Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296

In the
United States Court of Appeals
for the Federal Circuit

IN RE: CELLECT, LLC,

Appellant.

Appeals from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in Nos. 90/014,453, 90/014,454, 90/014,455, and 90/014,457.

BRIEF OF *AMICUS CURIAE* ALVOGEN PB RESEARCH & DEVELOPMENT LLC IN SUPPORT OF THE DIRECTOR AND AFFIRMANCE

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 22-1293, 22-1294, 22-1295, 22-1296

Short Case Caption In re: Cellect, LLC

Filing Party/Entity Alvogen PB Research & Development LLC

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

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1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Alvogen PB Research & Development LLC		See attached

☑ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☑ None/Not Applicable ☐ Additional pages attached

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

3. Parent Corporations and Stockholders Fed. Cir. R. 47.4(a)(3)

Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

Alvogen PB Research & Development LLC:

Alvogen Lux Holdings S.a.r.l. (Luxembourg) and Aztiq Pharma Partners S.a.r.l. (Luxembourg) are the parent companies of New Alvogen Group Holding, Inc., which is the parent company of Alvogen Group Inc., which is the parent company of Alvogen Pharma US, Inc., which is the parent company of Alvogen PB Research & Development LLC. No publicly held companies own 10% or more stock in Alvogen PB Research & Development LLC.

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TABLE OF ABBREVIATIONS

Abbreviation	Description
AIA	Leahy-Smith America Invents Act, 125 Stat. 285, 287 (2011)
Alvogen	Alvogen PB Research & Development LLC
ANDA	Abbreviated New Drug Application
Board	Patent Trial and Appeal Board
CREATE Act	Cooperative Research and Technology Enhancement Act of 2004, Pub. L. No. 108-453, 118 Stat. 3596 (2004)
FDA	U.S. Food and Drug Administration
OTDP	Obviousness-Type Double Patenting
Hatch-Waxman Act	Drug Price Competition and Patent Term Restoration Act, Public Law 98-417 (1994)
MPEP	Manual of Patent Examining Procedure (9th ed. Rev 10.2019, June 2020)
PTA	Patent Term Adjustment
PTE	Patent Term Extension or Hatch-Waxman Extension
PTO	U.S. Patent and Trademark Office
URAA	Uruguay Round Agreements Act, Pub. L. No. 103-46, 108 Stat. 4809, 4984 (1994)

INTEREST OF THE AMICUS CURIAE

Amicus curiae Alvogen PB Research & Development LLC[1] files ANDAs seeking FDA approval to market its pharmaceutical products. Alvogen is engaged in several patent lawsuits under the Hatch-Waxman Act at any given time.

The decision will clarify "loss of exclusivity" based on the end of patent term. Loss of exclusivity is a key date in the industry because it typically coincides with generic competition and lower prices. *See* Cong. Budget Off., Prescription Drugs: Spending, Use, and Prices 20 (2022). Most of the Court's recent OTDP decisions starting with *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), stem from pharmaceutical patent cases. And perhaps as is evident by the amicus filings, this case is important to the industry. Thus, as it is true for others, Alvogen has a substantial interest in this case.

[1] Alvogen submits this brief with the consent of all parties pursuant to Fed. R. App. P. 29(a)(2). No counsel for any party authored this brief in any part, and no party, counsel, or person other than Alvogen contributed money to fund the preparation and submission of this brief. Fed. R. App. P. 29(a)(4)(E).

The public also has a substantial interest in this case. "Prescription drugs are increasingly unaffordable for Americans." Majority Staff of H.R. Comm. on Oversight & Reform, 117th Cong., Drug Pricing Investigation, at ii (2021). High prescription drug cost has been a serious national issue for decades and "is draining our federal health care programs." *Id.* The Hatch-Waxman Act "is designed to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). Patent terms that extend beyond the statutory grant forestall generic competition and maintain high drug prices.

INTRODUCTION

The Court largely anticipated the question presented in *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*:

> [OTDP] is designed to prevent an inventor from securing a second, later patent for the same invention. That problem still exists. 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.

AbbVie, 764 F.3d 1366, 1373 (Fed. Cir. 2014) (internal citation omitted) (citing 35 U.S.C. § 154(b)). The Board in the present case and two district courts interpret OTDP consistent with the Court's statement in *AbbVie*. Two other

district courts do not. The divide centers on whether OTDP is a condition of patentability designed to limit one invention to one patent term or solely an equitable doctrine designed to prevent gamesmanship. Both positions rely on *Gilead* and subsequent cases. Yet both positions cannot be correct.

As set forth in this brief, OTDP is a condition of patentability that ensures one full statutory term per invention. Without OTDP, a later-expiring patent would extend the term of the invention claimed by an earlier-expiring patent. The terminal disclaimer is the only mechanism available to resolve OTDP because by cutting off the later term it ensures both patents expire simultaneously and remain commonly owned. It unites the patents in a way that is tantamount to having all claims together in one patent. *In re Van Ornum*, 686 F.2d 937, 948 (C.C.P.A. 1982). Any PTE granted for the regulated product would begin at the end of the reconciled term. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1323 (Fed. Cir. 2007).

The Board's position follows the Court's precedent and is consistent with *Merck* that Section 154 "expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays." *Id.* Furthermore, it aligns with the three historical principles that justify the

OTDP prohibition—i.e., unlawful extension, non-alienation, and exhaustion. The Court should affirm the Board.

ARGUMENT

I. OTDP Is Justified as a Condition of Patentability

It is the Patent Act's "core principle that, in exchange for a patent, an inventor must … promise to permit free use of [his invention] at the end of his patent term." *Gilead*, 753 F.3d at 1212. "The bar against double patenting was created to preserve that bargained-for right held by the public." *Id.* "It is upon this condition that the patent is granted." *Id.* (quoting *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896)). Thus, OTDP is designed "to prevent an inventor from securing a second, later expiring patent for the same invention." *AbbVie*, 764 F.3d at 1373 (citing *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197-198 (1894) and *Singer*, 163 U.S. at 185).

"Federal courts for over a century have applied the principles of the doctrine as a means to preserve the public's right to use not only the exact invention claimed by an inventor when his patent expires, but also obvious modifications of that invention that are not patentably distinct improvements." *Gilead*, 753 F.3d at 1212 (citing *Eli Lilly & Co. v. Barr Lab'ys,*

Inc., 251 F.3d 955, 967 (Fed. Cir. 2001)). If OTDP were not a condition of patentability, then "it would completely destroy the whole consideration derived by the public for the grant of the patent, viz. the right to use the invention at the expiration of the term." *Id.* (quoting *Odiorne v. Amesbury Nail Factory*, 18 Fed. Cas. 578, 579 (C.C.D. Mass. 1819) (No. 10,430)). "Thus, the doctrine of double patenting was primarily designed to prevent such harm by limiting a patentee to one patent term per invention or improvement." *Id*.

A. Statutory Justifications

While often called a judge-made doctrine, OTDP is grounded in the constitutional authority to secure for inventors exclusive rights in their discoveries "for limited Times," U.S. Const., art. I, § 8. It is rooted in the first statutory enactment of the patent laws, which said that an inventor may obtain "a patent," i.e., a single patent, for an invention. *See* Patent Act of 1790, ch. 7, § 1, 1 Stat. 109, 110 (1790). And it is rooted in all versions of the Patent Act since. *See* 35 U.S.C. § 101 (2018) ("a patent"). OTDP ties together several important sections of the Patent Act that directly implicate the prohibition and its impact on the end of patent term.

1. 35 U.S.C. § 253 – Terminal Disclaimer

OTDP serves as the practical basis for the Section 253 statutory disclaimer. Congress created the disclaimer in the Patent Act of 1952, ch. 950, § 253, Pub. L. No. 82-593, 66 Stat. 792, 809 (1952). Prior to its introduction, a patentee could not lawfully own OTDP patents with different expiration dates. *See, e.g.*, *Miller*, 151 U.S. at 197 ("[T]wo valid patents for the same invention cannot be granted … to the same … party."). Thus, the unavoidable consequence of double patenting was the invalidity of the later-expiring patent claims. With the creation of the Section 253(b) "terminal" disclaimer, however, common ownership of OTDP patents became possible.[2] *See Van Ornum*, 686 F.2d at 948.

Reconciling the OTDP expiration dates is the "very purpose" for which the terminal disclaimer "had been provided for in section 253." *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1280 (Fed. Cir. 1992). Terminal disclaimers are commonplace and provide "patent owners a

[2] Before 1971, a terminal disclaimer provided that the patents would "expire immediately" if they stopped being "commonly owned." *Van Ornum*, 686 F.2d at 948 (quoting 848 Off. Gaz. Pat. Office 1 (Feb. 14, 1968)). The current form of the terminal disclaimer (37 C.F.R. § 1.321(c)(3)) similarly requires the patent owner to retain ownership over both patents.

remedy against a double patenting charge by 'permit[ting] the patentee to cut back the term'" of the later-expiring patent. *Gilead*, 753 F.3d at 1213 (alteration in original) (quoting *In re Robeson*, 331 F.2d 610, 614 n.4 (C.C.P.A. 1964)). In essence, a valid terminal disclaimer creates a situation "which is tantamount for all practical purposes to having all the claims in one patent." *Van Ornum*, 686 F.2d at 948 (quoting *In re Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967)).

2. 35 U.S.C. § 121 – Divisional Safe Harbor

OTDP likewise serves as a basis for the Section 121 "safe harbor," which Congress also created in the 1952 Patent Act. § 121, 66 Stat. at 800-801 (1952). Until creation of the safe harbor, divisional claims could still be rejected for OTDP even if "consonant in scope" with an earlier restriction requirement that found the restricted claims to be "independent and distinct." *Studiengesellschaft Kohle mbH v. N. Petrochem Co.*, 784 F.2d 351, 358 (Fed. Cir. 1986) (Newman, J., concurring) (citing pre-1952 cases) *cited with approval by Boehringer Ingelheim Int'l GmbH v. Barr Lab'ys, Inc.*, 592 F.3d 1340, 1350 (Fed. Cir. 2010). With the introduction of the Section 121 safe harbor, claims found to be independent and distinct in an earlier restriction

requirement cannot be rejected for OTDP. 35 U.S.C. § 121 (2018). In other words, only those independent and distinct claims that fall within the scope of a restriction requirement are afforded safe harbor. Accordingly, the divisional safe harbor is not a statutory exception to OTDP. Rather, such claims do not violate the OTDP prohibition to begin with because they are independent and distinct.

Because a restriction requirement may nullify the use of OTDP as a grounds of rejection or invalidity in divisional applications, there is "a heavy burden on the [PTO] to guard against erroneous requirements for restrictions where … acquiescence to the restriction requirement might result in the issuance of several patents for the same invention." MPEP § 804.01 (9th ed. Rev 10.2019, June 2020). If through amendment or otherwise the claims of the divisional application are no longer consonant in scope with the restriction requirement, then the safe harbor of Section 121 no longer applies and an OTDP rejection can be made against the claims to uphold the prohibition. *Id.*; *see Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990).

3. 35 U.S.C. § 154 – Patent Term and Adjustment

The Uruguay Round Agreements Act of 1994 changed the patent term expiration date from 17 years after issuance to 20 years after the earliest effective filing date. *Gilead*, 753 F.3d at 1211; *see* URAA, Pub. L. No. 103-46, 108 Stat. 4809, 4984 (1994) (revising 35 U.S.C. § 154 to provide a "term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States.").

In 1999, Congress amended Section 154 to include more standard prosecution delays. *See Mayo Found. for Med. Educ. & Rsch. v. Iancu*, 938 F.3d 1343, 1345 (Fed. Cir. 2019). The amendment also expressly forecloses PTA from extending beyond the expiration date set forth in the terminal disclaimer:

> No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.

American Inventors Protection Act of 1999, Pub. L. No. 106-113, App. I, Tit. IV, § 4402, 113 Stat. 1501, 1501A-559 (1999);[3] *Merck*, 482 F.3d at 1322 ("§ 154(b)(2)(B) expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays.").

4. 35 U.S.C. § 156 – Patent Term Extension

For patents covering FDA-approved drugs, Section 156 permits a patentee in certain situations to select a single patent to receive PTE. 35 U.S.C. § 156 (2018); *see Merck*, 482 F.3d at 1320-21. PTE is meant to "restore value of the patent term that a patent owner loses during the early years of the patent because the product cannot be commercially marketed without approval from [FDA]." *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1369 (Fed. Cir. 2018). The "rights derived" during PTE are "limited" to any use approved for the product "before the expiration of the term of the patent"

[3] The earlier provisions of 35 U.S.C. §§ 154(b), (c) (1994) utilized the phrase "subject to any terminal disclaimers," which accounts for OTDP. In *Breckenridge*, the Court touched on this language but found that "no terminal disclaimer was necessary" because an earlier pre-URAA patent is "not a proper double patenting reference" to a later post-URAA patent. *Novartis Pharms. Corp. v. Breckenridge Pharm., Inc.*, 909 F.3d 1355, 1366 n.4 (Fed. Cir. 2018).

and "on or after the expiration of the regulatory review period upon which the extension of the patent was based." 35 U.S.C. § 156(b)(1) (2018).

By comparing the language between Sections 154 and 156, the Court found in *Merck* that a terminal disclaimer does foreclose PTA but not PTE when the patent is valid "under all other provisions of law":

> The express prohibition [in Section 154(b)] against term adjustment regarding PTO delays, the absence of any such prohibition [in Section 156] regarding [PTE], and the mandate in [Section] 156 that the patent term shall be extended … support the conclusion that a patent term extension under [Section] 156 is not foreclosed by a terminal disclaimer.

Merck, 482 F.3d at 1322. Accordingly, "if a patent, under its pre-PTE expiration date, is valid under all other provisions of the law, then it is entitled to the full term of its PTE." *Ezra*, 909 F.3d at 1374.

It follows that "valid under all other provisions of law" includes OTDP prevented by a terminal disclaimer. *Id*. Without a terminal disclaimer, PTE cannot extend the later patent that is otherwise invalid for OTDP. Thus, "[t]he computation of a [PTE] is from the expiration date resulting from the terminal disclaimer …." *Merck*, 482 F.3d at 1322-23. In this way, "[t]he purpose of the terminal disclaimer—to prevent [OTDP] remains fulfilled …

[and] [a]t the same time, the purpose of the patent term extension … is also satisfied." *Id*. at 1323.

B. Legislative Justifications

Congress has time and again amended the patent laws against the backdrop of OTDP. The legislative history makes clear two pertinent ideas—first that the main purpose of OTDP is to prevent a patentee from owning OTDP patents with different expiration dates, and second that a terminal disclaimer reconciles OTDP by uniting the patents as one.

In the Patent Law Amendments Act of 1984, which enacted PTE as part of the Hatch-Waxman Act, Drug Price Competition and Patent Term Restoration Act, Public Law 98-417, the Committee Report states that it "expects" the PTO to continue the prohibition against OTDP:

> The Committee expects that the [PTO] will reinstitute in appropriate circumstances the practice of rejecting claims in commonly owned applications of different inventive entities on the ground of double patenting. This will be necessary in order to prevent an organization from obtaining two or more patents with different expiration dates covering nearly identical subject matter. In accordance with established patent law doctrines, double patenting rejections can be overcome in certain circumstances by disclaiming the terminal portion of the term of the

> later patent, thereby *eliminating the problem of extending patent life*.

130 Cong. Rec. H10,527 (1984) (emphasis added); *see also In re Hubbell*, 709 F.3d 1140, 1153 (Fed. Cir. 2013) (Newman, J., dissenting) (discussing the legislative history). The "problem" referenced by the Committee is the later patent "extending patent life" of the earlier patent.

The CREATE Act of 2004, which post-dates the URAA transition statute and the American Inventors Protection Act (1999) redrafting the PTA provision, similarly uses OTDP as its backdrop. Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, § 2, 118 Stat. 3596 (2004) (codified as amended at 35 U.S.C. § 103(c) (2018)). The CREATE Act narrowed the scope of prior art for joint research efforts and, in doing so, allowed for the broader application of terminal disclaimers to overcome OTDP. *Id.* The legislative record considered OTDP "a matter of public policy" and reaffirmed its continued application:

> The double patenting doctrine exists *as a matter of public policy* to prevent a multiplicity of patents claiming patentably indistinct inventions from becoming separately owned and enforced. Thus, it applies to situations where multiple patents have issued, even if the patents are filed on the same day, issue on the same day and expire on the same day.

> *All that is required for double patenting to arise* is that one or more claims in each of the involved patents is determined to represent double patenting under established principles of law.

150 Cong. Rec. S7521 (daily ed. June 25, 2004) (statement of Sen. Hatch) (emphasis added). The Committee Report emphasized that the OTDP prohibition "shall apply to such patents" benefiting from the CREATE Act. H.R. Rep. No. 108-425, at 6 (2004). The Court's mandate in *Hubbell* that OTDP applies "no matter how the extension is brought about," 709 F.3d at 1145, is consistent with the "[a]ll that is required" statement in the Committee Report.

The uncodified AIA § 3(b)(2) incorporates by reference the legislative history of the CREATE Act:

> The enactment … is done with the same intent to promote joint research activities that was expressed, including in the legislative history, through the enactment of the … 'CREATE Act.'

Leahy-Smith America Invents Act, § 3(b)(2), 125 Stat. 285, 287 (2011); *see also* Joe Matal, *A Guide to the Legislative History of the American Invents Act: Part I of II*, 21 FED. CIR. B. J. 465, 486 (2012) ("One significant feature of the legislative history of the CREATE Act, effectively given the force of law by

section 3(b)(2) of the AIA, is its assurance that double-patenting rules will apply to patent-disclosure subject matter and claimed inventions deemed to be commonly owned pursuant to pre-AIA § 103(c).”). While the dissent in *Gilead* had concerns about OTDP in view of the AIA, 753 F.3d at 1220 (Rader, J., dissenting), such concerns must surely be mitigated by the fact that the AIA incorporates legislative history that reaffirms the OTDP prohibition.

C. Historical Justifications

The first historical principle that justifies OTDP is to prevent the “unjustified timewise extension” of a patent term. *Van Ornum*, 686 F.2d at 943-44. This principle emerged from the Supreme Court’s decision that “a new and later patent for the same invention would operate to extend or prolong the monopoly beyond the period allowed by law.” *Miller*, 151 U.S. at 198. As the Court recognized in *Gilead* and *AbbVie*, a patentee is guaranteed the full statutory term of the invention, which necessarily exists in its entirety in the earliest-expiring patent.

The second principle of non-alienation “is to prevent multiple infringement suits by different assignees asserting essentially the same patented invention.” *Hubbell*, 709 F.3d at 1145 (citing *In re Fallaux*, 564 F.3d

1313, 1319 (Fed. Cir. 2009) (stating that a principle of the OTDP doctrine is to prevent "harassment by multiple assignees")).[4] This principle emerged from the Supreme Court's decision in *Underwood*, as summarized by the 6th Circuit, that "splitting up of one indivisible right into two and subjecting the infringer to suits by two different owners of the right infringed justified applying the defense of double patenting…." *Sandy MacGregor Co. v. Vaco Grip Co.*, 2 F.2d 655, 657 (6th Cir. 1924) (citing *Underwood v. Gerber*, 149 U.S. 224 (1893)); *see Van Ornum*, 686 F.2d at 945 (similarly summarizing *Underwood*). The non-alienation principle applies even "if the patents are filed on the same day, issue on the same day and expire on the same day." 150 Cong. Rec. S7521 (daily ed. June 25, 2004) (statement of Sen. Hatch); *Underwood*, 149 U.S. at 225-29.

A third principle of exhaustion also emerged from the Supreme Court's decision in *Miller* – "the power to create a monopoly is exhausted by the first patent." *Miller*, 151 U.S. at 198. This principle has been characterized

[4] The scarcity of case law with harassment circumstances does not mean that the non-alienation principle is merely speculative any more than it proves that the terminal disclaimer has prevented harassment.

as "[t]he public should … be able to act on the assumption that upon the *expiration* of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been *obvious* to those of ordinary skill in the art at the time the invention was made …." *In re Longi*, 759 F.2d 887, 892-93 (Fed. Cir. 1985) (emphasis in original) (quoting *In re Zickendraht*, 319 F.2d 225, 232 (C.C.P.A. 1963) (Rich, J., concurring)). The "bedrock" principle of the patent system, therefore, is "that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention." *Gilead*, 753 F.3d at 1214 (citing *Longi*, 759 F.2d at 892). "The double patenting doctrine has always been implemented to effectively uphold that principle." *Id.*

II. OTDP Can Foreclose Term Including PTA

As a condition of patentability, OTDP can foreclose some or all of a later patent term (including its PTA), which otherwise extends the expiration date of the earlier patent term. As the Court recognized in *AbbVie*, OTDP can apply to related patents that share an effective filing date.

A. OTDP Applies to Related Patents

The concern in *Ezra* about OTDP cutting off "a statutorily-authorized time extension," 909 F.3d at 1375, can refer only to the Hatch-Waxman extension (PTE) and not the guaranteed patent term defined in Section 154 (20 years + PTA). Examples are abundant of OTDP being applied to related patents and causing the foreclosure of some of the statutory term of the later patent. *See, e.g.*, *Pfizer, Inc. v. Teva Pharms USA, Inc.*, 518 F.3d 1353, 1362 (Fed. Cir. 2008) (applying OTDP to continuation-in-part); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1371, 1375 (Fed. Cir. 2005) (same); *Gerber*, 916 F.2d at 684, 688-89 (applying OTDP to continuation); *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1348-50 (Fed. Cir. 2004) (same). In the pre-URAA cases, the terminal disclaimer would necessarily foreclose some or all of the 17 year term of the later patent. *See, e.g.*, *Van Ornum*, 686 F.2d at 937, 941, 947-48. And neither of the post-URAA patents in *Gilead* included PTA, such that the terminal disclaimer would have cut off some of the 20 year term of the later patent. *See Gilead*, 753 F.3d at 1210-11.

Furthermore, in both *Gilead* and *AbbVie*, OTDP applied even though the patentee gave up some priority. It follows that OTDP should apply even

more so to related patents with the same effective filing date. And the effective term post-issuance between the OTDP patents should not matter either. In *Gilead*, the effective term of the earlier-expiring patent was completely subsumed within the effective term of the later-expiring patent. *See Gilead*, 753 F.3d at 1211. As with the issue date in *Gilead*, the effective terms would not provide a stable benchmark. *See id.*

B. OTDP Applies to PTA

The language of Section 154 states that "no patent the term of which has been disclaimed beyond a specified date may be adjusted under [§ 154] beyond the expiration date specified in the disclaimer." 35 U.S.C. § 154(b)(2)(B) (2018). It follows that the OTDP that necessitated the terminal disclaimer can foreclose PTA accumulated by the later patent. That is not to say OTDP forecloses PTA altogether. Rather, it only forecloses PTA in the later patent that extends beyond the expiration date of the earlier patent (including its PTA). In this way, it ensures that the invention receives its full statutory term and no more. *Gilead*, 753 F.3d at 1212.

There is no tension between OTDP and statutory patent term (including PTA) when a terminal disclaimer unites the patents. There is

undoubtedly some tension between OTDP and PTE, however, because the latter can result in one invention claimed in separate patents having basically two expiration dates. But Congress made that policy choice for Hatch-Waxman extensions. That does not mean Congress made the same policy choice for PTA; nor can the same policy choice be inferred. PTE is limited to a single patent covering a regulated product, *see* 35 U.S.C. § 156(a) (2018), whereas PTA is exceedingly common. In addition, the patentee is free to select which eligible patent would receive PTE, regardless of any terminal disclaimers. *Merck*, 482 F.3d at 1323. There is no such flexibility for PTA. And the "rights derived" under PTE are "limited" to the approved product. 35 U.S.C. § 156(b) (2018). There are no limitations for PTA.

Furthermore, unlike the Hatch-Waxman extension, PTA cannot extend from a terminal disclaimer. Such a term adjustment is expressly prohibited by the statute and it would do nothing to resolve OTDP. 35 U.S.C. § 154(b)(2)(B) (2018). And it would be erroneous to suggest that the earlier patent should benefit from the later patent's PTA. In *AbbVie*, the parent application accumulated zero PTA whereas the much-later filed child application received 750 days of PTA. *AbbVie*, 764 F.3d at 1369-70. The Court

did not suggest any basis in law where the parent could benefit from the child's PTA. That outcome would have extended the statutory term of the earlier parent that accumulated no PTA.

C. Applying OTDP to PTA Is a Stable Benchmark

Applying OTDP to substantially duplicative patents with different PTA is a stable benchmark because it fulfills the three historical principles that justify the doctrine. First, it upholds the prohibition against unlawful extension of the earlier patent that accumulated less or no PTA. Second, it upholds the non-alienation principle because it requires common ownership over both patents through expiration. Finally, it upholds the principle of exhaustion because when the public looks at the earlier patent, it can act on the assumption that when that patent expires the claimed invention and any obvious variant of such invention becomes part of the public domain. *Gilead*, 753 F.3d at 1212; *Longi*, 759 F.2d at 892-93.

However, OTDP need not arise before PTA is awarded because, as is often the case, the applicant may not file an application subject to the OTDP prohibition until the other patent has been allowed or has issued with its PTA. For example, in *Gilead*, the later patent issued before the terminal

disclaimer was filed in the earlier patent. *Gilead*, 753 F.3d at 1210. "Permitting any earlier expiring patent to serve as a double patenting reference … 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." *Id.*

While it may be true that an earlier-filed application can be delayed more than the later-filed application, and therefore can receive more PTA, that may not necessarily be the case. For example, it was not the case in *AbbVie*, 764 F.3d at 1369-70. In addition, the earlier-filed application itself may not be the first application in the family. For example, OTDP can arise between two child applications or even between applications in different parts of the lineage. Accordingly, identification of related patents on the face of the earlier patent does not necessarily put the public on notice that the claimed invention is subject to later-expiring rights in another patent. Only the expiration date of the earlier patent provides the public with a stable benchmark that is not "vacillati[ng] … arbitrary, [and] uncertain" benchmark. *Gilead*, 753 F.3d at 1216.

D. Applicants Maintain Control over OTDP

Applying OTDP does not force patentees to choose between risking invalidation and filing a terminal disclaimer as a preemptive measure. In response to an OTDP rejection, an applicant can cancel or amend the claims that are not independent and distinct. The applicant can also traverse the rejection by establishing that the inventions are independent or that the combination of prior art references is not proper under Sections 102/103. Of course, the applicant can chose to file a terminal disclaimer knowing that a certificate of correction is not available later to withdraw the disclaimer. *Japanese Found. for Cancer Rsch. v. Lee*, 773 F.3d 1300, 1308-09 (Fed. Cir. 2014).

Finally, it is within the applicant's control whether to permit an OTDP patent to issue that will disrupt any PTA accumulated by another patent. The PTO provides the applicant with the estimated PTA prior to issuance, although the "official" notification would include any additional PTA between payment of the issue fee and issuance as indicated on the patent. *See* MPEP § 2733. Thus, if the applicant wishes to strategically allow the OTDP patent to issue, and therefore disrupt any PTA granted in another

patent, they are free to make that choice. But under no circumstances are they compelled to do so.

III. Equitable Considerations

As a condition of patentability (see above), OTDP has little in common with traditional equitable defenses, such as procedural unfairness (laches, estoppel) or unconscionable conduct (unclean hands). These defenses first developed in courts of equity, are not unique to patent cases, and are not conditions of patentability. Section 282 currently provides the statutory basis for these traditional equitable defenses by reference to "unenforceability," which according to its drafters includes "laches, estoppel and unclean hands." 35 U.S.C. § 282 (2018) ; s*ee* P.J. Federico, *Commentary on the New Patent Law*, 35 U.S.C.A. 1 (West 1954), *reprinted in* 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 170, 215-16 (1993).

The Court has only sparingly addressed equitable considerations in the context of OTDP. As discussed below, an OTDP prohibition based on the equitable circumstances of a given case is not a stable benchmark. Imposing a "gamesmanship" requirement could cause one invention with staggered terms to become commonplace. Only by treating OTDP as a condition of

patentability "no matter how the extension is brought about," *Hubbell*, 709 F.3d at 1145, will the prohibition continue "to preserve that bargained-for right held by the public." *Gilead*, 753 F.3d at 1212.

A. Gamesmanship Is Not a Requirement

Judge Rich entertained the possible equitable nature of OTDP and found that the prohibition "must be applied" when the applicant "was not forced into his present situation" and OTDP "was entirely of his own making." *In re Schneller*, 397 F.2d 350, 355 (C.C.P.A. 1968). In balancing the public's interest, Judge Rich stated as follows:

> Under these circumstances, even a minimal concern for the public interest requires an applicant to establish that the inventions are in fact independent and distinct and hence that *the grant of a patent on the later application will not result in a timewise extension of the protection afforded by his earlier patent*. Failing in this, an applicant's remedy lies in filing a terminal disclaimer which will effectively prevent this result.

Id. at 354 (emphasis added). Whatever the equitable nature of OTDP is, by reaching to the "grant of a patent," *id*., it remains a condition of patentability.

In *Hubbell*, the Court held that OTDP could still apply under the non-alienation principle despite a lack of common ownership. *Hubbell*, 709 F.3d at 1147-48. Nevertheless, the Court found that that a patentee who is not a

common owner "is not entitled to file [a terminal disclaimer] as an equitable measure." *Id*. at 1149. "On this circularity," according to Judge Newman's dissent, "the court denies the CalTech application on the ground of double patenting." *Id*. at 1153 (Newman, J., dissenting).

In *Immunex*, the Court characterized OTDP as an "equitable doctrine" in considering who is a common owner. *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020). The Court held that a stakeholder who satisfies a Section 281 substantial rights test can be considered an owner because it upholds the purposes of OTDP, but cautioned against importing tests from other statutory doctrines. *Id*. The Court did not address the substantive merits of OTDP, however, because it found no common ownership under the test. *Id*. at 1063.

In *Breckenridge*, the different terms resulted from the transition statute between the pre- and post-URAA schemes. *Breckenridge*, 909 F.3d at 1358. The Court found that pre-URAA law applied and, as such, the post-URAA patent is not a double patenting reference.[5] *Id*. at 1366. Thus, while not

[5] This happenstance will not likely be repeated as almost 30 years have passed since the URAA transition.

necessarily framed in terms of equity, the Court stated that "a change in patent term law should not truncate the term statutorily assigned to the pre-URAA [] patent." *Id*. at 1358. The Court also noted that, unlike the situation in *Gilead*, "the present facts do not give rise to similar patent prosecution gamesmanship because [OTDP arose] only due to happenstance of an intervening change in patent term law." *Id*. at 1364.

These statements have led some district courts to view *Gilead*, *Immunex*, and *Breckenridge* as standing for the proposition that OTDP is solely an equitable doctrine designed to prevent gamesmanship. However, there was no gamesmanship or other wrongdoing found or even alleged in *Gilead*. The "gamesmanship" language in *Gilead* appears when the Court rejects the issuance date as controlling the OTDP inquiry between two post-URAA patents. *Gilead*, 753 F.3d at 1215. The Court found that the expiration date controls because it is the only stable benchmark that is not "arbitrary, uncertain, and prone to gamesmanship." *Id*. at 1216. That language does not impose a gamesmanship requirement on OTDP. If anything, *Gilead* stands for the proposition that a patentee who has not engaged in gamesmanship is still subject to OTDP.

Finally, the two-way test's consideration of certain equitable factors in very limited circumstances is not a compelling reason to restrict the OTDP prohibition to an equitable defense. The PTO's current practice is that if "both applications are filed on the same day, only a one-way determination of distinctness is needed in resolving the issue of double patenting …." MPEP § 804.II.B.2.b. If the reference "patent is the later-filed application," then a "two-way test is to be applied." However, the test is limited to circumstances "when the applicant could not have filed the claims in a single application and the Office is solely responsible for any delays."[6] MPEP § 804.II.B.2.c. Furthermore, unless the "record clearly shows" these factors, "the examiner may use the one-way test and shift the burden to the applicant …." *Id*. With such a high burden, use of the two-way test for OTDP must be exceedingly rare. Even still, equitable considerations should not eclipse the

[6] The PTO's current restriction practice is that for "applications claiming inventions in different statutory categories, only a one-way distinctness is generally needed to support a restriction requirement." A "two-way" distinction is needed when the claims are "capable of being viewed as related in two ways, for example, as both combination-subcombination and also as species under a claimed genus, both applicable criteria for distinctness must be demonstrated to support a restriction requirement." MPEP § 806.05(c).

prohibition because OTDP applies "no matter how the extension is brought about." *Hubbell*, 709 F.3d at 1145.

B. Gamesmanship Is Not a Stable Benchmark

The district courts are presently split on whether *Gilead* imposes a gamesmanship requirement. In *Fresenius Kabi USA, LLC v. Fera Pharms., LLC* and *Magna Elecs., Inc. v. TRW Auto. Holdings Corp.*, both decided on the heels of *Gilead*, the district courts held the same view as the Board that OTDP has no gamesmanship requirement. *Fresenius*, No. 15-cv-3654 (KM)(MAH), 2016 WL 5348866, at *6-7 (D.N.J. Sept. 23, 2016); *Magna*, Nos. 1:12-cv-654 and 1:13-cv-324, 2015 WL 11430786, at *4-5 (W.D. Mich. Dec. 10, 2015). In *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*, citing *Gilead* and *Breckenridge*, the district court did not apply OTDP because it found that PTA provides "no potential for gamesmanship." *Mitsubishi*, 533 F. Supp. 3d 170, 213 (D.N.J. 2021) (quoting *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1374-75 (Fed. Cir. 2018)).

In *Amgen Inc. v. Sandoz Inc.*, No. 18-11026 (MAS)(DEA), 2021 WL 5366800 (D.N.J. Aug. 9, 2021), the district court heard evidence and made findings regarding the equities of applying OTDP to PTA:

> [T]he Court would exercise its equitable discretion not to apply the doctrine of ODP under the circumstances of this case because the difference in expiration dates … is not the result of prosecution gamesmanship or any improper conduct by Celgene. *Immunex Corp. v. Sandoz, Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020) (noting that ODP is an "equitable doctrine"); *Novartis Pharm. Corp. v. Breckenridge Pharm., Inc.*, 909 F.3d 1355, 1364 (Fed. Cir. 2018) (declining to apply ODP when difference in expiration dates was due to "happenstance of an intervening change in patent term law," rather than "prosecution gamesmanship" by the patentee); *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1210 (Fed. Cir. 2014) (applying ODP when patentee engaged in prosecution gamesmanship by structuring priority claims); *In re Braat*, 937 F.2d at 593.

Amgen, 2021 WL 5366800 at *27. From the parenthetical, the district court misunderstands *Gilead* as "applying ODP when patentee engaged in prosecution gamesmanship by structuring priority claims." *Id*. However, as discussed above, *Gilead* imposes no gamesmanship requirement.

Furthermore, the OTDP prohibition limits "a patentee to one patent term per invention or improvement." *Gilead*, 753 F.3d at 1212. Imposing a gamesmanship requirement would for the first time allow as commonplace multiple patent terms for the same invention. This is the result of both district court decisions in *Mitsubishi* and *Amgen*. With respect to the earlier-

expiring patent, such a result undermines "the whole consideration derived by the public for the grant of the patent, viz. the right to use the invention at the expiration of the term." *Id*. (quoting *Odiorne*, 18 Fed. Cas. at 579).

Finally, without any incentive for patentees to avoid OTDP, it would burden the public and PTO with evidencing gamesmanship in order to uphold the fundamental bargain. In litigation, OTDP would masquerade as an unclean hands or inequitable conduct defense. And as in *Amgen*, district courts would hear evidence and make equitable findings on whether OTDP applies. All of these things would be new and, other than gamesmanship, the contours of such an equitable doctrine are largely uncharted and unknown. This is not a stable benchmark.

CONCLUSION

For the reasons stated herein and in the Director's brief, the Court should affirm the Board.

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Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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