilead’s noncompliance with a MPEP subsection not yet in effect at the time of the ‘483 patent’s issuance, the dissent effectively asks: What harm does the public incur from Gilead’s decision to issue the ‘375 patent after already having issued the later-expiring ‘483 patent? With (1) the public on notice that the subject matter claimed in the ‘483 patent would be protected until the ‘483 patent’s expiration (i.e., with the issuance of the earlier-expiring ‘375 patent not extending protection of the ‘483 patent’s claimed subject matter, as Gilead argued), and (2) a terminal disclaimer having been filed in the application that became the ‘375 patent preventing harassment via suit by multiple assignees, both

classic public policy rationales for ODP appear inapplicable to the Gilead patents. Dissent, Slip Op. at 3-4.

The Gilead majority responds by suggesting that a public harm exists in the potential for “gamesmanship” during prosecution. Slip Op. at 13. Specifically, a patent applicant could file serial stand-alone applications with incrementally later earliest nonprovisional filing dates (and thus priority dates) directed to obvious modifications of an invention. The incrementally later earliest nonprovisional filing dates would incrementally expose each later application to a wider window of potential prior art but also provide incrementally later expiration dates. The applicant could then theoretically obtain a patent with a later expiration date via one of the later applications, while also obtaining a patent with an earlier nonprovisional filing date (and thus priority date) via one of the earlier applications, thereby effectively insulating the commonly claimed subject matter in the later-expiring patent from potential intervening prior art. Slip Op. at 14 (“[I]nventors 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.”).[15]

Hence, while the dissent notes that Gilead intentionally filed “the application that ultimately issued as the ‘483 patent as a separate family,” thereby choosing to “g[ive] up roughly 10 months of priority” and to “subject [the ‘483 patent] to roughly 10 months of intervening prior art” (Dissent, Slip Op. at 4), the majority finds to the contrary, i.e., that Gilead effectively did not give up any priority because the ‘483 patent’s apparent loss of 10 months of priority was captured upon issuance of the ‘375 patent.

In other words, the majority found that Gilead could have the benefit of either the ‘483 patent’s later expiration date or the ‘375 patent’s earlier priority date, but not both. Once Gilead issued the ‘483 patent, absent a terminal disclaimer, Gilead was precluded from later obtaining a patent to the earlier-expiring ‘375 patent as a hedge against possible prior art intervening during the 10 months preceding the ‘483 patent’s priority date.[16] The dissent views the majority’s public policy of discouraging such “strategizing” as an expansion of ODP and “a new judicially-created exception to invalidate patents.” Dissent, Slip Op at 6.

## **Conclusion**

Gilead involved two post-URAA patents with different earliest nonprovisional filing dates and therefore different expiration dates. It is this difference in expiration dates that the Gilead majority considers to be the key criteria for deciding the ODP relationship between the two patents and leads to the majority’s holding that the earlier-issued (but later-expiring) ‘483 patent could be invalidated for ODP in view the later-issued (but earlier-expiring) ‘375 patent. Although neither of the classic public policy rationales behind ODP appears to have been implicated, the Gilead majority nevertheless perceives that harmful “gamesmanship” could occur if the ODP inquiry is controlled by the patents’ respective issue dates instead of their expiration dates.

With the Gilead majority’s revised ODP criteria and underpinning policy rationale in mind, in part 2, we apply this criteria and rationale to recent Federal Circuit ODP decisions and common PTA and continuation situations in an effort to forecast Gilead’s “unforeseen consequences.”

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[1] D.I. 43, No. 2013-1418 (Fed. Cir. Jun. 23, 2014).

[2] D.I. 50, No. 2013-1418 (Fed. Cir. July 10, 2014); see also Law360, “BIO, PhRMA Ask Fed. Circ. To Revisit Double-Patent Ruling” (Jul. 14, 2014) (accessed at [http://www.law360.com/lifesciences/articles/556933?utm\\_source=shared-articles&utm\\_medium=email&utm\\_campaign=shared-articles](http://www.law360.com/lifesciences/articles/556933?utm_source=shared-articles&utm_medium=email&utm_campaign=shared-articles)).

[3] D.I. 51, No. 2013-1418 (Fed. Cir. Jul. 29, 2014).

[4] Although not involving a situation where an earlier-issued (but later-expiring) patent could be found invalid for ODP in view of a later-issued (but earlier-expiring) patent, the Federal Circuit’s recent decision in *AbbVie Inc. v. Kennedy Inst. of Rheumatology*, No. 2013-1545 (Fed. Cir. Aug. 21, 2014) (“*AbbVie*”) cites to and relies on *Gilead* in several respects, thereby confirming that *Gilead* will continue to influence court decisions on ODP.

[5] *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001); see also, e.g., *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985) (ODP “prohibit[s] the issuance of the claims in a second patent not patentably distinct from the claims of [a] first patent.”).

[6] The seemingly outlying opinion of the USPTO’s former Board of Patent Appeals and Interferences (“the Board”) in *Ex Parte Pfizer* notwithstanding, 2010 WL 532133, at \*21 (Bd. Pat. App. & Interf. Feb. 2, 2010) (holding that “it is the patent term and not the patent issue date that determines if [a later-issued patent] qualifies as a double patenting reference against [an earlier-issued] patent” and therefore finding two later-issued earlier-expiring patents to be ODP references against an earlier-issued later-expiring patent because “[t]he rule against double patenting seeks to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about”) (citing *In re Schneller*, 397 F.2d 350, 354 (CCPA 1968)).

[7] E.g., *Schneller*, 397 F.2d at 354.

[8] *In re Griswold*, 365 F.2d 834, 840 n.5 (CCPA 1966); *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009).

[9] The Uruguay Round Agreements Act of 1994 (“URAA”) brought U.S. patent laws into accordance with the Uruguay round negotiations of the General Agreement on Tariffs and Trade (“GATT”) and included a provision, which became effective on June 8, 1995, that changed the term for a U.S. patent from seventeen years from the patent issue date to twenty years from the patent’s earliest non-provisional filing date. Uruguay Round Agreements Act, Pub. L. No. 103-465, § 532(a), 108 Stat. 4809, 4983-85 (1994). Pursuant to the URAA, patents still in force and derived from applications filed before June 8, 1995 are subject to a term that is the later-expiring of either seventeen years from the issue date or twenty years from the earliest non-provisional filing date (those with the seventeen-year term being “pre-URAA” or “pre-GATT” patents). Patents stemming from applications filed on or after June 8, 1995 are subject to a term that is twenty years from the earliest non-provisional filing date (“post-URAA” or “post-GATT” patents).

[10] By “the patent’s earliest non-provisional filing date,” the *Gilead* majority – and this article – is

referencing “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.” Slip Op. at 3 n.1; 35 U.S.C. § 154(a)(2). This date is sometimes referred to as a patent’s earliest “priority date.” AbbVie, Slip Op. at 3, 5. However, this should not be confused with a patent’s earliest “priority date” for prior art purposes, which, unlike for determining patent term and expiration, may include priority claims to provisional and foreign applications.

[11] See also AbbVie, Slip Op. at 13 (“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.”) (emphasis added); Id., Slip Op. at 11 (patents in an ODP situation “have different expiration dates since the patent term is measured from the [earliest non-provisional filing] date”).

[12] Put another way, could the public first have had an expectation that the claimed subject matter of the ‘483 patent (and obvious variants thereof) was protected until the ‘483 patent’s expiration, but the moment the ‘375 patent issued, the public’s expectation instantly shifted to the expectation that the subject matter would be free to practice upon the earlier expiration of the ‘375 patent?

[13] Interestingly, the majority had already noted that Gilead’s filing of a terminal disclaimer in the application that became the ‘375 patent over the already-issued ‘483 patent “appear[ed] 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 patent application.” Slip Op. at 4. Hence, the majority impliedly recognizes that Gilead’s situation is not the one outlined in MPEP § 804(I)(B)(1), where “two pending patent applications . . . are subject to provisional obviousness-type double patenting rejections over each other.” On the other hand, the majority could be read to be suggesting that Gilead should have informed both examiners of the existence of the other application before the ‘483 patent issued so that an ODP rejection could have been made in that application.

[14] The majority does not mention that its cited passage from the current version of MPEP § 804(I)(B) (Ninth Edition, March 2014) that requires a terminal disclaimer in the later application, did not appear in the version applicable at the time of issuance of the ‘483 patent (Sixth Edition, Revision 3, July 1997). Rather MPEP § 804(I)(B) at the time of the ‘483 patent’s issuance stated:

If the “provisional” double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the “provisional” double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

If the “provisional” double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent.

The record suggests that, if a provisional ODP rejection had been made in the application that became the ‘483 patent in view of the application that became the ‘375 patent, at some point that rejection would have been the “only remaining rejection in that application,” and “the examiner should then [have] withdraw[n] that rejection and permit[ed] the application to issue as [the ‘483] patent.” At least because of the large gap between the issue dates of the ‘483 and ‘375 patents, the record suggests that it would have been unlikely that provisional ODP rejections in the applications that became the ‘483 and

'375 patents over one another would have been “the only rejections remaining in [both of] those applications.” Yet even then, the decision of which application to permit to issuance (and which to require filing a terminal disclaimer) appears at the time to have been a matter of USPTO examiner discretion (“e.g.”).

[15] Of course, such gamesmanship presupposes the failure of the USPTO to abide by MPEP § 804(I)(B)(1) and to issue provisional ODP rejections that require terminal disclaimers be filed in the later applications, assuming the USPTO is made aware of the copending applications.

[16] The majority also concludes that it is “too arbitrary, uncertain, and prone to gamesmanship” that the relative issue dates of two patents should control their ODP relationship and thus whether one is an improper extension of the other. Slip Op. at 14-15. However, the majority does not provide any reasoning for why the public should expect certainty as to a patent’s expiration date before the patent issues, especially considering the patent may never issue. In fact, as discussed in Part 2, a patent’s expiration date is often uncertain even after the patent issues.

## Gilead And Potential Unforeseen Consequences: Part 2

*Law360, New York (August 26, 2014, 9:40 AM ET) --*

In Part 1 of this article, we explored the majority's rationale for obviousness-type double patenting ("ODP") in the Court of Appeals for the Federal Circuit's decision in *Gilead Sciences Inc. v. Natco Pharma Ltd.*, No. 2013-1418 (Fed. Cir. Apr. 22, 2014). In particular, we considered the Gilead majority's holding that the decision of which of two qualifying post-URAA patents is the ODP reference patent, and which is the patent that is subject to ODP in view of the other, turns on the patents' relative expiration dates, which are predicted from their respective "earliest non-provisional filing dates,"[1] and not on the patents' relative issue dates. We also examined the majority's public policy concern for "gamesmanship" that could theoretically flow from using issue dates as the deciding criteria in determining the ODP relationship between two patents.



Carl Morales

In this article, we examine how courts might implement Gilead in other situations, first by applying the Gilead majority's revised ODP criteria to two recent Federal Circuit decisions on ODP, second by considering potential "unforeseen consequences" — forewarned by former Chief Judge Randall Rader's dissent — that result from application of the Gilead holding to common situations involving patent term adjustment ("PTA") and continuation applications.

### **Gilead's Conflict with Hubbell and Fallaux, Two Cases Having Similar Facts as Gilead**

The Gilead majority twice states that it reaches its holding that the later-issued (but earlier-expiring) '375 patent qualifies as an ODP reference against the earlier-issued (but later-expiring) '483 patent "under the circumstances of this case." Slip Op. at 6, 16. These "circumstances" seemingly cover at least situations involving two patents or patent applications with common ownership or overlap in inventorship that claim patentably indistinct subject matter (i.e., an ODP situation), wherein:

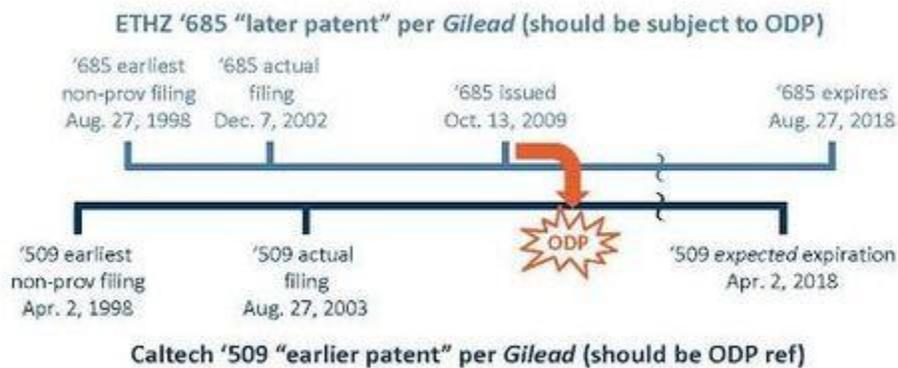
- (1) both patents or patent applications are post-URAA patents or applications (i.e., actually filed on or after June 8, 1995); and
- (2) the patents or patent applications have different earliest non-provisional filing dates and therefore different expected expiration dates.

In such situations, according to the Gilead majority, the patent with the later earliest nonprovisional filing date and therefore later expiration date (i.e., the "later patent") could be subject to ODP in view of

the patent with the earlier earliest nonprovisional filing date and therefore earlier expiration date (i.e., the “earlier patent”). Slip Op. at 13. Furthermore, pursuant to MPEP § 804(I)(B)(1), a terminal disclaimer should have been filed during the pendency of the application that led to the later patent because this patent was predicted to have the later expiration date because of its later earliest nonprovisional filing date.[2] Slip Op. at 15-16.

However, the Federal Circuit’s two recent ODP decisions in *In re Hubbell*[3] and *In re Fallaux*[4] suggest otherwise. Both *Hubbell* and *Fallaux* involved (1) only post-URAA patents and patent applications and (2) patents and patent applications with different earliest nonprovisional filing dates and therefore different expected expiration dates. Yet, unlike in *Gilead*, in *Hubbell* and *Fallaux*, the patent with the later expected expiration date was used as the ODP reference patent.

*Hubbell* involved an ODP situation between the California Institute of Technology (“Caltech”) ‘509 application and the Eidgenossische Technische Hochschule Zurich (“ETHZ”) ‘685 patent.[5] The ETHZ ‘685 patent was filed on Dec. 7, 2002, issued on Oct. 13, 2009, and claimed priority to two earlier continuation-in-part applications giving it an earliest nonprovisional filing date of Aug. 27, 1998. The Caltech ‘509 application was filed on August 27, 2003, but through priority claims to several earlier applications had an earliest non-provisional filing date of April 2, 1998:

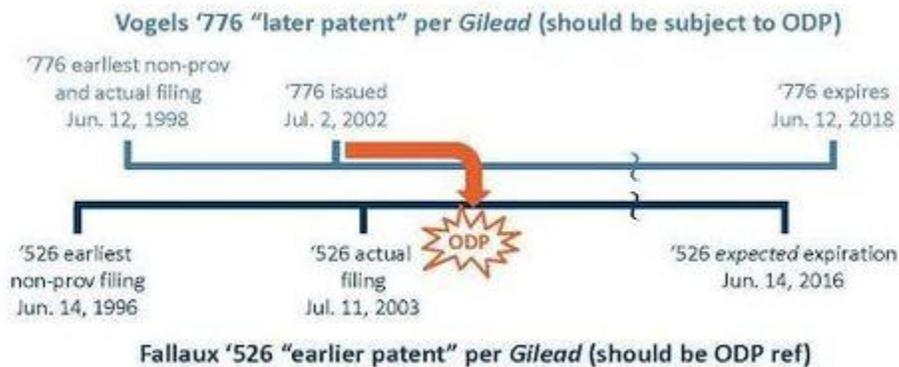


Pursuant to *Gilead*, the ETHZ ‘685 patent is the “later patent” because it has the later earliest nonprovisional filing date and thus the later expected expiration date of Aug. 27, 2018. In contrast, the Caltech ‘509 application is the “earlier patent” because it has the earlier earliest nonprovisional filing date and therefore the earlier expected expiration date of April 2, 2018. Accordingly, based on *Gilead*, as the “later patent,” the ETHZ ‘685 patent should be subject to ODP over any patent that were to issue from the Caltech ‘509 application.

Yet, in *Hubbell*, the Federal Circuit held the opposite and affirmed the Board of Patent Appeals and Interferences’ ODP rejection of the Caltech ‘509 application in view of the ETHZ ‘685 patent.[6] Unlike in *Gilead*, the *Hubbell* panel held that the patent with the later earliest nonprovisional filing date and later expiration date was the ODP reference patent instead of subject to ODP. Under the rationale of the *Gilead* majority, the Caltech ‘509 application should never have been rejected for ODP because it had the earlier expected expiration.

*Fallaux* involved an ODP situation between the *Fallaux* ‘526 application and, inter alia, the *Vogels* ‘776 patent.[7] The *Vogels* ‘776 patent had both an actual and earliest nonprovisional filing date of June 12,

1998 and an issue date of July 2, 2002. The Fallaux '526 application was filed on July 11, 2003, but through priority claims to five earlier applications and an initial PCT application had an earliest nonprovisional filing date of June 14, 1996:



The Gilead holding defines the Vogels '776 patent as the “later patent” because of its later expected expiration date (June 12, 2018) versus that of the Fallaux '526 application (June 14, 2016), which is therefore the “earlier patent.” As such, under Gilead, as the “later patent,” the Vogels '776 patent should be subject to ODP over any patent that were to issue from the Fallaux '526 application.

But, in Fallaux, the Federal Circuit held the opposite and affirmed the board’s ODP rejection of the Fallaux '526 application in view of the Vogels '776 patent.[8] Unlike in Gilead, but like in Hubbell, the Fallaux panel held that the patent with the later earliest nonprovisional filing date and later expiration date was the ODP reference patent instead of subject to ODP.[9] Again, under the rationale of the Gilead majority, the Fallaux '526 application should never have been rejected for ODP because it had the earlier expected expiration.

The difficulty in reconciling the Gilead holding with the earlier Federal Circuit panel decisions in Hubbell and Fallaux raises doubt as to how all three cases will be applied in the future under their shared set of similar facts.[10] Even further concern arises from consideration of “unforeseen consequences” that can occur when the Gilead holding is stripped from its facts and applied to situations involving PTA.

### Gilead’s Unforeseen Consequences 1 — PTA Situations

Due to examination delays by the USPTO, many patents issue with PTA awards pursuant to 35 U.S.C. § 154(b) that extend their patent terms. PTA awards are often measured in years, particularly for patents whose corresponding applications were pending during the USPTO’s examination backlog of the mid- to late-2000’s[11] and for patents issuing after the Federal Circuit’s 2010 Wyeth decision,[12] which held that the USPTO had been under-calculating PTA in certain circumstances. For patents in the pharmaceutical industry that cover therapeutic products, the PTA award can be especially important because the additional patent term often extends a branded product’s period of exclusivity during the more profitable terminal portion of the patent’s life.

However, PTA awards are frequently far from predictable, particularly before patent issuance. With recent “technical corrections” to the America Invents Act, the USPTO’s final determination of PTA is made only at the time the patent issues,[13] and even this “final” determination may be reconsidered[14] and then still appealed in court.[15] As a result, a patent’s final PTA award — and



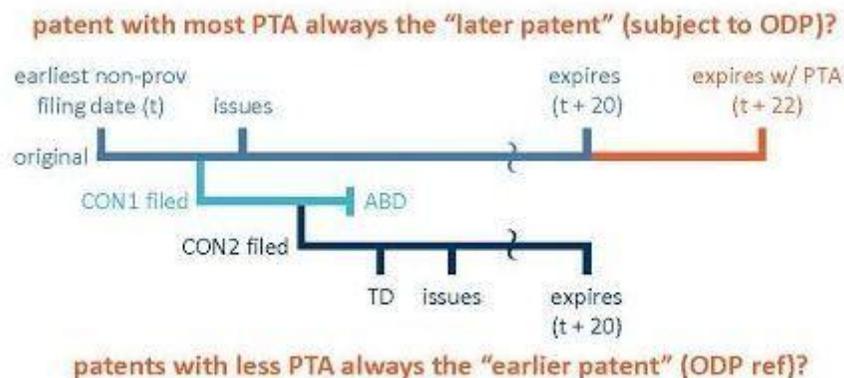
Note that a possible benefit of the PTA award is that the terminal disclaimer filed in the second patent may no longer disclaim term[17] (although common ownership is still required for enforcement). Yet this does not prevent the second patent from becoming the “earlier patent” for ODP purposes under Gilead because the one-year difference in earliest nonprovisional filing dates is less than the PTA award. With the first patent now subject to ODP in view of the second, the only cure would be to file a terminal disclaimer in the first patent over the second, thereby disclaiming at least some of the first patent’s PTA award.

Moreover, if the first and second patent at some point are assigned to different entities, a frightening ODP situation could arise where a terminal disclaimer would not be available to cure the ODP issue.[18] In such a scenario, issuance of the second patent combined with loss of common ownership would create a potentially unsolvable ODP problem for the original patent simply because the original patent was awarded PTA.

This hypothetical has different facts from Gilead: (1) the first patent has the earlier earliest non-provisional filing date, and therefore, unlike Gilead’s ‘473 patent, during prosecution the first patent could not have been predicted to have the later expiration; (2) because of the earlier earliest non-provisional filing date of the first patent, MPEP § 804(I)(B)(1) does not require a terminal disclaimer in the first patent over the second patent during prosecution; and (3) the patentee’s additional term in the first patent cannot be due to any perceivable “gamesmanship” but rather due to the USPTO’s own delay in examination.[19] Nevertheless, if the Gilead holding is applied at its broadest without regard for the Gilead facts (i.e., a later-issued earlier-expiring patent can be used as an ODP reference against an earlier-issued later-expiring patent), then the first patent could fall into an ODP predicament that did not exist at the time of its issuance.[20]

### Gilead’s Unforeseen Consequences 2 — PTA and Continuation Situations

Perhaps a more disquieting application of the Gilead holding is to situations where continuation[21] patents receive lower PTA awards than earlier-issued family members. For example, consider a family of three applications: a first “original” application, a continuation from the original application (CON1), and a second continuation from the first continuation (CON2). Suppose the first continuation is filed shortly before the original application issues with a PTA award of two years. Subsequently, the first continuation is abandoned, and the second continuation is filed shortly before the first continuation’s abandonment. A terminal disclaimer is filed in the second continuation over the now-issued original patent to overcome an ODP rejection, and the second continuation then issues with no PTA (or less PTA than the original patent):



If the Gilead holding is taken at its broadest, in light of the PTA award in the original patent, the later-issued earlier-expiring second continuation qualifies as the “earlier patent” because it expires earlier and, therefore, can be used as an ODP reference against the earlier-issued later-expiring original patent. In fact, such an application of Gilead suggests that any patent that has more PTA than its later continuation may be subject to ODP in view of that later continuation.

This application of Gilead could impose a chilling effect on issuing continuation applications because, if a continuation is not expected to have as much PTA as a parent patent, then the issuance of that continuation could create an ODP problem in the parent that would require a terminal disclaimer that disclaims some — or all — of the parent’s PTA.[22] Such an application of Gilead would effectively render PTA a nullity in patent families where a subsequent continuation issued without PTA.

Moreover, the mere evaluation of whether a continuation application would indeed pose an ODP problem for a PTA-adjusted parent patent is fraught with uncertainty because whether the continuation is awarded PTA (and thus whether it poses a problem — and how much of a problem — for the PTA-adjusted parent) is not known until the issuance of the continuation or possibly even years later if the continuation’s PTA determination is challenged.[23]

We emphasize that this broad application of the Gilead holding imperils already-issued patents in families where a parent patent issued with a significant PTA award, and subsequent continuations issued with less or no PTA, which is a common situation.[24]

Like the first hypothetical, this hypothetical also has different facts from Gilead: (1) both patents have the same earliest nonprovisional filing date because they are family members, and therefore, unlike Gilead’s ‘473 patent, during prosecution neither could have been predicted to have had a later expiration; (2) because the second continuation was not even in existence during the prosecution of the original application, a terminal disclaimer during the prosecution of the original application over the not-yet-existing second continuation could not have been required; and (3) the patentee’s additional term in the original patent cannot be due to any perceivable “gamesmanship” but rather due to the USPTO’s own delay in examination. Nevertheless, if the Gilead holding is applied at its most expansive without regard for the Gilead facts (i.e., a later-issued earlier-expiring patent can be used as an ODP reference against an earlier-issued later-expiring patent), then a parent patent with a PTA award could be subject to ODP in view of a later continuation with less or no PTA. Such an ODP problem did not exist at the time of the parent patent’s issuance.

## **Conclusion**

At its broadest, the Gilead majority held that a later-issued earlier-expiring patent can be used as an ODP reference against an earlier-issued later-expiring patent. While some will debate whether this holding is an expansion of ODP or a redefinition of how patents qualify for ODP post-URAA, the holding seems to conflict with recent Federal Circuit ODP opinions having similar facts. Furthermore, expansion of the Gilead holding to situations beyond the facts therein can create the type of “unforeseen consequences” presaged by former Chief Judge Rader. For example, application of Gilead to find ODP for patents with PTA awards, particularly in patent families with continuations, is a major “unforeseen consequence” that could both disturb settled expectations of already-issued PTA-adjusted patents as well as gut PTA’s capacity as a legislative remedy for examination delays attributable to the USPTO. The patent community, especially in the pharmaceutical industry, should pay close attention to the fallout from Gilead.

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[1] By the “earliest non-provisional filing date,” the Gilead majority – and this article – is referencing “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.” Slip Op. at 3 n.1; 35 U.S.C. § 154(a)(2). This date is sometimes referred to as a patent’s earliest “priority date.” *AbbVie Inc. v. Kennedy Inst. of Rheumatology*, No. 2013-1545 (Fed. Cir. Aug. 21, 2014) (“*AbbVie*”), Slip Op. at 3, 5. However, this should not be confused with a patent’s earliest “priority date” for prior art purposes, which, unlike for determining patent term and expiration, may include priority claims to provisional and foreign applications.

[2] Although MPEP § 804(I)(B)(1) does not define what is meant by “later-filed” or “earlier-filed” application as used therein for determining the ODP relationship between two applications, MPEP § 1490(VI)(D) makes clear that “later-filed” and “earlier-filed” are keyed off of “earliest non-provisional filing dates” (see note 1, supra) and not necessarily off actual filing dates.

[3] 709 F.3d 1140 (Fed. Cir. 2013).

[4] 564 F.3d 1313 (Fed. Cir. 2009).

[5] 709 F.3d at 1142-43.

[6] *Id.* at 1142. Because of a lack of common ownership between the Caltech ‘509 application and the ETHZ ‘685 patent, a terminal disclaimer was not available to cure the ODP rejection. *Id.* at 1147-48.

[7] 564 F.3d at 1315.

[8] *Id.* As in *Hubbell*, a lack of common ownership precluded use of a terminal disclaimer to cure the ODP rejection. *Id.* at 1319 n.5.

[9] While *Gilead* involved ODP between two patents, both *Hubbell* and *Fallaux* involved ODP between a patent and a pending application. However, this difference is not significant because *Gilead* cannot be read to support the notion that the ODP relationship between a patent and an application depends on whether the latter issues as a patent. Such a distinction would detach ODP from the relative expiration dates, which the *Gilead* majority emphasizes is the touchstone for determining the ODP relationship. Slip Op. at 13. Such a distinction also cannot be justified by either of the public policy rationales for ODP.

[10] Because a later Federal Circuit decision “may overrule a prior holding having precedential status only by an in banc decision” (e.g., *Mother’s Rest. Inc. v. Mama’s Pizza Inc.*, 723 F.2d 1566, 1573 (Fed. Cir. 1983)), the *Gilead* panel decision cannot overrule the earlier *Hubbell* and *Fallaux* decisions.

[11] See Crouch, D., “USPTO Continues to Reduce Patent Term Adjustments,” *Patently-O*, (August 8, 2014) (accessed at <http://patentlyo.com/patent/2014/08/continues-patent-adjustments.html>).

[12] *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010).

[13] *Leahy-Smith America Invents Technical Corrections*, Pub. L. No. 112-274, § 1(h), 126 Stat. 2456, 2457 (2013) (amending 35 U.S.C. § 154(b)(3)(B)(i)); 37 CFR § 1.705(a).

[14] 35 U.S.C. § 154(b)(3)(B)(ii); 37 CFR § 1.705(b).

[15] 35 U.S.C. § 154(b)(4)(A)

[16] Note that the “later patent” in *AbbVie*, while the recipient of over two years of PTA, was already the “later patent” in the absence of any PTA award because of that patent’s later earliest non-provisional filing date and therefore later expected/unadjusted expiration date. *AbbVie*, Slip Op. at 11 n.2. Hence, *AbbVie* was not a situation where a PTA award determined the ODP relationship between two patents.

[17] See 35 U.S.C. § 154(b)(2)(B) (“No patent term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.”). The term disclaimed in the second patent is that which extends beyond the term of the first patent, which, after the first patent’s PTA award, is no term. Cf. *Bayer AG v. Carlsbad Tech., Inc.*, 298 F.3d 1377, 1381-83 (Fed. Cir. 2002) (holding that the expiration date of a terminally disclaimed patent was “automatically” extended when the expiration date of the terminal disclaimer’s reference patent was extended “automatic[ally] by operation of law” due to the URAA).

[18] See notes 6 and 8, *supra*.

[19] Note, however, the Federal Circuit’s somewhat ominous dicta in *Fallaux* that “[i]n some cases there may still be the possibility of an unjust time-wise extension of a patent arising from patent term adjustment under § 154 or patent term extension under § 156.” 564 F.3d at 1319. See also *AbbVie*, Slip Op. at 11 (citing as a potential “problem” addressed by ODP that “[p]atents claiming overlapping subject matter that were filed at the same time still can have different patent terms [as a result of patent term adjustment under 35 U.S.C. § 154(b)] due to examination delays at the PTO”).

[20] A similar hypothetical situation could be envisioned where, instead of a PTA award changing the ODP relationship between two post-URAA patents, a patent term extension (“PTE”) award effects a similar change. However, unlike for PTA, in such a PTE situation, a terminal disclaimer, if available, could be filed in the first patent over the second patent to remove the ODP issue without reducing the PTE award. *Merck & Co., Inc. v. Hi-Tech Pharma. Co., Inc.*, 482 F.3d 1317, 1322-23 (Fed. Cir. 2007) (A terminal disclaimer does not disclaim patent term resulting from a PTE award, but rather “provides the date from which the patent term extension begins.”). Furthermore, the *Gilead* majority may have suggested that invocation of ODP as a result of a PTE award would be excluded from its holding. Slip Op. at 13 n.6 (“There are exceptions to [the] rule [that pre-URAA, later issued patents expired later] of course, such as patents that qualify for term extensions, but none are relevant to the facts or our discussion here.”) (emphasis added).

[21] This includes continuation-in-part (CIP) applications as well, but not necessarily divisional applications due to the double patenting safe harbor for divisionals. 35 U.S.C. § 121.

[22] Again, assuming common ownership and availability of the terminal disclaimer. See notes 6 and 8, supra.

[23] This concern applies to the first and second patent in the previous hypothetical as well.

[24] Often the original patent in a family has the largest PTA award since original applications typically have the longest pendencies, both because many were pending during the USPTO's examination backlog of the mid- to late-2000's (see note 11, supra), and because of longer examination times due to USPTO Examiners' initial unfamiliarity with the subject matter of original applications vis-à-vis their continuations.