2021-1876

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.

On appeal from the United States District Court for the District of New Jersey, Case No. 3:17-cv-05319-FLW-DEA, Hon. Freda L. Wolfson

OPENING BRIEF FOR DEFENDANT-APPELLANT

Jay R. Deshmukh
Hershy Stern
Joshua A. Whitehill
Jayita Guhaniyogi
Charles A. Naggar

KASOWITZ BENSON TORRES LLP
1633 Broadway
New York, NY, 10019
Telephone: (212) 506-1700
Email: jdeshmukh@kasowitz.com
hstern@kasowitz.com
jwhitehill@kasowitz.com
jguhaniyogi@kasowitz.com
cnaggar@kasowitz.com

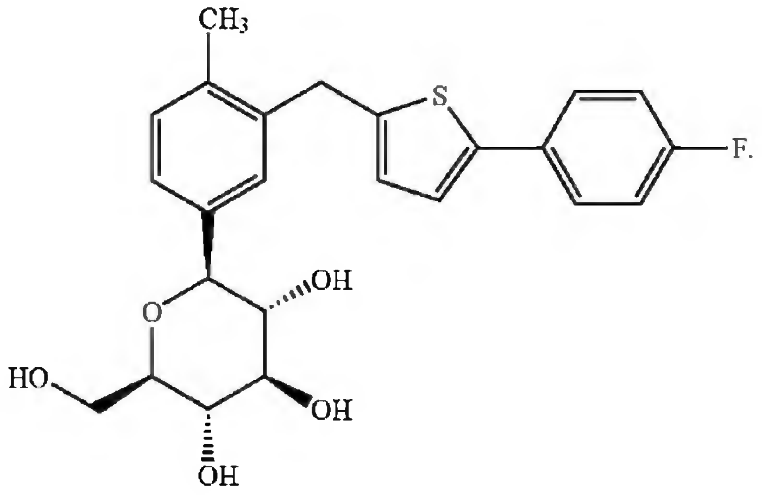
Counsel for Defendant-Appellant

July 6, 2021

Claims 12 and 20 of U.S. Patent No. 7,943,788

12. 1-(β-D-glucopyranosyl)-4-methyl-3-[5-(4-fluoro-phenyl)-2-thienylmethyl]benzene, or a pharmaceutically acceptable salt thereof.

20. A compound having the following structure:



(Appx298)

CERTIFICATE OF INTEREST

Case Number: 2021-1876

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

Filing Party/Entity: Defendant-Appellant Zydus Pharmaceuticals (USA) Inc.

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: July 6, 2021 Signature: /s/ Jay Deshmukh

Name: Jay Deshmukh

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.	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.
Zydus Pharmaceuticals (USA) Inc.	None/Not Applicable	Cadila Healthcare Limited

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).		
Saiber LLC: Sean R. Kelly, Geri L. Albin, and Katherine Ann Escanlar		
Kasowitz Benson Torres LLP: Trevor Welch (no longer with the firm) and Shelley Ivan.		
Arent Fox LLP: Bradford C. Frese, Gary A. Coad, Janine A. Carlan, and Richard J. Berman		

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).		
Mitsubishi Tanabe Pharma Corporation et al. v. Dr. Reddy's Laboratories, Inc. et al., Civil Action No. 3:19-cv-18764 (D.N.J.)		

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		

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

STATEMENT OF RELATED CASES

Pursuant to Fed. Cir. R. 47.5, Appellant states that no appeal from this same civil action was previously before this or any other appellate court.

Appellant further states that it is aware of the following other pending case that may directly affect or be directly affected by this court's decision in the pending appeal: *Mitsubishi Tanabe Pharma Corporation et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 3:19-cv-18764 (D.N.J.). That case concerns U.S. Patent No. 7,943,788, which is also the subject of the pending appeal.

The parties to this appeal are also engaged in a separate district court litigation concerning Appellant's same proposed generic pharmaceutical products that are at issue in this appeal, but different patents: *Mitsubishi Tanabe Pharma Corporation et al. v. Sandoz Inc. et al.*, Civil Action No. 1:17-cv-5005 (consolidated) (D.N.J.).

STATEMENT OF JURISDICTION

Defendant/Appellant Zydus Pharmaceuticals (USA) Inc. ("Zydus") timely appeals from a final judgment of the United States District Court for the District of New Jersey in a patent infringement action. The district court had jurisdiction over the parties' claims and counterclaims under 28 U.S.C. §§ 1331, 1338(a), and 2201 and 21 U.S.C. § 355(c)(3)(D). This Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

STATEMENT OF ISSUES PRESENTED

Whether the district court erred in rejecting Appellant's obviousness-type double patenting invalidity defense against the '788 patent by holding that the earlier-expiring '219 patent does not qualify as a double patenting reference against the later-expiring, commonly owned '788 patent, where the '788 patent expires later on account of having received a patent term adjustment pursuant to 35 U.S.C. § 154(b).

INTRODUCTION

The rule against obviousness-type double patenting ("OTDP") is a longstanding common-law doctrine that prevents a patent owner from obtaining two separate patents covering substantially similar, or "patentably indistinct," subject matter. Under this doctrine, if an asserted claim is patentably indistinct from a claim in an earlier, commonly-owned patent (*i.e.*, a "reference patent"), the asserted claim is invalid. In *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), this Court held that "the determining factor" for assessing which patent qualifies as an "earlier" OTDP reference against the other is the patents' expiration dates, establishing the general rule that "an earlier-expiring patent can qualify as an obviousness-type double patenting reference for a later-expiring patent[.]" *Id.* at 1215-17. This rule serves the "bedrock principle of our patent system 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." *Id.* at 1214.

The undisputed facts of this case establish that (a) U.S. Patent Nos. 7,943,788 ("the '788 patent") and 8,222,219 ("the '219 patent") are commonly-owned, (b) the '788 patent is set to expire more than two years after the '219 patent, and (c) the asserted claims of the '788 patent are patentably indistinct from claim 22 of the '219 patent. Thus, under this Court's precedent, the '219 patent

qualifies as an invalidating OTDP reference against the '788 patent, unless one of this Court's exceptions applies. But no such exception applies here.

That the '788 patent expires later only on account of having been granted a patent term adjustment ("PTA") pursuant to 35 U.S.C. § 154(b)[1] is of no moment. Under § 154(b), the United States Patent and Trademark Office ("PTO") may grant a patent a period of additional patent life due to PTO delays during the patent prosecution process, but § 154 does not at all exempt a patent from still complying with the rule against OTDP. To the contrary, as this Court noted in reaffirming *Gilead*, in situations where "[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[,] … the doctrine of obviousness-type double patenting ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension." *AbbVie, Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1372 (Fed. Cir. 2014) (citing, *inter alia*, 35 U.S.C. § 154(b)).

Moreover, § 154(b) specifically contemplates the applicability of OTDP by barring terminally disclaimed patents from benefiting from PTAs. *See* 35 U.S.C. § 154(b)(2)(B) ("No patent the term of which has been disclaimed beyond a

---

[1] Unless otherwise indicated, citations to statutes and regulations herein are to their current versions.

specified date may be adjusted under this section beyond the expiration date specified in the disclaimer."). A terminal disclaimer is a statutory mechanism that causes the later-expiring patent to expire at the same time as the earlier-expiring OTDP reference patent, thereby "supplant[ing] a finding of invalidity for double patenting" by fulfilling one of the doctrine's main goals of "prevent[ing] an inventor from securing a second, later expiring patent for the same invention." 35 U.S.C. § 253(b); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1373 (Fed. Cir. 2005); *AbbVie*, 764 F.3d at 1373; *Gilead*, 753 F.3d at 1213-14. The terminal disclaimer bar to PTAs in § 154(b), thus, reflects clear congressional intent that the roughly two century-old rule against OTDP should remain in full effect regardless of any PTO delays or eligibility for a PTA. Thus, when the '219 patent expires, the public should be free to use the '219 patent's claimed invention and the patentably indistinct modifications claimed in the '788 patent. *See Gilead*, 753 F.3d at 1214.

In rejecting Zydus's OTDP defense, the district court turned precedent on its head, erroneously concluding that the '219 patent cannot legally qualify as an OTDP reference against the '788 patent solely because the '788 patent expires later due to having received a § 154(b) PTA. Appx64-66. To reach that conclusion, the district court unduly expanded the narrow exception to OTDP that this Court carved out specifically for patent term extensions ("PTEs") under 35 U.S.C. § 156.

See Novartis AG v. Ezra Ventures LLC, 909 F.3d 1367, 1374-75 (Fed. Cir. 2018) (holding that a § 156 PTE cannot create an OTDP problem). As this Court has held, § 156 is a substantively different statute than § 154(b). See *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1322 (Fed. Cir. 2007) ("§ 154(b)(2)(B) expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays. There is no similar provision that excludes patents in which a terminal disclaimer was filed from the benefits of Hatch-Waxman extensions [under § 156]."). To expand *Ezra*'s narrow exception for § 156 PTEs to apply to § 154(b) PTAs, as the district court did below, defies the very logic for creating the PTE exception in the first place and permits the narrow exception to swallow the rule.

The district court further erred as a matter of law by requiring a showing of "gamesmanship." The invalidity defense of OTDP does not require a showing of gamesmanship, deceptive intent, or any other impropriety or *mens rea*. In any event, the district court's ruling clearly creates a potential for gamesmanship by significantly amplifying the value of avoiding OTDP rejections, and the resulting need to file terminal disclaimers, during prosecution. By treating OTDP disparately during prosecution and in post-prosecution litigation, the district court's ruling creates an exploitable loophole that incentivizes patent applicants to orchestrate prosecution in a manner that strategically avoids OTDP rejections

during prosecution, to obtain a § 154(b) PTA that would otherwise be unavailable if a terminal disclaimer was filed during prosecution and at the same time is immune from OTDP in post-prosecution litigation. Congress could not have possibly intended such an incongruous result that would discourage full and open disclosure to the PTO and permit circumvention of § 154(b)(2)(B).

The OTDP issue on appeal is an important question of law that will impact numerous other pending and future cases,[2] has been decided differently by at least one other district court,[3] and thus requires this Court's clarification of the law.

STATEMENT OF THE CASE

A. The Nature of the Case

This is an appeal from a district court judgment in a patent infringement litigation under the Hatch-Waxman Act. Appx2245. The case arises under 35 U.S.C. § 271(e)(2) from Zydus's submission of Abbreviated New Drug Applications ("ANDAs") seeking U.S. Food and Drug Administration ("FDA") approval of

---

[2] For example, the parties in this appeal are engaged in a separate pending action concerning a different canagliflozin patent that presents this very same legal question. *See Mitsubishi Tanabe Pharma Corp. v. Aurobindo Pharma USA, Inc.*, No. 17-cv-5005 (D.N.J.). Other cases involve the very same issue. *See, e.g., Kove IO, Inc. v. Amazon Web Services, Inc.*, No. 18-cv-8175 (N.D. Ill.), D.I. 304.

[3] *See Magna Elecs., Inc. v. TRW Auto. Holdings Corp.*, No. 12-654, 2015 WL 11430786 (W.D. Mich. (Dec. 10, 2015)).

generic canagliflozin drug products before the expiry of certain patents that purportedly cover the reference branded products. Appx4-5; Appx2244-2245.

B. The Parties and Their Products

Zydus is a New Jersey corporation that is engaged in the development, manufacture, and sale of generic drug products in the United States. Appx6; Appx2142; Appx2245. In 2017, Zydus filed ANDA Nos. 210541 and 210542, seeking FDA-approval to market generic versions of INVOKANA® and INVOKAMET®, respectively, prior to the expiration of the '788 and '219 patents and U.S. Patent No. 8,785,403 ("the '403 patent"), which are listed in the FDA's Orange Book with respect to the branded products. Appx4-6; Appx2244-2245.

Appellees collaborate in the patenting and marketing of INVOKANA® and INVOKAMET® in the United States. *Id.*

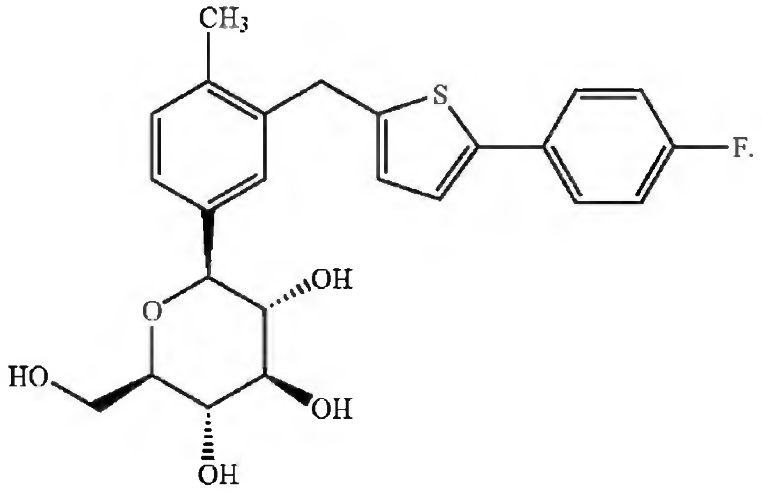
C. The Patent-at-Issue

The '788, '219, and '403 patents are part of the same patent family and concern canagliflozin and related compounds. Appx4-7; Appx2246-2248. This appeal concerns the validity of just claims 12 and 20 of the '788 patent, which Zydus contends are invalid for OTDP based on claim 22 of the '219 patent. Appx298; Appx414.

Claims 12 and 20 of the '788 patent, reproduced below, are directed to the same compound, canagliflozin:

> 12. 1-(β-D-glucopyranosyl)-4-methyl-3-[5-(4-fluoro-phenyl)-2-thienylmethyl]benzene, or a pharmaceutically acceptable salt thereof.

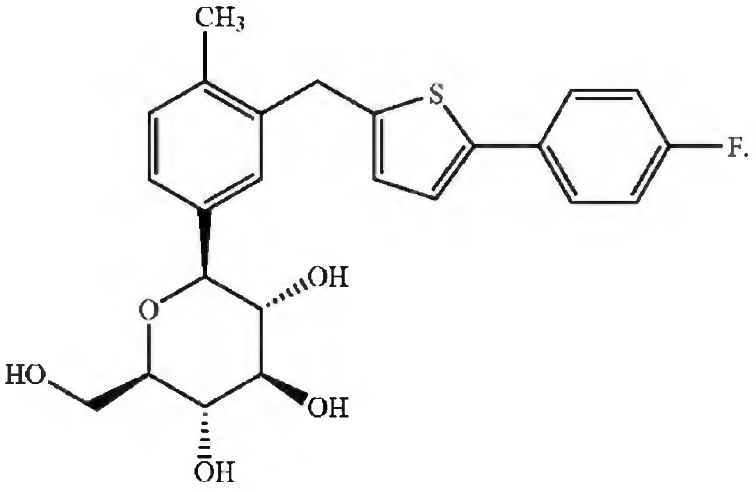
> 20. A compound having the following structure:



Appx6-7; Appx298.

Claim 22 of the '219 patent, reproduced below together with claims 20 and 21 from which it depends, covers a method of using canagliflozin to treat type 2 diabetes mellitus:

> 20. A method for treating or delaying the progression or onset of a disease selected from diabetes mellitus, diabetic retinopathy, diabetic neuropathy, diabetic nephropathy, delayed wound healing, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids, elevated blood levels of glycerol, hyperlipidemia, obesity, hypertriglyceridemia, Syndrome X, diabetic complications, atherosclerosis, and hypertension, which comprises administering to a mammalian species in need of treatment a therapeutically effective amount of a compound having the following structure:



21. The method according to claim 20, wherein the disease is diabetes mellitus.

22. The method according to claim 21, wherein the disease is type 2 diabetes mellitus.

Appx7-8; Appx414.

1. The Relevant Patent Family

The '788 patent-at-issue and the '219 reference patent stem from the same international application. Appx6-8. Four applications in this patent family are relevant to this appeal:

First, on July 30, 2004, the applicants filed International Application No. PCT/JP2004/011312 ("the international application"). Appx6; Appx2246.

Second, on January 31, 2005, the applicants filed U.S. Application No. 11/045,446 ("the '446 application") as a continuation-in-part of the international application. *Id.* On May 17, 2011, the '446 application issued as the '788 patent.

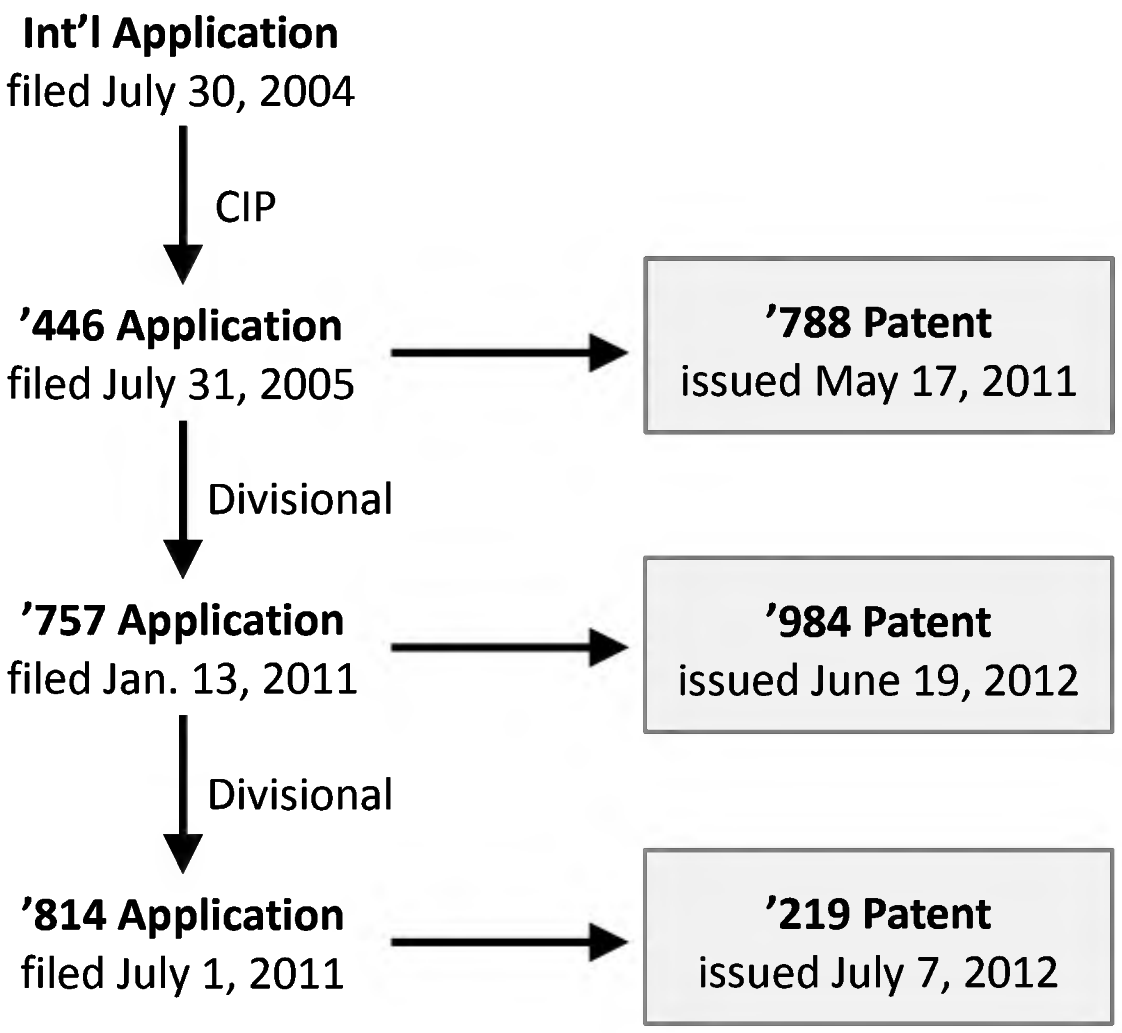
Id.; Appx182. The '788 patent is the patent-in-suit that Zydus contends is invalid for OTDP.

Third, on January 13, 2011, the applicants filed Application No. 13/005,757 ("the '757 application") as a purported divisional of the '446 application. Appx7; Appx2247. The patent that ultimately issued from the '757 application, U.S. Patent No. 8,202,984 ("the '984 patent"), was not asserted in this litigation. *See* Appx416 ("a division of application No. 13/005,757, filed on Jan. 13, 2011, now Pat. No. 8,202,984").

Fourth, on July 1, 2011, the applicants filed Application No. 13/174,814 ("the '814 application") as a purported divisional of the '757 application. Appx7; Appx2247. On July 17, 2012, the '814 application issued as the '219 patent.[4] *Id.*; Appx300. Zydus contends that the '219 patent qualifies as an OTDP reference against the '788 patent.

The relationships between these applications are illustrated below:

[4] The '403 patent, a continuation of the '219 patent, has no bearing on this appeal. Appx416.



2. Patent Expiration Dates

The '788 and '219 patents' statutory 20-year terms are measured from the international application's July 30, 2004 filing date. Accordingly, absent any extensions or adjustments, both patents would have been set to expire on July 30, 2024. Appx60-61.

Upon issuance, however, the '788 patent was granted a PTA pursuant to 35 U.S.C. § 154(b), extending the 20-year term of the patent by 1,079 days (*i.e.*,

nearly 3 years). Appx61. As a result, the '788 patent is currently set to expire on July 14, 2027, instead of July 30, 2024. *Id.*

The '219 patent, in contrast, did not receive a §154(b) PTA, but was granted a PTE pursuant to 35 U.S.C. § 156 that extends its term by 254 days beyond July 30, 2024. *Id.* As a result, the '219 patent will expire on April 11, 2025. *Id.* The '219 patent's PTE is not in dispute.

No terminal disclaimer has been filed against the '788 patent. Without any disclaimer, the '788 patent's expiry is more than two years after that of the later-filed '219 patent.

D. The Proceedings Below

On July 20, 2017, Plaintiffs filed a Complaint alleging that Zydus infringes the '788, '219, and '403 patents by virtue of having filed its ANDAs. Appx2140-2142, Appx2245. Prior to trial, Zydus stipulated to infringement, but maintained its invalidity defenses. Appx2213-2217.

The district court conducted a six-day remote bench trial over Zoom commencing on September 24, 2020, regarding the validity of the asserted claims of the three patents-in-suit. Appx5; Appx176-178. The first five trial days were primarily devoted to the issue of obviousness under 35 U.S.C. § 103, and the last day, November 5, 2020, was devoted to OTDP. *Id.* On that last day, the district court heard opening statements regarding OTDP, followed by testimony from each

sides' patent prosecution experts on issues relating to the applicability of the 35 U.S.C. § 121 safe-harbor. Appx1866-1870.

After the parties submitted proposed post-trial findings of fact and conclusions of law, Plaintiffs moved to strike three OTDP-related arguments in Zydus's papers that Plaintiffs contended were not previously raised. Appx178-179. On December 8, 2020, the district court issued an order denying two of the three parts of Plaintiffs' motion, but granting the third. Appx132-134. The district court found it "appropriate for Zydus to respond to" Plaintiffs' gamesmanship arguments and also permitted Zydus to argue that "the safe harbor cannot protect the '788 patent because the '219 was filed after the issuance of the '788 patent." Appx132-133. The district court, however, struck "Zydus's argument that a restriction requirement in the '984 patent prosecution prevents application of the safe harbor" because "the prosecution history of the '984 patent was not made part of the trial record nor does it appear that the patent was mentioned in any way during trial" and declined Zydus's request for the district court to take judicial notice of the prosecution history of the '984 patent. Appx134. The district court accepted Plaintiffs' request for oral argument on the two unstricken arguments, which the court heard on December 22, 2020. Appx2097-2100.

On March 22, 2021, the district court issued an Order (Appx67-68) and Opinion (Appx69-131), upholding the validity of all asserted claims of the patents-

in-suit. The district court subsequently corrected minor errors in the original Opinion and, on April 7, 2021, issued a Redacted & Corrected Opinion (hereinafter, "Opinion"). Appx4-66.

In its Opinion, the district court rejected Zydus's OTDP defense because the court concluded that the '219 patent did not qualify as an OTDP reference against the '788 patent, despite the commonly-owned '219 patent being the earlier-expiring patent. Appx60-66. The district court noted that "the Federal Circuit has not . . . had occasion to consider the instant situation[,]" but found that "in light of the Federal Circuit's decisions in *Ezra* and *Breckenridge*, ... the '219 Patent is not a proper reference to invalidate the '788 Patent under the principles of obviousness-type double patenting." Appx64. The district court found that "as in *Ezra* this case does not raise the traditional concern with obviousness-type double patenting of a patent owner 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.'" Appx64-65 (citing *Ezra*, 909 F.3d at 1374; internal quotation marks omitted). The district court stated that, "[u]nlike in *Gilead*, the granting of a PTA does not present the potential for gamesmanship by inventors to secure a second, later expiring patent for the same invention." Appx65. The district court further stated: "Perhaps more importantly, however, the district Court is swayed by the Federal Circuit's observation that 'a judge-made doctrine' should not be used to

'cut off a statutorily-authorized time extension.' Appx66. Agreeing with Zydus's position would mean just that." *Id.* (citing *Ezra*, 909 F.3d at 1375). The district court expressly declined to consider the parties' arguments on the safe-harbor issue. Appx66.

On April 5, 2021, the district court entered Final Judgment in favor of Plaintiffs. Appx1-3. Zydus timely appealed. Appx4282-4285.

SUMMARY OF THE ARGUMENT

The district court committed reversible error by rejecting Zydus's defense that asserted claims 12 and 20 of the '788 patent are invalid for OTDP in view of claim 22 of the '219 patent.

1. The undisputed record establishes that (a) the '788 and '219 patents are commonly owned, (b) the '788 patent is set to expire more than two years after the '219 patent's expiry, and (c) the asserted claims of the '788 patent are not patentably distinct from claim 22 of the '219 patent. Under these undisputed facts and this Court's precedent in *Gilead* and *AbbVie*, the earlier-expiring '219 patent qualifies as an OTDP reference against the later-expiring '788 patent, and the patentably indistinct asserted claims of the '788 patent are invalid. *See Gilead*, 753 F.3d at 1214-17; *AbbVie*, 764 F.3d at 1373-74.

2. That the '788 patent expires later only on account of having received a § 154(b) PTA does not change this conclusion. Indeed, this Court has

acknowledged that § 154(b) PTAs can cause related patents to expire at different times, which is the type of "problem" that the doctrine of OTDP was designed to correct to "ensure[] that a particular invention (and obvious variants thereof) does not receive an undue patent term extension." *AbbVie*, 764 F.3d at 1373. Furthermore, § 154(b)(2)(B) expressly bars terminally disclaimed patents (*i.e.*, patents whose terms the patentee voluntarily shortened to overcome an OTDP problem) from benefiting from PTAs. Thus, Congress clearly intended OTDP to apply in full force to patents that are otherwise eligible for § 154(b) PTAs.

3. The district court erred as a matter of law in concluding that the '219 patent does not qualify as an OTDP reference against the '788 patent. Appx61-66. In so concluding, the district court failed to appreciate the significance of § 154(b)'s express bar for terminally disclaimed patents, and the intertwined nature of terminal disclaimers and OTDP. Appx65. Instead, the district court wrongly expanded *Ezra*'s narrow OTDP exception, which this Court had carved out specifically for § 156 PTEs, to cover § 154(b) PTAs too. Appx64-66.

a. Unlike § 154(b), § 156 is silent as to the impact of terminal disclaimers. Based on this very textual distinction, this Court has held that Congress must have intended § 156 PTEs to be immune from the effects of terminal disclaimers. *Merck*, 482 F.3d at 1322. *Ezra*, in turn, was merely a "logical extension" of this Court's holding in *Merck*, and similarly concluded that

§ 156 PTEs cannot create OTDP problems. *Ezra*, 909 F.3d at 1373-74. *Ezra*'s narrow exception for § 156 PTE therefore stemmed from § 156's silence regarding terminal disclaimers, in contrast to § 154(b)'s express bar of PTAs for terminally disclaimed patents. The district court's expansion of *Ezra* to shield § 154(b) PTAs from OTDP therefore causes the exception to swallow the rule.

b. The district court was wrongly "swayed by the Federal Circuit's observation [in *Ezra*] that 'a judge-made doctrine' should not be used to 'cut off a statutorily-authorized time extension.'" Appx66 (citing *Ezra*, 909 F.3d at 1375). While that "observation" may have made sense in the specific context of § 156, which does not reference terminal disclaimers or OTDP, it is inapplicable to § 154(b), which specifically contemplates the applicability of OTDP. Under Supreme Court precedent, "where a common-law principle is well established, the courts may take it as given that Congress has legislated with an expectation that the principle will apply except when a statutory purpose to the contrary is evident." *See Arista Networks, Inc. v. Cisco Sys., Inc.*, 908 F.3d 792, 802 (Fed. Cir. 2018) (citations and quotation marks omitted). Given that OTDP is a "well-established," "longstanding doctrine of patent law" that the "Federal courts for over a century have applied" (*Gilead*, 753 F.3d at 1212-13), § 154(b) should be interpreted with understanding that OTDP is applicable to patents that are otherwise eligible for PTAs, particularly given that the statute specifically contemplates its applicability.

The district court therefore erred in expanding *Ezra*'s "observation" regarding § 156 to § 154(b).

c. The district court's opinion was also flawed because it required a showing of "gamesmanship" and found no "potential for gamesmanship" in the context of § 154(b) PTAs. Appx65-66. The invalidity defense of OTDP does not require a showing of gamesmanship, deceptive intent, or any other impropriety or *mens rea*. In any event, the district court's ruling creates significant potential for gamesmanship. Patent applicants are readily capable of tracking which and to what extent applications have faced PTO delays and are therefore eligible for § 154(b) PTAs. Applicants can use that information strategically to orchestrate the timing and applications in which to prosecute their claims to obtain the longest PTAs and avoid OTDP rejections for their most valuable claims. Under the district court's ruling, if an applicant can avoid an OTDP problem during prosecution and thereby avoid the need to file a terminal disclaimer during prosecution, the applicant can then receive the full benefit of a § 154(b) PTA in the resulting patent. If, however, the applicant discloses the OTDP problem during prosecution and files a terminal disclaimer, § 154(b)(2)(B) would then bar the resulting patent from benefiting from any PTA. Such an incongruous result is be contrary to congressional intent in enacting the terminal disclaimer bar to PTAs in

§ 154(b)(2)(B) and contrary to good patent policy that aims to encourage full and open disclosure during prosecution.

4. The district court expressly declined to decide Appellees' rebuttal argument below that a finding of OTDP is foreclosed by the safe-harbor of § 121. Appx66. Because Appellees failed to go forward with evidence sufficient to trigger the safe-harbor's potential application, this Court should reverse the district court's OTDP ruling and need not remand for the district court to make a safe-harbor determination.

ARGUMENT

I. LEGAL STANDARD

A. Legal Framework of Obviousness-Type Double Patenting

"A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for [OTDP]." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001). Invalidity based on OTDP "must be proven by clear and convincing evidence." *AbbVie*, 764 F.3d at 1372.

"The prohibition against double patenting is a longstanding doctrine of patent law … 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." *Gilead*, 753 F.3d at 1212 (discussing basis and history of OTDP, dating back to the 19th century). "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." *Id.* at 1212-13.

"While often described as a court-created doctrine, obviousness-type double patenting is grounded in the text of the Patent Act." *AbbVie*, 764 F.3d at 1372. The doctrine was created to "prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (quoting *Perricone*, 432 F.3d at 1373).

"There are two justifications for obviousness-type double patenting." *Id.* "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.'" *Id.* (quoting *In re Van Ornum*, 686 F.2d 937, 943-44 (C.C.P.A. 1982)); *see also Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1346 (Fed. Cir. 2010) ("[OTDP] prevent[s] the extension of the term of a patent ... by prohibiting the issuance of the claims in a second patent not patentably distinct from the claims of the first patent." (quoting *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985))). "The

second rationale is to prevent multiple infringement suits by different assignees asserting essentially the same patented invention." *Hubbell*, 709 F.3d at 1145.

"Generally, an obviousness-type double patenting analysis entails two steps." *Eli Lilly*, 251 F.3d at 968. "First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences." *Id.* Second, the district court determines whether the differences in subject matter between the two claims render the claims patentably distinct." *Id.* "A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." *Id.*

"[A]n earlier-expiring patent can qualify as an obviousness-type double patenting reference for a later-expiring patent[.]" *Gilead*, 753 F.3d at 1217. The patents' expiration dates—not their issuance dates—are "the determining factor for double patenting inquiries." *Id.* at 1215-16. "Permitting any earlier expiring patent to serve as a double patenting reference for a patent subject to the URAA [*i.e.*, The Uruguay Round Agreements Act of 1994] 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.* at 1216. "[U]sing the expiration date as a benchmark in post-URAA cases of obviousness-type double patenting preserves the ability of inventors to use a terminal disclaimer of later-expiring patents to create one expiration date for their term of exclusivity over their

inventions and obvious variants[.]" *Id.* The concepts of OTDP and terminal disclaimers are thus highly intertwined.

"While the ultimate conclusion that a patent is invalid under the doctrine of obviousness-type double patenting is reviewed *de novo*, the underlying factual determinations . . . are reviewed for clear error." *AbbVie*, 764 F.3d at 1372.

1. Effect of Terminal Disclaimers on Double Patenting

A terminal disclaimer is a voluntary and intentional relinquishment by the patentee of "the entire term, or any terminal part of the term, of the patent granted or to be granted." 35 U.S.C. § 253(b). "In cases where … 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." *Gilead*, 753 F.3d at 1217; *see also Perricone*, 432 F.3d at 1375 ("A terminal disclaimer can indeed supplant a finding of invalidity for double patenting."). "[A] terminal disclaimer 'causes such ... patents to expire together, a situation ... which is tantamount for all practical purposes to having all the claims in one patent.'" *Gilead*, 753 F.3d at 1213-14 (quoting *Application of Braithwaite*, 379 F.2d 594, 601 (C.C.P.A. 1967)). Indeed, terminal disclaimers "'had been provided for in section 253 of the 1952 patent act for that very purpose.'" *Id.* at 1213-14 (quoting *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1280 (Fed. Cir. 1992)).

2. Patent Term Adjustments under § 154(b)

Under the current statute, the term of a U.S. patent normally expires 20 years from the patent's earliest claimed U.S. application filing date, 35 U.S.C. § 154(a)(2); but that was not always the case. "The Uruguay Round Agreements Act of 1994, which became effective on June 8, 1995, changed the term for a U.S. patent from seventeen years from the patent issue date to twenty years from the earliest effective filing date." *See Gilead*, 753 F.3d at 1211; *see also* URAA, Pub. L. No. 103-465, 108 Stat 4809 (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"). "Because time spent in the PTO could now eat up part of the patent term, Congress also provided a list of specific situations in which the patent owner could seek an adjustment of the patent's term to offset delays in the PTO." *Chudik v. Hirshfeld*, 987 F.3d 1033, 1035 (Fed. Cir. 2021).

Under the URAA's then-new patent term regime, expiration dates would be calculated from the date of filing, but could be extended by a PTA for up to five years if prosecution was delayed by interference proceedings, secrecy orders, or appellate review of the application. 35 U.S.C. § 154(b) (1994). The new law, however, expressly foreclosed such an extension based on appellate review where the patent was "subject to a terminal disclaimer." *Id.* § 154(b)(2) ("A patent shall

not be eligible for extension under this paragraph if it is subject to a terminal disclaimer due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review").

In 1999, Congress partially rewrote § 154 to expand the availability of PTAs to broader categories of PTO delays. *See Mayo Found. for Med. Educ. & Research v. Iancu*, 938 F.3d 1343, 1345 (Fed. Cir. 2019). As part of that amendment, Congress deleted the "subject to a terminal disclaimer" exception language in § 154(b)(2) and rewrote it more broadly as new subparagraph (2)(B), which states as follows:

> 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.

Consolidated Appropriations Act, 2000, Pub. L. No. 106-113, § 4402, 113 Stat 1501, 1501A-559 (1999). Thus, in its current form, "§ 154(b)(2)(B) expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays." *Merck*, 482 F.3d at 1322.

In 2014, the Federal Circuit upheld the continued viability of applying the doctrine of OTDP to post-URAA patents, despite the URAA's change from a 17-years-from-issuance patent term regime to a 20-years-from-earliest-filing regime. *See AbbVie*, 764 F.3d at 1372-74. In maintaining the longstanding doctrine of OTDP, the Court recognized OTDP's "crucial purpose of … prevent[ing] an

inventor from securing a second, later expiring patent for the same invention"—a "problem [that] still exists" under the URAA. *Id.* As one of just two examples of the persistence of this problem under the URAA, the Court cited § 154(b) PTAs, under which "[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." *Id.* (citing, *inter alia*, 35 U.S.C. § 154(b)). The Court concluded that "[w]hen such situations arise, the doctrine of obviousness-type double patenting ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension." *Id.*

3. Patent Term Extensions under § 156

For patents covering FDA-approved drugs, 35 U.S.C. § 156 permits a patentee in certain situations to select a single patent covering the drug to receive a patent term extension (PTE) of up to five years. 35 U.S.C. § 156; *see Merck*, 482 F.3d at 1320-21. Section 156 was codified as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (*i.e.*, the Hatch-Waxman Act) to "restore the 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 a regulatory agency (*e.g.*, Food and Drug Administration approval)." *Ezra*, 909 F.3d at 1369. As such, "[t]he Hatch-Waxman Act provided for patent term extensions in § 156 to partially compensate NDA applicants" for the loss of patent

life during regulatory review. *Biogen Int'l GmbH v. Banner Life Scis. LLC*, 956 F.3d 1351, 1355 (Fed. Cir. 2020).

Unlike § 154(b), however, § 156 does not mention terminal disclaimers. *Merck*, 482 F.3d at 1322. Thus, unlike with a § 154(b) PTA, a terminal disclaimer cannot negate a § 156 PTE, which can operate to extend a patent's term even beyond a terminally disclaimed expiration date. *Id.* at 1322 ("The express prohibition [in § 154(b)] against a term adjustment regarding PTO delays, the absence of any such prohibition [in § 156] regarding Hatch-Waxman extensions, and the mandate in § 156 that the patent term shall be extended if the requirements enumerated in that section are met, support the conclusion that a patent term extension under § 156 is not foreclosed by a terminal disclaimer.").

Correspondingly, in *Ezra*, this Court found "as a logical extension of this court's holding in *Merck*" that the grant of § 156 PTE cannot in-and-of-itself create an OTDP problem, holding that an earlier-expiring patent may not be used as an OTDP reference against a patent that expired later only on account of having received a § 156 PTE. *Ezra*, 909 F.3d at 1375. The Court in *Ezra*, however, did not rule on the impact of a § 154(b) PTA on OTDP.

B. The § 121 Safe-Harbor

35 U.S.C. § 121 contains a safe-harbor provision that can protect a patent from otherwise being invalidated as a result of OTDP if certain requirements are met. Section 121 states 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 (bolding added). The safe-harbor provision, the third sentence of § 121 (in bold, above), "in certain circumstances protects a patent that issues on a divisional application from invalidation based on a related patent that issued on an application as to which a restriction requirement was made, or on an application filed as a result of such a requirement." *G.D. Searle LLC v. Lupin Pharm., Inc.*, 790 F.3d 1349, 1352 (Fed. Cir. 2015).

The Federal Circuit "appl[ies] 'a strict test' for application of section 121, 'given the potential windfall a patent term extension could provide to a patentee.'" *Id.* at 1354 (quoting *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1382 (Fed. Cir. 2003)); *see also Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1353 (Fed. Cir. 2009) (requiring "a strict application of the plain language of § 121"). Among other stringent requirements, a party invoking the § 121 safe-harbor must show that both the challenged patent and the reference patent were filed "as a result of" a restriction requirement. *Boehringer*, 592 F.3d at 1352; *G.D. Searle*, 790 F.3d at 1354.

"Whether the requirements of [35 U.S.C.] § 121 have been satisfied is a question of law that [this Court] address[es] *de novo*." *In re Janssen Biotech, Inc.*, 880 F.3d 1315, 1321 (Fed. Cir. 2018).

II. The Earlier-Expiring '219 Patent Qualifies as a Double Patenting Reference Against the Later-Expiring '788 Patent

The Federal Circuit should reverse the district court's erroneous ruling that claims 12 and 20 of the '788 patent are not invalid for OTDP. The undisputed facts of this case establish:

(a) the '788 and '219 patents are commonly-owned (Appx2244);

(b) the '219 patent is set to expire more than two years before the '788 patent (Appx61); and

(c) claims 12 and 20 of the '788 patent claim the same compound (canagliflozin) as that recited in claim 22 of the '219 patent, and are therefore not patentably distinct, Appx2246-2247, Appx830-832.[5]

Based on these undisputed facts, the district court should have found under this Court's precedent that the earlier-expiring '219 patent qualifies as an OTDP reference against the commonly-owned '788 patent and that claims 12 and 20 of the '788 patent are therefore invalid for OTDP in view of patently indistinct claim 22 of the '219 patent. *See Eli Lilly*, 251 F.3d at 968 ("A later claim that is not patentably distinct from an earlier claim in a commonly owned patent is invalid for obvious-type double patenting."); *Gilead*, 753 F.3d at 1215-17 (" [A]n earlier-expiring patent can qualify as an obviousness-type double patenting reference for a later-expiring patent[.]"); *AbbVie*, 764 F.3d at 1374 ("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.").

That the '788 patent expires later only on account of having received a § 154(b) PTA is of no moment. After all, "it is a bedrock principle of our patent system 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

---

[5] "A claim cannot be patentably distinct over anticipatory subject matter." *Geneva*, 349 F.3d at 1383.

modifications of that invention … [a]nd that principle is violated when a patent expires and the public is nevertheless barred from practicing obvious modifications of the invention claimed in that patent because the inventor holds another later-expiring patent with claims for obvious modifications of the invention." *Gilead*, 753 F.3d at 1214. Indeed, in *AbbVie*, this Court sustained the continued viability of applying the OTDP doctrine to post-URAA patents, recognizing that even in the post-URAA context "[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." *AbbVie*, 764 F.3d at 1373 (citing, *inter alia*, 35 U.S.C. § 154(b)). The Court concluded that "[w]hen such situations arise, the doctrine of obviousness-type double patenting ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension." *Id.* Thus, *AbbVie* confirmed OTDP's applicability to post-URAA patents due, in part, to its applicability to § 154(b) PTAs.

Contrary to the district court's ruling, § 154(b) does not exempt a patent with a PTA from complying with the rule against OTDP, but rather its statutory text compels compliance. The statute expressly prohibits patent from receiving the benefits of PTAs if they are subject to terminal disclaimers, which exist for the purpose of remedying OTDP problems. 35 U.S.C. § 154(b)(2)(B) ("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."); *Gilead*, 753 F.3d at 1213-14 ("[O]bviousness-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." (quoting *Gen. Foods*, 972 F.2d at 1280)).

By enacting the terminal disclaimer bar to PTAs in § 154(b), Congress was clearly more concerned about guaranteeing the public the right to use a claimed invention and its obvious variants upon patent expiration than it was about guaranteeing a patentee additional patent term due to PTO delay. *See Gilead*, 753 F.3d at 1214-15 ("[T]he primary ill avoided by enforcement of the double patenting doctrine is restriction on the public's freedom to use the invention claimed in a patent and all obvious modifications of it after that patent *expired*." (emphasis in original)); *Longi*, 759 F.2d at 894 ("Since the second patent would expire simultaneously with the first, this use of a terminal disclaimer is consistent with the policy that the public should be free to use the invention as well as any obvious modifications at the end of the patent's term.")

The '219 patent's qualification as an OTDP reference against the '788 patent is entirely consistent with the statutory text of § 154(b) and clear congressional intent for OTDP to remain broadly applicable notwithstanding any PTO delays that might otherwise qualify a patent for a PTA. The district court should be reversed.

A. The District Court Failed to Appreciate the Significance of § 154(b)'s Express Bar to Terminally Disclaimed Patents Receiving the Benefit of Patent Term Adjustments

In ruling that the '219 patent did not qualify as an OTDP reference against the '788 patent, the district court relied principally on this Court's holding in *Ezra*, which carved out a narrow exception to OTDP for patents with expiration dates that were extended as a result of § 156 PTEs. Appx61-63. There, the Federal Circuit held that the grant of a § 156 PTE could not cause a patent to become invalid for OTDP. *Ezra*, 909 F.3d at 1374-75 (holding that an earlier-expiring patent did not qualify as an OTDP reference where the challenged patent expired later only on account of having received a § 156 PTE). But there is no basis to extend *Ezra*'s narrow exception for § 156 PTEs to § 154(b) PTAs.

1. Sections 154(b) and 156 Are Not Analogous

The district court wrongly treated § 154(b) as analogous to § 156. Appx64-66. As this Court has recognized, they are very different statutes, particularly as they concern OTDP. *See Merck*, 482 F.3d at 1322. For example, § 154(b) expressly acknowledges the rule against OTDP by barring the grant of a PTA beyond a terminally disclaimed expiration date. *Id.*; *see* 35 U.S.C. § 154(b)(2)(B). By contrast, § 156 is silent as to terminal disclaimers or other issues related to OTDP. *See Merck*, 482 F.3d at 1322 (comparing 35 U.S.C. §§ 154(b)(2)(B) and 156). These statutes should therefore have very different OTDP outcomes.

In *Merck*, this Court addressed the impact of a terminal disclaimer, filed to overcome an OTDP rejection, on a § 156 PTE. *Id.* Applying rules of statutory interpretation, this Court concluded that by expressly referring to terminal disclaimers in § 154(b) but not in § 156, Congress clearly intended for terminal disclaimers to bar patents from receiving the benefit of PTAs based on PTO delay but not prevent patents from receiving PTEs due to FDA delay. *Merck*, 482 F.3d at 1322. In support of that conclusion, this Court observed 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." *Id.* (citing *Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993)).

Whereas Congress specifically wrote § 156 to provide a branded drug patentee with freedom to select which patent in its portfolio would receive the PTE, regardless of any terminal disclaimers, Congress did not provide such flexibility in § 154(b) for PTAs. *See id.* at 1323 ("Congress chose not to limit the availability of a [§ 156] patent term extension to a specific parent or continuation patent but instead chose a flexible approach which gave the patentee the choice. We see no reason why a patentee should not have the same choice as between an earlier patent and a later patent related by a terminal disclaimer.") Rather, Congress expressly intended that patentees not benefit from PTAs when their own

patents are patentably indistinct from one another. *See* 35 U.S.C. § 154(b)(2)(B). In contrast, § 156's silence as to terminal disclaimers reflects Congress's intent that PTEs be granted and enforced regardless of any terminal disclaimers. *Merck*, 482 F.3d at 1322-24.

Ezra was merely a "logical extension of this court's holding in *Merck*." *Ezra*, 909 F.3d. at 1368; *see also id.* at 1373 ("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."). But there is no parallel logical basis for extending this Court's holding in *Ezra* for § 156 PTEs to this case involving § 154(b) PTAs.

Whereas the *Merck* panel found that a terminal disclaimer filed to resolve an OTDP problem could not negate a PTE in light of the aforementioned difference in the statutory texts of § 154(b) and § 156, the *Ezra* panel found that a PTE could not in-and-of-itself create an OTDP problem. *Ezra*, 909 F.3d at 1373-74. Thus, this key textual distinction between § 154(b) and § 156 led the Court in *Ezra* to recognize a narrow exception to the rule against OTDP specifically for § 156 PTEs. *Id.* To then extend *Ezra*'s narrow exception for § 156 PTEs to apply to § 154(b) PTAs—as the district court did below—defies the very logic for creating the PTE exception in the first place and causes the exception to swallow the rule.

The district court failed to appreciate this important textual distinction between § 154(b) and § 156 or the congressional intent reflected in § 154(b)(2)(B). Instead, the district court—in a single footnote—focused only on how the two statutes were discussed in the context of *Ezra* (concerning a § 156 PTE) instead of on how § 154(b) should be interpreted and applied in the context of this case. Appx65 n.45.

2. Double Patenting and Terminal Disclaimers Are Fundamentally Intertwined

In a similar vein, the district court failed to appreciate the role of terminal disclaimers with respect to OTDP. The district court concluded its footnote by stating: "But even if the role of a terminal disclaimer affected the obviousness-type double patenting analysis, Zydus does not contend that a terminal disclaimer was required here." Appx65 n.45. The district court's statement is a non sequitur and evinces a lack of an appreciation of the intertwined relationship between terminal disclaimers and OTDP. *See, e.g.*, *Merck*, 482 F.3d at 1323 ("The purpose of the terminal disclaimer — to prevent extension of patent term for subject matter that would have been obvious over an earlier filed patent…"); *Gilead*, 753 F.3d at 1213-14 ("'[O]bviousness-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'" (quoting *Gen. Foods*, 972 F.2d at 1280)); *Perricone*,

432 F.3d at 1375 ("A terminal disclaimer can indeed supplant a finding of invalidity for double patenting.").

Zydus of course contends that the asserted claims of the '788 patent are invalid for OTDP. Contrary to the district court's footnote, however, a terminal disclaimer is never "required," and that is not even the operative question in dispute.[6] What matters in § 154(b) for purposes of deciding this case is whether Congress, by mandating that terminal disclaimers cut off the benefit of PTAs, intended the rule against OTDP to apply to patents extended by PTAs. By expressly restricting PTAs based on terminal disclaimers, Congress clearly intended the longstanding doctrine of OTDP to apply in full force to such patents.

Indeed, in *Ezra*, the appellee Mitsubishi (which is the same lead Appellee in this appeal) argued successfully to this Court: "*Merck* holds that a terminal disclaimer filed to overcome an OTDP rejection does not foreclose term restoration under Section 156. It logically follows that, if a terminal disclaimer does not

---

[6] If the claims are deemed invalid for OTDP, Appellees may opt to file a terminal disclaimer with the PTO to "supplant [the] finding of invalidity for double patenting[,]" but that would be Appellees' voluntary, strategic choice. *See Perricone*, 432 F.3d at 1375. For instance, Appellees could opt not to terminally disclaim and allow claims 12 and 20 to remain invalid, in favor of the patenet's unasserted claims that could still potentially benefit from the 1,079-day PTA. The Court need not consider what Appellees might do, nor issue an advisory opinion on the potential impact of a hypothetical terminal disclaimer. *See id.* at 1375 (declining to "make [a] determination about the retrospective effect of … a [hypothetical] terminal disclaimer" that had not yet been filed).

foreclose a term extension, neither can OTDP."[7] So, too, here: If a terminal disclaimer ***does foreclose*** a term extension, like it does in § 154(b), then so too can OTDP.

3. Section 154(b) Does Not Absolutely "Guarantee" a Patent Term Adjustment in the Event of Patent Office Delay

Contrary to Appellees' position below, § 154(b) does not absolutely "guarantee" a PTA in the event of PTO delay. Rather, § 154(b)(2) expressly limits the "guarantee" based on certain circumstances, including the filing of a terminal disclaimer. 35 U.S.C. § 154(b)(2)(B). That is, Congress intended patentably indistinct patents to expire at the same time, notwithstanding any PTO delay. Appellees chose to file separate applications for patentably indistinct inventions, and will receive the full statutory term for the earlier-expiring '219 patent, whose prosecution was not delayed by the PTO.

In ruling that PTAs could not create OTDP problems, the district court committed legal error by either disregarding or misconstruing Congress's reference to terminal disclaimers in § 154(b)(2)(B). The district court's ruling frustrates Congress's intent that commonly-owned, patentably indistinct patents expire at the

---

[7] Appellees' Corrected Brief Regarding the "One Patent Per Period" and Double Patenting Issues Raised by Ezra, at 28, *Novartis AG v. Ezra Ventures LLC,* Nos. 17-2284 & 17-2286, 2017 WL 6997987 (Fed. Cir. Jan. 9, 2019) (internal citations omitted).

same time, notwithstanding any PTO delay. Had the application for the '788 patent instead been rejected for OTDP during prosecution, the applicant could have obviated such a rejection by filing a terminal disclaimer, which indisputably would have barred the '788 patent from receiving the benefit of the PTA under the plain language of § 154(b)(2)(B). But that is not what happened.

Rather, the OTDP problem between the '788 and '219 patents did not become apparent until this civil litigation. It would defy logic to permit patentably indistinct claims to benefit from a PTA simply because their OTDP problem was not discovered until after the patents were already granted. As opposed to such an incongruous result, invalidity grounds like OTDP should be treated consistently during prosecution and post-issuance. *See, e.g., Perricone*, 432 F.3d at 1375 ("[T]he pre-issuance timing requirement of a terminal disclaimer to overcome a double patenting rejection does not dictate a prohibition on post-issuance terminal disclaimers."); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999) (holding that the enablement analysis is the same in prosecution and post-issuance litigation).

The district court improperly considered § 154(b) only through the lens of *Ezra*, which carved out a narrow exception to OTDP for § 156 PTEs. Through that misguided analysis, the district court extended *Ezra*'s narrow exception to swallow

the well-established, broadly applicable rule against OTDP. The district court should be reversed.

B. The District Court Was Unduly "Swayed" by the Inapplicable "Observation" in *Ezra* That "a Judge-Made Doctrine" Should Not "Cut Off a Statutorily-Authorized Time Extension"

In rejecting Zydus's OTDP challenge, the district court was unduly "swayed by the Federal Circuit's observation [in *Ezra*] that 'a judge-made doctrine' should not be used to 'cut off a statutorily-authorized time extension.'" Appx66 (quoting *Ezra*, 909 F.3d at 1375). That "observation" in *Ezra* is inapplicable here and, as broadly applied by the district court, is contrary to Supreme Court precedent.

1. Congress Intended Obviousness-Type Double Patenting to Broadly Apply to Commonly-Owned Patents Having Different Expiration Dates, with Only Narrow Exceptions That Are Inapplicable Here

Extending *Ezra*'s narrow exception for § 156 PTEs to § 154(b) PTAs, as the district court has done, is contrary to this Court's precedent. *Ezra*'s stated concern about permitting "a judge-made doctrine [to] cut off a statutorily-authorized time extension"—while it perhaps makes sense in the context of § 156—is plainly inapplicable to § 154(b) in light of the differences between the statutes.

As this Court has recognized, "Congress is understood to legislate against a background of common-law adjudicatory principles." *Arista*, 908 F.3d at 802 (quoting *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991)). "Thus, where a common-law principle is well established, the courts may take it as

given that Congress has legislated with an expectation that the principle will apply except 'when a statutory purpose to the contrary is evident.'" *Id.* (quoting *Isbrandtsen Co. v. Johnson*, 343 U.S. 779, 783 (1952)).

In that regard, the federal courts recognize many well-established judge-made doctrines that can materially limit statutorily authorized patent rights or defenses. For example, notwithstanding the statutory mandates that "[a] patentee shall have remedy by civil action for infringement of his patent" (35 U.S.C. § 281) and that noninfringement and invalidity "shall be defenses in any action involving the validity or infringement of a patent" (35 U.S.C. § 282(b)), courts have limited the availability of such remedies and defenses based on a variety of well-established, longstanding common-law doctrines. *See, e.g., SCA Hygiene Prod. Aktiebolag v. First Quality Baby Prod., LLC*, 137 S. Ct. 954, 967 (2017) (recognizing equitable estoppel as a defense to patent infringement); *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 335 (1971) (recognizing *res judicata* and collateral estoppel in patent cases); *Mars Inc. v. Nippon Conlux Kabushiki-Kaisha*, 58 F.3d 616, 620 (Fed. Cir. 1995) (upholding the application of claim preclusion in a patent case).

Indeed, the Supreme Court reaffirmed this legal principle just last week, when it upheld the continued viability of the common-law doctrine of assignor estoppel in patent cases. *See Minerva Surgical, Inc. v. Hologic, Inc.*,

594 U.S. ____, No. 20-440, slip op. at 10 (2021). Recognizing "a whole host of common-law preclusion doctrines" that apply in patent cases, the Court held that eliminating the common-law doctrine of assignor estoppel "would subvert congressional design" because "Congress legislates against a background of common-law adjudicatory principles, and it expects those principles to apply except when a statutory purpose to the contrary is evident." *Id.* (quotation marks and citation omitted)).[8]

It is beyond dispute that OTDP is a well-established common-law doctrine that the federal courts have applied since long before Congress first enacted § 154(b). "While often described as a court-created doctrine," OTDP is "a bedrock principle of our patent system," a "longstanding" common-law doctrine "grounded in the text of the Patent Act." *AbbVie*, 764 F.3d at 1372 (discussing OTDP's roots in § 101); *Gilead*, 753 F.3d at 1212-14 (discussing history of OTDP, dating back to 19th century case law). Although judge-created, the rule against OTDP can negate the validity of patents that would otherwise be valid under the express terms of the

---

[8] While the Supreme Court did place some limits on the applicability of assignor estoppel, slip op. at 14 ("Assignor estoppel should apply only when its underlying principle of fair dealing comes into play."), that has no impact on this case. As this Court already held in *AbbVie*, applying OTDP to patents with § 154(b) PTAs "ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension" and solves a "crucial purpose of the doctrine … to prevent an inventor from securing a second, later expiring patent for the same invention." *AbbVie*, 764 F.3d at 1373.

Patent Act. Accordingly, the Patent Act should be interpreted with the understanding that when Congress wrote and amended it, including § 154(b), Congress embraced the common-law rule against OTDP with the knowledge and foresight that the federal courts would continue to apply it, unless clearly prohibited by statute. Nothing in § 154(b) excludes or limits OTDP. To the contrary, the statute expressly contemplates the doctrine's applicability to patents subject to PTAs by limiting PTAs based on terminal disclaimers. 35 U.S.C. § 154(b)(2)(B).

Although Congress "shed little light on exactly why [it] enacted" the terminal disclaimer statute, 35 U.S.C. § 253(b), this Court and its predecessor have since recognized terminal disclaimers to have been authorized to be an effective means for removing OTDP problems. *See Application of Robeson*, 331 F.2d 610, 613-15 (C.C.P.A. 1964) ("[T]he only real objection to granting appellant's application is an extension of the monopoly. The terminal disclaimer, which Congress has expressly provided, removes any danger of such result[.]); *Gilead*, 753 F.3d at 1213-14 ("'[O]bviousness-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'" (quoting *Gen. Foods*, 972 F.2d at 1280)).

Congress, too, has since acknowledged the role of terminal disclaimers in obviating OTDP problems. For example, in connection with enacting the Patent

Law Amendments Act of 1984, Congress recognized OTDP's applicability and the use of terminal disclaimers to remove OTDP problems:

> The Committee expects that the Patent and Trademark Office 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.

Section-by-Section Analysis: Patent Law Amendments of 1984, 130 Cong. Rec. 28065, 28071 (1984), *reprinted in* 1984 U.S.C.C.A.N. 5827, 5834 (capitalization revised for clarity of reading).

Nothing in the Patent Act suggests that Congress intended to reduce the applicability of OTDP against patents that are otherwise eligible for § 154(b) PTAs. Congress enacted § 154(b) in 1994 to authorize PTAs except to the extent a patent was "subject to a terminal disclaimer," and then amended § 154(b) in 1999 to expand the availability of PTAs while still maintaining terminal disclaimers as a barrier to receiving their benefit. *See supra* at 25-26. Congress was plainly aware at the time of the courts' longstanding applications of the rule against OTDP and terminal disclaimers to resolve OTDP problems. Had Congress intended to exempt patents with PTAs from having to comply with the rule against OTDP, it

could have done so, but clearly it did not. *See Lorillard v. Pons*, 434 U.S. 575, 580 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change.").

Unlike § 156, where Congress's comparative silence about terminal disclaimers in the statute evinced "a statutory purpose to the contrary" of allowing terminal disclaimers to constrain PTEs, § 154(b) is unequivocal that terminal disclaimers can constrain PTAs. *See Arista*, 908 F.3d at 802; *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. There is no similar provision that excludes patents in which a terminal disclaimer was filed from the benefits of Hatch-Waxman extensions.").

Furthermore, beyond § 156 PTEs, there are other statute-based exceptions to the applicability of OTDP, such as patents protected by the safe-harbor of 35 U.S.C. § 121,[9] and situations involving both pre-URAA and post-URAA patents.[10]

---

[9] *See supra* § I.C.

[10] *See Novartis Pharm. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1366-67 (Fed. Cir. 2018) (holding that a later-issuing, earlier-expiring post-URAA patent was not a proper OTDP reference against the challenged pre-URAA patent because the post-URAA patent expired earlier only due to the intervening change in patent term law imposed by the URAA).

None of these exceptions apply here though.[11] To the contrary, by expressly imposing terminal disclaimers as a bar to patents receiving the benefit of PTAs, Congress embraced the applicability of OTDP to such patents. Absent anything in the Patent Act that constrains the reach of OTDP to patents with § 154(b) PTAs, the Court should assume that Congress intended the doctrine to apply to such patents in full force, without restriction.

2. The "Observation" in *Ezra* Arose from a Wholly Unrebutted, One-Sided Argument and Should Not Be Broadly Applied

In *Ezra*, as an ancillary basis for rejecting the appellant's argument that a § 156 PTE could create an OTDP problem, the Court noted that it had previously "described obviousness-type double patenting as a 'judge-made doctrine' that is intended to prevent extension of a patent beyond a 'statutory time limit.'" *Ezra*, 909 F.3d at 1375 (quoting *In re Berg*, 140 F.3d 1428, 1431–32 (Fed. Cir. 1998)). The Court "declined" to agree with the appellant because to do so "would mean that a judge-made doctrine would cut off a statutorily-authorized time extension." *Ezra*, 909 F.3d at 1375.

---

[11] *See infra* § III.

This paragraph in the *Ezra* opinion, however, arose from the appellee's[12] wholly unrebutted argument that "no 'judicially crafted exception' can subvert the 'statutory text'; 'so long as the [statutory] elements are met,' the applicant is entitled to a patent term extension." Appellees' Corrected Brief Regarding the "One Patent Per Period" and Double Patenting Issues Raised by Ezra, at 28, *Novartis AG v. Ezra Ventures LLC,* No. 17-2284, 2017 WL 6997987 (Fed. Cir. Jan. 9, 2018) (citing *United States v. Gilbert*, 430 F.3d 215, 216, 218-19 (4th Cir. 2005).

The proposed "judicially crafted exception" in *Gilbert*, however, was the polar opposite of the well-established, more-than-century-old common-law doctrine of OTDP. In *Gilbert*, a criminal defendant attempted "to overturn his conviction as a felon in possession of a firearm by invoking an affirmative defense of 'innocent possession'" that was "wholly absent from the statutory text." *Gilbert*, 430 F.3d at 216. In rejecting the defense, the Fourth Circuit reasoned that there was no "common law" basis for an "innocent possession" defense, and the closest common law defense of "justification" was to be construed "very narrowly." *Id.* at 219 ("Thus, unlike justification, the innocent possession defense could create an exception that swallows the rule."). For whatever reason, the

---

[12] The appellee in *Ezra* was Mitsubishi Tanabe Pharma Corporation, the lead Appellee in the instant appeal.

appellant in *Ezra* never directly responded to the appellee's reliance on *Gilbert* or argument that no judicially crafted exception can subvert the statutory text.[13]

In stark contrast to the essentially novel proposed criminal defense in *Gilbert*, "[t]he prohibition against double patenting is a longstanding doctrine of patent law" that "[f]ederal courts for over a century have applied . . . 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 1212-13. Thus, the panel's "observation" in *Ezra* was made in response to a one-sided, incomplete picture of the case law, and should not be applied broadly outside of the specific circumstances of that case. While the panel's reasoning made sense in the context of § 156, which does not mention OTDP, the district court erred in adopting the "observation" as an essentially all-encompassing statement of the law and extending it to § 154(b) despite the statute's unequivocal recognition of OTDP.

C. Public Policy Favors Applying the Rule Against Double Patenting to Patents with § 154(b) Patent Term Adjustments

In rejecting Zydus's OTDP defense, the district court found that, "[u]nlike in *Gilead*, the granting of a PTA does not present the potential for gamesmanship by

---

[13] *See generally* Reply Brief of Defendant-Appellant Ezra Ventures LLC (ECF No. 74), at 28, *Novartis AG v. Ezra Ventures LLC,* No. 17-2284 (Fed. Cir. Jan. 24, 2018).

inventors to secure a second, later expiring patent for the same invention." Appx65 (citing *Ezra*, 909 F.3d at 1374-75). As an initial matter, "gamesmanship" is not a requisite element of an OTDP defense. Furthermore, allowing a patent to benefit from a PTA while simultaneously shielding it from an OTDP challenge from a related patent, as the district court has done, presents the opportunity for gamesmanship.

1. Double Patenting Has No "Gamesmanship" Requirement

Contrary to the district court's suggestion, "gamesmanship" is not a requisite element of OTDP. OTDP does not require a showing of an inappropriate prosecution strategy, deceptive intent, or any other mental state. In *AbbVie*, this Court expressly rejected the notion that OTDP's main goal is to "curb abuses" in patent prosecution strategy. *AbbVie*, 764 F.3d 1373. Rather, the Court held that OTDP "is designed to prevent an inventor from securing a second, later expiring patent for the same invention" and "ensures that the public gets the benefit of the invention after the original period of monopoly expires." *Id.* To that end, the Court noted that this "problem still exists" in the post-URAA world, citing § 154(b) PTAs as an example of a problematic situation. *Id.* The Court concluded that "[w]hen such situations arise, the doctrine of obviousness-type double patenting ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension." *Id.* Thus, applying OTDP to § 154(b)

PTA furthers the doctrine's key public policy goals, regardless of any gamesmanship.

In addition, the "second justification for obviousness-type double patenting—harassment by multiple assignees"—can occur regardless of any gamesmanship or ill intent. *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009).

Moreover, requiring an element of subjective intent to prove OTDP would unnecessarily increase the costs of litigation by impelling defendants to take fact discovery of patent prosecutors and others to discern the patentees' specific patenting strategies, much of which would likely be shielded by privilege or lead to extensive discovery motion practice. Unlike equitable defenses like inequitable conduct, unclean hands, and waiver, OTDP is not grounded in equity and the specific patentee's subjective intent should be irrelevant. Rather, OTDP is "grounded in public policy" "to preserve that bargained-for right held by the public" so that the "public is free to use" a patented invention and patentably indistinct variants upon expiration. *AbbVie*, 764 F.3d at 1372; *Gilead*, 753 F.3d at 1214.

2. Allowing a Patent to Benefit from a Patent Term Adjustment While Simultaneously Shielding It from an Double Patenting Challenge Is Contrary to Public Policy

Relying on *Ezra* and *Breckenridge*, the district court concluded that the situation presented in this case does not present any "potential for gamesmanship." Appx64-65. That is wrong.

Unlike in the situations presented in *Ezra* (§ 156 PTEs) and *Breckenridge* (intervening change in law), a patent applicant is generally aware of PTO delays during prosecution and therefore can readily determine during prosecution whether and to what extent a resulting patent will qualify for a § 154(b) PTA and plan accordingly. Section 154(b) lays out how PTAs should be calculated, which a patent practitioner can readily track during prosecution. 35 U.S.C. § 154(b)(1); *see, e.g., Pfizer, Inc. v. Lee*, 811 F.3d 466, 468-69 (Fed. Cir. 2016); *Novartis AG v. Lee*, 740 F.3d 593, 595-97 (Fed. Cir. 2014). Thus, during prosecution, a reasonable applicant should be well-aware of which applications in a patent family are most likely to receive the longest PTAs, and can use that information to orchestrate prosecution in a manner that selectively obtains PTAs and avoids OTDP rejections for specific applications to maximize the terms of the desired patents beyond what the applicant is entitled to due to OTDP problems.

The PTO's Manual of Patent Examining Procedure ("MPEP") provides guidance for how examiners should deal with OTDP issues between co-pending

applications. *See* MPEP § 804(I)(B), at 800-26–28 (9th ed., 10.2019 rev., June 2020).[14] The MPEP instructs examiners to issue a "provisional" OTDP rejection in each co-pending application, to make the "applicant aware of the potential double patenting problem if one of the applications became a patent." *Id.* at 800-26. The MPEP further provides that where "both applications are actually filed on the same day, or are entitled to the same earliest effective filing date[,] … the provisional nonstatutory double patenting rejection made in each application should be maintained until the rejection is overcome." *Id.* § 804(I)(B)(1)(b)(ii), at 800-27–28. The applicant can overcome such a rejection "by either filing a reply showing that the claims subject to the provisional nonstatutory double patenting rejections are patentably distinct or filing a terminal disclaimer in the pending application." *Id.* Thus, where claims in co-pending applications are not patentably distinct, an applicant needs to either file a terminal disclaimer or amend or cancel the claims. Because a terminal disclaimer during prosecution will cut off any PTA that the resulting patent might otherwise receive, there can be considerable value in avoiding OTDP rejections (provisional or otherwise) and terminal disclaimers during prosecution.[15]

---

[14] Available at https://www.uspto.gov/web/offices/pac/mpep/mpep-0800.pdf.

[15] Indeed, the pharmaceutical legal community has written much on strategies for avoiding OTDP rejections and terminal disclaimers during prosecution and maximizing PTAs. *See, e.g.*, Rob Sahr & Kady Bruce, *Protecting pharmaceutical*

Under the district court's ruling, a patent applicant has even greater incentive to orchestrate prosecution in a manner that prevents the PTO from recognizing OTDP problems during prosecution and thereby avoids terminal disclaimers. For example, an applicant could strategically stagger the filing of its patentably indistinct continuing applications—as Appellees did here by filing the application for the '219 patent only after the '788 patent had already issued—which would avoid the risk of OTDP rejections in the earlier application based on the patentably indistinct continuing applications and the resulting need to file a terminal disclaimer during prosecution. Such a strategy would allow the resulting patent to benefit from a PTA and be shielded from OTDP challenge from its patentably indistinct family members during post-issuance litigation.

---

exclusivity: Avoiding the hidden dangers of double patenting, Pharmaceutical Commerce, Jan. 27, 2021, available at https://www.pharmaceuticalcommerce.com/view/protecting-pharmaceutical-exclusivity-avoiding-the-hidden-dangers-of-double-patenting (last visited July 6, 2021); Leslie A. McDonell & Christina M. Rodrigo, *Practice Tips for Avoiding Terminal Disclaimers and Maintaining PTA*, Landslide, Nov./Dec. 2017, available at https://www.finnegan.com/en/insights/articles/practice-tips-for-avoiding-terminal-disclaimers-and-maintaining-pta.html (last visited July 6, 2021); Alicia Russo, *Defeating Double Patenting: Strategies For Maximizing Patent Term*, American Conference Institute, at 36-38 (Feb. 27, 2017), available at https://www.americanconference.com/life-sciences-patents/wp-content/uploads/sites/1728/2017/02/Day1_4.45_Lowe.Russo_.Todaro.Combined.pdf (last visited July 6, 2021); Courtenay C. Brinckerhoff, *Patent Term Adjustment and Double Patenting*, PharmaPatents Blog (Mar. 4, 2014), available at https://www.foley.com/en/insights/publications/2014/03/patent-term-adjustment-and-double-patenting (last visited July 6, 2021).

On a similar note, the district court's ruling also puts immense pressure on the PTO to catch each and every potential OTDP problem during prosecution. If the PTO inadvertently overlooks a true OTDP problem based on a related patentably indistinct patent and the application issues with a § 154(b) PTA, the resulting patent would then be immune from an OTDP challenge based on that same patentably indistinct patent.

To allow a PTA to immunize a granted patent against an OTDP challenge based on a patentably indistinct related patent, as the district court seems to have done, would incentivize applicants to serially file applications for patentably indistinct inventions, with the hope that the PTO will miss the OTDP problems[16] and thereby allow further extension of the patentably indistinct inventions' term though additional PTAs. Such a result would be directly contrary to the "bedrock principle" of OTDP that, upon patent expiration, "the public is free use" to the patented invention and its patentably indistinct variants, and contrary to "the fundamental reason for the rule of [OTDP] … *to prevent unjustified timewise extension of the right to exclude* granted by a patent no matter how the extension is

---

[16] "The examiners of the Patent Office are highly qualified for the work performed by them, but they are not infallible, and it is conceivable that sometimes relevant references may be overlooked by them." *In re Lee*, 139 F.2d 717, 720 (C.C.P.A. 1943). As evidenced by the plethora of cases in which patents have been found invalid for OTDP in post-issuance litigation, the PTO may overlook OTDP problems during prosecution from time to time.

brought about." *Gilead*, 753 F.3d at 1214; *Boehringer*, 592 F.3d at 1347-48 (emphasis in original; quotation marks and citation omitted).

Congress could not have intended to allow patent applicants to so easily circumvent the express terminal disclaimer bar to PTAs in § 154(b)(2)(B) simply by timing prosecution in a way that prevents the PTO from discovering OTDP problems or by lucking out with the PTO not noticing an OTDP problem during prosecution.

Along those same lines, the district court's ruling is contrary to public policy because it creates a major incentive for patentees to conceal potential OTDP problems from the PTO in hopes of obtaining a valuable PTA that could otherwise be unavailable. If a patent applicant is aware of a potential OTDP problem based on a related patent but conceals it to avoid filing a terminal disclaimer during prosecution, the applicant can obtain a highly valuable § 154(b) PTA of the resulting patent and the resulting patent would then be immune to being challenged based on that OTDP problem in a subsequent litigation. If, however, the applicant were to disclose the OTDP issue to the examiner during prosecution, the applicant could need to file a terminal disclaimer during prosecution to resolve the OTDP problem, which would then bar the resulting patent from receiving the benefit of a PTA by operation of § 154(b)(2)(B). Congress could not have intended such an incongruous result that discourages open disclosure to the PTO. *See* 37 C.F.R.

§ 1.56 (establishing duty to disclose information material to patentability to the PTO); 35 U.S.C. § 2(b) (conveying to the PTO the power to promulgate regulations not inconsistent with law).

The incentive to avoid terminal disclaimers during prosecution is even more pronounced in the pharmaceutical field, where the initial patent applications for a new drug are typically filed many years before the New Drug Application ("NDA") is filed and approved.[17] Applicants for new drug patents therefore often have little reason to rush to get their application granted. Instead, they benefit significantly from PTO delay since it accumulates PTA at the end of the patents' terms, when the drugs are on the market and the value of the patents is at its highest because they can be used to stave off potential competition.

With regard to *Ezra*, the Court there found "no potential gamesmanship issue" in a patentee's selection of which one patent covering its FDA-approved drug should receive the § 156 PTE. *Ezra*, 909 F.3d at 1374. Unlike with § 154(b), "Congress chose not to limit the availability of a patent term extension to a specific parent or continuation patent but instead chose a flexible approach which gave the patentee the choice." *Id.* at 1369-70 (quoting *Merck*, 482 F.3d at 1323). As the

---

[17] For example, in this case, Appellees filed their initial patent application for canagliflozin in 2005, but did not file their NDA until 2012 or for receive FDA-approval for INVOKANA® until 2013. Appx6; Appx8-9; Appx1732 (trial testimony of Dr. Williams).

Court recognized in *Merck*, "[t]he legislative history of § 156 indicates that Congress was aware of concerns over the effects of extending related patents—at least as to parent, continuation, and continuation-in-part patents—and chose to provide the patentee with the option to select to extend the term of only one of either the parent patent or a continuation patent." *Merck*, 482 F.3d at 1323 (citing 130 Cong. Rec. 23765, 24444 (1984)). But in enacting § 154(b), Congress did not intend to grant applicants a similar flexibility in choosing which patents to extend.

Breckenridge is also inapposite. There, the Court was dealing with a completely different situation—a pre-URAA patent and post-URAA patent with divergent terms due to the intervening change in law defining patent term. *Breckenridge*, 909 F.3d at 1355. Indeed, the Court in *Breckenridge* found *Gilead* and *AbbVie* to be "inapposite because [they both] involved two post-URAA patents." *Breckenridge*, 909 F.3d at 1364-65. Like in *Gilead* and *AbbVie*, the '788 and '219 patents in this case are both post-URAA. In addition, the *Breckenridge* panel found that "the present facts do not give rise to similar patent prosecution gamesmanship" because the challenged patent expired later "only due to happenstance of an intervening change in patent term law." *Id.* at 1364. There is no parallel change in law or "happenstance" here.

Ultimately, Appellees chose to file serial applications for patentably indistinct inventions, and timed their filings so that the applications for the '788

and '219 patents were never co-pending before the PTO.[18] Appellees will receive a full statutory term based on the earlier-expiring '219 patent, whose prosecution was not delayed by the PTO. Consistent with the foundational principles of OTDP, when the '219 patent expires, the public should be free to use its claimed inventions and all patentably indistinct variations thereof, including claims 12 and 20 of the '788 patent. *Gilead*, 753 F.3d at 1214. When the '219 patent for the use of canagliflozin expires, the public should be free to use canagliflozin, as claimed in the '788 patent.

III. THE § 121 SAFE-HARBOR IS INAPPLICABLE

The district court expressly declined to rule on Appellees' argument below that the safe-harbor provision of 35 U.S.C. § 121 shields the '788 patent from Zydus's OTDP challenge. Appx66. The Court should reverse the district court's OTDP ruling and need not remand this appeal for the district court to decide whether the § 121 safe-harbor applies because Appellees failed to even meet their burden of production to trigger potential application of the safe-harbor.

---

[18] *See Application of Simmons*, 312 F.2d 821, 825 (C.C.P.A. 1963) ("The mere fact that [applicant] filed two separate applications in the considered belief that two patentable inventions were present does not entitle him to two patents. [Applicant] suggests that he is being 'penalized' for not consolidating the copending applications. If [applicant] is penalized, it is his own doing.")

Although Zydus ultimately bears the burden of proof to show invalidity for OTDP, once Zydus established that an OTDP issue existed between the commonly-owned, patentably-indistinct '788 and '219 patents, the burden of production shifted to Appellees to go forward with rebuttal evidence. *See Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008) ("A quite different burden is that of going forward with evidence—sometimes referred to as the burden of production—a shifting burden the allocation of which depends on where in the process of trial the issue arises."); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305-06 (Fed. Cir. 2008) ("Once [defendant] established by clear and convincing evidence that the [reference] was § 102(b) prior art to the asserted claims of the [asserted] patents, the burden was on [plaintiff] to come forward with evidence to the contrary.").

Accordingly, at trial, Appellees bore the burden of production to establish the applicability of the § 121 safe-harbor. *See Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1347-48 (Fed. Cir. 2004) ("As section 121 has been interpreted by this court, [the patentee] is entitled to invoke the statutory [safe-harbor]"); *Geneva*, 349 F.3d at 1381 (holding that the patentee "d[id] not meet its burden to show" the applicability of the § 121 safe-harbor).

Among other requirements, § 121 authorizes safe-harbor protection only where the divisional application was filed "as a result of" a restriction requirement

and "before the issuance of the patent on the other application." 35 U.S.C. § 121. Plaintiffs failed to go forward with evidence sufficient to establish these statutory requirements.

The '219 patent's application was filed as a purported divisional of the '757 application (which issued as the '984 patent), which in turn was a purported divisional of the '788 patent's application. *See supra* at 11-13. Thus, the '788 patent's application is the grandparent of the '219 patent's application, with an intermediate application between them. It is undisputed that the PTO issued a restriction requirement in the '788 patent's prosecution on March 24, 2008. Appx16802-16823. It is also undisputed, however, that '219 patent's application was not filed until July 1, 2011, which is after the application for the '788 patent had already issued on May 17, 2011. Appx60-61; Appx2246-2247. Thus, Appellees never went forward with evidence that "the divisional application [wa]s filed before the issuance of the patent on the other application," as required by § 121.

Relatedly, to establish that the '219 patent's application was filed "as a result of" the restriction requirement in the '788 patent's application, Appellees bore the burden of production to go forward with evidence sufficient to show that the restriction requirement "carried forward" to the '219 patent. *See G.D. Searle LLC v. Lupin Pharm., Inc.*, 790 F.3d 1349, 1356-58 (Fed. Cir. 2015) (holding that the

patentee failed to establish the "as a result of" prong of § 121 because there was "[n]o evidence show[ing] that the PTO intended the restriction requirement to carry forward to the [later] application" or "that the examiner made any reference to the restriction requirement [imposed in the grandparent application] at all during prosecution of the [challenged patent] application."). Appellees, however, failed to link the restriction requirement in the '788 patent's application to the filing of its grandchild, the '219 patent's application.

More specifically, Appellees did not offer any evidence that that the PTO intended the restriction requirement to survive beyond the '788 patent's issuance or to carry forward to or be reinstated in the grandchild application for the '219 patent. *See, e.g.*, Appx20405 (Oct. 15, 2010 Notice of Allowance in '788 patent prosecution) ("Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on March 24, 2008 is hereby withdrawn**." (emphasis in original)). No divisional applications were filed until after the March 24, 2008 restriction requirement had already been withdrawn. *See Application of Ziegler*, 443 F.2d 1211, 1215-16 (C.C.P.A. 1971) ("[T]he restriction requirement was withdrawn and the withdrawal of the restriction requirement deprived appellants of any possible benefit from § 121."). Moreover, nothing in the prosecution of the '219 patent's application refers back to the March 24, 2008 restriction requirement.

Even to the extent Appellees contend that the restriction requirement carried forward to the '219 patent by way of the intermediate '757 application, they failed to go forward with evidence supporting that. Appellees bore the burden of production, but they did not offer the '757 application into evidence and even objected to having the district court consider its prosecution history. Appx132-134. Thus, Appellees did not meet their burden of production to establish a link between the filing of the '219 patent and the restriction requirement in its grandparent application.

Because Appellees failed to go forward with evidence sufficient to establish that the '219 patent's application was filed "as a result of" the restriction requirement in the '788 patent,[19] they never triggered any potential application of the § 121 safe-harbor. The Court can reverse the district court, without remand.

---

[19] The trial record further established the '219 patent's application was in fact not filed "as a result of" any administrative requirements imposed by the PTO because, after the restriction requirement issued (Appx16802-16823), the applicants affirmatively and voluntarily "cancelled" the method of treatment claims in the '788 patent's application "in order to expedite prosecution," despite the claims being withdrawn and there being no requirement to cancel them. Appx16938-16942 (Mar. 3, 2009 Amendment); Appx20407 (Index of Claims); Appx2000-2019 (trial testimony of Mr. Carmichael). Some of these facts, however, were disputed between the parties' experts, and the district court did not make complete findings in that regard.

IV. CONCLUSION

For these reasons, the Court should reverse the district court's judgment regarding the '788 patent. Claims 12 and 20 of the '788 patent are invalid for OTDP over claim 22 of the '219 patent.

Dated: July 6, 2021

Respectfully submitted,

By: /s/ Jay Deshmukh

Jay Deshmukh
KASOWITZ BENSON TORRES LLP
1633 Broadway
New York, NY, 10019
Telephone: (212) 506-1700
Email: jdeshmukh@kasowitz.com

Counsel for Defendant-Appellant Zydus Pharmaceuticals (USA) Inc.