No. 2021-1876

In the United States Court of Appeals for the Federal Circuit

MITSUBISHI TANABE PHARMA CORPORATION; JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA NV; JANSSEN RESEARCH AND DEVELOPMENT LLC; CILAG GMBH INTERNATIONAL,

Plaintiffs-Appellees,

v.

ZYDUS PHARMACEUTICALS (USA) INC.,

Defendant-Appellant.

Appeal from the United States District Court
for the District of New Jersey in No. 3:17-cv-05319-FLW-DEA.
The Honorable **Freda L. Wolfson**, Judge Presiding.

BRIEF OF AMICUS CURIAE ALVOGEN PB RESEARCH & DEVELOPMENT LLC IN SUPPORT OF APPELLANT

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2021-1876

Short Case Caption Mitsubishi Tanabe Pharma Corporation v. Zydus Pharmaceuticals (USA) Inc.

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).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 07/13/2021

Signature: /s/ Jeremy Lowe

Name: Jeremy Lowe

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	Lotus Pharmaceutical Co., Ltd. See attached	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).

☑ None/Not Applicable ☐ Additional pages attached

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

2. Real Party in Interest Fed. Cir. R. 47.4(a)(2)

Lotus Pharmaceutical Co., Ltd.:

Alvogen Lux Holdings S.a.r.l. is the parent company of Alvogen Emerging Markets Holdings Limited (Hong Kong), which is the parent company of Lotus Pharmaceutical Co., Ltd.

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. is the parent company of Alvogen Holdings (Hungary) LLC, 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.

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INTEREST OF THE AMICUS CURIAE

Amicus curiae Alvogen PB Research & Development LLC ("Alvogen")[1] is a global specialty pharmaceutical company that frequently files ANDAs seeking approval from FDA to market its drugs. At any given time, Alvogen is engaged in several patent lawsuits under the Hatch-Waxman Act.

The district court framed the issue on appeal as "whether a later-filed, later-issued patent that expires before the earlier-filed, earlier-issued patent due to a statutorily allowed term extension under § 154(b), can act as an obviousness-type double patenting reference." Appx64. By stating the question in this way, the district court attempted to distinguish this case from this Court's decision in *Gilead*, which presented the "narrow question: Can a patent that issues after but expires before another patent qualify as a double patenting reference for that other patent?" *Gilead Scis.*,

[1] Pursuant to Fed. R. App. P. 29(a)(3), Alvogen files contemporaneously herewith its motion for leave to file this amicus brief. 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).

Inc. v. Natco Pharma Ltd., 753 F.3d 1208, 1212-13 (Fed. Cir. 2014), *cert. denied*, 575 U.S. 902 (2015). The first expiring patent in *Gilead* was earlier-filed whereas, according to the district court below, the first expiring patent in this case was later-filed.[2] Based on this narrow distinction, the district court found *Gilead* did not apply to these facts. Appx64.

The *Gilead* Court explained in detail why the expiration dates, and not the filing or issuance dates, were the important consideration in obviousness-type double patenting (OTDP). *Gilead*, 753 F.3d at 1215-16. The doctrine exists to prevent substantially duplicative patents with different expiration dates:

> We therefore hold that an earlier-expiring patent can qualify as an obviousness–type double patenting reference for a later-expiring patent under the circumstances here. In cases where such

[2] The patentee in *Gilead* sacrificed priority in the later-filed patent and, in doing so, put the later-filed patent at risk with respect to intervening prior art. *Gilead*, 753 F.3d at 1219 (Rader, J., dissenting). That is not the case in the present appeal, where the competing patents have the same priority claim. Appx64. It is this priority claim based on the effective filing date, not the actual filing date, which defines the beginning of the patent term and scope of prior art that can be raised against the patents. 35 U.S.C. § 154(a)(2); *see* MPEP § 2141 (9th ed., 10.2019 rev., June 2020).

> obviousness-type double patenting is present, a terminal disclaimer can preserve the validity of the later-expiring patent by aligning its expiration date with that of the earlier-expiring patent.

Id. at 1271. That holding does not turn on whether the OTDP reference is "later-filed, later-issued." What matters under *Gilead* is whether there is an extension in term regardless of issuance dates *or* filing dates.[3] *Id.* at 1214.

The two patents at issue in the present appeal are related[4] because they claim priority to a common parent and have the same effective filing date. Appx65. Thus, the relevant issue on appeal is whether OTDP applies

[3] The *Gilead* dissenting opinion confirmed the correct framing of the issue and this precise holding: "the court holds that in the case of competing patents, a patentee is stuck with the earliest expiration date *irrespective of filing or issue dates*." *Id.* at 1219 (Rader, J., dissenting) (emphasis added).

[4] Throughout this brief, the term "related" refers to patents that have a common ancestry, such as by way of continuation or continuation-in-part applications, but does not specifically refer to divisional applications that fall within the safe harbor provisions of 35 U.S.C. § 121.

to related patents that have different expiration dates due to Patent Term Adjustments (PTAs).[5] Alvogen has a significant interest in this issue.[6]

At least one district court previously determined that OTDP applies to related patents that have different expiration dates because of PTAs. The district court acknowledged *Magna Elecs., Inc. v. TRW Auto. Holdings Corp.*, Nos. 1:12-cv-654; 1:13-cv-324, 2015 WL 11430786, at *4-5 (W.D. Mich. Dec. 10, 2015), but did not find it persuasive.[7] Appx64 at n.44. The opinion in

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[5] OTDP commonly applies to related patents. *See*, *e.g.*, *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366 (Fed. Cir. 2014) (finding the later-expiring continuation patent that included PTA invalid for OTDP in view of the earlier-expiring parent). The MPEP also instructs United States Patent and Trademark Office (PTO) examiners to maintain OTDP rejections in both competing applications "that are entitled to the same earliest effective filing date" until the rejection is overcome by a showing of patentable distinctness or filing of a terminal disclaimer. *See* MPEP § 804(I)(B)(1)(b)(ii).

[6] That issue has arisen as part of a confidential "Notice Letter" that an Alvogen affiliate has submitted to a reference product sponsor of a patented brand drug product. Alvogen expects that a lawsuit will be filed in the coming weeks, and will provide the case title at the appropriate time pursuant to Fed. Cir. R. 47.4(a)(5).

[7] In a second case, which also arose from the District of New Jersey, but was not cited below, the district court read *Gilead* as requiring an OTDP analysis in the same circumstances as here, but it ultimately did not resolve that issue because the patentee filed a terminal disclaimer in the later-expiring patent before the court ruled. *See Fresenius Kabi USA, LLC v. Fera*

this case, therefore, establishes a split among district courts, which has created a cloud of uncertainty with respect to Alvogen's legal options, business decisions and product planning.

THE PHARMACEUTICAL INDUSTRY

The high cost of small molecule pharmaceutical products has been a national issue for many years, first giving rise to the Hatch-Waxman Act in 1984 to promote generic competition. In some ways, the Hatch-Waxman Act has been a resounding success by encouraging small molecule drug manufactures to design around patented products or to challenge the validity of the patents that protect the products. However, the cost of patent drugs continues to rise. For example, from 2006-2013, the price of brand name drugs "climbed about three times faster than the rate of inflation."[8]

Pharms., LLC, No. 15-cv-3654 (KM)(MAH), 2016 WL 5348866, at *6-7 (D.N.J. Sept. 23, 2016).

[8] Daniel J. Kevles, *Medicare, Medicaid, and Pharmaceuticals: The Price of Innovation*, 15 Yale J. Health Pol'y, L. & Ethics 241 (2015).

The rising prices for branded pharmaceutical products is often attributed to the rising cost of drug development. However, neither has necessarily resulted in increased innovation. The former Editor in Chief of The New England Journal of Medicine found that from 1998 to 2002, FDA approved 415 new drugs, but only 14 percent were "truly innovative."[9] And in 2015, an FDA study found that "rising research and development (R&D) expenditures are not being matched by a proportionate discovery of innovative medicines."[10] In fact, a study of FDA records from 2005 to 2015 found that "78% of the drugs associated with new patents in the FDA's records were not new drugs coming on the market, but existing drugs."[11]

Patent terms that extend beyond the statutory grant (such as by a substantially duplicative, later-expiring patent) exacerbate the high cost

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[9] Marcia Angell, *The Truth About The Drug Companies: How They Deceive Us and What To Do About It* (2004).

[10] U.S. Food & Drug Admin., *Targeted Drug Development: Why Are Many Diseases Lagging Behind?*, 1 (July 2015), https://www.fdanews.com/ext/resources/files/07-15/7-15-FDA-Report.pdf?1520448564 [https://perma.cc/TS9J-8UEN].

[11] Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J. L. & Biosciences 590, 598 (2018).

problem by forestalling generic competition on what is typically a non- or marginally-innovative drug product. Accordingly, this case involves an important question of law and, respectfully, counsels in favor of the continued application of a robust OTDP doctrine that is firmly rooted in the statute and historical principles.

ARGUMENT

This Court has recognized that related continuation "[p]atents claiming overlapping subject matter that were filed at the same time still can have different patent terms due to examination delays at the PTO" under § 154(b). *AbbVie*, 764 F.3d at 1373. The question presented is:

> Does OTDP apply to related patents that have different expiration dates by virtue of patent term adjustments under 35 U.S.C. § 154(b)?

As set forth herein, OTDP should apply in such circumstances because (1) it upholds the historical principles that underlie the OTDP doctrine, and (2) it is the most natural construction of § 154(b).

A. The OTDP Doctrine is Firmly Rooted in Historic Principles

"The prohibition against double patenting is a longstanding doctrine of patent law." *Gilead*, 753 F.3d at 1212. "It is based on the core principle

that, in exchange for a patent, an inventor must fully disclose his invention and promise to permit free use of it at the end of his patent term." *Id*. "The bar against double patenting was created to preserve that bargained-for right held by the public." *Id*. (citing cases).

This Court has expressly identified two justifications for OTDP—"unjustified extension" and "non-alienation." The first is "'to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about.'" *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (*quoting In re Van Ornum*, 686 F.2d 937, 943-44 (C.C.P.A. 1982)). That 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 v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894) (emphasis added).

The *Gilead* Court relied upon the principle articulated in *Miller* when it held that the focus of the inquiry is on the expiration dates of the patents, not the filing or issuance dates. 753 F.3d at 1215. Allowing the later-expiring patent in one family to have primacy over the earlier-expiring patent in another family could impermissibly result in unjustified

extensions of patent term of the earlier-expiring patent. The expiration dates provide a stable benchmark for the OTDP doctrine that is not "arbitrary, uncertain, and prone to gamesmanship." *Id*. at 1216.

To be clear, there was no gamesmanship or other wrongdoing alleged in *Gilead*. Rather, the Court reasoned that giving primacy based on the issuance date rather than the expiration date would result in a loophole that patentees could exploit. *Id.* Focusing on expiration dates and giving primacy to the earlier-expiring patent closes that loophole and allows OTDP to apply "no matter how the extension is brought about." *Hubbell*, 709 F.3d at 1145 (quoting *Van Ornum*, 686 F.2d at 943-44). Thus, *Gilead* stands for the proposition that a patentee who has followed the statute and has otherwise done nothing "unjust" is still subject to the OTDP doctrine.[12]

[12] This Court's decision in *Breckenridge* does not limit *Gilead* to the prevention of gamesmanship. Rather, *Breckenridge* closed what *Gilead* expressly left open, i.e., different expiration dates of pre- and post-URAA patents. *Novartis Pharms. Corp. v. Breckenridge Pharm., Inc.*, 909 F.3d 1355 (Fed. Cir. 2018) (citing Uruguay Round Agreements Act of 1994 (URAA), § 532, Pub. L. No. 103-465, 108 Stat. 4809, 4983 (1994)). In doing so, the Court addressed a "narrow legal question" and found that in view of the transition statute, "a change in patent term law should not truncate the term statutorily assigned to the pre-URAA [] patent." *Id*. at 1358, 1361.

The second justification of "non-alienation" "is to prevent multiple infringement suits by different assignees asserting essentially the same patented invention." *Id.* 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")). By giving primacy to the earlier-expiring patent and necessitating a terminal disclaimer to preserve the validity of the later-expiring patent, the Court in *Gilead* upheld the principle of "non-alienation."[13]

A third justification of "exhaustion," which is discussed at length in *Gilead*, also emerged from the Supreme Court's decision in *Miller* – "the power to create a monopoly is *exhausted* by the first [expiring] patent." *Miller*, 151 U.S. at 198 (emphasis added). This principle has been characterized 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

[13] In *Gilead*, the earlier-expiring patent was already terminally disclaimed over the later-expiring patent. 753 F.3d at 1210. A terminal disclaimer in the later-expiring patent would ensure common ownership throughout the entire period of enforceability of the duplicative invention claimed in both patents.

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) (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*. (emphasis added).

Gilead provides the appropriate framework for any application of the OTDP doctrine, which accounts for (1) the public's ability to act on the assumption that once a patent expires its subject matter becomes part of the public domain; (2) the prohibition against a patentee obtaining an unjustified extension of the statutory patent term, and (3) the agreement of non-alienation linking common ownership to enforceability. It did not exalt one principle over the others—all are on equal footing.

B. Applying OTDP to Related Patents with Different PTAs Upholds the Historic Principles that Underlie the Doctrine

Continuation and continuation-in-part patents have no § 121 safe harbor.[14] Only divisional patents claiming a distinct invention falling within the scope of the restriction requirement are afforded safe harbor from OTDP. 35 U.S.C. § 121. That is why § 121 "imposes 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.

Outside of the limited statutory safe harbor constrained by the requirement of patentable distinctness, only a valid § 253 terminal disclaimer allows for the common ownership of substantially duplicative patents with different expiration dates. Because there is no statutory mechanism to extend the term of the earlier-expiring patent, an effective

[14] Through the implementation of § 121, it is evident that the statute contemplates OTDP rejections for related patents. The safe harbor provides that one restricted application "shall not be used as a reference" against the other. 35 U.S.C. § 121. No such safe harbor exists with respect to continuation or continuation-in-part applications. Furthermore, this Court in *AbbVie* applied OTDP to a later-expiring child patent (that included PTA) in view of the earlier-expiring parent. *AbbVie*, 764 F.3d at 1373-74.

terminal disclaimer would operate to truncate the additional term of the later-expiring patent that extends beyond the term (including any PTA) of the earlier-expiring patent. In this way, the terminal disclaimer applied to related patents satisfies the principles that underlie the OTDP doctrine and the policies that underlie § 154.

Applying something akin to a § 121 safe harbor to related, non-divisional applications, without the statutory mooring and protection afforded by a terminal disclaimer, would essentially ignore the continued balance struck in the evolution of the Patent Act. It would be tantamount to jettisoning OTDP in all but the narrowest of circumstances for unrelated patents. And it would effectively eliminate the principles that have historically supported the OTDP doctrine.

This Court in *AbbVie* reaffirmed *Gilead* in the context of related patents:

> 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[15] of monopoly solely because it filed a separate [child] application unless the two inventions are patentably distinct.

AbbVie, 764 F.3d at 1374. Thus, in *AbbVie*, this Court found that the earlier-expiring parent patent could be an OTDP reference to the later-expiring child patent: "[t]he ban on double patenting ensures that the public gets the benefit of the invention after the original period of monopoly expires." *Id.* at 1373. In other words, *AbbVie* did not limit the *Gilead* framework to unrelated patents or solely to curb potential abuse based on sequential filings.

As to related patents, the actual filing date does not necessarily define the term and therefore, like the issuance date in *Gilead*, is a "vacillati[ng] … arbitrary, [and] uncertain" target. *Gilead*, 753 F.3d at 1216. It does not provide a stable benchmark and "preserve[] the public's right to use the invention (and its obvious variants) that are claimed in a patent

[15] In *AbbVie*, the parent patent expired in October 2012 and the child application expired in August 2018 due to, in part, approximately two years of PTA. 764 F.3d at 1370; *see AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 956 F. Supp. 2d 429, 470 (S.D.N.Y. 2013). Thus, the Court implicitly acknowledged that PTA of the child patent contributed to the "unjust extension" and forestalled the "exhaustion" of the parent patent.

when that patent expires." *Id*. Even the effective filing date, from which the term is actually measured, is not a stable benchmark when PTAs provide different expiration dates for duplicative patents having the same priority claim. The Court in *Gilead* discussed in detail why the expiration date is the only stable benchmark upon which to apply the OTDP doctrine:

> Looking instead to the earliest expiration date of all the patents an inventor has on his invention and its obvious variants best fits and serves the purpose of the doctrine of double patenting. Permitting any earlier expiring patent to serve as a double patenting reference for a patent subject to the URAA 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. Only using the expiration date as the benchmark can the principles of "exhaustion," "unjust extension" and "non-alienation" be upheld.

As to the principle of "exhaustion," the assumption underlying the principle would largely evaporate if the public were tasked to actively uncover duplicative patents having later expiration dates within these often complex patent families. The identification of related patents on the face of the patent does not necessarily put the public on notice that the patent is subject to later-expiring rights. 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 always be true, particularly if the applications were filed close in time. Furthermore, the earlier-filed application itself may not be the originally-filed parent application. The related applications may each be a separate child of a common parent or may be in different parts of the lineage with some just a thread of common ancestry. "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*. Thus, applying OTDP to related patents with different expiration dates due to PTAs upholds the principle of "exhaustion."

As to the principle of "unjustified extension," as the Court recognized in *Gilead* and *AbbVie*, what has been extended by virtue of the later-expiring patent is the full statutory term of the earlier-expiring patent. The patentee always receives its full statutory term, including any PTA, for a patent that claims the duplicative subject matter. However, there is no justification or statutory mechanism to "extend" the term of the earlier-

expiring patent such that it expires at the same time as the later-expiring patent. Thus, under *Gilead*, the earlier-expiring patent rather than the earlier-issued patent is the primary (or reference) patent for purposes of OTDP. Under the proper analysis, what OTDP "truncates" is any term beyond that statutory grant by way of invalidity or terminal disclaimer of the later-expiring secondary patent. And applying OTDP to the later-expiring patent upholds the principle against "unjust extension" of the full term of the earlier-expiring patent.

Applying OTDP to related patents also upholds the principle of "non-alienation." A terminal disclaimer in the earlier-expiring patent would not wholly mitigate the risk of separate parties suing on two patents. Upon expiration of the earlier patent, the terminal disclaimer would also expire, and the patentee would be free to assign the still-existing later-expiring patent. The only way to fully uphold the principle of "non-alienation" is to require a terminal disclaimer in the later-expiring patent, so as to ensure common ownership of the duplicative patents throughout the entire period of enforceability.

Finally, applying these historical principles does not *force* patentees to choose between risking invalidation of a later-expiring patent for OTDP and disclaiming as a protective measure any part of that patent term that extends beyond the expiration of an earlier-expiring duplicative patent. The patentee in *Gilead* allowed the earlier-expiring patent to issue *after* the later-expiring patent issued. Furthermore, the PTO calculates the estimated PTA for any given application prior to its issuance.[16] It is entirely within the applicant's control, therefore, whether to permit a duplicative patent to issue that will disrupt any PTA granted in the competing patent.

[16] The PTO employs a computer program that uses the information recorded in the PTO's automated patent application information system (the Patent Application Location and Monitoring system or PALM). The computer program determines the amount of adjustment to the term of patent pursuant to 35 U.S.C. § 154(b) and 37 C.F.R. §§ 1.702-1.704. The computer program will perform the PTA calculation at the time of issuance of the patent and will be included in the Issue Notification Letter that is mailed to applicants approximately three weeks prior to the issuance of the patent. Any request for reconsideration pursuant to 37 C.F.R. § 1.705(b) of the PTA calculation shall be made within two months of the issuance of the patent. *See* 37 C.F.R. § 1.705(b). Any request for reinstatement under 37 C.F.R. § 1.705(c) of all or part of the period of adjustment pursuant to 37 C.F.R. § 1.704(b) for failing to reply to a rejection, objection, argument, or other request within three months of the date of the Office Communication notifying the applicant of the rejection, objection, argument or other request must be filed prior to the issuance of the patent.

If the patentee wishes to strategically allow the duplicative patent to issue, and therefore disrupt any PTA granted in the competing patent, they are free to make that choice. But under no circumstances are they compelled to do so. And whatever can be said about the fairness (or unfairness) of the outcome of OTDP anchored by these historic principles must be credited to Congress's continued reliance on the applicability of OTDP and the use of the terminal disclaimer as the sole statutory mechanism that allows for common ownership of duplicative patents.

C. Applying OTDP to Related Patents with Different PTAs Upholds the Purposes of PTAs and OTDP

"Congress is understood to legislate against a background of common-law adjudicatory principles." *Arista Networks, Inc. v. Cisco Sys., Inc.*, 908 F.3d 792, 802 (Fed. Cir. 2018) (*quoting Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991)). In view of the deep history of the OTDP doctrine (*see Gilead*), this Court may "take it as given that Congress has legislated with an expectation" that OTDP will continue to apply except "when a statutory purpose to the contrary is evident." *Id.* (quoting *Isbrandtsen Co. v. Johnson*, 343 U.S. 779, 783 (1952)); *see also AbbVie*, 764 F.3d

at 1372 (discussing OTDP's roots in § 101); *Gilead*, 753 F.3d at 1212-14 (discussing OTDP's history dating back to the 19th century).[17]

Against this backdrop, the two statutory provisions relevant to this appeal are Section 253 terminal disclaimers and Section 154 patent term adjustments.

1. Section 253 Terminal Disclaimers

Congress created the terminal disclaimer in the Patent Act of 1952 in conjunction with the statutory safe harbor under § 121.[18] Prior to the introduction of the terminal disclaimer, the patent system did not permit a

[17] Furthermore, AIA § 3(b)(2) references the legislative history of the CREATE Act, which manifested the intent of Congress that courts and the PTO continue to apply OTDP and allow for terminal disclaimers in consideration of duplicative disclosures that the various amendments to the Patent Act have removed as prior art. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(b)(2), 125 Stat. 284 (2011) and H.R. Rep. No. 108-425, at 6. Thus, while the dissent in *Gilead* had "concerns" about the Court's ruling in view of the AIA, *Gilead*, 753 F.3d at 1220 (Rader, J., dissenting), such concerns must surely be mitigated by the fact that the AIA itself incorporates legislative history that encourages continued use of the OTDP doctrine.

[18] Until the creation of the safe harbor under § 121, the claims of the divisional application could still be rejected for OTDP. *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 Labs., Inc.*, 592 F.3d 1340, 1350 (Fed. Cir. 2010).

patentee to own duplicative patents. *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 OTDP was the invalidity of the last-expiring patent. With the creation of the terminal disclaimer, however, single ownership of duplicative patents became possible. *See Van Ornum*, 686 F.2d at 948.

Terminal disclaimers "provided patent owners a remedy against a double patenting charge by 'permit[ting] the patentee to cut back the term'" of the later-expiring patent so as to expire at the same time as the earlier-expired patent. *Gilead*, 753 F.3d at 1213 (*quoting Application of Robeson*, 331 F.2d 610, 614 n.4 (C.C.P.A. 1964); *see also Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1280 (Fed. Cir. 1992) (explaining that "obviousness-type double patenting … could be overcome by filing a terminal disclaimer, which had been provided for in section 253 of the 1952 Patent Act for that very purpose"). 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 *Application of Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967)).

Section 253 terminal disclaimers uphold the historic principles that underlie the OTDP doctrine. Specifically, through a terminal disclaimer, a patent owner may disclaim the portion of the patent term in the later-expiring patent that extends beyond the term of the earlier-expiring patent. 35 U.S.C. § 253; 37 C.F.R. § 1.321(c). This upholds the principles of "exhaustion" and "unjust extension." The terminal disclaimer also requires the patent owner to retain ownership over both patents.[19] *See* 37 C.F.R. § 1.321(c)(3). This upholds the principle of "non-alienation." Thus, a valid terminal disclaimer accounts for all three principles upheld in *Gilead*.

2. Section 156 Patent Term Extensions

Section 156, introduced as part of the Hatch-Waxman Act, allows for the extension of the term of a patent claiming a product that requires regulatory approval prior to being sold, such as a new drug.[20] 35 U.S.C. § 156. Significantly, this Court in *Merck* found that a patent term extension

[19] Before the 1971 promulgation of this rule, a terminal disclaimer provided that the patent would "expire immediately" if it stopped being "commonly owned." *Van Ornum*, 686 F.2d at 948 (quoting 848 Off. Gaz. Pat. Office 1 (Feb. 14, 1968)).

[20] A company needs approval from FDA before it can market a new drug. 21 U.S.C. § 355(a).

(PTE) under § 156 may be applied to an OTDP patent subject to a terminal disclaimer. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1321 (Fed. Cir. 2007). In doing so, the court upheld the purposes of both PTEs and the OTDP doctrine.

This Court in *Merck* first turned to the language of § 156. *Id*. at 1321 (*citing Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999) ("As in any case of statutory construction, our analysis begins with 'the language of the statute.' And where the statutory language provides a clear answer, it ends there."(citations omitted))). The Court noted that § 156 does not expressly reference terminal disclaimers, uses the word "shall," and that the statutory language is "unambiguous." *Id*. at 1322. Under that statute, therefore, that "[a] patent term extension under § 156 may be applied to a [single, eligible] patent subject to a terminal disclaimer."[21] *Id.* at 1324.

[21] This Court's decision in *Ezra*, upon which the district court placed significant reliance, does not address § 154, but rather is a "logical extension" of this Court's ruling in *Merck* under § 156. *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1373 (Fed. Cir. 2018) ("We conclude, as a logical extension of our holding in *Merck & Co. v. Hi-Tech Pharmacal Co.*, that obviousness-type double patenting does not invalidate a validly obtained PTE in such a scenario.").

The language of § 154, which "expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays," also supported the Court's decision. *Id.* at 1322. Without the "express prohibition" of § 154 found in § 156, the Court concluded that PTEs are "not foreclosed by a terminal disclaimer." *Id.* (citing *Leatherman v. Tarrant Cnty. Narcotics Intel. & Coordination Unit*, 507 U.S. 163, 168 (1993) (observing that an action that is expressly required under one federal rule but not included among the enumerated actions from another federal rule indicates that the action is not a requirement of the later federal rule)).

With respect to PTEs, therefore, "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. "The computation of a [PTE] is from the expiration date resulting from the terminal disclaimer …." *Merck*, 482 F.3d at 1322-23. Consequently, "the 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.

The extension of a terminally disclaimed patent arguably runs against the "exhaustion" principle that underlies the OTDP doctrine, at least during the extended term. However, the risk is mitigated by the fact that PTE patents cover a specific product and are notorious, at least in the pharmaceutical industry. Furthermore, the "legislative history of § 156 indicates that Congress was aware of concerns over the effects of extending related patents," *id.*, and chose a statutory purpose that balanced competing policies of OTDP and PTEs under very limited circumstances.

3. Section 154 Patent Term Adjustments

The passage of the American Inventors Protection Act of 1999 expanded the availability of patent term adjustments (PTAs) to broader categories of PTO delays. *See Mayo Found. for Med. Educ. & Rsch. v. Iancu*, 938 F.3d 1343, 1345 (Fed. Cir. 2019). PTAs differ from PTEs in two material respects. First, whereas PTEs are limited to a single patent covering a regulated product, PTAs potentially apply to all patents. Second, whereas § 156 allows for the PTE of a terminally disclaimed patent, § 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). In other words, unlike PTEs, the terminal disclaimer may truncate some or all of the PTA. *Merck*, 482 F.3d at 1322.

This Court in *Merck* stated that § 154 "expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays." *Id.* Although § 154(b)(1) "Patent Term Guarantees" provide for PTAs under certain enumerated conditions, each of those guarantees are "subject to the limitation" that PTAs cannot go beyond the terminally disclaimed date. Specifically, the "Guarantee of prompt patent and trademark office responses" are "[s]ubject to the limitations under paragraph (2)," § 154(b)(1)(A). The "Guarantee of no more than 3-year application pendency" are likewise "[s]ubject to the limitations under paragraph (2)," § 154(b)(1)(B). The "Guarantee of adjustments for delays due to derivation proceedings, secrecy orders, and appeals" are again "[s]ubject to the limitations under paragraph (2)," § 154(b)(1)(C).

The "limitations under paragraph (2)" referenced in each sub-section of § 154(b)(1) reads, in part, "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" 35 U.S.C. § 154(b)(2)(B).[22] Consequently, any reference that the patent "shall" be extended under these enumerated conditions in § 154(b)(1) is expressly conditioned on the limitations in § 154(b)(2). That is, with the "express prohibition" found in § 154(b)(2)(B), the guaranteed PTAs enumerated in § 154(b)(1) are foreclosed beyond the terminal disclaimer resulting from OTDP as a matter of the express statutory language of § 154.

Therefore, § 154 unambiguously fulfills the purposes of both the OTDP doctrine and PTAs by not permitting PTAs beyond the terminal disclaimer filed to overcome OTDP.

[22] Suppose related, duplicative patents A and B have the same priority claim and effective filing dates. Patent A receives PTA of one year and Patent B receives PTA of two years. OTDP requires a terminal disclaimer in Patent B such that it expires at the same time as Patent A. Consequently, under § 154(b), Patent B could still receive the benefit of at least one year of its PTA, but not the full two years, by virtue of being terminally disclaimed over Patent A that has had its term adjusted by one year. In this way, the terminal disclaimer in Patent B fulfills the purposes of both OTDP and § 154. One of those patents could then be extended under § 156 if the requisite conditions are met, thus fulfilling the purposes of both OTDP and § 156.

CONCLUSION

For these reasons, the Court should find that OTDP does apply to related patents that have different expiration dates due to patent term adjustments under 35 U.S.C. § 154(b).

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FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2021-1876

Short Case Caption: Mitsubishi Tanabe Pharma Corporation, et al v. Zydus Pharmaceuticals (USA) Inc.

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