THE INTERACTION OF OBVIOUSNESS-TYPE DOUBLE PATENTING AND PATENT TERM ADJUSTMENT

Han K. D. Le[†]

TABLE OF CONTENTS

DOI: https://doi.org/10.15779/Z38KS6J69T

† Doctor of Philosophy (Ph.D.), University of California, Berkeley, Department of Chemistry, 2024. I am especially grateful to Allison Schmitt and Wayne Stacy for their guidance and support in preparing this Note. I would also like to thank Sue Wang and Gabrielle LaHatte for their time and incredible insights. Lastly, thank you to Yasameen Joulaee, Michelle D'Souza, Alex Choi, Jesse Wang, and the editors of the Berkeley Technology Law Journal for their invaluable feedback, discussions, and editorial assistance.

I. INTRODUCTION

One of the highest-grossing drugs in the world, Humira reached a peak of $21.2 billion in sales in 2022.[1] This equates to over $58 million per day. In January 2023, nearly two decades after Humira first entered the market, its key patents expired, opening the floodgates to biosimilar competition.[2] The effects

1. Press Release, AbbVie, AbbVie Reports Full Year and Fourth Quarter 2022 Financial (Feb. 9, 2023), https://investors.abbvie.com/news-releases/news-release-details/abbvie-reports-full-year-and-fourth-quarter-2022-financial.

2. Noah Higgins-Dunn, *The Top 15 Blockbuster Patent Expirations Coming This Decade*, FIERCEPHARMA (July 12, 2021), https://www.fiercepharma.com/special-report/top-15-blockbuster-patent-expirations-coming-decade.

were immediate: Humira's sales plunged by nearly $7 billion in 2023, translating to a daily loss of nearly $20 million.[3] Humira's story highlights just how critical each day of a patent term can be in the life sciences industry.

Currently, a United States utility patent expires twenty years from its effective filing date.[4] This length of patent term may appear to be set in stone, but the reality strays far from this. In certain situations, a patent owner may seek to either shorten or extend this period. A patentee may voluntarily shorten the term of her patent by filing a terminal disclaimer to address a double patenting rejection.[5] Under the doctrine of double patenting, inventors cannot improperly extend their patent monopoly by obtaining multiple patents on the same invention (statutory double patenting) or obvious variants of it (nonstatutory, or obviousness-type double patenting).[6] By filing a terminal disclaimer to cure an obviousness-type double patenting (ODP) rejection, the second patent's term is shortened to the same term as that of the first patent.[7] On the other hand, patent owners may also lengthen the term of their patent through mechanisms such as patent term adjustment (PTA). PTA is automatically granted when the United States Patent and Trademark Office (USPTO) causes delays in the patent prosecution process.[8] A patent may be subjected to all of these term modification mechanisms simultaneously. In such cases, the doctrine of double patenting becomes complex and sometimes inconsistent when interacting with PTA.

The Federal Circuit's recent decision in *In re Cellect* brought this complicated interaction to the forefront, threatening thousands of patents previously understood to be safe from double patenting challenges and leaving patentees scrambling to evaluate such risks in their portfolios.[9] *Cellect* held that if a patent's extended term is due to granted PTA, an ODP analysis must use the patent's expiration date *after* PTA has been added.[10] This means that patents with awarded PTA can be invalidated for ODP based on earlier-expiring patents in the same family. Since *Cellect*, courts have wrestled with ODP challenges involving PTA. In *Allergan USA, Inc. v. MSN Laboratories Private Ltd.*, a district court, relying on *Cellect*, exposed the first patent in a family

3. Press Release, AbbVie, AbbVie Reports Full Year and Fourth Quarter 2023 Financial (Feb. 2, 2024), https://investors.abbvie.com/news-releases/news-release-details/abbvie-reports-full-year-and-fourth-quarter-2023-financial.

4. 35 U.S.C. § 154(a)(2).

5. 35 U.S.C. § 253; U.S. PAT. & TRADEMARK OFF., MPEP § 1490 (9th ed. Rev. 1, 2024).

6. 35 U.S.C. § 253; MPEP § 1490 (9th ed. Rev. 1, 2024).

7. *Id.*

8. 35 U.S.C. § 154(b).

9. *See generally In re* Cellect, LLC, 81 F.4th 1216 (Fed. Cir. 2023).

10. *Id.* at 1229.

to ODP invalidation by a child patent simply because that first patent received PTA, but the child did not.[11] The Federal Circuit later dispelled this extreme interpretation on appeal, bringing a sigh of relief to patent owners.[12]

More than half of all U.S. patents receive PTA, making the interaction of ODP and PTA a critical matter for the patent community in all industries.[13] On average, these patents get more than a year of PTA.[14] For sectors like pharmaceuticals and biotechnology, where development timelines are long and investments are substantial, each additional day of patent term could amount to millions of dollars in revenue and is worth fighting for.[15] Like PTA, ODP challenges are also prevalent, with nearly half of small-molecule and biologic drug patents facing ODP threats in the last two decades.[16] Yet, the murky interaction between ODP and PTA continues to linger in the background. A lack of statutory and common law guidance directly linking statutory PTA

---

11. *See* Allergan USA, Inc. v. MSN Labs. Priv. Ltd., 694 F. Supp. 3d 511 (D. Del. 2023). A "patent family" refers to a group of patent applications related to each other by common priorities. A "child" patent application is a follow-up of a previously filed patent application, or a "parent" patent application. The various types of child applications include continuation applications, continuation-in-part applications, and divisional applications. When a child patent application is linked to a parent application through a priority claim, the child application benefits from the parent application's earlier priority date.

12. Allergan USA, Inc. v. MSN Labs. Priv. Ltd., 111 F.4th 1358, 1361–78 (Fed. Cir. 2024).

13. Mark A. Lemley & Jason Reinecke, *Our More-Than-Twenty-Year Patent Term*, 39 BERKELEY TECH. L.J. 681, 683–84 (2024) (finding that, of the 4.5 million studied patents filed on or after May 29, 2000 and issued by the USPTO since 2005, 63.6% of these patents receive at least some PTA.); *see also* U.S. PAT. & TRADEMARK OFF., PATENT EXAMINATION RESEARCH DATASET (PatEx) (2002), https://www.uspto.gov/ip-policy/economic-research/research-datasets/patent-examination-research-dataset-public-pair (finding the total number of patents issued in 2023 is 144,054 patents, and 54 percent of those patents have PTA).

14. Lemley & Reinecke, *supra* note 13, at 683. The authors stated that "[t]he patents that do get PTA get more than a year on average (411 days, a median of 290 days), and more than 25% of all patents have more than a year of extra term. A small number of patents have much more PTA. Five percent of all patents get more than 1000 days of additional term; one percent get more than four years of additional term."

15. *See* Henry G. Grabowski, Joseph A. DiMasi & Genia Long, *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, 34 HEALTH AFFS. 2, 302–03 (2015); *see also* Jaime F. Cárdenas-Navia, *Thirty Years of Flawed Incentives: An Empirical and Economic Analysis of Hatch-Waxman Patent-Term Restoration*, 29 BERKELEY TECH. L.J. 1301, 1317, 1347 (2014) (giving an example of U.S. Patent No. 7,037,917, covering the drug PREZISTA (darunavir) and INTELENCE (etravirine), and stating that two days of lost patent term for this patent could mean millions of dollars in lost revenue. The author also posits that a blockbuster drug with yearly revenues of $1 billion could lose $1.4 million per day once patent protection ends.).

16. S. Sean Tu, Aaron S. Kesselheim & Bernard Chao, *Extent of Drug Patents with Terminal Disclaimers and Obviousness-Type Double Patenting Rejections*, 332 JAMA 10, 837 (2024).

mechanisms to the judge-made ODP doctrine has done nothing but create uncertainty for courts, inventors, and other stakeholders alike.

This Note uses *Allergan* to outline the complex interactions of ODP and PTA. This Note argues that the Federal Circuit rightly decided *Allergan*, and that the first patent in a family with PTA-lengthened terms cannot, and should not, be invalidated for ODP based on other earlier-expiring patents without PTA. Part II of this Note traces the history of ODP jurisprudence and its interaction with patent term modification mechanisms to contextualize the decisions in *Allergan*. Part III delineates *Allergan*'s background, procedural history, and the Federal Circuit's reasoning for its decision. Part IV draws on legislative history and the context surrounding the establishment of ODP and PTA to explain why the Federal Circuit's decision in *Allergan* is a much-needed, necessary exception to *Cellect*. Part IV then proposes a two-prong approach to an ODP analysis—one that considers both traditional equitable concerns and the propriety of reference patents used for invalidation. Additionally, Part IV poses ODP scenarios with PTA not covered by *Allergan* and, using the proposed approach, emphasizes that patent invalidation is possible in these scenarios based on the equitable circumstances underlying the ODP doctrine. Lastly, Part IV lays out practical strategies that practitioners and patentees can adopt to ameliorate ODP risks and uncertainties.

II. HISTORY OF OBVIOUSNESS-TYPE DOUBLE PATENTING JURISPRUDENCE WITH PATENT TERM ADJUSTMENT

The doctrine of double patenting is a simple rule: one invention, one patent.[17] In practice, however, the doctrine has become troublesome, especially when interacting with other patent term modification mechanisms. Section II.A begins by providing a basic overview of obviousness-type double patenting (ODP). Section II.B explains patent term and patent term modification mechanisms, which are necessary to understand the complex interaction between ODP and patent term adjustment (PTA) in *Allergan*. Section II.C traces the formative ODP jurisprudence related to its interaction with term modification mechanisms before *Allergan*.

A. OVERVIEW OF OBVIOUSNESS-TYPE DOUBLE PATENTING

The statutory basis for double patenting is nothing more than a single letter in 35 U.S.C. § 101: "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and

17. *See* discussion *infra* Section II.A for the doctrine of double patenting in 35 U.S.C. § 101.

useful improvement thereof, may obtain *a* patent therefor."[18] Thus, an inventor may obtain "*a* patent," not multiple patents, for an invention. This provision forms the foundation of statutory, or same-invention, double patenting, which prohibits obtaining multiple patents for the "same invention."[19] Put another way, identical subject matter cannot be claimed twice.[20] Although identical wording in the claims is not required, two claims must be effectively identical in scope for statutory double patenting to apply.[21]

Statutory double patenting is seldom found in practice because patentees rarely file separate patent applications with identical claims. The doctrine of double patenting also covers, however, far more common situations where a later application claims not the exact same invention, but obvious variations of it—referred to as "obviousness-type double patenting" (ODP).[22] The primary justification for ODP is to "prevent unjustified timewise extension of the right to exclude granted by a patent."[23] This can happen when a patentee attempts to extend her patent monopoly by obtaining multiple patents that claim obvious variants of the same invention with different expiration dates. Thus, ODP ensures that the public is entitled to free use of "not only the invention claimed in the patent but also any modifications or variants thereof" after the original period of patent monopoly expires.[24] The public would be deprived of this right if a subsequent patent were granted on an invention that is not patentably distinct from the initial patent.[25]

Because the primary purpose of ODP is to prevent a patentee from unduly extending their patent monopoly, for ODP to apply, the two patents or applications in consideration must have some commonality of inventorship or ownership.[26] In other words, the patents or applications must have at least one common inventor, be commonly assigned or owned, or be subject to a joint research agreement.[27] This means that the types of patents most likely to be at

18. 35 U.S.C. § 101 (emphasis added).
19. MPEP § 804 (9th ed. Rev. 1, 2024).
20. *Id.*
21. *Id.*
22. *Id.*
23. *In re* Van Ornum, 686 F.2d 937, 943–44 (C.C.P.A. 1982) (quoting *In re* Schneller, 397 F.2d 350, 354 (C.C.P.A. 1968)); *see also In re* Hubbell, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (stating that "[t]here 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," as stated. The second purpose of ODP is to avoid multiple lawsuits from owners of different patents with no collateral estoppel, if patent ownership is divided.).
24. *In re* Longi, 759 F.2d 887, 892–93 (Fed. Cir. 1985); Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 967–68 (Fed. Cir. 2001).
25. *See id.*
26. MPEP § 804 (9th ed. Rev. 1, 2024).
27. *Id.*

risk for ODP are often continuations within the same patent family that claim additional aspects of an invention, or commonly owned patents from separate families where one patent is obvious over the other.

In an ODP analysis, an alleged reference patent is used to evaluate the challenged patent. The obviousness-type double patenting analysis involves two steps:

> First, the court "construes the claim[s] in the *earlier* patent and the claim[s] in the *later* patent and determines the differences." Second, the court "determines whether those differences render the claims patentably distinct." "A later claim that is not patentably distinct from," i.e., "is obvious over[ ] or anticipated by," an earlier claim is invalid for obviousness-type double patenting.[28]

Given that the terms "earlier" and "later" can be used to describe any of a patent's filing, issuance, or expiration dates, courts have issued unclear guidance about what constitutes a proper ODP reference. This ambiguity becomes even more complicated when the various dates associated with a patent are shifted with patent term modification mechanisms, such as PTA.

A patentee can overcome ODP rejections by filing a terminal disclaimer under 35 U.S.C. § 253, which disclaims any portion of the patent term that extends beyond the expiration of the reference patent.[29] Filing of a terminal disclaimer permits the issuance of the patent on the obvious variation, provided that the term of this patent does not extend beyond that of the reference patent.[30] The terminal disclaimer must be filed before the reference patent expires.[31]

B. PATENT TERM AND PATENT TERM ADJUSTMENT (PTA)

The length of a U.S. patent term has changed under different patent law regimes, with mechanisms like PTA further adjusting the base term. As *Allergan* addresses the complex interaction between ODP and PTA, with rationales grounded in intricate patent term and ODP jurisprudence, this

---

28. Sun Pharm. Indus., Ltd. v. Eli Lilly & Co., 611 F.3d 1381, 1385 (Fed. Cir. 2010) (emphasis added) (alteration in original) (quoting Pfizer, Inc. v. Teva Pharm. USA, Inc., 518 F.3d 1353, 1363 (Fed. Cir. 2008) and *Eli Lilly v. Barr*, 251 F.3d at 968) (stating that "[t]he second step generally follows an obviousness analysis under 35 U.S.C. § 103."); *see also* AbbVie v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr., 764 F. 3d 1366, 1378 (Fed. Cir. 2014) (stating that "the law of obviousness-type double patenting looks to the law of obviousness generally.").

29. 35 U.S.C. § 253; MPEP § 1490 (9th ed. Rev. 1, 2024).

30. *Id.*

31. *Id.*

Section provides an overview of patent term calculations under various U.S. patent law regimes and PTA mechanisms.

1. *Patent Term Before and After the Uruguay Round Agreements Act (URAA)*

35 U.S.C. § 154 governs the term length for a U.S. patent.[32] Before 1994, the term of a U.S. patent was seventeen years from the issue date.[33] However, in 1994, Congress enacted the Uruguay Round Agreements Act (URAA) and amended 35 U.S.C. § 154 to align U.S. patent term provisions with international standards.[34] Under the URAA, patents filed on or after June 8, 1995 expire twenty years from their earliest effective U.S. filing date.[35] Thus, if the USPTO took three years to issue a patent, the applicant would still receive seventeen years of patent term, similar to the pre-URAA system. However, under the URAA, each day patent issuance was delayed from prosecution at the USPTO is a day lost from the overall patent term. As an extreme example, if the USPTO delays prosecution of a patent application for twenty years, the patentee will lose her entire patent term. This loss of term—arising entirely from administrative delay and beyond the applicant's control—posed a significant challenge for patentees, until Congress passed the Patent Term Guarantee Act.

2. *Patent Term Adjustment (PTA) as a Term Modification Mechanism*

To remedy and compensate inventors for the shortened term caused by any prosecution delays at the USPTO after the URAA, Congress introduced the Patent Term Guarantee Act of 1999, outlining the provisions for patent term adjustment (PTA).[36] Governed by 35 U.S.C. § 154(b), PTA adds one day to the patent term for each day the USPTO delays prosecution.[37]

---

32. 35 U.S.C. § 154(a)(2).

33. Patent Act, 950 Pub. L. No. 593, 66 Stat. 792, 804 § 154 (1952); 35 U.S.C. § 154 (1952); *see also, e.g.*, Mark A. Lemley, *An Empirical Study of the Twenty-Year Patent Term*, 22 AIPLA Q.J. 369, 374 (1994) ("[T]he fundamental baseline of the 1952 Act was a seventeen-year term across industries.").

34. Uruguay Round Agreements Act, 103 Pub. L. No. 465, 108 Stat. 4809 (1994); *see* discussion *infra* Section IV.B for a legislative history behind the change in US patent term and introduction of PTA after the passage of the URAA.

35. *Id.* at 4983–85; 35 U.S.C. § 154(a)(2). The "effective filing date" is the earlier of: (1) the actual filing date of the application, or (2) the filing date of the earliest priority application (i.e., the earliest filed provisional, nonprovisional, international, or foreign application) to which a patent application is entitled to a right of priority.

36. *See* American Inventors Protection Act, Pub. L. No. 106-13, tit. IV, § 401–402 (1999).

37. 35 U.S.C. § 154(b), (b)(1)(A).

Three main categories of USPTO delays qualify for PTA. First, a patent is entitled to PTA if the USPTO fails to take specific administrative actions within certain timeframes (A-delays).[38] These actions include a failure to issue a first Office Action or Notice of Allowance within fourteen months of the application filing date, an Office Action within four months of an applicant's reply, or the patent within four months of issue fee payment.[39] Second, PTA is added if the USPTO takes more than three years to issue a patent (B-delays).[40] Third, Congress guarantees PTA for delays due to derivation proceedings, secrecy orders, and appeals (C-delays).[41] However, any patentee-caused delays also reduce PTA. The patentee can lose PTA if they "fail to engage in reasonable efforts to conclude prosecution of the application."[42] For instance, failing to respond to an Office Action within three months of receiving notice can result in the loss of PTA.[43] Thus, this statutory framework ensures compensation for USPTO delays, upholding Congress's longstanding policy of protecting diligent applicants from being penalized by such delays.

In the context of ODP, PTA can cause patents within the same family to have different expiration dates. For instance, patents in the same family usually share the same priority date and thus would expire at the same time (i.e., twenty years from the earliest effective filing date). However, if the USPTO causes a prosecution delay for a patent application, PTA can extend the patent's term and cause it to expire later than other patents in the family with the same priority date. This raises the question of whether a patent can be invalidated for ODP on the grounds of a PTA-lengthened term, and whether PTA, which is statutorily guaranteed by Congress, can trigger a judge-made doctrine such as ODP.

It is important to point out that while this Note focuses on PTA, there is another patent term modifier, known as "patent term extension," or "PTE."[44] PTE allows patentees to extend the patent term to compensate for delays in obtaining regulatory approval for a product covered by the patent.[45] Available under the Hatch-Waxman Act, PTE is codified in 35 U.S.C. § 156.[46] PTE is only available for specific types of patents, most commonly those related to

38. 35 U.S.C. § 154(b)(1)(A).
39. *Id.*
40. 35 U.S.C. § 154(b)(1)(B).
41. 35 U.S.C. § 154(b)(1)(C).
42. 35 U.S.C. § 154(b)(2)(C)(i).
43. 35 U.S.C. § 154(b)(2)(C)(ii).
44. 35 U.S.C. § 156.
45. 35 U.S.C. § 156(a).
46. 35 U.S.C. § 156; Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

pharmaceuticals and medical devices that undergo lengthy review by the Food and Drug Administration (FDA) before they can be marketed.[47] PTE is essential because, although the USPTO may grant a patent, FDA approval can take several years, delaying the company's ability to market the product.[48] As a result, the patent term would continue running during such regulatory delays, depriving the company of any patent-based market exclusivity benefits.[49] PTE thus compensates the patentees for any patent term lost due to regulatory processes.[50] There have been debates over the statutory differences and purposes of PTA and PTE, as well as how each interacts with ODP.[51]

C. EVOLUTION OF ODP JURISPRUDENCE INVOLVING PATENT TERM MODIFICATION

Several seminal cases trace the evolution of ODP jurisprudence, providing nuances into what qualifies as a proper ODP reference while underscoring the equitable roots that form the foundation of the doctrine. Despite a few district court cases, prior to *In re Cellect* ("*Cellect*") and *Allergan*, the Federal Circuit had scarcely addressed the interaction between ODP and PTA.[52] Before the URAA, PTA did not exist, and courts relied on the patent's issuance date to assess whether a patentee attempted to improperly prolong the seventeen-year exclusivity period. The URAA's statutory changes raised a fundamental question: should issuance dates remain relevant in an ODP analysis, now that patent term is based on the filing date? Addressing this mismatch, *Gilead Sciences, Inc. v. Natco Pharma Ltd.* ("*Gilead*") and *AbbVie v. Mathilda & Terence Kennedy Institute of Rheumatology Trust* ("*AbbVie*") set the scene for the use of expiration dates in a post-URAA world to determine ODP outcomes and

47. Stephanie Plamondon Bair, *Adjustments, Extensions, Disclaimers, and Continuations: When Do Patent Term Adjustments Make Sense*, 41 CAP. U. L. REV. 458, 486 (2013).

48. *Id.* at 486.

49. *Id.*

50. *Id.*

51. *See, e.g.*, *In re* Cellect, LLC, 81 F.4th 1216, 1224–28 (Fed. Cir. 2023); Petition for a Writ of Certiorari at *15, Cellect, LLC v. Vidal, (May 20, 2024) (No. 23-1231), 2024 WL 2379649; Brief for the respondent in opposition at *13–14, Cellect, LLC v. Vidal, (Aug. 21, 2024) (No. 23-1231), 2024 WL 3914202; *see also* Abiomed, Inc. v. Maquet Cardiovascular LLC, 2023 WL 4038564, at *33–34 (D. Mass. 2023). In *In re Cellect*, Cellect contended that "PTA and PTE should be factored into an ODP analysis in the same way" because they have similar statutory limitations, legislative intent, and precedents. The USPTO, however, argued that the statutory language and precedents support treating PTA and PTE differently from each other in an ODP analysis. The Federal Circuit in *Cellect* ultimately agreed with the USPTO on their treatment of PTA and PTE when analyzing ODP.

52. *See generally* Magna Elecs., Inc. v. TRW Auto. Holdings Corp., 2015 WL 11430786, at *3–6 (W.D. Mich. 2015); Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc., 533 F. Supp. 3d 170 (D.N.J. 2021); *Abiomed*, 2023 WL 4038564, at *33–34; *Cellect*, 81 F.4th 1216; *Allergan*, 111 F.4th 1358.

contextualize the courts' concerns about patentee gamesmanship.[53] The implementation of the URAA also triggers a series of double patenting scenarios due to the statutory change in patent term calculations—particularly in transitional cases where one patent application was filed before the passage of the URAA and another after it. Cases such as *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc.* ("*Breckenridge*") and *Novartis AG v. Ezra Ventures LLC* ("*Ezra*") emphasized that expiration dates are not always dispositive in an ODP analysis and offered analogous perspectives to ODP cases with statutorily-granted term modification mechanisms.[54] Finally, *Cellect* brought the interaction between ODP and PTA to the forefront, and *Allergan* began to refine the legal contours set by *Cellect*.[55] This Section reviews these ODP legal precedents and rationales in detail to further contextualize *Allergan*.

1. Gilead *Leads the Transition from Issuance Dates to Expiration Dates as an ODP Proxy, with the Intent to Curb Gamesmanship*

Prior to *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, the Federal Circuit had used patent issuance dates as a benchmark to determine whether a patentee was improperly extending her patent term in an ODP analysis.[56] This was a result of a pre-URAA world, where the patent term was seventeen years from the issuance date.[57] Thus, an earlier-issued patent would generally expire earlier and could often be used as an ODP reference to invalidate a later-issued, later-expiring patent.[58] Most of the time, an earlier-issued patent was also filed earlier, so double patenting practically only posed a problem for the later-filed and later-issued patent.[59]

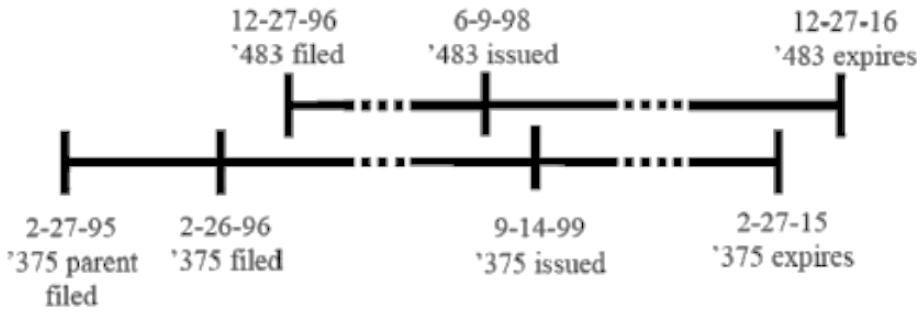
However, in a post-URAA world, where a patent's issuance date is no longer tied to its expiration date, double patenting issues persist when the later-issued but earlier-expiring patent now serves as an ODP reference. This raises the question: can a later-expiring but earlier-issued patent be invalidated for ODP by an earlier-expiring but later-issued patent?

Gilead addresses this question in an ODP scenario involving two post-URAA patents from separate chains of priorities.[60] It considers whether a patent that was filed before, issued after, but expiring before another patent

53. *See Gilead*, 753 F.3d 1208, 1215–16 (2014); *AbbVie*, 764 F.3d 1366, 1373–74 (2014).
54. *See generally Breckenridge*, 909 F.3d 1355 (2018); *Ezra*, 909 F.3d 1367 (2018).
55. *See generally Cellect*, 81 F.4th 1216; *Allergan*, 111 F.4th 1358.
56. *See Gilead*, 753 F.3d at 1208.
57. *See* Uruguay Round Agreements Act, *supra* note 34.
58. Daniel Kazhdan, *Obviousness-Type Double Patenting: Why It Exists and When It Applies*, 53 AKRON L. REV. 1017, 1029 (2019).
59. *Id.*
60. *Gilead*, 753 F.3d at 1208.

qualifies as an ODP reference.[61] Gilead's patents at issue, the '483 and '375 patents, do not claim priority to a common patent application, and thus, have different expiration dates.[62] Natco argued that the '483 patent should be invalidated for ODP over the '375 patent since the '483 patent expired after the '375 patent.[63] Gilead asserted that the '375 patent could not serve as an ODP reference against the '483 patent because the '483 patent was issued before the '375 patent.[64] Figure 1 depicts the relationships between these patents and their respective filing, issuance, and expiration dates.

Figure 1: Filing, issuance, and expiration dates for *Gilead* patents[65]



The Federal Circuit in *Gilead* addressed ODP in relation to issuance dates and expiration dates.[66] In *Gilead*, the Federal Circuit asserted that the issuance date is only a "stand-in for the date that really matter[s]—patent expiration."[67] Rejecting Gilead's emphasis on the issuance date, the Federal Circuit instead held that only the expiration date is relevant in an ODP analysis to prevent improper extensions of exclusivity.[68] Thus, the *Gilead* court held that an earlier-expiring patent could be used as a reference against the later-expiring patent, even though the later-expiring patent had been issued first.[69] This decision was grounded in the principle that, upon patent expiration, the public should be free to use an invention and its obvious modifications.[70]

61. *Id.*
62. *Id.* at 1209.
63. *Id.* at 1210.
64. *Id.* at 1209.
65. *Id.* at 1210.
66. *Id.* at 1214–17.
67. *Id.* at 1215.
68. *Id.* at 1215–16.
69. *Id.* at 1217.
70. *Id.* at 1214.

The *Gilead* decision also emphasized the role of patentee misconduct in an ODP analysis. Gilead had crafted two separate chains of applications with different priority dates.[71] The court noted that "if the double patenting inquiry was limited by issuance date, inventors could routinely orchestrate patent term extensions by (1) filing serial applications on obvious modifications of an invention, (2) claiming priority to different applications in each, and then (3) arranging for the application claiming the latest filing date to issue first. If that were to occur, inventors could obtain additional patent term exclusivity for obvious variants of their inventions while also exploring the value of an earlier priority date during prosecution."[72] The *Gilead* court held that focusing on the expiration date "guarantees a stable benchmark that preserves the public's right to use the invention . . . when that patent expires."[73]

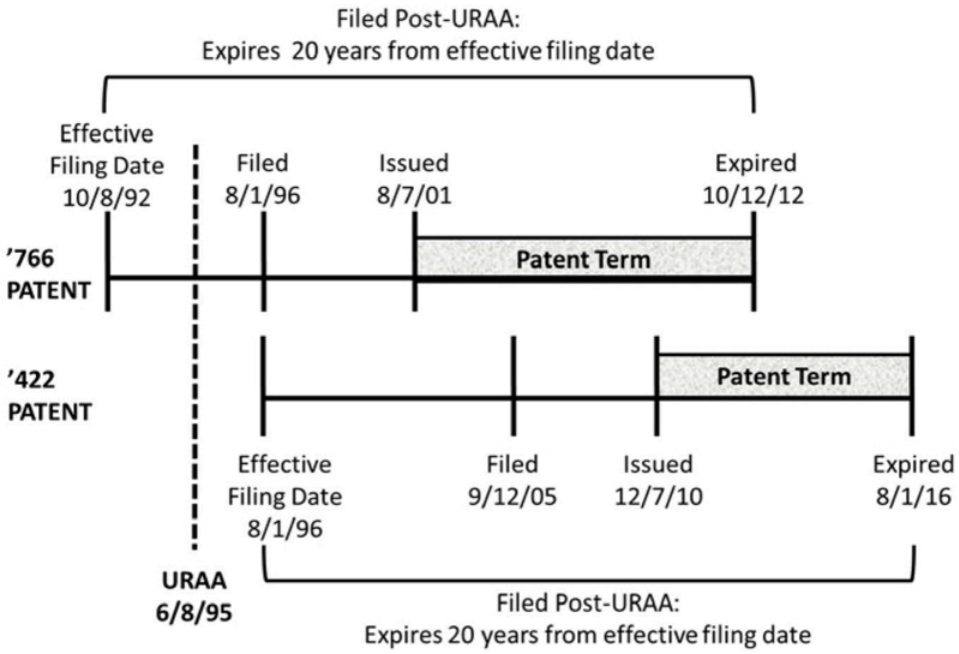
2. AbbVie *Reaffirms the Applicability of the ODP Coctrine and its Public Policy Goals Under the URAA*

AbbVie v. Mathilda & Terence Kennedy Institute of Rheumatology Trust followed *Gilead* in 2014 and resolved the question of whether the doctrine of ODP still applied post-URAA.[74] In *AbbVie*, the Federal Circuit made *Gilead* explicit by holding that ODP continued to apply to prevent gamesmanship, where two patents were directed to claims that were not patentably distinct but had different expiration dates.[75] Like *Gilead*, the Mathilda and Terrance Kennedy Institute of Rheumatology Trust (Kennedy) owned two related post-URAA patents filed in separate priority chains.[76] Filed on August 1, 1996, the first patent was the '766 patent, which claimed priority to a 1992 application through a continuation-in-part.[77] The second patent, the '442 patent, claimed priority to the date the '766 patent was filed, August 1, 1996.[78] The '442 patent also had 750 days of PTA, and thus was set to expire six years after the expiration of the '766 patent (Figure 2).[79]

---

71. *Id.* at 1210.
72. *Id.* at 1215.
73. *Id.* at 1216.
74. *AbbVie*, 764 F.3d at 1374.
75. *Id.*; *see also* Acadia Pharmas. Inc. v. Aurobindo Pharma Ltd., 706 F. Supp. 3d 477, 488 (D. Del. 2024) (stating that "*AbbVie* applied the *Gilead* rationale, making clear that the availability of OTDP remained viable to prevent gamesmanship in certain narrow instances.").
76. *AbbVie*, 764 F.3d at 1368–71.
77. *Id.* at 1369.
78. *Id.* at 1370.
79. *Id.*

Figure 2: Filing, issuance, and expiration dates for *AbbVie* patents[80]



AbbVie licensed the '766 patent but not the '442 patent.[81] Unwilling to secure an additional license for the '442 patent, AbbVie sued Kennedy for a declaratory judgment that the '442 patent was invalid for ODP over the '766 patent.[82] Following a bench trial, the district court held that the '442 patent was invalid for ODP.[83] The Federal Circuit affirmed the district court's finding and invalidated the '442 patent against the '766 patent under ODP.[84]

While *AbbVie* did not directly address PTA, the *AbbVie* court noted in passing that ODP remains relevant post-URAA, particularly when separate applications claiming overlapping subject matter have different expiration dates due to examination delays at the PTO or different priority dates.[85] Some

80. *See id.*; Kevin E. Noonan, *Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc. (Fed. Cir. 2018)*, PATENT DOCS (Dec. 11, 2018), https://www.patentdocs.org/2018/12/novartis-pharmaceuticals-corp-v-breckenridge-pharmaceutical-inc-fed-cir-2018.html.

81. *AbbVie*, 764 F.3d at 1368.

82. *Id.* at 1370.

83. AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr., 956 F. Supp. 2d 429, 429 (S.D.N.Y. 2013).

84. *AbbVie*, 764 F.3d at 1381.

85. *Id.* at 1373 (stating that "[ODP] is designed to prevent an inventor from securing a second, later expiring patent for the same invention. That problem still exists [post-URAA]. Patents claiming overlapping subject matter that were filed at the same time still can have different patent terms due to examination delays at the PTO . . . When such situations arise,

have interpreted the *AbbVie* court's commentary as suggesting that a PTA-extended patent term is a scenario in which ODP may apply and override.[86]

3. Ezra *and* Breckenridge *Refine the Use of Expiration Dates in an ODP Analysis After* Gilead

The *Gilead* and *AbbVie* courts held that a patent's expiration date serves as a proper benchmark in an ODP analysis—in the specific context of patentably indistinct applications filed in separate priority chains that naturally result in different expiration dates.[87] The courts, however, left open whether ODP should apply when the difference in expiration dates arises from other circumstances. In the aftermath of *Gilead* and *AbbVie*, patent infringement defendants have sought to extend *Gilead*'s reasoning to other situations. Patents were brought under scrutiny and challenged for ODP even when Congress explicitly granted a longer patent term, such as through patent term extension (PTE)[88] or through the URAA's intervening change in law.

Novartis AG v. Ezra Ventures LLC further clarified the scope of *Gilead* and addressed the relationship between ODP and PTE.[89] In *Ezra*, a pre-URAA patent was challenged under ODP because its PTE caused it to expire after a later-issued post-URAA patent (Figure 3).[90] The Federal Circuit held that ODP does not invalidate a validly obtained PTE if the claims are otherwise valid under its pre-PTE expiration date.[91] In making this determination, the court pointed out that it is the earlier-filed, earlier-issued patent that has the later expiration date due to PTE.[92] The court asserted that *Ezra* does not raise the traditional ODP concern of a patentee trying to extend her patent exclusivity through a "*later*-filed patent that [is] not patentably distinct from claims in the *earlier*-filed patent."[93] The court also noted that, unlike *Gilead*, *Ezra* did not present the same risks of "gamesmanship" through the structuring of priority dates.[94] More importantly, the *Ezra* court held that ODP, as a "judge-made

---

the doctrine of obviousness-type double patenting ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension." (citations omitted)).

86. *See Magna Elecs.*, 2015 WL 11430786, at *1.

87. *See Gilead*, 753 F.3d at 1212, 1217; *AbbVie*, 764 F.3d at 1374.

88. *See* discussion *supra* Section II.B.2 for patent term extension (PTE) in 35 U.S.C. § 156 and its purposes.

89. *Ezra*, 909 F.3d at 1369.

90. *Id.* at 1369–70.

91. *Id.* at 1374.

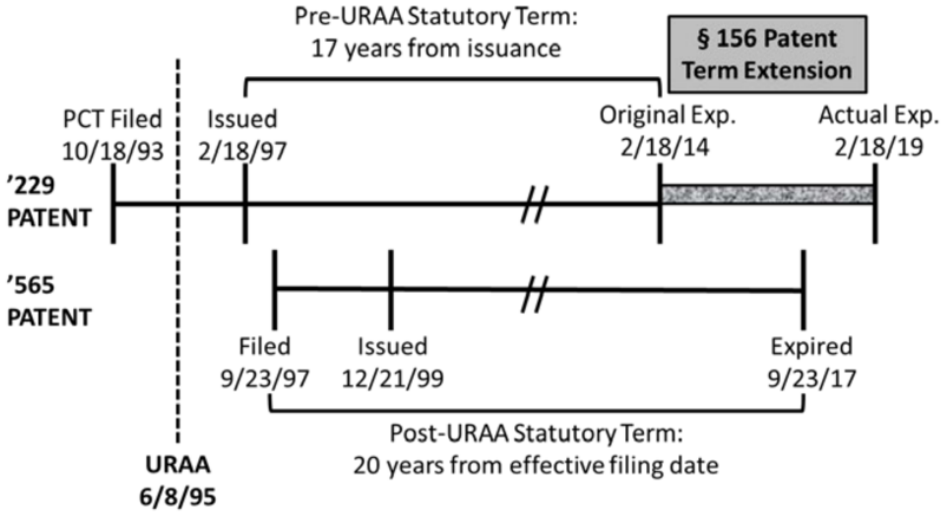
92. *Id.*

93. *Id.* (emphasis added).

94. *Id.*

doctrine," cannot cut off "a statutorily authorized time extension," such as PTE.[95]

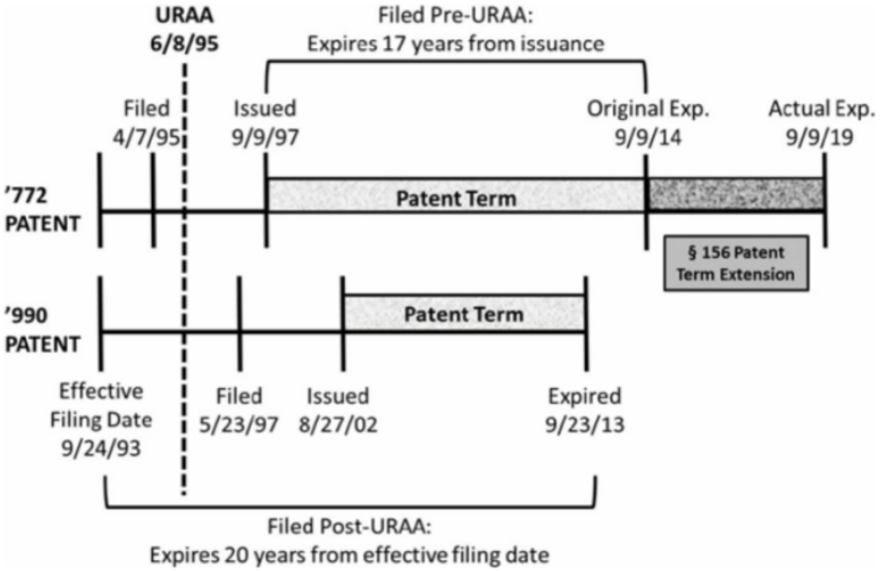
Figure 3: Filing, issuance, and expiration dates for *Ezra* patents[96]



Novartis Pharmaceuticals Corp. v. Breckenridge Pharmaceutical Inc. provides another instance where the implementation of the URAA's new patent term law by Congress caused an earlier-filed, earlier-issued, pre-URAA patent to expire before a later-filed, later-issued, post-URAA patent (Figure 4), creating an ODP issue.[97] In a ruling issued on the same date as *Ezra*, the Federal Circuit emphasized that an earlier-expiring post-URAA patent is not a proper ODP reference against a later-expiring pre-URAA patent.[98] The court acknowledged that the pre-URAA patent expires after the post-URAA patent not because of "prosecution gamesmanship," but because of "happenstance of an intervening change in patent term law."[99] The court clarified that its holding in *Gilead* applies only to post-URAA patents, and that a change in patent term law should not truncate the default, statutorily assigned term in the pre-URAA patent.[100] More importantly, the court held that expiration dates alone are not always dispositive in an ODP analysis.[101]

95. *Id.* at 1375.
96. *Id.* at 1370.
97. *Breckenridge*, 909 F.3d at 1357–58.
98. *Id.* at 1358, 1362.
99. *Id.* at 1364.
100. *Id.* at 1358.
101. *Id.* at 1362–64.

Figure 4: Filing, issuance, and expiration dates for *Breckenridge* patents[102]



Both *Ezra* and *Breckenridge* pushed back against efforts to use ODP to cut short statutorily guaranteed patent terms. In both cases, the Federal Circuit rejected the use of an earlier-expiring patent to invalidate a later-expiring patent under ODP, when the difference in expiration dates was not the result of prosecution gamesmanship, but rather of mandated legislative mechanisms.[103] Although transitional cases involving pre- and post-URAA patents are now rare—pre-URAA applications had to be filed before June 7, 1995, and are largely obsolete today[104]—the underlying rationale in *Ezra* and *Breckenridge* remains relevant to a more common scenario of post-URAA patents. For patents with PTA that extend expiration dates beyond those of other patents, a key question lingers: in what circumstances can an earlier-expiring patent serve as an ODP reference against a later-expiring patent? Just as the earlier-filed, earlier-issued patent in *Ezra* received more PTE due to extended FDA review, an earlier-filed, earlier-issued patent may accrue more PTA due to USPTO prosecution delays, thus expiring later than other patents. While *Ezra* temporarily put an end to post-*Gilead* ODP challenges related to

102. *Id.* at 1360.
103. *See Ezra*, 909 F.3d at 1374; *Breckenridge*, 909 F.3d at 1358.
104. Kazhdan, *supra* note 58, at 1046.

PTE, courts have provided inconsistent guidance on the interaction of ODP and PTA.

4. *District Courts Grappled with the Interaction of ODP and PTA Before* Cellect *and* Allergan

Long before *Cellect* and *Allergan*, district courts grappled with ODP cases involving PTA. In *Magna Electronics, Inc. v. TRW Automotive Holdings Corp.*, the U.S. District Court for the Western District of Michigan applied ODP to two patents in the same family with different expiration dates because one of them accrued PTA while the other did not.[105] Both patents had the same priority date, and without PTA, both would have expired on the same date.[106] Following *Gilead*'s instruction of looking to the expiration dates in an ODP analysis, the court used the later-filed, later-issued, but earlier-expiring patent (without PTA) as the ODP reference to invalidate the later-expiring, but earlier-filed, earlier-issued patent (with PTA).[107] In other words, the court ruled that the earlier-expiring patent without PTA qualified as an ODP reference—effectively invalidating the later-expiring patent and eliminating its PTA in the process.[108]

However, some district courts have refused to invalidate patents based on ODP, where the only difference in expiration dates came from PTA. In *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.* ("*Mitsubishi*"), the District Court for the District of New Jersey found that the later-expiring patent with PTA was not a proper ODP reference to invalidate the earlier-expiring patent without PTA.[109] The court found that "[t]his case does not raise the traditional concern with obviousness-type double patenting" and that "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."[110] The defendant later appealed the district court's decision to the Federal Circuit.[111] The case was remanded to the district court for modification of the final judgment consistent with the district court's indicative ruling in favor of the patentees.[112]

---

105. *Magna Elecs.*, 2015 WL 11430786, at *3–6 (W.D. Mich. 2015).
106. *Id.*
107. *Id.*
108. *Id.* at *4.
109. *Mitsubishi*, 533 F. Supp. 3d 170 (D.N.J. 2021).
110. *Id.* at 214.
111. Notice of Appeal to the Federal Circuit, Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc., 533 F. Supp. 3d 170 (D.N.J. 2021) (No. 3:17-cv-05319).
112. Text Order terminating Motion, Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc., 533 F. Supp. 3d 170 (D.N.J. 2021) (No. 3:17-cv-05319).

Abiomed, Inc. v. Maquet Cardiovascular LLC ("*Abiomed*") followed *Mitsubishi* and reached a similar outcome.[113] In *Abiomed*, the first-filed patent with 407 days of PTA was challenged on the grounds of ODP by a second patent, which claimed priority to the first patent. The second patent was filed ten years later, received only ninety-eight days of PTA, and thus expired before the first patent.[114] The District Court for the District of Massachusetts held that ODP did not invalidate the first patent in this case.[115] Abiomed had attempted to distinguish itself from *Ezra*, but the district court found the arguments unpersuasive.[116] The court drew a comparison between PTA and PTE and found the case analogous to *Ezra*, where there were no gamesmanship concerns underlying the ODP doctrine by the applicant.[117] In addressing PTA, the court emphasized that "[e]ven if . . . such an extension is unfair to the public, the statutory text commits the task of correcting that unfairness to Congress, not courts applying a judicially-created doctrine."[118] *Abiomed* is currently on appeal at the Federal Circuit.[119]

5. Cellect *Spotlights the Interplay Between ODP and PTA, Putting PTA-Extended Patents at Risk in an ODP Challenge*

While the muddy interaction between ODP and PTA had occasionally surfaced in district court cases, *In re Cellect* thrust this issue into the spotlight.[120] In an ex parte reexamination, the USPTO determined that the claims in four of Cellect's patents were invalid based on ODP over a reference patent and issued a rejection.[121] Each of these four challenged patents shared the same effective filing date as the reference patent.[122] Each of the challenged patents

113. *Abiomed*, 2023 WL 4038564, at *33–34.

114. *Id.* at 33.

115. *Id.* at 34.

116. *Id.* at 33–34 (Abiomed attempted to distinguish itself from *Ezra* by contending in three ways. First, it contended that the term extension by the first patent is unfair to the public ("failing to apply the ODP doctrine here would allow patentees to obtain varying, extended terms for multiple patents that claim obvious variations of the same invention.") Second, it contended that the statutory language of 35 U.S.C. § 154 suggests that "*any* patent extended by § 154 cannot be extended past another patent claiming overlapping subject matter." Third, it contended that 35 U.S.C. § 154 and 35 U.S.C. § 156 have different statutory purposes.).

117. *Id.* at 33.

118. *Id.*

119. Notice of Appeal to the Federal Circuit, Abiomed, Inc. v. Maquet Cardiovascular LLC, 2023 WL 4038564, at *33–34 (D. Mass. 2023) (No 1:16-CV-10914); Abiomed, Inc. v. Maquet Cardiovascular LLC (Fed. Cir. 2023) (No. 24-01062).

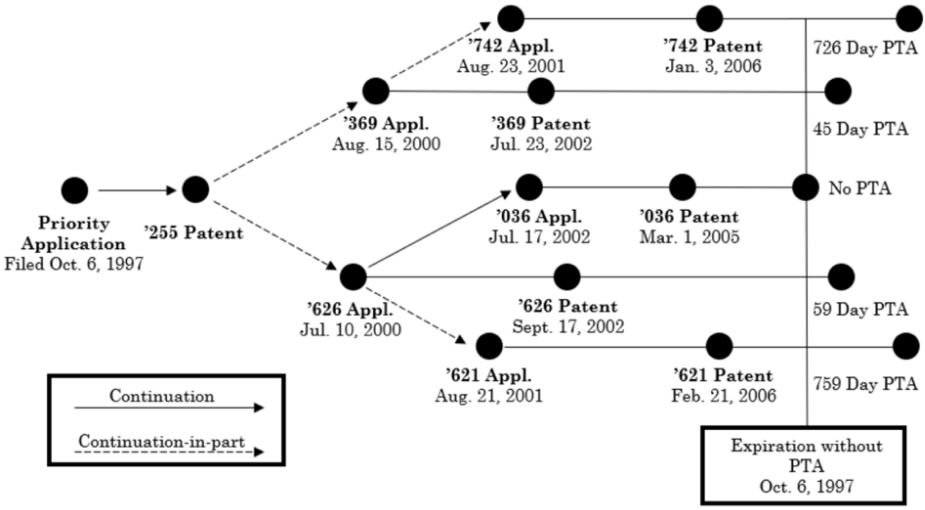
120. *See* discussion *supra* Section II.C.5 for district court cases dealing with the interaction of ODP and PTA.

121. *Cellect*, 81 F.4th at 1219.

122. *Id.* at 1219–20. The four challenged patents are part of a complex patent family and are all interrelated. The ODP reference patents to invalidate these four challenged patents

was filed before the reference patent; however, each of them also accrued PTA and thus expired later than the reference patent, which had no PTA (Figure 5).[123] None of the challenged patents were subject to a terminal disclaimer, as they had never been rejected under ODP during their original prosecution.[124]

Figure 5: Filing, issuance, and expiration dates for *In re Cellect* patents[125]



Cellect first appealed the Examiner's rejections to the Patent Trial and Appeal Board (PTAB). The PTAB agreed with the Examiner's rejections and held that ODP should be based on the patent's adjusted expiration date, including PTA.[126] Cellect then appealed to the Federal Circuit. The Federal Circuit affirmed the PTAB's findings and concluded that ODP is determined based on a patent's expiration date *after* PTA has been added.[127] In arriving at this ruling, the court pointed out that the statutory provisions for PTA and PTE have different rationales and purposes.[128]

---

form a network across four ex parte reexamination proceedings. However, all invalidated claims can be traced back to the '036 patent, the only family member that did not receive PTA and shared the same priority date with the four patents.

123. *Id.*
124. *Id.* at 1219.
125. *Id.* at 1220.
126. *Id.* at 1221–22.
127. *Id.* at 1229.
128. *Id.* at 1227–28.

Cellect filed an en banc petition seeking a rehearing at the Federal Circuit in January 2024, but the court denied the petition.[129] In May 2024, Cellect filed a petition for a writ of certiorari with the U.S. Supreme Court.[130] Several brand-name and generic drug companies, industry groups, and bar associations have since filed amicus briefs in response to the writ of certiorari to voice their opinions and policy justifications.[131] However, in October 2024, the Supreme Court denied Cellect's petition for a writ of certiorari, allowing the rulings of the Federal Circuit to stand.[132]

III. *ALLERGAN V. MSN*

Following *Cellect*, district courts were left to continue navigating the interaction between ODP and PTA on their own. This has proven challenging. Courts have taken divergent approaches, interpreting the *Cellect* decision differently and issuing conflicting rulings in PTA-related ODP cases. The confusion is most pronounced in the District of Delaware, which hears many patent cases.[133] In *Acadia Pharmaceuticals Inc. v. Aurobindo Pharmaceuticals Ltd.* ("*Acadia*") and *Allergan*, two judges in the District of Delaware reached opposing conclusions on whether ODP can invalidate an earlier-filed patent that expires later due to PTA, despite the cases having similar fact patterns.[134] In *Acadia*, the district court held that "only earlier-filed patents are proper [ODP] references."[135] The court asserted that "the claims in the challenged

129. Petition for Rehearing En Banc, *Cellect*, 81 F.4th 1216 (Fed. Cir. 2023) (Nos. 22-1293, 22-1294, 22-1295, 22-1296).

130. Petition for a Writ of Certiorari, *denied*, Cellect, LLC v. Vidal, 145 S. Ct. 153 (Oct. 7, 2024) (No. 23-1231).

131. *See generally* Brief Amicus Curiae of The New York Intell. Prop. L. Assoc., Cellect, LLC v. Vidal, 2024 WL 2798145 (May 28, 2024) (No. 23-1231); Brief Amicus Curiae of Intell. Prop. L. Assoc., Cellect, LLC v. Vidal, 2024 WL 3162077 (June 20, 2024) (No. 23-1231); Brief Amicus Curiae of Teige P. Sheehan, Cellect, LLC v. Vidal, 2024 WL 3179564 (June 21, 2024) (No. 23-1231); Brief Amici Curiae of Pharm. Rsch. & Mfrs. of Am., et al., Cellect, LLC v. Vidal, 2024 WL 3179568 (June 21, 2024) (No. 23-1231); Brief Amici Curiae of Sonos, Inc., et al., Cellect, LLC v. Vidal, 2024 WL 3179567 (June 21, 2024) (No. 23-1231); Brief Amicus Curiae of Am. Intell. Prop. L. Assoc., Cellect, LLC v. Vidal, 2024 WL 3179569 (June 21, 2024) (No. 23-1231); Brief Amici Curiae of Sanofi, et al., Cellect, LLC v. Vidal, 2024 WL 3179565 (June 21, 2024) (No. 23-1231); Brief Amicus Curiae of Inari Agric., Inc., Cellect, LLC v. Vidal, 2024 WL 3936689 (Aug. 21, 2024) (No. 23-1231).

132. Petition for a Writ of Certiorari, *denied*, Cellect, LLC v. Vidal, 2024 WL 2379649 (May 20, 2024) (No. 23-1231).

133. *Delaware Disclosure Debacle Depressed District's NPE Filings in 2024*, RPX (Feb. 26, 2025), https://www.rpxcorp.com/data-byte/delaware-disclosure-debacle-depressed-districts-npe-filings-in-2024/ (finding that District of Delaware was in second place for overall patent litigation in 2024).

134. *See Acadia*, 706 F. Supp. 3d 477, 489 (D. Del. 2023); *Allergan*, 694 F. Supp. 3d at 590.

135. *Acadia*, 706 F. Supp. 3d at 487.

patent were earlier-filed and thus are entitled to their full term, including the PTA."[136] However, in *Allergan*, the district court went one step further and invalidated the first-filed, first-issued patent under ODP solely because it had PTA and expired later, stating that the "first-filed, first-issued distinction [was] immaterial."[137] The Federal Circuit later reversed the district court's decision and held that ODP cannot cut short the term of a first-filed, first-issued patent based on later-filed family members with less or no PTA.[138] This Part delineates *Allergan*'s background and procedural history from the district court to the Federal Circuit.

A. CASE BACKGROUND

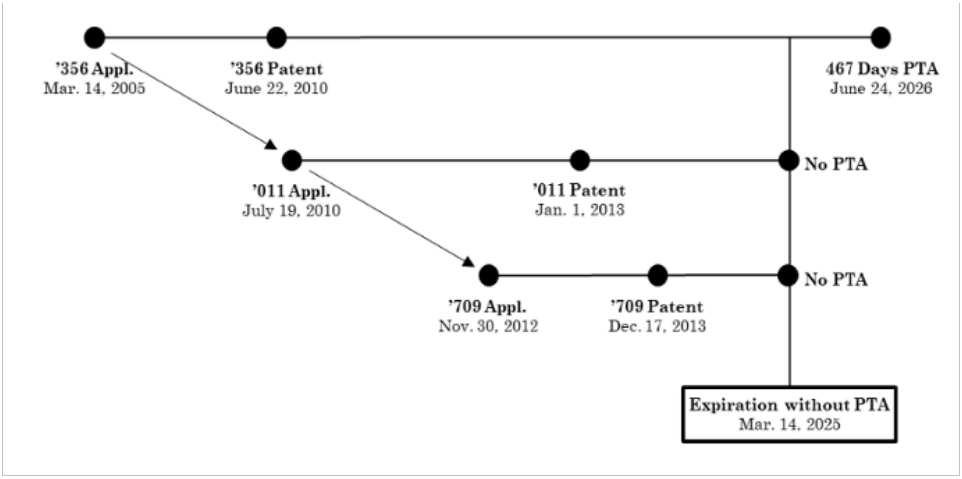
Allergan markets and sells eluxadoline tablets under the brand name Viberzi, following FDA approval in 2015.[139] The first patent application covering eluxadoline, assigned to Janssen, was U.S. Patent Application No. 11/079,647.[140] This application was filed on March 14, 2005, and issued on June 22, 2010 as U.S. Patent No. 7,741,356 ("the '356 patent").[141] Due to delays during prosecution at the USPTO, the '356 patent received a PTA of 1,107 days.[142] It also received an additional 1,068 days of PTE to compensate for the FDA's delay in approving Viberzi.[143] As part of obtaining PTE after FDA approval, Janssen disclaimed all but 467 days of the awarded PTA.[144] Thus, the '356 patent will expire on June 24, 2026, after accounting for PTA.[145]

Janssen owns two other patents relevant to this case, U.S. Patent No. 8,344,011 ("the '011 patent") and 8,609,709 ("the '709 patent").[146] These patents claim priority from the March 14, 2005 filing date of the '356 patent, and are related to the '356 patent as continuations.[147] Both the '011 and the '709 patents did not receive any PTA and will expire on March 14, 2025, twenty years from their priority dates.[148] Because all three patents share a priority date, all would have expired on the same day.[149] However, because the '356 patent

136. *Id.*
137. *Allergan*, 694 F. Supp. 3d at 540.
138. *Allergan*, 111 F.4th at 1369.
139. *Id.* at 1362.
140. *Id.*; U.S. Patent App. No. 11/079,647 (filed Mar. 14, 2005).
141. *Allergan*, 111 F.4th at 1362.
142. *Id.* at 1363.
143. *Id.*
144. *Id.*
145. *Id.*
146. *Id.*
147. *Id.*
148. *Id.*
149. *Id.* at 1364.

had accrued an additional 467 days of PTA, it now expires later than the '011 and the '709 patents.[150] Figure 6 depicts the relationships between these patents and their respective filing, issuance, and PTA-adjusted expiration dates.

Figure 6: Filing, issuance, and expiration dates for *Allergan* patents[151]



In July 2019, Sun Pharmaceutical Industries (Sun) filed an Abbreviated New Drug Application (ANDA) to the FDA, seeking approval to sell a generic version of Allergan's Viberzi.[152] Per the ANDA filing requirements under the Hatch-Waxman Act, Sun submitted a Paragraph IV certification, asserting that the claims in Allergan's '356 patent were invalid or not infringed by the manufacture, use, or sale of Sun's generic product.[153] On October 8, 2020, Sun notified Allergan of its certification via a notice letter.[154]

Three weeks later, Allergan filed a complaint against Sun for directly infringing claim 40 of its '356 patent.[155] As part of its defense strategy, Sun contended that claim 40 of the '356 patent was invalid for ODP over certain claims in Allergan's '011 patent and '709 patents.[156] Sun asserted that the '356 patent was invalid for ODP because it had accrued PTA, and thus, expired after the '011 and '709 patents, and because the claims are not patentably

150. *Id.*
151. *Id.*
152. *Id.* at 1364–65.
153. *Id.* at 1365.
154. *Id.*
155. *Id.*
156. *Id.*

distinct.[157] In response, Allergan argued that ODP was not applicable because the '356 patent was the first eluxadoline patent to be filed and issued.[158] Allergan did not contest that claim 40 was not patentably distinct from the reference claims.[159]

B. PROCEDURAL HISTORY

1. District of Delaware

The district court sided with Sun, finding claim 40 of the '356 patent invalid for ODP.[160] Allergan had argued that, as the first-filed, first-issued patent for eluxadoline, the '356 patent should not be subject to ODP over the later-filed, later-issued reference patents.[161] The district court, however, deemed this "first-filed, first-issued" distinction "immaterial."[162] Instead, the court emphasized the use of patent expiration dates for ODP, citing *Gilead*'s holding that ODP is determined by comparing "patent expiration dates, rather than filing or issuance dates."[163] The court also relied on the Federal Circuit's recent decision in *Cellect*, which established that "ODP for a patent that has received [patent-term adjustment (PTA)], regardless [of] whether or not a terminal disclaimer is required or has been filed, must be based on the expiration date of the patent after PTA has been added."[164] As a result, the court invalidated claim 40 of the '356 patent because its PTA-adjusted expiration date extended beyond that of the '011 and '709 patents, despite being filed and issued first.[165] The court also noted that ODP should not be influenced by equitable concerns, a line of reasoning that *Cellect* had previously rejected.[166]

2. Federal Circuit

After the district court's ruling, Allergan appealed to the Federal Circuit.[167] On August 13, 2024, the Federal Circuit, which consisted of the same three-judge panel that decided *In re Cellect*, reversed the district court's decision and

157. *Id.*
158. *Id.*
159. *Id.*
160. *Id.*
161. *Id.*
162. *Allergan*, 694 F. Supp. 3d at 540.
163. *Id.* (citing *Gilead*, 753 F.3d at 1215–17).
164. *Id.* at 540, 522 (citing *Cellect*, 81 F.4th at 1229).
165. *Id.* at 541.
166. *Id.* at 540; *see also Cellect*, 81 F.4th at 1230 (The Federal Circuit in *Cellect* held that "an applicant's ability to show that it did not engage in gamesmanship in obtaining a grant of PTA is not sufficient to overcome a finding that it has received an unjust timewise extension of term.").
167. *Allergan*, 111 F.4th at 1366.

held that "a first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date."[168] In other words, the "first-filed, first-issued patent in [the] family" establishes "the maximum period of exclusivity for the claimed subject matter."[169] The Federal Circuit provided four key rationales for its decision.

First, the Federal Circuit addressed the district court's reliance on *Cellect*. To reconcile its seemingly contrasting decisions in *Cellect* and *Allergan*, the Federal Circuit clarified that *Cellect* was not applicable in this case as it addressed a different question related to ODP.[170] Specifically, the Federal Circuit pointed out that *Cellect* "does not address, let alone resolve, any variation of the question presented here—namely, under what circumstances can a claim properly serve as an ODP reference."[171] In other words, *Cellect* did not resolve any question as to what patents can and cannot serve as ODP reference patents. The patentee in *Cellect* never disputed whether the asserted reference patents were appropriate ODP references, instead arguing only that (i) ODP can never be invoked to negate a PTA and (ii) that ODP should not apply in that case on equitable grounds because there was no strategic manipulation of patent term or risk of separate ownership.[172] Because the patentee in *Cellect* did not raise the question of whether the ODP reference was appropriate, they waived these arguments, allowing the court to subsequently use the unvetted reference in an ODP analysis without addressing its propriety.[173]

The Federal Circuit in *Allergan* explained that, while *Cellect* requires consideration of a PTA-adjusted expiration date in an ODP analysis, this does not mean that the '356 patent must be invalidated by the child patents simply because it expires later.[174] Distinguishing from *Cellect*, the Federal Circuit further held that the '011 and '709 patents were not proper ODP references because they were both filed and issued after the '356 patent.[175] Citing *Miller v. Eagle Manufacturing Co.*, the court reiterated that the purpose of ODP is to prevent inventors from improperly extending the term of the *first* patent by

168. *Id.* at 1369.
169. *Id.*
170. *Id.* at 1368–69.
171. *Id.*
172. *Cellect*, 81 F.4th at 1222, 1229–30.
173. *See Acadia*, 706 F. Supp. 3d at 487 (stating that "Cellect opted not to challenge the availability of the reference patents being used in an OTDP challenge, and 'instead focused its argument on whether or not [OTDP] could cut short a grant of PTA' (quoting *In re Cellect*, 81 F.4th at 1222).").
174. *Allergan*, 111 F.4th at 1368.
175. *Id.* at 1369.

obtaining a *second* patent for a non-distinct invention.[176] Here, the court held that the '356 patent was the *first* eluxadoline patent—whether measured by filing date or issuance date.[177] Because the applications for the '011 and '709 patents were filed after the '356 patent had already been issued, both of these patents were "unquestionably '*second*' to [the '356] patent."[178] As such, it was improper to use them in an ODP analysis to invalidate the earlier-issued '356 patent.[179] The court concluded that as the "first-filed, first-issued patent in its family," the '356 patent "sets the maximum period of exclusivity for the claimed subject matter."[180]

Second, the Federal Circuit asserted that its conclusion aligned with established case law.[181] Referencing *Ezra*, the court explained that "the traditional concern with obviousness-type double patenting" does not apply when "the earlier-filed, earlier issued . . . patent, not the later-filed, later-issued . . . patent, (. . .) has the later expiration date."[182] The court also cited *Breckenridge*, noting that an earlier-filed, earlier-issued, pre-URAA patent that expires after a later-filed, later-issued, post-URAA patent should not be invalidated for ODP due to changes in statutory patent term law.[183]

Third, the Federal Circuit addressed the district court's use of patent expiration dates for ODP in light of *Gilead*. In *Gilead*, the Federal Circuit had established that an ODP analysis must rely on the expiration dates, rather than the previously used issuance dates.[184] However, *Gilead* involved a situation where the asserted patent, though issued first, had a later filing and priority date, resulting in it expiring after the reference claims.[185] As a result, by focusing on the expiration dates, *Gilead* held that a later-issued, earlier-expiring patent can serve as an ODP reference to invalidate an earlier-issued, later-expiring patent.[186] The post URAA scenario contemplated in *Gilead* can give rise to gamesmanship, where an inventor claims obvious variants in unrelated applications and improperly extends the patent term.[187]

176. *Id.* (citing *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894)).
177. *Id.*
178. *Id.* (emphasis added).
179. *See id.*
180. *Id.*
181. *Id.* at 1370.
182. *Id.* (citing *Ezra*, 909 F.3d at 1374).
183. *Id.* (citing *Breckenridge*, 909 F.3d at 1366).
184. *Id.* (*see Gilead*, 753 F.3d at 1215–17).
185. *Id.*
186. *Id.*
187. *Id.*

Unlike in *Gilead*, here, the '356 patent was both filed and issued before the '011 and '709 patents.[188] All three of Allergan's patents shared the same priority date, and the difference in expiration dates was solely due to PTA of the challenged patent.[189] Thus, the risk of gamesmanship was minimal. The Federal Circuit highlighted this distinction and clarified that *Gilead* "did not address the role of filing dates."[190] Consequently, the court concluded that because the '356 patent was the first patent in its family to be filed and issued, it did not "extend . . . the monopoly . . . beyond the period allowed by law."[191]

Finally, the Federal Circuit acknowledged that the prosecution of "a first-of-its-kind invention" typically requires "greater time and effort by the applicant and examiner alike."[192] Thus, first-filed applications are more likely to receive PTA than later-filed continuing applications covering modifications of that invention, which "proceed[s] much more efficiently through prosecution."[193] As a result, child patents generally receive little to no PTA and often expire "no later than the parent patent."[194] Therefore, no improper patent term lengthening can reasonably result from the child patents.[195] The parent patent also cannot be said to improperly extend the term of a child patent that might not have even existed when the parent was issued.[196] As such, the court concluded that invalidating a first-filed, first-issued parent patent with PTA based on a later-filed, later-issued child patent "would not only run afoul of the fundamental purposes of ODP, but effectively abrogate the benefit Congress intended to bestow on patentees when codifying PTA."[197] In other words, such a decision would force patent owners to disclaim any PTA awarded to the parent patent to match the term of the child patent, effectively negating any benefits Congress intends to provide with PTA and guaranteed statutory term.[198]

Following the Federal Circuit's opinions, Sun filed a combined petition for panel rehearing and rehearing en banc.[199] Citing *Cellect* and *Gilead* in its petition, Sun contended that the Federal Circuit's decision conflicted with these cases

188. *Id.*
189. *Id.*
190. *Id.*
191. *Id.* (citing *Miller*, 151 U.S. at 198).
192. *Id.* at 1371.
193. *Id.*
194. *Id.*
195. *Id.*
196. *Id.*
197. *Id.*
198. *Id.*
199. Combined Petition for Panel Rehearing and Rehearing En Banc, Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd., 111 F.4th 1358 (Fed. Cir. 2024) (No. 24-1061).

and that the Federal Circuit lacked the authority to "create exceptions to this Court's precedent."[200] In November 2024, Sun withdrew its rehearing petition.[201]

IV. *ALLERGAN* PROVIDES A NECESSARY CLARIFICATION FOR THE INTERACTION BETWEEN ODP AND PTA

Part IV examines the Federal Circuit's reasoning for its precedential decision in *Allergan* and argues that *Allergan* is consistent with ODP case law, equitable doctrine, congressional intent behind PTA, and current patent practice. This Part also discusses how *Allergan* will affect ODP scenarios with PTA moving forward and explores how patentees can best navigate these scenarios.

A. *ALLERGAN* CLARIFIES SCOPES OF ODP POST-*CELLECT*

The Federal Circuit's decision in *Cellect* and the district court's decision in *Allergan* put patent families with PTA at risk of invalidation due to ODP. More than four hundred thousand patents issued over the past twenty years could face ODP invalidation due to one family member having PTA, and thus, a longer patent term.[202] Many of these at-risk patents are first-filed, first-issued patents that expire later than their continuations due to PTA.[203] The Federal Circuit's decision in *Allergan* provides reassurance for the patent community in this critical scenario by holding that a first-filed, first-issued, later-expiring patent cannot be invalidated for ODP by a later-filed, later-issued, earlier-expiring patent having a common priority date.[204] This Section contends that this decision aligns with the equitable concerns underlying the ODP doctrine and clarifies previous courts' use of patent expiration dates in an ODP analysis.

---

200. *Id.* at 4–5 (stating that "[r]egardless of the merits, the panel cannot create exceptions to this Court's precedent: 'In this Circuit, a later panel is bound by the determinations of a prior panel, unless relieved of that obligation by an en banc order of the court or a decision of the Supreme Court.' *Deckers Corp. v. United States*, 752 F.3d 949, 959 (Fed. Cir. 2014).")

201. Unopposed Motion for Withdrawal of Combined Petition for Panel Rehearing and Rehearing En Banc, Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd., 111 F.4th 1358 (Fed. Cir. 2024) (No. 24-1061).

202. Dennis Crouch, *Cellect: Unveiling the Potential Impact on Patent Term Adjustment*, PATENTLY-O (July 8, 2024), https://patentlyo.com/patent/2024/07/unveiling-potential-adjustment.html.

203. *Id.*

204. *Allergan*, 111 F.4th at 1369.

1. Allergan *Addresses the Equitable Concerns Under Which ODP Doctrine Was Established*

The Federal Circuit rightly decided *Allergan*, as the decision is consistent with the equitable concerns and circumstances underlying the ODP doctrine. Historically, ODP was established to prevent a patentee from extending their "exclusive rights to an invention through claims in a *later-filed* patent that are not patentably distinct from claims in the earlier[-]filed patent."[205] The purpose of ODP is to prevent a patent owner from "*extending* the exclusivity rights over his invention *beyond a full patent term*."[206] This ensures that "the public gets the benefit of the invention after the *original period* of monopoly expires."[207] A patent represents a bargain struck with the public: in exchange for fully disclosing an invention, the inventor obtains patent exclusivity for a period of time, after which the public is free to use the invention.[208] The prohibition on double patenting prevents a patentee from "extend[ing] or prolong[ing] the monopoly beyond the period allowed by law."[209] Courts have consistently reinforced this foundational principle, prohibiting patentees from extending their monopolies through obvious variants of the original invention.[210]

In this historical context, the first-filed, first-issued patent is the patent that defines the original monopoly period and the inventor's agreement with the public, establishing when the invention becomes freely available for public use. The first-filed patent cannot be the one with which the patentee tries to improperly extend this term, because it sets the original term.[211] In other words, there is no previously claimed subject matter to double patent, nor any monopoly to extend, until the first-filed patent issues.[212] Moreover, patentees cannot file terminal disclaimers on a first-filed patent at the time of issuance, as later-filed patents do not yet exist.[213] Thus, in *Allergan*, the alleged reference patents were inappropriate ODP references to the first-filed patents, because they are continuations filed years later.[214] They expire earlier merely due to the variations in the timing of their prosecution by the USPTO. Therefore, ODP

---

205. Procter & Gamble Co. v. Teva Pharm. USA, Inc., 566 F.3d 989, 999 (Fed. Cir. 2009) (emphasis added).

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

207. *AbbVie*, 764 F.3d at 1373 (emphasis added).

208. *Gilead*, 753 F.3d at 1212.

209. *Miller*, 151 U.S. at 198.

210. *See id.*; *AbbVie*, 764 F.3d at 1373; *Gilead*, 753 F.3d at 1214–15; *Ezra*, 909 F.3d at 1374.

211. *See* Brief for Plaintiffs-Appellants, Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd., 111 F.4th 1358 (Fed. Cir. 2024) (No. 24-1061).

212. *Id.*

213. *Id.* at 5.

214. *Allergan*, 111 F.4th at 1368.

cannot apply in such circumstances, as there is no inequity concern in preserving the full term of the first-filed patent. The inventor's bargain with the public remains intact.[215] Thus, *Allergan* confirms ODP as an equitable doctrine as precedents require.

2. *Rigid Application of Expiration Dates for ODP Analysis Has Never Been Some Previous Courts' Intent*

A closer reading of the Federal Circuit's opinion in *Cellect* suggests that the court likely did not intend to subject the first-filed, first-issued patent in the family to ODP if it expires earlier than the later-filed, later-issued patents. However, the district court in *Allergan* mechanically applied *Cellect*, holding that any earlier-expiring patent could serve as an ODP reference patent.[216] The Federal Circuit in *Allergan* reversed, and to reconcile two seemingly contrasting rulings in *Cellect* and *Allergan*, it clarified that *Cellect* did not address which patents can serve as ODP references.[217] Because the patentee in *Cellect* waived this issue, the court never had the opportunity to determine which "earlier-filed" patents could be properly used as ODP references.[218] In fact, *Allergan* is, in some ways, consistent with *Cellect*. The *Cellect* court stated that "claims in . . . challenged patents are entitled to their full term, including the duly granted PTA, unless they are found to be *later-filed* obvious variations of *earlier-filed*, commonly owned claims."[219] The court in *Cellect* also repeatedly emphasized that ODP "limits the term of a patent or, at least, ties *later-filed*, commonly owned, obvious variations to the expiration date of an *earlier-filed reference patent*."[220] Moreover, the court asserted that "ODP determination depends on an assessment of obviousness, i.e., whether the claims of a *later*-expiring patent would have been obvious over the claims of an *earlier*-expiring patent owned by the same party."[221] Thus, the *Cellect* court never likely intended to invalidate a first-filed, first-issued patent for ODP based on a later-filed, later-issued patent.

Allergan is also consistent with precedents set before *Cellect*. Following the *Cellect* decision, the district court in *Allergan* rigidly applied a rule that any earlier-expiring patent can serve as an ODP reference patent.[222] A closer

215. *See, e.g.*, *AbbVie*, 764 F.3d at 1372–73; *Ezra*, 909 F.3d at 1374 (The "traditional concern" of "extending his exclusive rights" is not implicated where "it is the earlier-filed, earlier-issued" patent "that has the later expiration date.").

216. *See Allergan*, 694 F. Supp. 3d at 511.

217. *Allergan*, 111 F.4th at 1368–69.

218. *Acadia*, 706 F. Supp. 3d at 487–88.

219. *Cellect*, 81 F.4th at 1230 (emphasis added).

220. *Id.* at 1226 (emphasis added).

221. *Id.* (emphasis added).

222. *See generally Allergan*, 694 F. Supp. 3d.

reading of *Gilead* and *Breckenridge* indicates that the court never intended the use of a proxy date for ODP to be as rigid and absolute as *Cellect* implies. The court did not aim to rely solely on a simplistic comparison of either expiration dates or issuance dates (pre-URAA) in an ODP analysis. Instead, these dates originate from the unique circumstances arising from changes in patent term law, as well as the specific fact patterns of the case.[223] For instance, the *Gilead* court stated that it was deciding only the "*narrow question*" of "[c]an a patent that issues after but expires before another patent qualify as a [ODP] reference for that other patent," and held only that, "*under the circumstances* of this case . . . it *can*."[224] In other words, previous courts have made it clear that using issuance dates or expiration dates is not a bright-line rule in an ODP analysis.

In *Gilead*, the patentee had received the full statutory term for the first-filed patent, but continued to extend its monopoly by pursuing patentably indistinct claims in a separate chain of application.[225] The Federal Circuit in *Gilead* reasoned that relying solely on the issuance date in an ODP analysis in a post-URAA world would allow applicants to engage in "significant gamesmanship during prosecution."[226] The *Gilead* court then limited its holding to the circumstances of the case to prevent gamesmanship when issuance dates are used in an ODP analysis.[227] Thus, the Federal Circuit's rationale for moving away from the issuance dates stems from its intent to curtail gamesmanship, where patentees could file multiple applications with different filing dates and allow the latest filed to issue first.[228] In post-URAA cases like *Allergan*, when two patents share the same priority date, the risk of unjustified term extension is reduced since both patents are expected to expire simultaneously—unless a term extension is granted by Congress, such as through PTA or PTE.

Similarly, the Federal Circuit in *Breckenridge* made it clear that ODP should not be determined solely by a mechanical comparison of expiration dates.[229] There, the Federal Circuit held that an earlier-expiring post-URAA patent could not be used to invalidate a later-expiring pre-URAA patent.[230] Although *Breckenridge* addressed whether a later-issued, earlier-expiring post-URAA patent could serve as an ODP reference against an earlier-issued, later-expiring

223. *Gilead*, 753 F. 3d at 1211–12, 1217.

224. *Id.* ("We therefore hold that an earlier-expiring patent *can* qualify as an [ODP] reference for a later-expiring patent *under the circumstances here*.") (emphasis added).

225. *Id.* at 1210.

226. *Id.* at 1215.

227. *Id.* at 1212, 1217.

228. *See id.* at 1215–16.

229. *Breckenridge*, 909 F.3d at 1364–67.

230. *Id.* at 1366.

pre-URAA patent, the same reasoning applies in *Allergan*. The court in *Breckenridge* noted that "[h]ere, critically, [the patentee] did *not seek to extend its patent rights* over its . . . invention beyond one patent term."[231] Similar to *Allergan*, *Breckenridge* merely sought to preserve its original monopoly period—the first-filed "patent's statutorily-granted 17-year patent term."[232] The court emphasized that "[t]o find that [ODP] applies here because a post-URAA patent expires earlier would abrogate [the patentee's] right to enjoy one full patent term on its invention."[233] Thus, ODP cannot shorten the statutorily guaranteed term of a first-filed, first-issued patent.

B. *ALLERGAN* REFLECTS DEFERENCE TO CONGRESS'S LEGISLATIVE INTENT IN CREATING PTA

ODP thwarts any unjustified timewise extension of the original patent term beyond what is warranted. The passage of the URAA and the codification of PTA under 35 U.S.C. § 154(b) did not change this core principle.[234] Thus, the Federal Circuit's decision in *Allergan* reflects deference to congressional intent to compensate diligent applicants for USPTO prosecution delays.

For a long time, the term of a U.S. patent was seventeen years from the date of issuance. On December 8, 1994, Congress enacted the URAA, which changed the patent term to twenty years from the earliest effective U.S. filing date.[235] This change in the patent term law was driven by two major factors. First, it aligned the U.S. patent term with international standards, as most foreign jurisdictions had already adopted a twenty-year term from the earliest filing date standard.[236] Second, the change reduced incentives for patentees to prolong prosecution and create so-called "submarine patents."[237] Under the old seventeen-year rule, where the patent term was based on the issuance date, patentees could game the system by keeping their related patents pending at the USPTO for extended periods, thereby delaying the start of their patent term. This strategy allowed patentees to continuously update their patent

231. *Id.* at 1367 (emphasis added).

232. *Id.*

233. *Id.*

234. *See, e.g.*, *AbbVie*, 764 F.3d at 1374; *Breckenridge*, 909 F.3d 1355.

235. Uruguay Round Agreements Act, *supra* note 34.

236. This change was required for member nations of the World Trade Organization that entered into the General Agreement on Tariffs and Trade (GATT) treaty during the Uruguay Round and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

237. Analogous to a submarine, submarine patents could lurk for an extended period, only to surface unexpectedly and torpedo the market. *See* Mark A. Lemley, *An Empirical Study of the Twenty-Year Patent Term*, 22 AIPLA Q.J. 369, 377–80 (1994); Patricia Montalvo, *How Will the New Twenty-Year Patent Term Affect You? A Look at the Trips Agreement and the Adoption of a Twenty-Year Patent Term*, 12 SANTA CLARA HIGH TECH. L.J. 139, 156–57 (1996).

applications with new technological developments, wait for market conditions to mature, and then surprise competitors with enforceable rights over supposedly "new" technology.[238] One notorious submarine patent case involved a patentee who kept his applications pending at the USPTO for forty years.[239] Such submarine patents not only delayed public access to technological developments but also disrupted industry innovation and investment.[240] Thus, setting the patent term to twenty years from the filing date curbed the incentives to engage in submarine patenting, because every day spent in prosecution reduced the enforceable term of a patent. As a result, patentees are motivated to expedite prosecution.

The change to the new patent term regime was highly controversial when it was first introduced.[241] The new law took effect on June 8, 1995, prompting a surge of patent filings at the USPTO in the weeks leading up to the deadline.[242] Inventors rushed to file patent applications, fearing that the new law might reduce their guaranteed seventeen years of protection under the previous system.[243] As a result, the USPTO experienced a huge influx of patent applications, leading to a significant backlog.[244] Under the previous regime, using the issuance date to calculate the term of a patent meant that any delays in prosecution by the USPTO did not affect the overall patent term. The patent term only began once the patent was issued. With the new law regime, patents filed on or after June 8, 1995 would face greater disadvantages because they would be subject to a longer pendency period and lose patent term from USPTO delays.[245]

Faced with mounting concerns that the change in patent term law could shorten patent terms due to prosecution delays—often lasting three or more years—Congress enacted the American Inventors Protection Act (AIPA) in 1999.[246] The AIPA included the Patent Term Guarantee Act, incorporating

238. Montalvo, *supra* note 237, at 156–57.

239. *See, e.g.*, Symbol Tech., Inc. v. Lemelson, 277 F.3d 1361, 1363 (Fed. Cir. 2002); *see also* Montalvo, *supra* note 237, at 157; Lemley, *supra* note 237, at 379.

240. Montalvo, *supra* note 237, at 156–57.

241. Lemley, *supra* note 237, at 376; *see also* Montalvo, *supra* note 237, at 159–62; *see, e.g.*, Dana Rohrabacher, *Pennies for Thoughts: How GATT Fast Track Harms American Patent Applicants*, 11 ST. JOHN'S J. LEGAL COMMENT. 491 (1996); Dana Rohrabacher & Paul Crilly, *The Case for a Strong Patent System*, 8 HARV. J.L. & TECH. 263, 265 (1995). Critics of this change, including universities and biotechnology industry, raised concerns that the new patent term regime might not only shorten the life of their patents but also increase opportunity for foreign competitors.

242. Montalvo, *supra* note 237, at 162.

243. *Id.* at 162–63.

244. *Id.* at 163.

245. *Id.*

246. Lemley & Reinecke, *supra* note 13, at 686–87.

protections into the statute to guarantee a minimum seventeen-year patent term for diligent applicants—consistent with the pre-URAA framework. That guaranteed protection was implemented in the form of patent term adjustment (PTA).[247]

Indeed, the legislative history of PTA reinforces Congress's intent to provide guaranteed term extensions and maintain the benefits of the previous seventeen-year term system. PTA is necessary because even a diligent patentee can "lose years of effective patent term due to delays in the PTO and other *circumstances beyond [their] control*."[248] Representative Dana Rohrabacher, one of the PTA bill's co-sponsors, emphasized that the goal of PTA was to "assure a minimum patent term of 17 years from the date a patent is granted" via the "guarantee that the PTO will extend the patent term as necessary to assure a term of 17 years from filing for non-dilatory applicants . . . essentially giv[ing] back to the non-dilatory patent holder . . . a guaranteed 17 year patent term."[249]

The *Allergan* decision thus reflects judicial deference to Congress's legislative intent and statutory authority. Allowing a later-filed patent to cut short Allergan's first-filed patent solely based on their expiration dates would mean that the first-filed patent would receive only fourteen years, nine months, and two days of statutory patent term—despite Congress's guarantee of a minimum seventeen-year term.[250] Moreover, under the doctrine of separation of powers, a judge-made rule such as ODP cannot override a statutory mandate.[251] Allowing such judicial doctrine to do so would "give judges a 'legislation-overriding' role that is beyond the Judiciary's power."[252] Indeed, the Constitution empowers Congress to enact legislation governing patents, and "it is the province of the legislative branch of the government to say when a patent to an inventor shall expire."[253] This principle applies directly here, where Congress has established a minimum PTA-adjusted statutory term under 35

247. Uruguay Round Agreements Act, *supra* note 34; 35 U.S.C. § 154(b)(1).

248. *See* H.R. REP. NO. 106-287, pt. 1, at 33, 49, 50 (1999); *id.* at 49–50 (stating that the Patent Term Guarantee Act amendments "compensate patent applicants for certain reductions in patent term that are *not the fault* of the applicant," and penalize only "those who purposely manipulate the system") (emphasis added).

249. 145 CONG. REC. H6944 (daily ed. Aug. 3, 1999).

250. *See* Brief for Plaintiffs-Appellants, *supra* note 211, at 15.

251. U.S. CONST. art. 1, § 1.3.1; *see also Ezra*, 909 F.3d at 1375 ("[A] judge-made doctrine" cannot "cut off a statutorily-authorized time extension.").

252. *See* Brief for Plaintiffs-Appellants, *supra* note 211, at 43 (citing to SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC, 580 U.S. 328, 335 (2017) and quoting Petrella v. Metro-Goldwyn-Mayer, Inc., 572 U.S. 663, 680 (2014)).

253. U.S. CONST. art. 1, § 8, cl. 8 ("[The Congress shall have Power] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."); Bate Refrigerating Co. v. Sulzberger, 157 U.S. 1, 43 (1895).

U.S.C. § 154(a)(2) and § 154(b)(1). Using ODP to undermine this statutory framework would unduly encroach upon legislative power.

Additionally, when enacting the Patent Term Guarantee Act, Congress acknowledged that patentees may still need to file terminal disclaimers for later-filed applications if an earlier patent had already exhausted the monopoly for that invention.[254] Congress codified this principle into 35 U.S.C. § 154(b)(2)(B), which states that "[n]o 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."[255] In *Cellect*, the Federal Circuit interpreted the statutory language in § 154(b)(2)(B) to hold that both ODP and terminal disclaimers should be applied *after* PTA is added to a patent's expiration date.[256] In other words, terminal disclaimers can cut short PTA, and a grant of PTA cannot extend beyond the expiration date set by a terminal disclaimer.[257] However, the statutory language in 35 U.S.C. § 154(b)(2)(B) is also clear that this limitation only applies to a patent whose term "has been disclaimed"—a condition that does not apply to a first-filed, first-issued patent, such as the challenged patent in *Allergan*.[258] Patentees cannot file terminal disclaimers on a first-filed patent upon its issuance, as no other patents from the same family exist at that time to justify such a disclaimer. Thus, § 154(b)(2)(B) cannot apply to first-filed patents, and PTA for first-filed patents should not be cut off by terminal disclaimers or ODP, as the Federal Circuit concluded in *Allergan*.[259]

C. *ALLERGAN* IS CONSISTENT WITH WELL-ESTABLISHED PATENT PRACTICE

A patent is part of an ongoing continuum of innovation. Technology often advances in incremental, interconnected steps. In many industries, the first fundamental invention is just the foundation for further applications and improvements. The doctrine of double patenting encourages incremental secondary innovations and follow-on research in continuation applications by presenting a trade-off between patent term and patent scope.[260] In exchange for broader patent claim coverage and a lead over competitors researching

254. 35 U.S.C. § 154(b)(2)(B).
255. *Id.*
256. *Cellect*, 81 F.4th at 1226–29.
257. *See id.*
258. *See id.*
259. *See Allergan*, 111 F.4th at 1371.
260. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 1165 (8th ed. 2021).

similar improvements, the patentee must forfeit any additional patent term that might come with the later-filed applications.[261]

The *Cellect* ruling calls on inventors to preemptively file terminal disclaimers to avoid unforeseen ODP challenges.[262] The Federal Circuit's decision in *Cellect* introduces uncertainty into the continuation application practice, a common and longstanding practice under 35 U.S.C. § 120 that allows inventors to protect the full scope of their inventions.[263] The risk of ODP-based invalidation after *Cellect* affects patentees who file continuation applications that share the same priority date as the original patent. In fact, in the aftermath of *Cellect*, terminal disclaimer filings increased by fifty percent from 2022 to 2023.[264]

In contrast, the *Allergan* decision better aligns with continuation practices and addresses post-*Cellect* concerns from patentees. ODP originated before the URAA, when patent terms were calculated from the issuance date, allowing for submarine patenting and gamesmanship to delay the issuance of a patent and improperly extend its term. ODP, therefore, was designed to prevent an abuse of continuation practice.[265] However, after the URAA, the term of a patent is now twenty years from its earliest filing date.[266] As a result, continuations under the new law generally do not result in any additional patent term, as they typically share the same priority date as the original application. Continuation practices ensure rapid disclosure of follow-on research, since the inventor does not need to keep the original patent pending through claim amendments as new developments emerge.[267] In practice,

261. MERGES & DUFFY, *supra* note 260.

262. Robert S. Rigg, Daniel H. Shulman & Sudip K. Mitra, *In re Cellect: The Federal Circuit Alters Terminal Disclaimer Strategy*, VEDDERPRICE (Sep. 2023), https://www.vedderprice.com/in-re-cellect-the-federal-circuit-alters-terminal-disclaimer-strategy.

263. 35 U.S.C. § 120; *see also* Stephen T. Schreiner & Patrick A. Doody, *Patent Continuation Applications: How the PTO's Proposed New Rules Undermine an Important Part of the U.S. Patent System with Hundreds of Years of History*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 556, 559–70 (2006) (stating that "[c]ontinuation practice has been statutorily recognized for more than 50 years since the passage of the Patent Act of 1952." The authors also noted that "[c]ontinuation applications are important because they allow the inventor to secure patent coverage for the various aspects of the invention that are not captured in the first patent" and listed reasons why the first patent might not provide sufficient coverage.).

264. *See* Dennis Crouch, *Terminal Disclaimers: A Growing Concern in Patent Practice*, PATENTLY-O (May 10, 2024), https://patentlyo.com/patent/2024/05/terminal-disclaimers-practice.html.

265. *See AbbVie*, 764 F.3d 1366, 1373 (Fed. Cir. 2014); Ricoh Co., Ltd. v. Nashua Corp., 185 F.3d 884, No. 97–1344, slip op. at *3 n.3 (Fed. Cir. 1999).

266. Uruguay Round Agreements Act, *supra* note 34; *see* discussion *infra* Section IV.B for a legislative history behind the change in U.S. patent term and introduction of PTA after the passage of the URAA.

267. MERGES & DUFFY, *supra* note 260.

inventors frequently file multiple patents for the same technology, with an initial application that discloses, but may not claim, related inventions.[268] An inventor might also accept narrow initial claims to expedite the issuance of a first foundational patent. However, if inventors fear losing patent terms due to ODP, they may be compelled to file applications with broad claim scope from the beginning. These broader applications would take longer to draft and process, thus overburdening the USPTO. As noted in *In re Braithwaite*, "all [the patentee] is getting from this [later-filed] application—and for only the remainder of the same term—are additional, more specific claims which would serve as a second line of defense if the dominating claims should prove to be vulnerable."[269] Discouraging patentees from prosecuting such continuations "would principally serve to deprive the public of the knowledge contained in the added disclosures."[270]

D. TWO-PRONG INQUIRY TO DETERMINE OUTCOMES FOR ODP SCENARIOS WITH PTA

While *Allergan* has limited *Cellect* in a critical scenario for the patent community, courts have yet to address several other ODP scenarios involving PTA post-*Cellect*. This Section first clarifies what has been implicitly assumed in ODP jurisprudence by proposing a two-prong approach to ODP analysis—one that considers both the propriety of the alleged ODP reference and any equitable concerns. It then examines other ODP scenarios involving PTA that were not covered by *Allergan*—specifically when the patents share the same priority date and the only difference in expiration dates is due to PTA granted to the challenged patent. Applying the two-prong approach in these scenarios, this Section shows that a prior patent can still invalidate a later patent if traditional ODP concerns are present, because such a prior patent would qualify as a proper ODP reference.[271] Finally, this Section identifies measures patentees can take to reduce ODP risks in these scenarios.

---

268. *Id.*

269. *In re* Braithwaite, 379 F.2d 594, 601 (C.C.P.A. 1967).

270. *Id.*

271. This Section uses "first" versus "second" and "earlier" or "prior" versus "later" interchangeably to denote the order of the filing, issuance, and expiration dates of the patents in the scenario analysis. The main point is to consider any patents that might extend the *original* patent monopoly. Strictly speaking, using "earlier" or "prior" versus "later" offers a broader, more generalized description. In *Allergan*, the court strictly limited its language and decision to the "first-filed, first-issued" patent that was challenged, but did not address other broader scenarios.

1. An ODP Analysis Requires a Dual Approach that Considers Both ODP Reference Propriety and Traditional Concerns, and an Assessment of Effective Filing Dates and Expiration Dates

The recent *Allergan* decision suggests that courts may need to adopt a combined approach—analyzing both the effective filing dates and the expiration dates—to assess whether an alleged ODP reference is proper. Examining patent expiration dates is crucial to ensure that there is no unjustified term extension, which is the core concern of ODP. As explained in *Gilead*, "[p]ermitting any earlier expiring patent to serve as a double patenting reference for a patent . . . guarantees a stable benchmark that preserves the public's right to use the invention (and its obvious variants) that are claimed in a patent when that patent expires."[272]

However, considering effective filing dates as part of the analysis helps prevent situations like the one in *Allergan*. For patents with different effective filing dates (e.g., patents from different families), this combined approach allows for a straightforward ODP reference determination: an earlier-filed patent, with or without PTA, can serve as an ODP reference for a later-filed patent. In such cases, ODP rejections would only apply to the later-filed patent, preserving the equitable purpose of ODP. For patents with the same effective filing dates (e.g., continuations in a family), looking at the effective filing dates would create a tie between the two patents. In that case, a two-prong analysis may be necessary: first, to determine whether an alleged reference is a proper ODP reference (i.e., ODP reference propriety) (Prong One), and second, to determine whether the challenged patent raises any traditional ODP equitable concerns (i.e., unjustified timewise extension of a patent monopoly based on later obvious variations of the same invention) (Prong Two). If both conditions are met, ODP may still cut off the PTA-extended term of the challenged patent. Courts have implicitly used this two-prong approach in traditional ODP jurisprudence. However, in complex ODP cases involving concurrent term modification mechanisms, this inquiry becomes particularly vital and warrants an emphasis.

Allergan presents an ideal example to apply this two-prong inquiry. Under Prong One, the later-filed, later-issued patent in *Allergan* would be an improper ODP reference for the first-filed, first-issued patent. Under Prong Two, no traditional concerns with ODP would arise in this case, as there is no unjustified timewise extension of patent monopoly. Thus, *Allergan* fails both tests: the term of the challenged patent can be extended via PTA. Further, there are other ODP scenarios involving PTA that remain unresolved by

272. *Gilead*, 753 F.3d at 1216.

Allergan. In such cases, the joint analysis of effective filing dates and expiration dates might prove inconclusive. The following Section explores these scenarios and further demonstrates how this two-prong approach can be applied to achieve fair and consistent outcomes.

2. ODP Scenarios with PTA Not Covered by Allergan

Figure 7 illustrates five common post-URAA ODP scenarios involving PTA. Scenarios 1 and 2 in this Figure represent the typical ODP fact pattern, where two patents have different effective filing dates and, thus, different expiration dates. Consistent with the holding in *Gilead*, which involved patents from separate priority chains, the earlier-expiring patent in these two scenarios qualifies as a proper ODP reference for the later-expiring patent. Any PTA granted to the later-expiring patent would only further shift its expiration date, and ODP could still truncate the PTA-lengthened term.

Allergan narrowed *Cellect* in one specific instance: it protects *first-filed, first-issued* patents that receive PTA, shielding them from ODP challenges by later-filed continuations that share the same priority date (depicted broadly as Scenario 5 in Figure 7).[273] In other words, a first-filed patent is immune from an ODP challenge posed by a later-filed but earlier-expiring patent within the same family. Now that *Cellect*'s writ of certiorari to the Supreme Court has been denied, several other ODP scenarios remain unresolved.

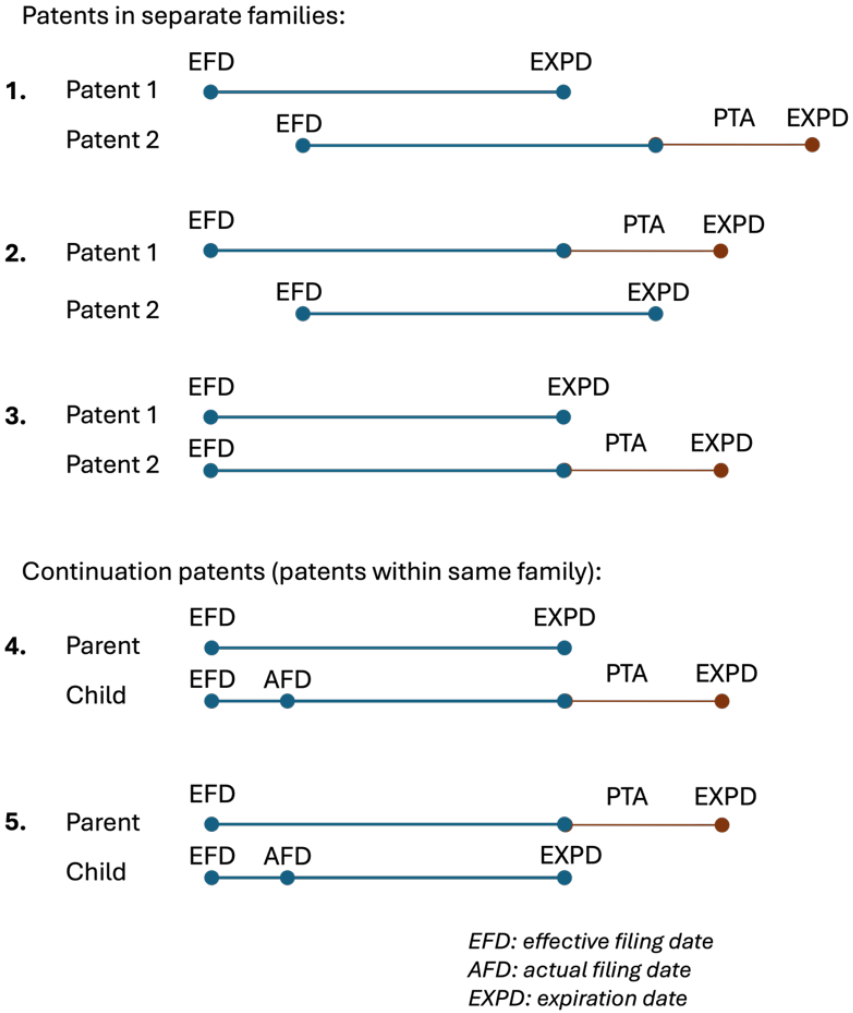
First, the *Allergan* court confined its holding to "first-filed, first-issued" challenged patents,[274] rather than adopting broader language such as "earlier-filed, earlier-issued." Thus, *Allergan* might be interpreted as narrowly applicable to this exact fact pattern—namely, a patent issuing from the first nonprovisional application in a family cannot be invalidated by later-filed, later-issued patents. It is unclear whether continuation patents filed and issued within the priority chain, other than the first-filed, first-issued patents, would remain vulnerable to ODP challenges.

Second, *Allergan* did not address scenarios where two patents share the same effective filing dates, but the second patent—either a child continuation or another patent from a separate family—receives PTA (Scenarios 3 and 4 in Figure 7). This Section describes these two scenarios and emphasizes that the ODP doctrine will still apply to invalidate the second patent and cut off its PTA. To analyze the ODP outcomes in these two scenarios, this Section uses the two-prong approach outlined above and demonstrates that a prior patent can still invalidate a later patent, even when the sole factor causing their

273. *See generally Allergan*, 111 F.4th.
274. *Id.*

expiration dates to differ is the PTA granted to the later patent.[275] The following Section then outlines strategies that patentees could implement to minimize ODP risks.

Figure 7: Five main post-URAA ODP scenarios with PTA



275. *See* discussion *supra* Section IV.D.1 for the proposed two-prong approach to determine outcomes for ODP scenarios with PTA.

a) Scenario 1: The Parent and Child Patents Have the Same Effective Filing Dates, and the Child Patent Receives PTA

In *Allergan*, the Federal Circuit clarified its previous decision in *Cellect*, rejecting the interpretation that a first-filed patent with PTA could be invalidated for ODP by a later-filed child patent that expires earlier and does not have PTA.[276] However, an open question remains: should a child patent expiring later than its parent due to PTA also be immune from an ODP challenge (Scenario 4 in Figure 7)?

Although courts have not addressed this specific scenario, it is common in the pharmaceutical industry to file continuations that result in a PTA-extended term for a child patent. An example of this scenario is when an earlier patent covers broad (genus) claims while a later patent focuses on narrower (species) claims. The first step a court will take in assessing an ODP challenge is determining whether the alleged reference patent qualifies as a proper ODP reference.[277] This is "a threshold issue."[278] Once the court has determined whether a reference is proper, it then proceeds with the substantive ODP analysis.[279] Thus, the central question in this scenario is whether the parent patent qualifies as an ODP reference for the child patent with PTA.

ODP jurisprudence has indicated that this is possible. *Allergan* confirms that only earlier-filed patents are proper ODP references. Historically, ODP has always been about challenging the "second" patent (see Table 1).[280] By definition, a child patent is the "second" patent. This rationale for the double patenting doctrine is rooted in anticipation, as seen in *Miller v. Eagle Manufacturing Co.*, the first case where the Court gave definitive justification for the ODP doctrine.[281] The Court said that "[w]hen a patentee anticipates himself, he cannot, in the nature of things, give validity to the second patent."[282] The Court invalidated the second patent with a simple rationale: if a *prior* patent to a *different party* can invalidate a *later* patent to the same invention, then a *prior* patent issued to the *same party* can also invalidate the *later* patent.[283] The Court said:

---

276. *See generally Allergan*, 111 F.4th.

277. *See Acadia*, 706 F. Supp. 3d at 487; *Ezra*, 909 F.3d at 1375 n.4.

278. *Acadia*, 706 F. Supp. 3d at 487; *see also Ezra*, 909 F.3d at 1375 n.4 ("Because we find that the '565 patent is not a double patenting reference for the '229 patent, we need not address Ezra's arguments as to whether the '229 patent is patentably indistinct from the '565 patent.").

279. *Acadia*, 706 F. Supp. 3d at 487; *see Breckenridge*, 909 F.3d 1355, 1359 (Fed. Cir. 2018).

280. *Acadia*, 706 F. Supp. 3d at 487.

281. *See Miller*, 151 U.S. at 196–98.

282. *Id.* at 197.

283. *See id.* at 196–98.

> Under these circumstances can it be held that the second patent has any validity, or must it be treated as having been *anticipated* by the grant of the 1879 patent? If, upon a proper construction of the two patents, which presents a question of law to be determined by the court, (*Heald v. Rice*, 104 U. S. 749,) and which does not seem to have been passed upon and decided by the court below, they should be considered as covering the same invention, then the later must be declared void, under the well-settled rule that two valid patents for the *same invention* cannot be granted either to the *same* or to a *different party*.[284]

Indeed, the ODP doctrine exists to prevent an inventor from receiving an undue patent term extension by securing a *second, later-expiring* patent for the same invention.[285] The doctrine ensures that "the power to create a monopoly is exhausted by the *first* patent," so that "a new and later patent for the same invention" does not "operate to extend or prolong the monopoly beyond the period allowed by law."[286] In numerous ODP decisions, courts have reiterated that the purpose of ODP is to "ensure[] that the public gets the benefit of the invention after the *original* period of monopoly expires,"[287] and to "prevent a patent owner from 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."[288] Therefore, in this scenario, a parent patent qualifies as an ODP reference for a child patent—regardless of whether the child patent has PTA. As U.S. Circuit Judge Giles Rich noted in the *In re Zickendraht* decision:

> Where there are in fact two inventions, whether or not they are patentable, this statute would seem to be inapplicable and the second patent has to be denied, if it is denied on some other ground. The ground one finds stated in the cases is to the effect that the second invention must be patentable on its own account, over the invention claimed in the issued patent, just as though the invention so claimed were in the prior art, and tested (since 1953) by the unobviousness requirement of 35 U.S.C. § 103.[289]

Now that Prong One—assessing whether the alleged ODP reference is proper—courts may proceed to Prong Two to apply the equitable doctrine of

---

284. *Id.* at 196–97 (emphasis added).

285. *See id.* at 196–98.

286. *Id.* at 198; *see* Odiorne v. Amesbury Nail Factory, 18 F. Cas. 578, 579 (C.C.D. Mass. 1819).

287. *AbbVie*, 764 F.3d at 1373 (emphasis added).

288. *Procter & Gamble*, 566 F.3d 989, 999 (emphasis added); *see also Cellect*, 81 F.4th at 1226 (stating that ODP "limits the term of a patent or, at least, ties *later-filed* commonly owned, obvious variations to the expiration date of an *earlier-filed* reference patent.") (emphasis added).

289. Application of Zickendraht, 50 C.C.P.A. 1529, 1536 n.4 (1963).

ODP. This analysis could lead to the invalidation of the child patent—regardless of whether it has PTA—if courts identify traditional inequitable concerns or signs of gamesmanship associated with ODP. In these instances, a child patent might not be entitled to its PTA if granting PTA would result in an improper extension of patent term. In other words, if the timewise extension introduces opportunities for gamesmanship or other inequitable outcomes that ODP is meant to prevent, the granted PTA in a later-filed, later-issued patent could still be cut off.

Indeed, courts have invalidated child patents with term adjustments or extensions under ODP over the past years. In *AbbVie*, the Federal Circuit applied ODP to invalidate a challenged child patent, thereby eliminating not only part of its 20-year patent term but also the 750-day PTA it had been granted.[290] In *Boehringer*, a child patent was awarded over 1,500 days of PTE, but was later challenged for ODP over a parent patent.[291] Boehringer argued that it did not enjoy any unjustified advantage or unentitled rights as it had lawfully obtained PTE under 35 U.S.C. § 156.[292] However, the court disagreed, ruling that the rights enjoyed by a patentee during the original term of a patent are not the same rights enjoyed by a patentee during the term of an extension under § 156.[293] The court emphasized that "[t]he fundamental reason for the rule [of obviousness-type 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*."[294] These outcomes reflect broader public policy concerns applicable to all continuations and child patents filed from a parent patent, regardless of whether PTA is involved. In other words, if courts identify a risk of gamesmanship, they may cut off PTA in the child patents.

However, in the second step, if the case does "not raise the traditional concern with [ODP]" and "there is no potential gamesmanship issue through structuring of priority claims,"[295] then term adjustments and extensions for a child patent may still be justified and permissible, as the Federal Circuit recognized in *Ezra*. Following precedent in *Merck & Co. v. Hi-Tech Pharmacal Co.*, the *Ezra* court held that "a PTE pursuant to § 156 is valid so long as the extended patent is otherwise valid *without the extension*."[296] One example the

290. *AbbVie*, 764 F.3d 1366.

291. Boehringer Ingelheim Intern. GmbH v. Barr Lab'ys, Inc., 592 F.3d 1340, 1345 (Fed. Cir. 2010).

292. *Id.* at 1349.

293. *Id.*

294. *Id.* at 1347 (quoting *In re* Van Ornum, 686 F.2d 937, 943–44 (C.C.P.A. 1982)) (emphasis added).

295. *Ezra*, 909 F.3d at 1374.

296. *Id.* at 1375 (emphasis added).

court provided where ODP may invalidate a patent is "a patent, under its original expiration date without a PTE that should have been (but was not) terminally disclaimed."[297] However, the court also asserted that "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."[298] Since *Cellect*, the comparison between PTA and PTE statutes and their respective purposes has sparked debates. However, until further guidance is provided, it remains uncertain how courts will interpret PTA in these scenarios. It is important to recognize that in some ODP cases, defendants rarely contested the non-obviousness of the claims. An ODP rejection arises only when the claims are very similar or obvious to each other. It is easy to solely focus on patent term and overlook the fundamental principle of ODP: one should not obtain a second patent with extended term for obvious variants of the same invention. As stated in *In re Braat*, "only if the extension of patent right is *unjustified* is a double patenting rejection appropriate. There are situations where the extension is justified."[299]

297. *Id.* at 1374.
298. *Id.*
299. *In re* Braat, 937 F.2d 589, 595 (Fed. Cir. 1991).

Table 1: Past cases at the Federal Circuit concerning the interaction of ODP and patent term modifiers (e.g., PTA, PTE, and changes in patent term law), demonstrating that only earlier-filed patents are proper ODP references.[300]

Cases	Same v. Different Patent Families	Same v. Different Priority Dates	Challenged Patent(s)	Patent Used To Invalidate	Invalid Under ODP?
Gilead	Different	Different	Second-filed First-issued Second-expired	First-filed Second-issued First-expired	Yes
AbbVie	Same	Different	Second-filed Second-issued Second-expired (PTA)	First-filed First-issued First-expired	Yes
Ezra	Different	Different	First-filed (pre-URAA) First-issued Second-expired (PTE)	Second-filed (post-URAA) Second-issued First-expired	No
Breckenridge	Same	Same	First-filed (pre-URAA) Second-issued Second-expired (PTE)	Second-filed (post-URAA) Second-issued First-expired	No
Cellect	Same	Same	Four interrelated challenged patents, all later-expired (PTA)	Later-filed Earlier-expired	Yes
Allergan	Same	Same	First-filed First-issued Second-expired (PTA)	Second-filed Second-issued First-expired	No

300. Transitional cases involving pre- and post-URAA patents include *Ezra* and *Breckenridge*, as noted within Table 1. The remaining cases involve post-URAA patents. Additionally, the term "filed" in this Table, used to describe the challenged patents and the alleged reference patent, refers to the actual filing dates of these patents. With the exception of *Cellect*, these exemplary cases have shown that only the earlier-filed patents (e.g., first-filed) can be used to invalidate the challenged patents under ODP.

b) Scenario 2: Two Patents in Separate Families Have the Same Effective Filing Date, and One of the Patents Receives PTA

Another ODP scenario not covered by *Allergan* involves two patents from different families sharing the same effective filing date, where one of the patents receives PTA due to prosecution delays (Scenario 3 in Figure 7). The two patents would ordinarily have expired on the same day because they share the same filing date, but the granted PTA results in one of the patents expiring later. This scenario can be common in pharmaceutical patents, which often involve large, intricate patent portfolios spanning multiple families with related technologies. For example, one patent family might claim a new compound while discussing its method of using that compound in the specification, while another family might claim a method of using or manufacturing that new compound.[301] If these inventions are not filed within the same patent, a restriction requirement will not be triggered,[302] but instead, the patents may be interpreted as obvious over one another.

Based on ODP jurisprudence, it is entirely possible that the earlier-expiring patent can invalidate the later-expiring patents with PTA. An ODP rejection can only occur if the two inventions are deemed obvious over one another. This hypothetical scenario closely mirrors the fact patterns in *Gilead* and would satisfy both steps in the two-prong analysis. The patents in *Gilead*, despite being similar, did not belong to the same patent family and were not considered by the same examiner.[303] Instead, Gilead crafted separate chains of applications, resulting in patents with different priority dates and, consequently, different expiration dates.[304] The Federal Circuit in *Gilead* addressed whether "a patent that issues after but expires before another patent qualif[ies] as a double patenting reference for that other patent."[305] The court held that "an earlier-expiring patent can qualify as an obviousness-type double patenting reference for a later-expiring patent" in this scenario.[306] The main concern in *Gilead*, and also in this hypothetical scenario, was the potential for "significant gamesmanship during prosecution."[307] In other words, allowing applicants to structure their filings this way would enable them to "obtain additional patent term exclusivity for obvious variants of their inventions while also exploring the value of an earlier priority date during prosecution."[308] This

301. *See generally AbbVie*, 764 F.3d at 1366.
302. *See* discussion *infra* Section IV.D.3 for restriction requirements.
303. *Gilead*, 753 F.3d at 1210.
304. *Id.*
305. *Id.* at 1211–12.
306. *Id.* at 1217.
307. *Id.* at 1215.
308. *Id.*

rationale applies to any patent—regardless of whether it has PTA—and a term adjustment can be valid so long as the patent is valid without the adjustment.

AbbVie further reinforced the *Gilead* rationale, holding that an ODP analysis must consider the potential for applicant gamesmanship.[309] The *AbbVie* court emphasized that ODP remains viable "where, as here, the applicant chooses to file separate applications for overlapping subject matter and to claim different priority dates for the applications."[310] Indeed, the court outright asserted:

> 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. We hold that Kennedy is not entitled to an extra six years of monopoly solely because it filed a separate application unless the two inventions are patentably distinct.[311]

3. Strategies for Patentees to Minimize ODP Risks

Given the ongoing risks of ODP invalidation for patents with PTA and the evolving complexity of ODP jurisprudence, patentees must proactively address ODP risks. The following Section outlines strategies available to patentees to mitigate potential ODP risks.

Allergan establishes protection for the first-filed, first-issued patent in a family against ODP challenges.[312] This decision is likely to influence patent portfolio strategies to cover the most critical subject matter and secure the maximum PTA for first-filed patents. Patentees may prioritize broader claims in the initial patent rather than seeking a quick issuance for an initial patent.[313] Given the value of PTA and the likelihood of a first-filed patent obtaining some PTA, patentees should also prosecute patents diligently to avoid any PTA penalty that may reduce the amount of PTA awarded. Pending additional judicial guidance, patent owners should also actively and thoroughly review their patent portfolios and identify patents that could face ODP challenges due to varying expiration dates caused by PTA. It is also important to note that an ODP rejection may not be issued during prosecution. As seen in *Cellect*, examiners may not raise ODP concerns during prosecution at the USPTO, leaving the patentee vulnerable to future ODP challenges in

309. *Acadia*, 706 F. Supp. 3d at 487; *see also AbbVie*, 764 F.3d at 1374.

310. *AbbVie*, 764 F.3d at 1373.

311. *Id.* at 1374.

312. *See generally Allergan*, 111 F.4th 1358.

313. Dennis Crouch, *Family Planning Patent Style: Allergan, Cellect, and the ODP Maze*, PATENTLY-O (Aug. 13, 2024), https://patentlyo.com/patent/2024/08/family-planning-patent-style-allergan-cellect-and-the-odp-maze.html.

litigation.[314] Enhanced IP due diligence is critical to mitigate ODP risks early and avoid post-grant invalidation.

One common prosecution strategy is to force a restriction requirement for the first-filed patent. This approach allows for later divisional applications from the first-filed patent to be protected against any ODP challenges, under what is known as the "safe harbor" provision of 35 USC § 121.[315] Section 121 creates an exception to the ODP doctrine, by providing that "a patent issuing on an application with respect to which a requirement for restriction . . . has been made, or on an application filed as a result of such a requirement, shall not be used as a reference . . . against a divisional application or against the original application."[316] The USPTO issues a restriction requirement when an examiner determines that a patent application claims more than one distinct and independent invention. In such cases, the patentee must elect a single, claimed invention for examination, while the other claims may be pursued in a later divisional application. For instance, if the patent application has both composition and method claims within the same application, the examiner may require the patentee to elect one set of claims to move forward with the current application, while the other claims can be filed in a later divisional application.[317] Section 121 thus exists to prevent an unfair outcome where the USPTO requires an applicant to divide claims into separate patents to comply with the restriction requirements, only for them to later use the original application to issue a double patenting rejection for the later-filed application.[318] The safe harbor provision addresses "difficulties created by restriction requirements imposed by the [USPTO] during examination, followed by double patenting challenges in the courts."[319]

To trigger the requirement restriction in a first-filed patent application, patentees can present multiple claim types (e.g., composition versus method claims) or claims from independent, distinct inventions. Once the divisional applications are filed, safe harbor protections can be invoked against ODP rejections. However, patentees must meet specific requirements to qualify for the safe harbor protection. First, divisional applications must be filed as a result of restriction requirements.[320] Continuation or continuation-in-part (CIP)

314. *See Cellect*, 81 F.4th at 1219.

315. 35 U.S.C. § 121; *see also Acadia*, 706 F. Supp. 3d at 482.

316. 35 U.S.C. § 121.

317. *Id.*

318. *Id.*; Pub. L. No. 82-593, 66 Stat. at 800–01 (1952).

319. St. Jude Med., Inc. v. Access Closure, Inc., 729 F.3d 1369, 1376–77 (Fed. Cir. 2013).

320. 35 U.S.C. § 121; *see also* Bristol-Myers Squibb Co. v. Pharmachemie B.V., 361 F.3d 1343, 1347–48 (Fed. Cir. 2004) ("[the patentee] is entitled to invoke the statutory prohibition against the use of the [reference] patent 'as a reference' against the divisional application that

applications are not entitled to the ODP safe harbor.[321] In fact, courts have consistently invalidated continuation patents challenged with ODP that failed to be designated as divisional applications.[322] Patentees should ensure that the filings are correct as divisional applications—not continuations. Second, the claims in the divisional applications must maintain "consonance" with the restriction requirements. The doctrine of consonance "requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be maintained."[323] In other words, consonance ensures that the claims in the divisional applications adhere to the original boundaries set by the restriction. Claims must not overlap with inventions elected in the parent application.[324]

Lastly, when facing an ODP rejection, patentees can argue that the claims are patentably distinct or amend the claims to obviate the ODP rejection for the child patent.[325] Patentees can also file terminal disclaimers for later-filed patents, sacrificing the child patent's term to preserve PTA for another family member with more valuable claims.[326] A terminal disclaimer can only overcome an ODP rejection if the earlier patent has not yet expired.[327] Patentees should assess the validity of an ODP rejection before submitting a terminal disclaimer. Terminal disclaimers carry certain implications, as not only

---

resulted in the [challenged] patent only if the *divisional application was filed as a result of a restriction requirement* and is consonant with that restriction requirement." (emphasis added)).

321. *See, e.g.*, *In re* Janssen Biotech, Inc., 880 F.3d 1315 (Fed. Cir. 2018); *see also* Pfizer, Inc. v. Teva Pharms. USA, Inc., 518 F.3d 1353, 1362 (Fed. Cir. 2008) ("[T]he protection afforded by section 121 to applications (or patents issued therefrom) filed as a result of a restriction requirement is limited to divisional applications.").

322. *See, e.g.*, *Pfizer*, 518 F.3d at 1359–63 (holding that safe harbor does not apply to patents issued from continuation-in-part (CIP) applications); *see also* Amgen Inc. v. F. Hoffman-La Roche Ltd., 580 F.3d 1340, 1352–53 (Fed. Cir. 2009) (holding that safe harbor does not apply to patents issued from continuation applications).

323. Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688 (Fed. Cir. 1990); *see also* Geneva Pharm., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1381 (Fed. Cir. 2003) ("Section 121 shields claims against a double patenting challenge if consonance exists between the divided groups of claims and an earlier restriction requirement."); MPEP § 804.02 (9th ed. Rev. 1, 2024).

324. *Gerber Garment Tech.*, 916 F.2d 683, 687 (stating that "a divisional application filed as a result of a restriction requirement may not contain claims drawn to the invention . . . in the parent application.").

325. MPEP § 804 (9th ed. Rev. 1, 2024).

326. 35 U.S.C. § 253; MPEP § 1490 (9th ed. Rev. 1, 2024).

327. *See Boehringer*, 592 F.3d 1340 (Fed. Cir. 2010); *In re Lonardo*, 119 F.3d at 965 (Fed. Cir. 1997) ("With obviousness-type double patenting, . . . a terminal disclaimer may overcome that basis for unpatentability, *assuming that the first patent has not expired.* In this case, the [patent] over which the claims have been rejected . . . has expired, so a terminal disclaimer cannot cure these rejections.") (emphasis added).

do they tie the terms of the patents together, but they may also link the patents for licensing purposes when a common owner is involved.[328] Further, if ownership of the patents is later divided, the disclaimed patents may become unenforceable.[329]

V. CONCLUSION

Double patenting, though seemingly straightforward, remains a complicated and unsettled area of patent law. In *Allergan*, the Federal Circuit reached an outcome that was both equitable and consistent with the foundational principles of the ODP doctrine and double patenting jurisprudence. The ruling clarifies what qualifies as a proper ODP reference, while reinforcing PTA's original purpose—a statutory safeguard to compensate diligent applicants, rather than a tool for exposing patents to ODP invalidation.

Unfortunately, prosecution delays at the USPTO are here to stay, and PTA and ODP continue to remain in each other's crosshairs. From October 2023 until now, only thirty-two percent of patent applications received their first action within fourteen months of filing.[330] Addressing the unresolved ODP scenarios with PTA post-*Allergan*, this Note offers a systematic approach for analyzing ODP outcomes—one that balances the propriety of ODP references with traditional equitable concerns. In the meantime, while Sun has withdrawn its en banc rehearing petition and *Allergan* has narrowed *Cellect* in one acute instance, other cases involving ODP and PTA remain on appeal at the Federal Circuit.[331] These future appeals will provide the court further opportunities to refine its view on the interaction between PTA and ODP. Until the courts provide a definitive clarification, the interplay between PTA and ODP will continue to leave this area of law ambiguous and unsettled.

---

328. Gary Maze & Jeffrey Wendt, *Prosecution and Litigation Implications of Subsequent Patent Applications (Part IV)*, IPWATCHDOG (Dec. 28, 2020), https://ipwatchdog.com/2020/12/28/prosecution-litigation-implications-subsequent-patent-applications-part-iv/id=128451/.

329. 37 C.F.R. § 1.321(c)(3); *see also* Email Link Corp. v. Treasure Island, LLC, 2012 WL 4482576, at *4 (D. Nev. 2012); Voda v. Medtronic, Inc., No. CIV-09-95-L, 2011 WL 10820070, at *3 (W.D. Okla. 2011).

330. *Patent Term Adjustment Data August 2024*, USPTO PATENTS DASHBOARD, https://www.uspto.gov/dashboard/patents/patent-term-adjustment-new.html (last visited Nov. 17, 2024).

331. *See, e.g.*, *Abiomed*, 2023 WL 4038564, at *33–34 (D. Mass. 2023); *Acadia*, 706 F. Supp. 3d at 487 (as of April 20, 2025, both cases are under appeal at the Federal Circuit).