IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACADIA PHARAMCEUTICALS INC., Plaintiff, v. AUROBINDO PHARMA LIMITED *et al.*, Defendants.	C.A. No. 20-985-GBW CONSOLIDATED

MEMORANDUM ORDER

Defendants MSN Laboratories PVT. Ltd. and MSN Pharmaceuticals, Inc. (collectively, "MSN") filed an Abbreviated New Drug Application ("ANDA") for a generic version of the Parkinson's drug Nuplazid®. The FDA tentatively approved MSN's ANDA. Acadia Pharmaceuticals, Inc. ("Acadia") asserted five patents against MSN but has voluntarily dismissed or stipulated to non-infringement of four of them. D.I. 144, 176. Acadia also has resolved its disputes with all other defendants, either by stipulating to dismissal or reaching an agreement to be bound by the outcome of the present case. D.I. 87; D.I. 236; D.I. 253; D.I. 254. The parties have reached an agreement to limit the dispute to just the invalidity of claim 26 of U.S. Patent No. 7,601,740 ("the '740 patent") and have stipulated to a set of undisputed facts to support a summary judgment on this issue. D.I. 256, 257, 258. The Court heard oral argument on the parties' cross-motions for summary judgment on September 26, 2023. Transcript. ("Tr."). For the reasons given below, the Court denies MSN's motion for summary judgment and grants Acadia's cross-motion for summary judgment.[1]

[1] MSN argues that Acadia has not properly requested leave to file a cross-motion. D.I. 263 at 1. Because the parties stipulated to resolution of the case on summary judgment, D.I. 256, the Court holds that Acadia's cross-motion is proper.

I. BACKGROUND

The facts are not in dispute for this motion. D.I. 158 ("Joint Statement of Undisputed Facts").[2] MSN challenges the '740 patent based on U.S. Patent No. 9,566,271 ("the '271 patent"). The challenged '740 patent traces back to U.S. Patent Application No. 10/759,561 ("the '561 application"), which was filed on January 15, 2004. JSUF ¶ 16. The reference '271 patent traces back to U.S. Patent Application No. 11/416,527 ("the '527 application") filed on May 3, 2006. *Id.* at ¶ 21. The '527 application was initially filed as a continuation of the '561 application. *Id.* at ¶ 33. On July 5, 2007, the Examiner issued a restriction requirement on the '561 application. *Id.* at ¶ 26. Acadia elected a subset of claims to pursue in the '561 application. *Id.* at ¶ 27. Acadia cancelled its pending claims in the '527 application and replaced them with reserved claims from the '561 application. *Id.* at ¶ 36-37. On July 1, 2009, Acadia stated an intention to change the '527 application to a divisional of the '561 application. *Id.* at ¶ 37. The '561 application issued as the '740 patent on October 13, 2009. *Id.* at ¶ 16. The PTO calculated that it delayed issuance of the initially examined '740 patent and granted 980 days of patent term adjustment (PTA). *Id.* at ¶ 17-19. The '740 patent also received a 1,315-day patent term extension (PTE) for FDA delay. *Id.* at ¶ 20. On January 26, 2010, the Examiner allowed the cancellation of the existing claims of the '527 application. *Id.* at ¶ 38. On April 13, 2010, Acadia amended the '527 specification, changing it from a "continuation" to a "divisional" of the '561 application. *Id.* at ¶ 39. The '271 patent issued on February 14, 2017 and expires on January 15, 2004. *Id.* at ¶ 21-22.

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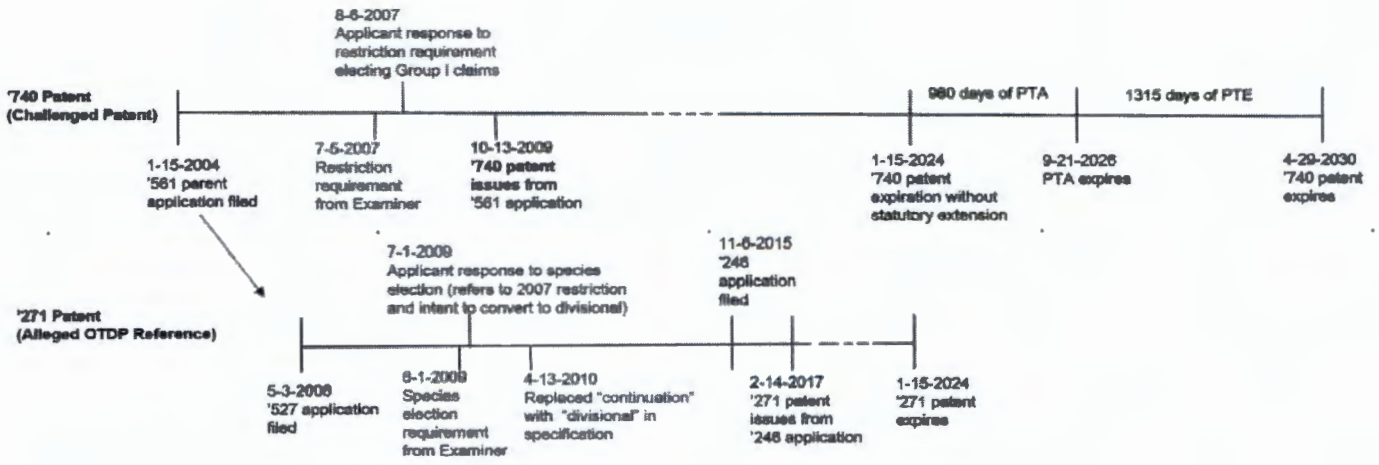
[2] The paragraphs of the Joint Statement of Undisputed Facts, D.I. 258, are cited as "JSUF ¶ __" and the Bates-numbered JSUF exhibits are cited with their exhibit and Bates numbers, as "JSUF Ex. _ at 0___.

The following timeline, Exhibit A from Acadia's Answering Brief (D.I. 261), is clarifying:

Exhibit A
Timeline of Relevant Prosecution Events



Claim 5 of the '271 patent is directed to a method for treating hallucinations by administering the tartrate salt of pimavanserin. JSUF ¶ 11. Claim 26 of the '740 patent is directed to tartrate salt of pimavanserin. *Id.* at ¶ 8. Both parties agree that, if the '271 patent is a proper obvious-type double patenting (OTDP) reference to the '740 patent, and OTDP can cut off a PTA on a first-filed, first-issued patent, then claim 5 of the '271 patent anticipates claim 26 of the '740 patent. D.I. 259 at 9.

II. LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a).

After the implementation of the Uruguay Round Agreements Act ("URAA"), a U.S. patent issued on an application filed on or after June 8, 1995 has a patent term that "end[s] 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications …, from the date on which the earliest such application was filed." 35 U.S.C. § 154(a)(2), as amended by Pub. L. 103-465, Title V, § 532(a)(1), Dec. 8, 1994, 108 Stat. 4809, 4983; *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1215 (Fed. Cir. 2014). The 20-year patent term can be lengthened for "1 day for each day after the end of the period specified in clause [(i)-(iv) for patent office delays]." 35 U.S.C. § 154(b)(1)(A) (commonly referred to as "patent term adjustment" or "PTA"). In addition, and separately from a PTA, the term of a patent within certain categories relating to an FDA-approved pharmaceutical product can be extended under 35 U.S.C. § 156 to compensate for FDA delays. This is commonly referred to as "patent term extension" or "PTE."

A patent confers exclusive rights only "for limited Times." U.S Const., art. I, § 8; *Kimble v. Marvel Ent., LLC*, 576 U.S. 446, 451 (2015) ("Patents endow their holder with superpowers, but only for a limited time."). Once a patent expires, the public is entitled to free use of the invention described in the patent—this is the grand bargain of the entire patent scheme. *Singer Mfg. Co., v. June Mfg. Co.*, 163 U.S. 169, 185 (1896); *Kimble*, 576 U.S. at 451; *Gilead*, 753 F.3d at 1212. The "judicially created" OTDP doctrine prohibits different expiries for two commonly owned patents (or two patents sharing an inventor) that claim obvious variants of the same invention. *Gilead*, 753 F.3d at 1212-14 (discussing OTDP history). OTDP "is designed to prevent an inventor from securing a second, later expiring patent for the same invention." *AbbVie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust*, 764 F.3d 1366, 1373 (Fed. Cir. 2014). OTDP was created "to prevent unjustified timewise extension of the right to exclude granted by a patent

no matter how the extension is brought about." *Eli Lilly & Co. v. Barr Labs. Inc.*, 251 F.3d 955, 967-68 (Fed. Cir. 2001) (internal quotations omitted). Post-URAA, "the doctrine of obviousness-type double patenting continues to apply where two patents that claim the same invention have different expiration dates." *AbbVie*, 764 F.3d at 1374. "The ban on double patenting ensures that the public gets the benefit of the invention after the original period of monopoly expires." *Id.* at 1373.

For a parent application and its divisional application claiming overlapping patented subject matters, a "safe harbor" was established to protect them from OTDP. 35 U.S.C. § 121; Pub. L. No. 82-593, 66 Stat. at 800-01 (1952).

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

Id. "The safe harbor provision arose from difficulties created by restriction requirements imposed by the [PTO] during examination, followed by double patenting challenges in the courts. . . . This conflicting result was recognized as inherently unfair, and the safe harbor was created to preclude it." *St. Jude Med., Inc. v. Access Closure, Inc.*, 729 F.3d 1369, 1376–77 (Fed. Cir. 2013). Courts "follow[] 'a strict application of the plain language of § 121.'" *In re Janssen Biotech, Inc.*, 880 F.3d 1315, 1321 (Fed. Cir. 2018) (quoting *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1353 (Fed. Cir. 2009)).

III. DISCUSSION

A. 35 U.S.C. § 121 Distinguishes Challenges to Original and Divisional Applications.

The parties dispute the proper reading of 35 U.S.C. § 121. The parties disagree on whether the language in § 121, which requires the divisional patent be filed "before the issuance of the patent on the other application" and "as a result" of a restriction requirement, applies when the challenged patent is the original patent, not the divisional patent. Careful bolding helps set clear the parties' respective positions. Acadia argues that the statute should be read as granting "paramount" protection to original applications. D.I. 261 at 5. Acadia reads the statute as follows:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. **A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts** against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

35 U.S.C. § 121. In Acadia's view, the bolded portions discuss two types of reference patents—a patent issuing on an application with respect to which a requirement for restriction has been made, or patents issuing on applications filed as a result of such a requirement. The underlined portions, meanwhile, describe challenged patents/applications—divisional applications, and original applications. As such, in Acadia's reading the "filed before the issuance of the patent" requirement applies exclusively to a challenged divisional patent, not a challenged original application.

On the other hand, MSN reads the statute as follows:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If

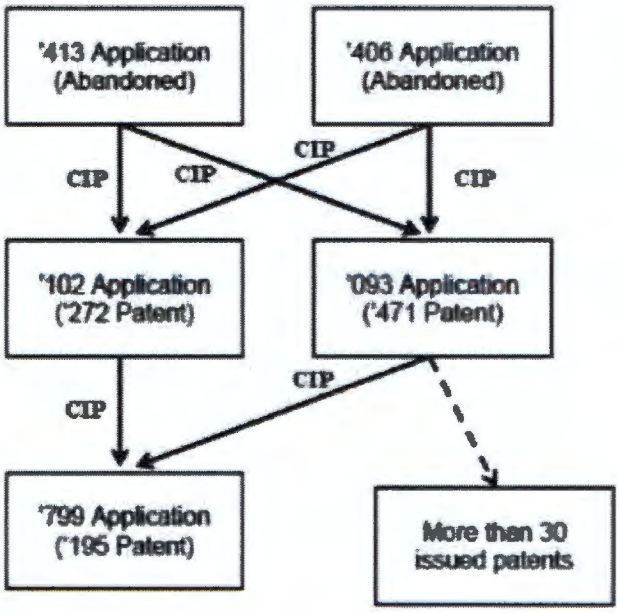
> the **other invention is made the subject of a divisional application** which complies with the requirements of section 120 it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application **filed as a result of such a requirement**, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, **if the divisional application is filed before the issuance of the patent on the other application**. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

35 U.S.C. § 121. In essence, MSN argues that the second sentence defines a divisional application. MSN argues that, within the meaning of the statute, a divisional application is an application filed "as a result" of a restriction requirement because it contains the "other invention." Thus, in MSN's view, "the divisional application" can refer to the reference patent, which is "filed as a result of a restriction requirement." Therefore, a divisional application can be used as a reference patent only if it is filed as a result of a restriction requirement "before the issuance of the patent on the other application."

The clearest Federal Circuit statement on this issue is that it described, in a parenthetical, 35 U.S.C. § 121 as "sheltering from attack 'a divisional application or . . . the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.'" *Amgen* 580 F.3d 1340 at 1353 (Fed. Cir. 2009) (omission in original). This dictum supports Acadia's interpretation that the "divisional application" that must be filed pre-issuance is a challenged patent, not a reference patent. However, this is hardly dispositive. Similarly inconclusive is the Federal Circuit's statement in *Pfizer, Inc. v. Teva Pharms. USA, Inc.* that "safe harbor, by its literal terms, protects only 'divisional application[s]' (or the original application) and patents issued on such applications . . . [T]he drafters of section 121 chose to refer specifically and only to divisional (and original) applications." 518 F.3d 1353, 1360, 1362 (Fed. Cir. 2008). Again, this could indicate that the

"divisional application" that needs to be filed pre-issuance of the other patent is a challenged patent, not a reference patent.

MSN argues that "the Federal Circuit has held that a later-filed child patent can, and did, invalidate an earlier-filed parent patent under OTDP." D.I. 263 at 2. MSN cites *In re Janssen Biotech, Inc.*, where it claims the "'195 patent from a [continuation-in-part] child application [was] used as a reference to invalidate the parent '471 patent under OTDP." 880 F.3d at 1318-19. However, in *Janssen*, the challenged '471 patent was not the original patent (the '413 was the application which received a restriction requirement), and the reference patent was a continuation-in-part of multiple patents. The opinion described the relationship between the relevant patents in a helpful diagram:



Janssen, 880 F.3d at 1318. Unlike the application at issue in the present action, neither the '093 application nor the '799 application in *Janssen* could have benefitted from any "original" protection, since the '413 application was the original application and the one that received the restriction requirement. *Id.* *Janssen* also arguably contains language which makes clear that the "before the issuance of the patent" requirement applies to the challenged patent, not the reference

patent: "For a *challenged* patent to receive safe-harbor protections, the application must be properly designated as a divisional application, at the very latest, by *the time the challenged patent issues on that application*." 880 F.3d at 1323 (emphasis added). A ruling in MSN's favor today would thus go beyond what the Federal Circuit held in *Janssen*.

On balance, the Court is persuaded that Acadia's position is the correct interpretation of § 121. Under this interpretation of the statute, the statute describes reference patents under the portion stating a "patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference." 35 U.S.C. § 121. The statute then describes challenged patents by the portion stating, "against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application." *Id.* On the other hand, MSN's interpretation, where "divisional application" refers to an "application filed as a result of such a requirement," imports additional limitations not present in the statutory language. *Id.* The Court's reading is supported by the limited Federal Circuit precedent. *Janssen*, MSN's primary case, indicates that the "filed before" requirement applies to challenged patents, not reference patents. 880 F.3d at 1323. While the "safe harbor provision [is] not a model of clarity," the Court's interpretation is consistent with the statutory language and the Federal Circuit's precedent. *St. Jude*, 729 F.3d at 1377.

MSN argues that it is arbitrary which group of claims Acadia chose to prosecute in the original application. D.I. 263 at 2. MSN further argues that it is "mere happenstance" which branch of the patent family would result in a patent grant first. *Id.* at 3. In reply, the Court first notes that there is no requirement that Congress construct a perfectly rational schema. Moreover, Congress in crafting the safe harbor provision could rationally have been focused on preserving

original rights, such that a restriction requirement would not harm the inventor in any instance. Also, that it is happenstance which branch issues first weighs against a finding of gamesmanship, insofar as Acadia could not have predicted a particularly advantageous outcome by choosing to amend an existing application rather than filing a new divisional application.

Therefore, the Court holds that the "filed before the issuance of the patent" requirement in the 35 U.S.C. § 121 safe harbor is inapplicable when the challenged patent issued from the original application.

B. The '740 Patent is Protected by the Safe Harbor Provision.

Having adopted Acadia's reading of 35 U.S.C. § 121, the Court now must analyze whether the reference patent was "filed as a result of" a requirement for restriction. Because precedent dictates that an amendment constitutes filing for purposes of 35 U.S.C § 121, the Court holds that 35 U.S.C § 121 provides a safe harbor to the '740 patent.

This Court previously held that an application is "filed as a result of" the restriction requirement when an initially non-divisional application is amended to comport with a restriction requirement in another patent. *Union Carbide Corp. v. Dow Chem. Co.*, 619 F. Supp. 1036, 1059-60 (D. Del. 1985). Specifically, the Court, in *Union Carbide*, held that an "amended application is one 'filed as a result of such a requirement' as set forth in § 121" when "the claims of an application are amended in toto to reflect the division of a co-pending application." *Id.* at 1060. The court explained that "[n]o practical distinction exists between an application filed for the first time as a result of a restriction requirement, and an application which is amended in full to comport with that requirement." *Id.* This interpretation also complies with Federal Circuit precedent which states that § 121 is "not concerned with . . . how any [particular divisional] applications are filed. To prevent loss of safe harbor in dividing out claims to non-elected inventions, what is required is consonance with the restriction requirement." *Boehringer Ingelheim Intern. GmbH v. Barr Labs.,*

Inc., 592 F.3d 1340, 1353-54 (Fed. Cir. 2010) (holding that two serially-filed divisional applications met the "filed as a result of" requirement despite one of the divisional applications having been initially filed as a continuation).

MSN's attempt to distinguish *Union Carbide* is unavailing. MSN argues that *Union Carbide* relied on a mistaken reading of the law, in that "the text of § 121 actually does not require the challenged patent to be filed 'as a result of a restrict requirement,' and therefore, "[t]he district court's discussion in *Union Carbide* . . . is based on an expansive reading of the 'as a result of' requirement on the challenged patent." D.I. 263 at 8. However, the Federal Circuit has explicitly held that "the 'as a result of' requirement must be satisfied by both the [reference] patent and the [challenged] patent." *Boehringer*, 592 F.3d at 1352. *Union Carbide* clearly indicates that an amendment constitutes filing for the purposes of § 121.

For the first time at oral argument, MSN argued that *Union Carbide* would only apply to pre-URAA patents. Tr. 8:15-9:22. However, the rationale of *Union Carbide* is not based on a rationale that would only apply to pre-URAA patents, but on a plain reading of the unaltered text and purpose of § 121. *See* 619 F. Supp. at 1059-60; *compare* 35 U.S.C. § 121 (1984) *with* 35 U.S.C. § 121 (identical text, except that the modern version replaces "Commissioner" with "Director" and removes an option to forego an applicant's signature). The text of the safe harbor provision makes no distinction between pre-URAA and post-URAA patents. Once again, there is no "practical distinction" between an application filed for the first time as a result of a restriction requirement, and one amended in full to comport with that requirement. *Union Carbide*, 619 F. Supp. at 1060. MSN has not provided any reason to distinguish between pre-URAA and post-URAA patents for purposes of the safe harbor analysis.

MSN similarly fails to distinguish *Boehringer*. MSN argues that its reading of § 121 leaves "the choice of how to prosecute non-elected inventions" "up to the applicant" as *Boehringer* states, but the applicant will still just face the consequences. D.I 263 at 8 (quoting *Boehringer*, 592 F.3d at 1353-54). MSN also notes that the continuation in *Boehringer* was filed after the restriction requirement and amended to a divisional application later. 592 F.3d at 1343-44. In contrast, the continuation in the instant claim was filed before the restriction requirement, then amended to a divisional application. Drawing these distinctions ignores the plain language of *Boehringer* that what is relevant is not "how any such applications are filed," but the application being "due to the administrative requirements imposed by the [PTO], in the sense that, absent the restriction requirement, the applicant could have retained in the [original application] the claims prosecuted in the [descendant] application." 592 F.3d at 1353-54. There is no dispute that this requirement is satisfied in this action. D.I. 263 at 7 ("Acadia could have filed a divisional application for those claims that it eventually chose to add to the '527 Application in 2009."). Prior precedent thus makes clear that the filing requirement can be satisfied by amendment.

The cases that MSN provides to the contrary do not change this conclusion. MSN cites *In re Janssen* for the proposition that amendment is permissible, but an amendment outside the safe harbor window does not trigger the safe harbor protection. 880 F.3d at 1322-24. It similarly cites *G.D. Searle LLC v. Lupin Pharms., Inc.*, for the proposition that retroactive designation as a divisional does not trigger Section 121. 790 F.3d 1349, 1354-55 (Fed. Cir. 2015). Both *Janssen* and *G.D. Searle* address attempts by patentees to re-designate challenged patents after they issued, a straightforward case of gamesmanship absent in the present action. *Janssen*, 880 F.3d at 1223; *G.D. Searle*, 790 F.3d at 1354-55. *Union Carbide* and *Boehringer* address the more analogous cases of amendment during prosecution and indicate that it is a permissible "filing." 619 F. Supp.

1059-60; 592 F.3d at 1353-54. Thus, the Court finds that the reference '271 patent was filed "as a result of" the original '740 patent, within the meaning of the statutory safe harbor.

C. In the Alternative, the '271 Patent Does Not Qualify as a Proper Reference Against the '740 Patent.

"[C]laims in the 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." *In re Cellect*, No. 2022-1293, 2023 WL 5519761, at *10 (Fed. Cir. Aug. 28, 2023). The Court has been unable to identify a case where, when challenged, a later-filed, later-issued, earlier-expiring patent was used as an OTDP reference to invalidate an earlier-filed, earlier-issued, later-expiring patent. Here, the claims in the challenged patent were earlier-filed and thus are entitled to their full term, including the PTA.

That only later-filed patents are proper references is equitable, since the purpose of OTDP doctrine is 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." *Proctor & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 99 (Fed. Cir. 2009); *see also Cellect*, 2023 WL 5519761, at *7 (OTDP "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."). If a later-filed patent is used as a reference, the logic and purpose of OTDP is flipped on its head: rather than preventing a patent owner from unjustifiably extending the term of a patent, OTDP would operate to cut off a patent term that would have been valid but for a later-filed patent.

Whether a patent qualifies as an OTDP reference is a threshold issue. *See Novartis AG v. Ezra Ventures LLC*, 909 F.3d at 1375 n.4 (Fed. Cir. 2018) ("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"). Only after the reference

determination has been made does the Court conduct an OTDP analysis. *See Novartis Pharms. Corp. v. Breckenridge Pharma. Inc.*, 909 F.3d 1355, 2359 (Fed. Cir. 2018). That this determination must be made in each instance explains why the Federal Circuit in *Cellect*, despite its clear statement that OTDP only applies to "later-filed obvious variations of earlier-filed, commonly owned claims," invalidated an earlier-filed patent. 2023 WL 5519761, at *10. 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 O[T]DP could cut short a grant of PTA."[3] *Id.* at *3. Accordingly, the court did not independently consider whether the reference patents were available. *Cf. In re Fallaux*, 546 F.3d 1313, 1315 n.1 ("Neither party raised or argued the question of whether a patent may be used as a reference for an obviousness-type double patenting rejection . . . . This opinion should not be read to decide or endorse the PTO's view on this issue."). The Federal Circuit instead merely reiterated the standard that challenged patents must be "later-filed obvious variations of earlier filed, commonly owned claims" and held it had "no basis for the consideration of that issue here." *Cellect*, 2023 WL 5519716, at *10.[4]

The cases that MSN cites do not change the conclusion that putative OTDP references must be later-filed to be available as a reference. MSN points to *Gilead Scis., Inc. v. Natco Pharma Ltd.* for the proposition that "it is the comparison of [the] patent expiration dates that should control,

[3] *Cellect* involved a tangled web of earlier- and later-filed patents, and the patentee seems to have focused its arguments on those positions applicable to all challenged patents. 2023 WL 5519716, at *1-2.

[4] The Court recognizes that another court in this district has interpreted *Cellect* to cut off OTDP even for first-filed, first-issued patents. *Allergan USA, Inc. v. MSN Laboratories Private Ltd., et al.*, C.A. No. 19-1727-RGA, D.I. 483 (D. Del. Sept. 27, 2023). The arguments dispositive in this case do not appear to have been briefed in *Allergan*, and the *Allergan* Court did not analyze the language in *Cellect* discussing "later-filed obvious variations of earlier-filed, commonly-owned claims." 2023 WL 5519716, at *10. Accordingly, the Court does not find itself persuaded by *Allergan*.

not merely the issuance dates." 753 F.3d 1208, 1210 (Fed. Cir. 2014). *Gilead* addressed the "narrow question" of "[c]an a patent that issues after but expires before another patent qualify as a double patenting reference" and limited its decision to the "circumstances of this case." *Id.* at 1211-12. It therefore did not address filing dates, the relevant inquiry under *Cellect* and before this Court. Indeed, the reference patent in *Gilead* was earlier-filed. *Id.* The Federal Circuit in *Gilead* relied heavily on the idea that issue dates are "too arbitrary, uncertain, and prone to gamesmanship;" thus, the Court instead compared the expiration dates of the patents. *Id.* at 1216. Like expiration dates, but unlike issue dates, filing dates are not prone to gamesmanship. Accordingly, the chief concerns of *Gilead* do not apply to this case, nor does *Gilead* overcome the clear language of *Cellect*.

Similarly unpersuasive is *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.* 764 F.3d 1366 (Fed. Cir. 2014). *AbbVie* addressed a challenge to a later-filed, later-expiring patent, and thus again did not reach the issue of whether a later-filed patent may be used as an invalidating reference. *Id.* at 1369. *AbbVie* applied the *Gilead* rationale, making clear that the availability of OTDP remained viable to prevent gamesmanship in certain narrow instances. *Id.* at 1373. The Federal Circuit in *Ezra* distinguished *AbbVie* because there no "concern that [a patent owner], once its [] patent issued, sought to subsequently 'secur[e] a second, later expiring patent for the same invention.'" 909 F.3d at 1375 (quoting *AbbVie*, 764 F.3d at 1373). The same circumstances are present in this action, in that the Court finds no concern that Acadia was subsequently securing a second, later-expiring patent. The '740 patent retains the same expiration date it has always had.

Because a patent must be later-filed to be available as an OTDP reference, the Court finds that the '271 patent does not qualify as a proper reference against the '740 patent. This is an

independent basis for the Court's decision and does not rely on or alter the Court's interpretation of the safe-harbor statute.

IV. CONCLUSION

For all of the foregoing reasons, the Court grants summary judgment to Acadia.

* * *

WHEREFORE, at Wilmington this 13th day of December, 2023, **IT IS HEREBY ORDERED** that:

1. MSN's Motion for Summary Judgment of Invalidity of U.S. Patent No. 7,601,740 For Double Patenting (D.I. 260) is **DENIED.**
2. Acadia's Cross Motion for Summary Judgment and No Invalidity of Claim 26 of U.S. Patent No. 7,601,740 (D.I. 262) is **GRANTED.**

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE