No. 22-1293

In the
United States Court of Appeals
for the Federal Circuit

IN RE: CELLECT, LLC

Appellant.

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

BRIEF OF *AMICUS CURIAE* BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF APPELLANT

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 22-1293

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Signature: /s/ Kevin E. Noonan

Name: Kevin E. Noonan

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.
☐ None/Not Applicable	☑ None/Not Applicable	☑ None/Not Applicable
Biotechnology Innovation Organization		

☐ Additional pages attached

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

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

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INTEREST OF THE *AMICUS CURIAE*[1]

The Biotechnology Innovation Organization ("BIO") is the world's largest biotechnology trade association, providing advocacy, development, and communications services for over 1,100 members worldwide. BIO members—most of whom are small, emerging companies—are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products. BIO also represents state and regional biotechnology associations, service providers to the biotechnology industry, and academic centers. BIO's members help foster a healthy economy by creating many well-paying biotechnology jobs. BIO regularly represents the interests of its members before Congress and the United States Patent and Trademark Office ("USPTO") and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. BIO expresses no opinion on the ultimate validity of the patents at issue in this appeal, but submits this brief in the hope that it will assist the Court in the orderly development of the law of obviousness-type double patenting. This brief reflects the prevailing views of BIO's members[2], but not necessarily the individual

[1] No party's counsel authored this brief in whole or part; no party or party's counsel contributed money intended to fund preparing or submitting the brief; and no person other than *amicus*, its members, or counsel contributed money intended to fund preparing or submitting the brief. Consent has been sought from each party, none of whom opposed the filing of this brief. Fed. R. App. P. 29(a)(4)(E).

[2] https://www.bio.org/bio-member-directory

views of any particular BIO member company.

ARGUMENT

I. INTRODUCTION

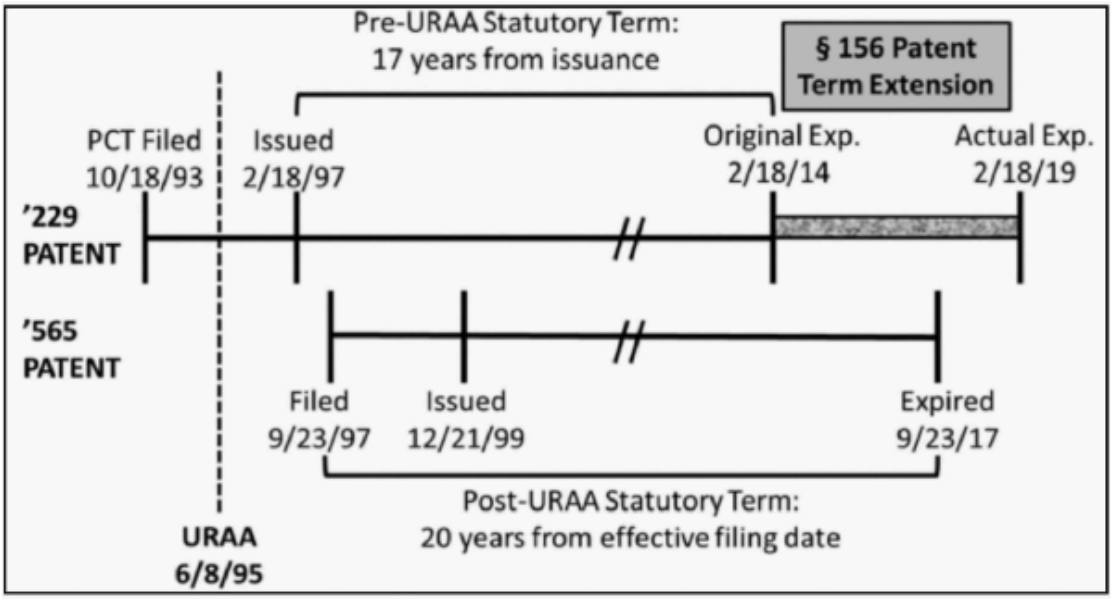
By statute, Congress has authorized the grant of patent term adjustment ("PTA") to compensate patent applicants for delays caused by the USPTO during examination of a given patent application. *See* 35 U.S.C. § 154. Applications having the same priority date (*e.g.*, continuation and divisional applications) often experience differences in such delays and thus may be granted different PTA terms. However, in the consolidated cases now before this Court, the USPTO's Patent Trial and Appeal Board ("PTAB") has improperly applied the doctrine of obviousness-type double patenting ("ODP") to invalidate patents whose expiry dates differ solely due to PTA granted under § 154. Congress expressly authorized PTA to "guarantee[] diligent applicants at least a 17-year term" by adding term to compensate for USPTO delays in examination. H.R. Rep. No. 106-287, pt. 1, at 50 (1999). Applying ODP in a way that obviates the PTA awarded for delays in USPTO examination, as the PTAB did here, would, in many cases, result in patent terms shorter than 17 years, flouting the very purpose of § 154. It also results in an illogical scenario: USPTO delays would trigger PTA; this PTA would then trigger the need for a terminal disclaimer; and that terminal disclaimer would then trigger a limitation on the PTA. That result reduces the incentive to innovate and slows the advance

of science and technology. A strong and robust patent system must be able to grant and enforce statutorily mandated PTA to spur innovation and investment by stakeholders. The Board's decisions must be reversed.

II. THE BOARD'S DECISIONS ARE INCONSISTENT WITH THIS COURT'S PRECEDENT HOLDING THAT A STATUTORY TERM EXTENSION CANNOT GIVE RISE TO ODP.

This Court has made clear that a statutorily mandated term extension cannot give rise to ODP. *See Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018). The *Ezra* Court considered whether the challenged patent was invalid due to ODP because the term extension it received under 35 U.S.C. § 156 caused the patent to expire after a related patent. 909 F.3d at 1370. The Court concluded that ODP does not invalidate a validly obtained PTE in such a scenario. *Id.* at 1369.

A timeline for the patents in *Ezra* is reproduced below:



Id. at 1370. As shown above, the challenged patent (the '229 patent) had an original expiration date that was *earlier* than the expiration date of the reference patent (the '565 patent). Under normal circumstances, this would have disqualified the reference patent from being used as a basis for an ODP rejection. *See Gilead Scis., Inc. v. Natco Pharma Ltd*., 753 F.3d at 1210 (Fed. Cir. 2014) ("[ODP] prohibits an inventor from extending his right to exclude through claims in *a later-expiring patent* that are not patentably distinct from the claims of the *inventor's earlier-expiring patent*....") (emphasis added). However, because the challenged patent's term was statutorily extended beyond the expiration date of the reference patent, defendant Ezra argued that the '229 patent was invalid for ODP, or otherwise terminally disclaimed for the patent term past the expiration date of the '565 patent. *Ezra*, 909 F.3d at 1370. Rejecting Ezra's arguments, this Court found that the '565 patent was not a proper ODP reference to the '229 patent.

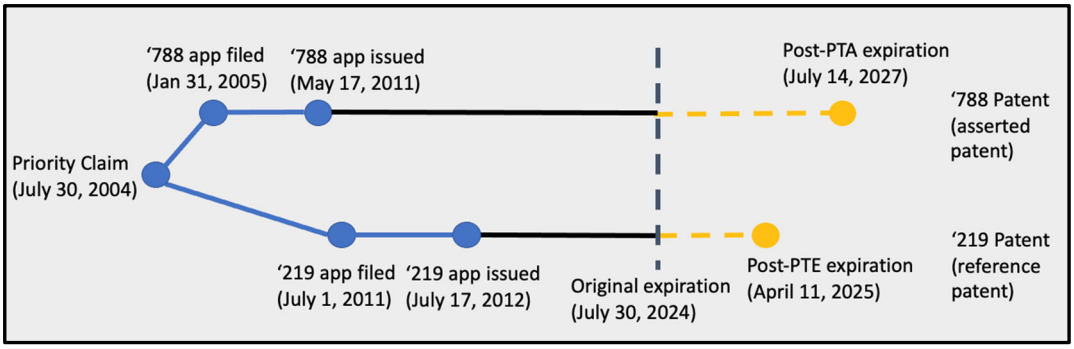
This Court's decision was predicated on three principal grounds. First, the Court pointed to its ruling in *Merck & Co. v. Hi-Tech Pharmacal Co.* that "a patent term extension under § 156 is not foreclosed by a terminal disclaimer." 482 F.2d 1317, 1322 (Fed. Cir. 2007). The *Ezra* Court reasoned that "as a logical extension of our holding in *Merck,*" ODP does not invalidate validly obtained PTE under similar scenarios. *Ezra*, 909 F.3d at 1373.

Second, this Court recognized that the case at hand "[did] not raise the traditional concern[s] with [ODP]" because there was no potential gamesmanship by the plaintiff, Novartis, through structuring of priority claims as identified in *Gilead*. 753 F.3d at 1210. Nor was there any indication that Novartis attempted to improperly "secur[e] a second, later expiring patent for the same invention." *Id.* at 1374-75.[3] Lastly, this Court acknowledged that ODP is a "judge-made doctrine," and refused to allow a judge-made doctrine to cut off a statutorily authorized term extension. *Ezra*, 909 F.3d at 1375.

Several district courts have likewise concluded that differences in patent term that arise solely from PTA granted under 35 U.S.C. § 154 cannot serve as the basis for ODP. In *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*, the court considered whether certain claims of a PTA-extended patent (the '788 patent) were invalid for ODP over claims of an earlier expiring reference patent (the '219 patent). 533 F. Supp. 3d 170, 211.

Below is a timeline of the relevant dates of the two patents in *Mitsubishi*:

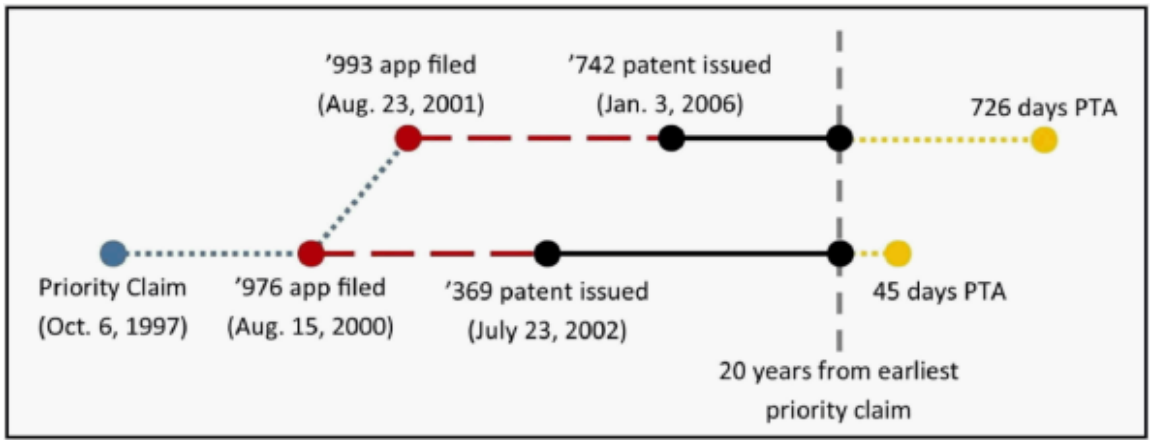
[3] As this Court noted, but for the PTE, the '229 patent would have expired *before* the '565 patent.



Defendant Zydus argued that based on *Gilead* the post-PTA expiration dates of the two patents should govern the ODP analysis. *Id*. at 213. Yet, the district court interpreted *Gilead* as being limited to its facts and found *Ezra*'s rule regarding PTE and ODP as more relevant to the question of PTA and ODP. *Id*. In particular, the district court found that, as in *Ezra*, "[t]his case does not raise the traditional concern with [ODP] of a patent owner extending his exclusive rights to an invention through claims in a later-filed patent" because absent the PTA granted to the '788 patent, the '788 patent would have expired before the '219 patent. *Id*. (internal quotations omitted). Further, the district court found that, like *Ezra*, "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" and that "a judge-made doctrine should not be used to cut off a statutorily authorized time extension." *Id.* For these reasons, the district court held that the '219 patent could not be used as an ODP reference against the '788 patent under Federal Circuit law. *See also Amgen, Inc. v. Sandoz Inc.,* No. CV1811026, 2021 WL 5366800, at *26 (D.N.J. Sept.

20, 2021) (finding that "[a] difference in expiration dates between two patents that arises solely from a statutorily authorized time extension, such as a patent-term adjustment pursuant to 35 U.S.C. § 154(b) or a patent-term extension pursuant to 35 U.S.C. § 156, cannot be the basis for an application of ODP").

In the case before this Court, the PTAB argued, in contrast with the *Mitsubishi* court, that an ODP analysis should be based on the post-PTA expiration date, and not the original, pre-PTA expiration date. Below is a timeline of the relevant dates for two of the patents at issue in the consolidated cases before this Court:



Ex parte Cellect LLC, No. 2021-005303, 2021 WL 5755329, at *2 (P.T.A.B. Dec. 1, 2021). As shown above, the challenged patent (the '742 patent) originally would have had the same expiration date as the reference patent (the '369 patent). However, due to a grant of PTA, the challenged patent's term

was statutorily extended beyond the expiration date of the reference patent.[4] Consequently, at issue on reexamination was whether the earlier-expiring '369 patent could qualify as an ODP reference against the later-expiring '742 patent where the different expiration dates are solely attributable to PTA due to USPTO delays during prosecution of the underlying applications.

Declining to accept the holding from *Mitsubishi*, the PTAB interpreted *Ezra* and the text of 35 U.S.C. § 154(b) to mean that ODP should be considered *after* application of any PTA. Relying on that interpretation, the PTAB determined that the '742 patent was invalid for ODP in view of the '369 patent. *See also Magna Electronics, Inc. v. TRW Automotive Holdings Corp.,* No. 1:12-CV-654, 2015 WL 11430786, at *4 (W.D. Mich. Dec. 10, 2015) (determining that "*Gilead* stands for the simple proposition that a court should look to the expiration dates not the issuance dates to determine if a patent can be used as the prior art patent under the doctrine," and applying ODP to invalidate a patent in view of its post-PTA expiration date).

This Court is the only body that can correct the Board's flawed reasoning. And this Court should act quickly before district courts or the

[4] The reference patent was also granted PTA, but only 45 days of PTA, as compared with the challenged patent's 726 days of PTA. Nonetheless the situation here is similar to *Mitsubishi*, in that absent an award of PTA the challenged patent would have expired before the reference patent.

PTAB issue additional opinions on this issue. Indeed, failure to act now could cause additional layers of confusion regarding the relationship between PTA and ODP. Resolving this issue in a fair and logical manner will not only help settle the controversy at issue in this case but will also allow district courts and the PTAB to apply the law in a more predictable and just manner in the future.

III. THE PTAB INCORRECTLY INTERPRETED 35 U.S.C. § 154(b) COUNTER TO FEDERAL CIRCUIT PRECEDENT

The PTAB's conclusions are based on an incorrect interpretation of 35 U.S.C. § 154(b).

A. The PTAB erred by misinterpreting *Merck v. Hi-Tech* and *Novartis v. Ezra* for when to apply PTE and PTA.

The PTAB drew a distinction between the way PTE and PTA should be applied because this Court in *Merck* partially based its conclusion on the principle that "'§ 154(b)(2)(B) expressly excludes patents in which a terminal disclaimer was filed from the benefit of a term adjustment for PTO delays,' but there is an 'absence of any such prohibition regarding Hatch-Waxman extensions' under § 156." 482 F.3d at 1322. Additionally, because *Ezra* recited this portion of this Court's opinion when summarizing the *Merck* case, the PTAB emphasized its importance. *Ezra,* 909 F.3d at 1373-74. This was error.

While this Court contrasted PTE and PTA in *Merck*, this Court did not conclude how double patenting should be evaluated, and more specifically

whether PTA should be applied to a challenged patent's original expiration date before an ODP analysis. That is, even if PTE and PTA have been distinguished with respect to whether a patentee may enjoy the benefit of each extension following the filing of a terminal disclaimer, *Merck* does not mandate how PTA should be treated with respect to PTE for the purposes of ODP.

B. The PTAB erred in concluding that the statutory language in § 154 "is clear" that any terminal disclaimer should be applied after any PTA.

The PTAB misinterpreted 35 U.S.C. § 154 when stating that the language "is clear" that any terminal disclaimer should be applied after any PTA. *Ex parte Cellect*, No. 2021-005258, at *12. The statute states that "No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer." 35 U.S.C. § 154(b)(2)(B). In other words, if a patent is subject to a terminal disclaimer, PTA cannot extend the patent's term ***beyond the terminal disclaimer***. If anything, this indicates that the proper time for an ODP analysis is *before* PTA is added to the challenged patent. Under the plain terms of § 154(b)(2)(B), it is the length of the terminal disclaimer that controls the available amount of PTA—not the amount of PTA that controls the terminal disclaimer. Thus, because the amount of available PTA is dependent on the presence of any disclaimer in the first place, the statute necessarily envisions

that the conditions that cause the need for the disclaimer must exist *before* PTA is awarded. The PTAB's interpretation, on the other hand, would lead to a circular and illogical reading of the statute: USPTO delays would trigger PTA; this PTA would then trigger the need for a terminal disclaimer; and that terminal disclaimer would then trigger a limitation on the PTA.

To avoid such a strained reading of the statute, it would be more consistent with the fundamental purposes of both PTA and ODP for the expiration date of a reference patent to be determined according to its full statutory term (including the PTA, if any, to which it is entitled), while the PTA for the challenged patent is not taken into account for purposes of an ODP analysis. The "original" expiration date of the challenged patent is the only date under which applicant gamesmanship could be relevant or even possible. In situations where the reference patent expires after the expiration date of the challenged patent based on the challenged patent's priority date, ODP should not apply, and the provisions of § 154(b)(2)(B) are not applicable. Having ODP apply solely due to the challenged patent's PTA is inconsistent with Congress' intent in establishing PTA and this Court's rationale enunciated in *Gilead*. The formula suggested above would avoid this inequitable outcome.

C. The PTAB erred in concluding that Congress' reference to terminal disclaimers in § 154 is "tantamount" to addressing obviousness-type double patenting.

The PTAB concluded that "given that terminal disclaimers arise almost exclusively to overcome obviousness-type double patenting, Congress expressly addressing terminal disclaimers in § 154 is tantamount to addressing obviousness-type double patenting." *See Ex parte Cellect*, No. 2021-005258, at *12-13 (citing *In re Van Ornum*, 686 F.2d 937, 948 (C.C.P.A. 1982); 37 C.F.R. § 1.321(c), (d); M.P.E.P. § 1490(II)). Further, the PTAB emphasized that this Court recognized in *Ezra* that a rule for terminal disclaimers should also apply to obviousness-type double patenting as "a logical extension." 909 F.3d at 1373. Based on this questionable logic, the PTAB concluded that obviousness-type double patenting and terminal disclaimers are two sides of the same coin: "the problem and the solution," and held that the statutory rule for terminal disclaimers in § 154 is directly relevant to double patenting and therefore is governed by § 154 as a "logical extension." *See Ex parte Cellect*, No. 2021-005258, at *12-13. However, not only is the PTAB's determination conclusory – applicants and patentees can and do file terminal disclaimers for any number of reasons, not just double patenting – but it is also not correct. The PTAB drew its conclusion regarding the application of § 154 to ODP analyses without taking into account the actual language of the statute or the congressional intent behind it. According to the congressional report of the first session of the 106th Congress, for example, PTA was described as an "award"

for "administrative delays caused by the USPTO that were beyond the control of the applicant" so as to "compensate applicants fully for USPTO caused administrative delays" and to reward "diligent applicants." H.R. Rep. No. 106-464, at 125 (Nov. 9, 1999) (Conf. Rep.). Thus, the legislative history makes clear that Congress intended this provision to be a reward for applicant diligence rather than a punitive measure.

IV. A JUDICIALLY CREATED DOCTRINE SHOULD NOT SERVE AS THE BASIS TO UNFAIRLY OVERRIDE A STATUTORY GRANT OF PATENT TERM

This Court has long held that ODP is a judge-made doctrine to prevent an unjustified extension of patent term. *See In re Berg*, 140 F.3d 1428, 1431–32 (Fed. Cir. 1998). In *Berg*, this Court chose to delineate between a one-way and a two-way test for ODP rejections but did so based on fairness, considering when problems arose "through no fault of the applicant." *Id.* at 1432. In the present case, the record makes clear that the applicant received no ODP rejection during the initial prosecution of the patents, but it was only upon reexamination after the expiration of both patents when the USPTO issued such a rejection. As a result, and through no fault of its own, the current patentee is left with no recourse, as a terminal disclaimer to overcome any such ODP rejection cannot retroactively be filed after the expiration of the patents. *See Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1347

(Fed. Cir. 2010). Such a result leaves the patentee, and an unknown number of future patentees, in an impossible position.

An applicant has no duty to raise an ODP rejection *sua sponte* as part of the duty of candor and good faith in communications with the USPTO. *See generally* 37 C.F.R. § 1.56. Instead, the USPTO is charged with issuing proper rejections during the course of prosecution. *See* M.P.E.P. § 706 ("The goal of examination is to clearly articulate any rejection *early* in the prosecution process *so that the applicant has the opportunity to provide evidence of patentability* and otherwise reply completely at the earliest opportunity.") (emphasis added). Although the process of reexamination is designed to address issues of patentability that might have been overlooked during the course of regular prosecution, Congress did not intend for reexamination to serve as a trap for unsuspecting applicants nor permit arbitrary application of U.S. patent law. Instead, reexamination was intended to strike a balance between the patentee's interest and the public interest, protecting the public from improperly issued patents, while ensuring that patentees are provided due process to address any rejections from the USPTO. *See In re Recreative Techs. Corp.*, 83 F.3d 1394, 1396 (Fed. Cir. 1996); *see also Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 601-602 (Fed. Cir. 1985) ("Congressman Kastenmeier, who introduced the legislation in the House, described the bill as

'an effort to reverse the current decline in U.S. productivity by strengthening the patent and copyright systems to improve investor confidence in new technology.'") (citing 126 Cong. Rec. 29,895 (1980)). Although patentees in cases such as this one are left with little recourse, this Court can exercise its discretion to provide relief in this circumstance. *See, e.g., Amgen*, 2021 WL 5366800, at *27; *Mitsubishi*, 533 F. Supp. 3d at 213.

Moreover, while the PTAB properly identified that gamesmanship plays a role when determining whether to sustain an ODP rejection, the PTAB misapplied the authority it cites. In *Amgen*, the district court held that statutory grants of PTE and PTA do not cause a patent to be invalid for ODP. 2021 WL 5366800, at *25. Indeed, the *Amgen* court specified that "the Court would exercise its equitable discretion not to apply the doctrine of ODP under the circumstances of [the] case because the difference in expiration dates between the '638 and '283 Patents is not the result of prosecution gamesmanship or any improper conduct by [the patentee]." *Id.* at *27 (citing *Immunex Corp. v. Sandoz, Inc.*, 964 F.3d 1049, 1059 (Fed. Cir. 2020) (noting that ODP is an "equitable doctrine")); *see also Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d at 1364 (Fed. Cir. 2018) (declining to apply ODP when the difference in expiration dates was due to "happenstance of an intervening change in patent term law," rather than "prosecution gamesmanship" by the

patentee); *cf. Gilead*, 753 F.3d at 1210 (applying ODP when the patentee was deemed to have engaged in prosecution gamesmanship by structuring priority claims); *In re Braat*, 937 F.2d 589, 593 (Fed. Cir. 1991)). Thus, where there has been no showing that the patentee engaged in any form of prosecution gamesmanship, and where the central issues in the case ultimately trace back to USPTO prosecution delays, an inflexible application of ODP serves no equitable outcome. Under such circumstances it is difficult to see any potential for gamesmanship, as both PTA and PTE are awarded on a statutory basis and are entirely free from the influence of an applicant.

In the precedent that the PTAB relied upon, *In re Fallaux,* this Court contemplated that "[i]n some cases there may still be the possibility of an *unjust* time-wise extension of a patent arising from patent term adjustment under § 154 or patent term extension under § 156," but the operative word (apparently ignored by the PTAB) is "unjust." 564 F.3d at 1319. In *Ezra*, this Court explicitly recognized that the defendant had failed to show gamesmanship during prosecution that it had deemed present in *Gilead* (and that was a factor in this Court's decision therein). 909 F.3d at 1375. The Court declined to invalidate Novartis' patent for ODP finding that "a judge-made doctrine" cannot "cut off a statutorily authorized time extension." *Id.*

In the absence of potential or actual gamesmanship, in the absence of any

fault of the patentee (who by statute is entitled to an extension of term as a result of USPTO delay), and in the absence of any recourse (besides this Court), it is manifestly unfair to determine that a patentee's statutorily authorized extension in cases such as this one can serve as the basis for ODP.

V. CONCLUSION

For these reasons, the Board's decisions should be reversed.

Respectfully submitted,

/s/ Kevin E. Noonan

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FOR THE FEDERAL CIRCUIT

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