2026-1333

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE ABLYNX N.V., SANOFI,
Appellants

Appeal from the United States Patent and Trademark Office,
Patent Trial and Appeal Board in Serial No. 17/409,019.

BRIEF FOR APPELLEE, DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Representative Claim

51. A fusion protein comprising at least two immunoglobulin single variable domains (ISV), wherein one of the at least two ISVs is at the C-terminal end of the fusion protein, wherein the ISV at the C-terminal end of the fusion protein is a VHH, a humanized VHH, a VH, or a camelized VH that: does not bind to serum albumin; and has a C-terminal end of the sequence $VTVSS(X)_n$ (SEQ ID NO: 34), in which n is 1, 2, 3, 4, or 5, and in which each X is chosen from the group consisting of alanine (A), glycine (G), valine (V), leucine (L), and isoleucine (I), except with the proviso that when n is 3, each X is chosen from the group consisting of glycine (G), valine (V), leucine (L), and isoleucine (I), wherein the fusion protein does not comprise an ISV that binds IL-23 or other interleukins.

Appx151.

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STATEMENT OF RELATED CASES

The Director is not aware of any other appeal in connection with the Patent Trial and Appeal Board ("Board") proceeding below that is before this or any other court. The Director is also unaware of any other case pending in this or any other court that will directly affect, or be directly affected by, the Court's decision in this appeal.

I. STATEMENT OF THE ISSUE

Appellants Ablynx N.V. and Sanofi seek claims to a fusion protein that they admit are patentably indistinct from claims in six prior-issued patents owned, in whole or in part, by one or both Appellants. The claims were rejected for obviousness-type double patenting (ODP) based on this Court's precedent applying ODP to address concerns over divided ownership and the risk of harassment by multiple assignees. There is no dispute that any patent that would issue from the underlying application will not result in extending the term of Appellants' six other patents. The issue on appeal is straightforward: whether this Court's precedent supports an ODP rejection based solely on the risk of harassment by multiple assignees.

II. STATEMENT OF THE CASE

This appeal arises from the examination of application serial no. 17/409,019 (the '019 application or Appellants' application), which is assigned to Appellants Ablynx N.V. and Sanofi. Appx20-151; Appx1169-1171.[1] The Examiner rejected pending claims 51 and 54-56 for ODP as being unpatentable over claims of six reference patents. Appx4; Appx3424-3441; Appx4789-4808. Ablynx owns, alone or in part, all six reference patents, whereas Sanofi (or Merck) shares ownership

[1] "Appx__" refers to the Joint Appendix in this case; "Br. __" refers to Appellants' Opening Brief.

for some of the six reference patents. Appx5-6; Appx4792-97; Appx182-188; Appx3625; Appx3816; Appx3978; Appx4121; Appx4209; Appx4714; Br. at 9. Each reference patent also shares at least one common inventor to the '019 application. *Id*. The Board affirmed the Examiner's ODP rejections (Appx1-19), and this appeal followed.

A. Appellants admit their pending claims are not patentably distinct over their issued patent claims.

The '019 application was filed on August 23, 2021, and is a continuation application in a series of applications that claim priority to International Application PCT/EP2012/062251, filed June 25, 2012. Appx20. Appellants rely on that PCT application date as the patent-term filing date for their application (*i.e*., the date from which their 20-year patent term is calculated). Br. at 3. The first-filed application in the series of applications was filed June 25, 2012, as Application No. 14/128,681 (the '681 application), the national stage entry of PCT/EP2012/062251. Appx12; Appx190; *see* 35 U.S.C. § 363.

Prior to filing the '019 application, Appellants filed at least five other continuation applications in the same family, claiming priority to that first-filed '681 application, resulting in the grant of four patents (which are not part of the underlying rejections here). The following chart identifies the family of applications claiming priority to the '681 application, with the '019 application on

appeal indicated in yellow and the four earlier-filed, patented applications indicated in green:

Child Continuity Data

Application #	Filing or 371(c) Date	Status	Patent #	AIA	Description	Parent Application #
14/698,917	2015 Apr 29	Expressly Abandoned--During Examination	-	No	is a Division of	14/128,681
15/615,197	2017 Jun 06	Patented Case	11192937	No	is a Continuation of	14/128,681
15/615,281	2017 Jun 06	Patented Case	11192938	No	is a Continuation of	14/128,681
15/975,834	2018 May 10	Abandoned--Failure to Respond to an Office Action	-	No	is a Continuation of	14/128,681
16/822,186	2020 Mar 18	Patented Case	10858418	No	is a Continuation of	14/128,681
16/823,412	2020 Mar 19	Patented Case	12006352	No	is a Continuation of	14/128,681
17/408,893	2021 Aug 23	Patented Case	12662525	No	is a Division of	14/128,681
17/408,937	2021 Aug 23	Final Rejection Mailed	-	No	is a Continuation of	14/128,681
17/408,987	2021 Aug 23	Patented Case	12516105	No	is a Continuation of	14/128,681
17/409,019	2021 Aug 23	Application Involved in Court Proceedings	-	No	is a Continuation of	14/128,681
18/299,871	2023 Apr 13	On Appeal--Awaiting Decision by the Board of Appeals	-	No	is a Continuation of	14/128,681

(Continuity of the '681 application, retrieved from https://data.uspto.gov/patent-file-wrapper/search/details/14128681/continuity).[2]

During prosecution of the '019 application, Appellants filed terminal disclaimers to overcome separate ODP rejections over the then-pending first-filed '681 application and over two of those issued patents in the family, U.S. Patent

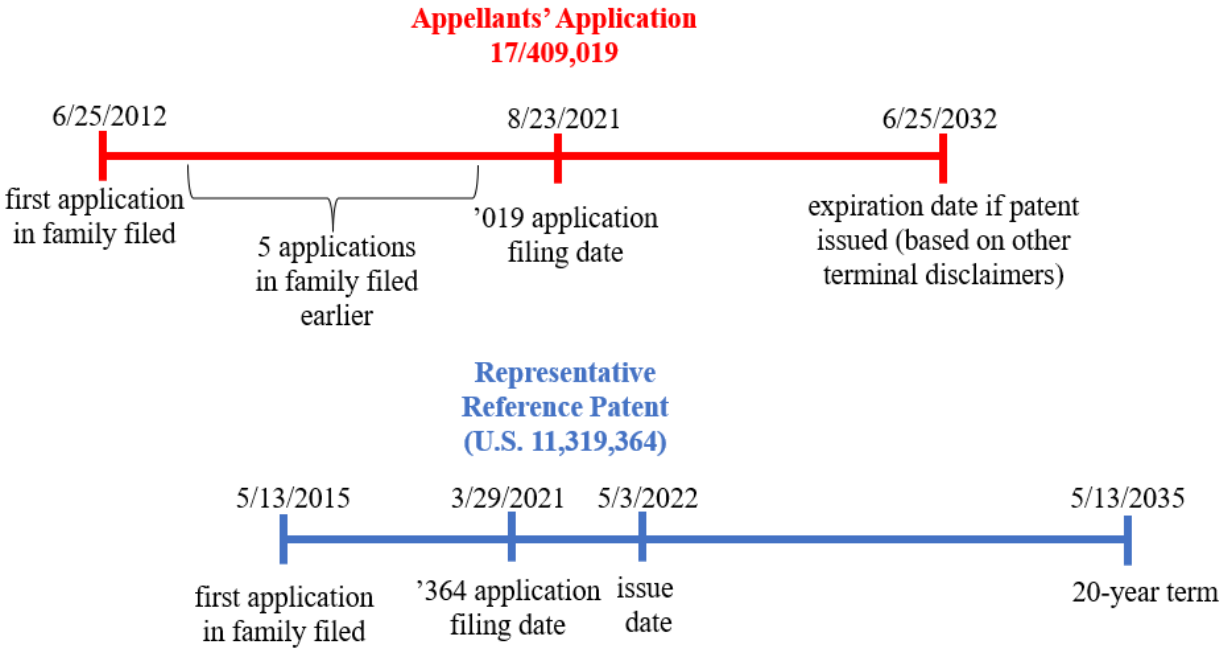
[2] Although the continuity chart is not in the Joint Appendix, the Court may take judicial notice of this information as it is a matter of public record and readily verifiable. *Cyntec Co., Ltd. v. Chilisin Elecs. Corp.,* 84 F.4th 979, 989 n.6 (Fed. Cir. 2023).

Nos. 11,192,938 and 10,585,418. Appx3303-3305; Appx3457-3459; 35 U.S.C. § 253; 37 C.F.R. § 1.321. According to Appellants, because those issued patents expire on June 25, 2032, any patent that issues from the ’019 application would expire then as well. Br. at 11.

As relevant to the ODP rejections on appeal, Appellants concede that the pending claims of the ’019 application are patentably indistinct over claims of six reference patents used to reject the claims, each owned by one or both Appellants. Br. at 12. Those reference patents are U.S. Patent Nos. 11,319,364 (the ’364 reference patent), 11,603,401, 11,813,307, 11,932,702, 11,999,797, and 12,129,308. None of the reference patents share a priority claim with the ’019 application. Appx5; Appx190; Appx3625; Appx3816; Appx3978; Appx4121; Appx4209; Appx4714; Appx4799.

Although there are six reference patents underlying the ODP rejections, Appellants admit that the ’364 reference patent is representative of the relative timing of the ’019 application and each of the six reference patents. Br. at 12. The ’019 application was filed after the application that issued as the ’364 reference patent, and Appellants admit that the claims of the ’019 application are patentably indistinct from the claims of the ’364 reference patent. Appellants also acknowledge that the ’019 application has several preceding continuation applications in its family. The following figure illustrates relevant dates and

information about the pending ’019 application and the representative ’364 reference patent:



B. The Board affirmed the Examiner’s ODP rejections of Appellants’ pending claims.

The Board affirmed the Examiner’s rejection of Appellants’ pending claims as being unpatentable under ODP over claims in the six reference patents. Appx1-19. The Board determined that this Court’s decision in *In re Fallaux*, 564 F.3d 1313 (Fed. Cir. 2009) “is directly on point” to the instant case, and under that binding precedent, it was appropriate for the Examiner to reject the pending claims under ODP. Appx8-17. The Board explained that although any patent granted on the ’019 application would expire before the reference patents, the Examiner’s rejection was proper because “there is a second justification for obviousness-type

double patenting—harassment by multiple assignees." Appx9 (quoting *Fallaux*, 564 F.3d at 1318).

Appellants did not contest that the '019 application claims subject matter that is patentably indistinct from their six prior-issued reference patents. Appx10. Instead, Appellants argued that (1) the reference patents do not qualify as ODP references because they have a later patent-term filing date than the '019 application; (2) the two-way test for an ODP rejection should apply when the reference patent's patent-term filing date is later than that of the challenged application; and (3) that principles of equity favor no ODP rejection. The Board was not persuaded.

First, the Board rejected Appellants' assertion that the reference patents do not qualify as ODP references. Appx6-8. Appellants relied on a series of decisions by the Federal Circuit to argue that the reference patents have later patent-term filing dates and thus are ineligible to serve as ODP references. *Id*. This is so, Appellants argued, because preventing term extension is "the fundamental purpose" of ODP, any patent that were to issue from the '019 application would not extend the patent term of any of the reference patents that expire later, and therefore the rejection was improper. Appx6-7.

The Board found Appellants' cited decisions have limited application to the facts of this case. Appx7-8. The Board observed:

- *Novartis AG v. Ezra Ventures LLC,* 909 F.3d 1367, 1373-74 (Fed. Cir. 2018) addresses the interaction between patent term extension (PTE) under 35 U.S.C. § 156 and ODP. Appx7.

- *In re Cellect, LLC,* 81 F.4th 1216, 1226-29 (Fed. Cir. 2023) grapples with how patent term adjustment (PTA) affects an ODP analysis. Appx7.

- In *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.,* 909 F.3d 1355, 1366 (Fed. Cir. 2018), the Court encountered a "particular situation" involving "an earlier-filed, earlier-issued, pre-URAA patent that expires after the later-filed, later-issued, post-URAA patent due to a change in statutory patent term law." The Court used the pre-URAA patent's issuance date as the reference point for its ODP analysis. *Id*.; Appx7.

- The Court in *Gilead Sciences, Inc. v. Natco Pharma Ltd.,* 753 F.3d 1208, 1211-12, 1217 (Fed. Cir. 2014) answered "a narrow question: Can a patent that issues after but expires before another patent qualify as a double patenting reference for that other patent?" and held that "an earlier-expiring patent can qualify as an obviousness-type double patenting reference for a later-expiring patent under the circumstances" of that case. Appx7-8.

- The Court in *Allergan USA, Inc. v. MSN Labs. Priv. Ltd.,* 111 F.4th 1358, 1366 (Fed. Cir. 2024) also answered a narrow question: "can a first-filed, first-issued, later-expiring claim be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date?" and held "that it cannot." Appx8.

- *Acadia Pharms. Inc. v. Aurobindo Pharma Ltd.*, 706 F. Supp.3d 477 (D. Del. 2023), *aff'd*, 2025 WL 1618201 at *1 (Fed. Cir. June 9, 2025) "is entirely controlled by" *Allergan* and "appl[ied] *Allergan's* holding that 'a first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date.'" Appx8.

The Board concluded that the facts underpinning Appellants' cited precedent materially differed from the facts of this case (e.g., this case does not involve PTE, PTA, a pre-URAA patent, or a first-filed patent in its family), and that this case

instead mirrored the scenario in *Fallaux*, a case Appellants did not mention before the Board. Appx8-9. Much like the facts at issue here, in *Fallaux*, this Court affirmed an ODP rejection even though "the reference patents have later patent-term filing dates compared to the application under examination" and "any patent issued from the application would expire before the reference patents expired," based on a second justification underlying ODP—the risk of harassment by multiple assignees. Appx9. As the Board observed, *Fallaux* "is binding" and "remains good law," and this second justification applies to the facts of this case. *Id*. The Board further noted that Appellants had not identified any legal authority rejecting the anti-harassment rationale as a sole basis for an ODP rejection, and that this Court has reaffirmed the multiple-assignee harassment rationale following *Fallaux*. Appx16; Appx17 (citing *In re Hubbell,* 709 F.3d 1140, 1148 (Fed. Cir. 2013) and *Cellect*, 81 F.4th at 1230). The Board also found the "risk of separate ownership" is highlighted here where Appellants complained of their potential inability to alienate their patent rights if ODP applies. Appx17.

Second, the Board was not persuaded by Appellants' assertion that the two-way test should be applied to assess patentable distinctiveness. Appx10-13. The Board explained that the one-way test is normally applied in an ODP analysis, which assesses whether application claims are obvious variants of the reference claims. Appx11. The two-way test is a narrow exception to the standard ODP

analysis, where in addition to making the above assessment, the Examiner looks at whether the reference claims are obvious variants of the application claims. Appx11. The two-way test may apply when reference claims issue from a second-filed application but only in the unusual circumstance where the USPTO is *solely* responsible for the delay in causing the second-filed application to issue prior to the first. Appx11 (citing *Fallaux*, 564 F.3d at 1316).

The Board determined that the narrow two-way test exception did not apply to Appellants' claims. Appx11-13. The Board found that Appellants waited to prosecute the claims in the '019 application for more than nine years after the priority application was filed. Appx12-13. Appellants did not dispute that they were not precluded from prosecuting these claims earlier. Appx12. Under these facts, much like those in *Fallaux*, the Board determined that the USPTO was not solely responsible for delay that caused the reference claims to issue earlier, and therefore that the two-way test did not apply. Appx13.

Finally, the Board was not swayed by Appellants' equitable arguments. Appx13-18. The Board was not persuaded that the rejection should not lie because it does not fit within the fundamental purpose of the ODP doctrine, which Appellants argued is to prevent patentees from obtaining a second patent on a patentably indistinct invention to effectively extend the life of a first patent to that subject matter. Appx16. The Board explained that this Court has recognized that

although such a rationale may have limited force in post-URAA patents (where patent term is measured from date of priority), it has also recognized that the ODP doctrine has continued importance and can be justified solely by the anti-harassment rationale. Appx16-17 (citing *Fallaux*, 564 F.3d at 1318; *Allergan*, 111 F.4th at 1367; *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014); *Hubbell*, 709 F.3d 1147-1148). And that the risk of harassment exists even if ownership is not currently divided. Appx17 (citing *Cellect*, 81 F.4th at 1230.)

Appellants' other policy arguments—that ODP rejections would stifle innovation and restrict their ability to alienate their patent rights even when there is no unjustified time-wise extension—also did not overcome *Fallaux*. Appx16-17. As the Board observed, a terminal disclaimer over the later-expiring patent (covering the later technology) would not cut short the term of the patent covering the earlier-developed technology. Appx15. Further, the Board explained that Appellants are not without recourse to obviate an ODP rejection and receive a patent. For example, Appellants can file a timely terminal disclaimer that satisfies the common ownership requirement. *Id*. Appellants could also amend their claims to be patentably distinct or traverse the rejection. *Id*.

For all the foregoing reasons, the Board affirmed the Examiner's ODP rejections, explaining that it was proper to require a terminal disclaimer to address

the risk of separate ownership of patentably indistinct claims even if there would not be unjustified patent term extension. Appx17.

III. SUMMARY OF THE ARGUMENT

The Board correctly determined that Appellants' pending claims are unpatentable for ODP. Appellants concede they already own at least six patents that claim subject matter that is patentably indistinct from the claims on appeal. The doctrine of ODP places limits on an inventor's ability to obtain multiple patents on a single invention or obvious variant thereof. Appellants' approach would limit ODP only to scenarios where patent issuance would result in unjustified patent term extension. Appellants circumvent the anti-harassment rationale for ODP that this Court has repeatedly endorsed as a mechanism to avoid separate ownership and enforcement of multiple patents on essentially the same invention. The Board's decision properly applied this Court's binding precedents on ODP.

Appellants' primary argument on appeal is that their issued patents do not qualify as ODP references because they have later expiration dates (with later patent-term filing dates) than Appellants' pending claims and therefore no unjustified time-wise extension of patent term is possible. Preventing an unjust time-wise extension of a patentee's exclusive rights, however, is not the only purpose of the ODP doctrine. This Court's binding precedent recognizes that ODP

also seeks to prevent the risk of harassment by multiple assignees. The Board properly applied that binding precedent and its reasoning to this case. Here, if the '019 application were to issue, Appellants could separate ownership of patentably indistinct claims and create the very harassment risk ODP is designed to prevent. Indeed, Appellants themselves express a desire to separate patent rights for their patentably indistinct inventions among multiple owners. Appellants also offer no other reason for refusing to file a terminal disclaimer for their commonly-owned reference patents. The Board recognized the risk of separate ownership and harassment, and, under this Court's precedent, properly affirmed the Examiner's rejection of the claims for ODP on that basis. This Court should affirm.

IV. ARGUMENT

A. Standard Of Review

Appellants have the burden to show that the Board committed reversible error. *In re Watts*, 354 F.3d 1362, 1369 (Fed. Cir. 2004). The ultimate conclusion of obviousness-type double patenting is a question of law that this Court reviews de novo. *In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997).

B. The Board correctly determined that the cited reference patents render Appellants' pending claims unpatentable for ODP.

Section 101 of the Patent Act prohibits an individual from "obtaining ***more than one patent on the same invention***." 35 U.S.C. § 101 (emphasis added); *see Abbvie*, 764 F.3d 1366. ODP is a judicially created doctrine grounded in § 101 and

in public policy to limit the issuance of multiple patents on non-distinct inventions. *Abbvie*, 764 F.3d at 1372-74. One policy rationale underlying the doctrine is to protect the public from the risk of harassment by multiple assignees who could separately assert infringement of patents claiming the same invention or an obvious variant. *See Fallaux*, 564 F.3d at 1319 (affirming the Board's ODP rejection because of the potential for harassment by multiple assignees even though there was no time-wise extension of the patent); *Hubbell*, 709 F.3d at 1147 (reaffirming *Fallaux* and the multiple-assignee harassment rationale); *In re Van Ornum*, 686 F.2d 937, 944-48 (C.C.P.A. 1982) (approving the requirement for common ownership in terminal disclaimers because of the potential for harassment by multiple assignees). The multiple-assignee harassment rationale renders the underlying ODP rejections appropriate and Appellants' pending claims unpatentable.

Appellants concede that, if the '019 application's claims were to issue, it would be at least the *seventh* patent[3] to claim patentably indistinct subject matter, and under Appellants' approach would not have a terminal disclaimer tying the '019 patent to any of those six reference patents. True, the six reference patents at issue in this appeal would expire after any patent granted on the '019 application's

[3] In response to other ODP rejections, Appellant filed terminal disclaimers over three other patents or patent applications. Appx3303-3305; Appx3457-3459.

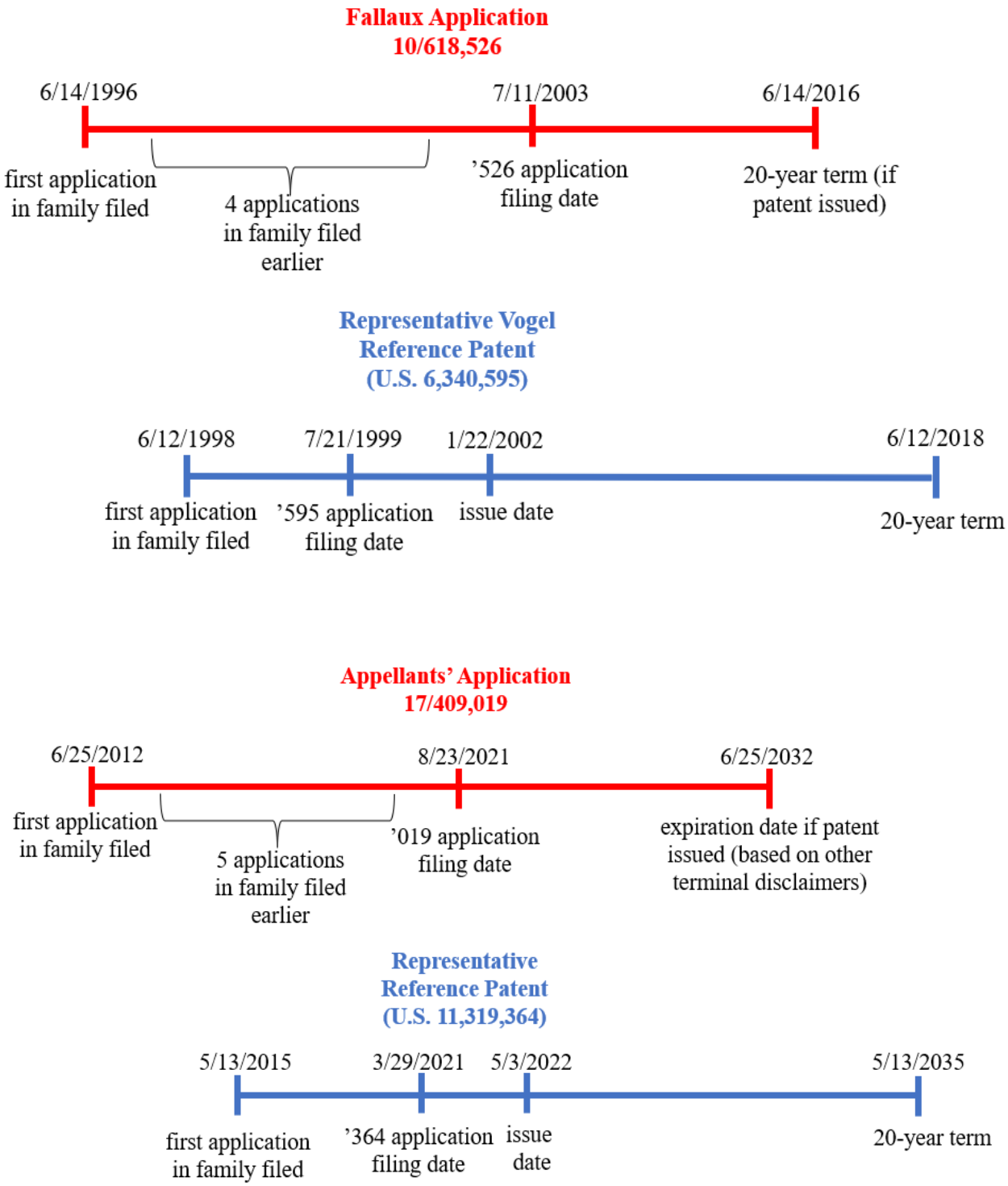
pending claims. But the risk of harassment by multiple assignees still exists without a terminal disclaimer to tie ownership of the '019 application to Appellants' other patentably indistinct patents—*i.e.*, effectively tying the claims together into ***one patent***. *See Van Ornum*, 686 F.2d at 948 (explaining a terminal disclaimer tying two patents together "is tantamount for all practical purposes to having all claims in one patent"). Without a terminal disclaimer, if the '019 application's claims were to issue in a patent, Appellants would be able to sell that patent—containing patentably indistinct claims—to another entity and expose the public to multiple infringement suits by different parties for the same conduct. Indeed, Appellants have expressed a desire to alienate their patent rights. Br. at 38. This Court has recognized the risk of harassment in the ODP context and held it justifies holding claims unpatentable.

1. This Court's precedent mandates that the USPTO reject Appellants' pending claims even when there is no unjustified time-wise extension because a risk of harassment remains.

This Court has repeatedly validated application of ODP principles like those on appeal here. As the Board properly determined, this Court's precedential decision in *In re Fallaux* is directly on point and controls the outcome in this case. Appx10-17. The facts here meaningfully mirror those in *Fallaux* (using the '364 reference patent as representative):

- The ’019 application’s priority date is earlier than the ’364 reference patent’s priority date;
- The ’019 application’s actual filing date is later than the ’364 reference patent’s application’s actual filing date;
- The ’364 reference patent is not in the same patent family as the ’019 application but shares a common inventor;
- The ’019 application is not the first-filed application, but a continuation application in its family; and
- The ’364 reference patent’s 20-year patent term would likely expire after the ’019 application’s 20-year patent term (*i.e.*, there does not appear to be a time-wise extension of the patent right).

See Fallaux, 564 F.3d at 1315. As the figures below illustrate, the timelines for the Fallaux application (No. 10/618,526) and a reference patent in that case (U.S. Patent No. 6,340,595) are strikingly similar to the timelines for the ’019 application and the ’364 reference patent:



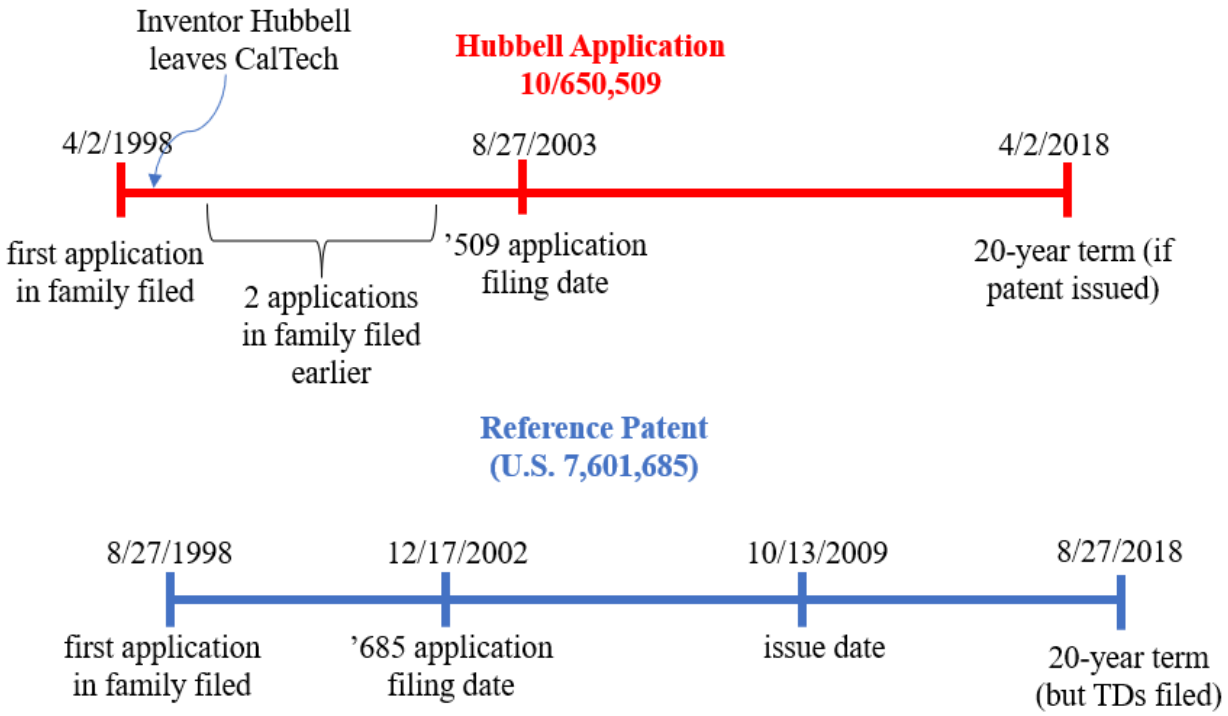
In *Fallaux*, this Court affirmed the Board's ODP rejection based on later-expiring reference patents with later patent-term filing dates. *Id.* at 1319. As the

Board noted here (Appx16-17), *Fallaux* acknowledged that "the unjustified patent term extension justification for obviousness-type double patenting has limited force in [this case]," but it identified a second, independent justification for obviousness-type double patenting—"harassment by multiple assignees"—to affirm the ODP rejection. *Id.* at 1318-19.

The *Fallaux* decision cited this Court's decision in *Van Ornum*, which also relied on the multiple-assignee-harassment justification. *Id.* at 1319 (citing *Van Ornum,* 686 F.2d at 944-48). In *Van Ornum*, an application's claims were rejected for ODP over two reference patents and the Court affirmed. *Van Ornum*, 686 F.2d at 944-48. The Court approved of the USPTO's regulation (37 C.F.R. § 1.321), which permits applicants to overcome an ODP rejection by filing a terminal disclaimer. *Id*. As the Court explained, a terminal disclaimer ties together both the patent term and the ownership of patents (claiming indistinct inventions)—creating a situation that is tantamount to having all of the claims in one patent—and serves to avoid the risk of harassment by multiple assignees. *Id*. at 948 (citations omitted).

The multiple-assignee harassment rationale was again applied in *Hubbell,* 709 F.3d at 1148, as the exclusive reason to affirm an ODP rejection. Much like *Fallaux*, the reference patent in *Hubbell* also had a later patent-term filing date than the application being examined but was still rejected for ODP. *Id*. at 1142-43, nn. 1-2. As the figure below demonstrates, the timeline for the Hubbell application

(No. 10/650,509) and the reference patent (U.S. Patent No. 7,601,685) also bears a striking resemblance to the timelines (included above) depicting the facts in *Fallaux* and of this case:



The Court again relied only on the second justification underlying ODP and affirmed the rejection, holding that "the multiple assignee harassment justification adopted in *Van Ornum* and reaffirmed in *Fallaux* applies here." *Hubbell*, 709 F.3d at 1148. The Court also explained that "the harassment justification is 'particularly pertinent' in cases where, as here, the application and the conflicting patent are not commonly owned." *Id.* at 1147.

To be sure, this Court has noted that preventing an unjust extension of patent term is a "fundamental" purpose of ODP. *See* Br. at 15-24, 30. But Appellants are

incorrect that ODP applies *only* in those circumstances. *See, e.g.*, Br. at 29. While *Allergan*, *Ezra*, and *Gilead* evaluated ODP issues based on concerns about unjustified patent-term extension, those cases did not limit the application of ODP to that scenario. None of those decisions discusses the additional, alternative anti-harassment rationale imposed by this Court's prior precedent. Nor can the Court's silence in those decisions about the anti-harassment rationale be read to speak to that rationale's continued viability because there is no indication that the parties to those appeals advanced the rationale. Appellants' invitation to impute holdings into those decisions on issues not raised should be rejected. *See Greenlaw v. United States*, 554 U.S. 237, 243 (2008); *Allergan*, 111 F.4th at 1369 n.6 (applying *Greenlaw* and principles of party presentation to reject argument that precedent should be read to address an issue that was not raised). The discussion in these decisions about protecting against unjustified patent term extension under particular factual circumstances does not disturb multiple prior occasions where the Court held that, even for post-URAA patent applications and patents, the policy of preventing litigation harassment by multiple assignees justifies an ODP rejection. *See, e.g.*, *Fallaux*, 564 F.3d at 1318-19; *Hubbell*, 709 F.3d at 1147. Moreover, the anti-harassment justification was the sole basis for this Court upholding ODP rejections in those cases. *See Fallaux*, 564 F.3d at 1319; *Hubbell*, 709 F.3d at 1149.

Even more recently, as the Board correctly noted (Appx17), this Court's decision in *Cellect* agreed "that a terminal disclaimer would have been required to ensure common ownership" in the ODP context because the "risk of separate ownership existed" and the "risk remains for multiple assignees to seek past damages." *Cellect*, 81 F.4th at 1230. Even Cellect's promises to not divide ownership of the patents could not overcome the terminal disclaimer requirement or the ODP issue because "[p]romises do not substitute for sound applications of rules of law." *Id.* Though it would not cure Appellants' ODP problem, Appellants have made no such promises here to maintain common ownership, and in fact insinuate a desire to divide ownership. *See* Br. at 38. Ultimately, as the Board correctly noted, *Fallaux* "remains good law," is "directly on point," and controls the outcome here. Appx9; Appx11.

Appellants argue *Fallaux* and *Hubbell* do not control because the Court did not decide in those cases whether the reference ODP claims qualified as proper ODP reference claims.[4] Br. at 33-37. That argument fails.

[4] Appellants also assert that the Board's reliance on *Cellect* was misplaced because that case addressed a different ODP question and the patent owner there did not challenge whether the reference claims were proper ODP references. Br. at 36-37. But the Board simply relied on *Cellect*'s reaffirmation of separate assignee harassment as a justification underlying ODP and that a terminal disclaimer, requiring common ownership, can be filed to overcome an ODP rejection (promises not to alienate do not suffice), which Appellants do not dispute. Appx17.

In *Fallaux*, the Court acknowledged that "the unjustified patent term extension justification for [ODP] has limited force in this case," but nonetheless affirmed the ODP rejection based on the "second justification for obviousness-type double patenting—harassment by multiple assignees." *Fallaux*, 564 F.3d at 1318-19. *Fallaux* thus affirmatively answers the question Appellants argue is unsettled: can ODP apply even when there is no unjustified time-wise extension at issue? Appellants try to avoid *Fallaux* by arguing the Court did not address whether a later-filed, later-expiring patent may serve as an ODP reference against an earlier-filed application, but instead only addressed whether the two-way test should apply there. Br. at 14, 34-36. That ignores how the Court reached the issue. Fallaux argued that the two-way test applied when there was no unjustified time-wise extension. *Fallaux*, 564 F.3d at 1318-1319. And in that case, there was no time-wise extension because the ODP reference was later-expiring compared to any patent that would issue from the application at issue with its earlier patent-term filing date (as the figure above illustrates). The Court nevertheless affirmed the ODP rejection based on the anti-harassment rationale. *Id*. at 1319. The fact that the Court did not articulate the ODP issue and the anti-harassment rationale using Appellants' explicit formulation does not detract from the clear import of the Court's analysis. Indeed, if not for the anti-harassment rationale, Appellants'

argument amounts to one that the rejections in *Fallaux* were affirmed for no reason. That cannot be.

Likewise, in *Hubbell*, which reaffirmed *Fallaux*, the Court again relied on harassment by multiple assignees as an independent basis for ODP. 709 F.3d at 1146-48. The other ODP rationale—unjustified time-wise extension of patent term—was inapplicable because, as the figure above demonstrates, the challenged application, like Appellants' application, would expire before the reference patent. *See id.*, 709 F.3d at 1142-43 nn.1, 2 (discussing the progeny of the '509 application at issue and '685 reference patent, with the '685 reference patent having a later patent-term filing date).

2. None of the narrow circumstances where this Court has limited the application of ODP apply here.

Despite Appellants already owning or co-owning six patents on claims patentably indistinct from those in the '019 application, Appellants attempt to avoid ODP by trying to squeeze the facts of their application into one of the few instances this Court has held ODP inapplicable. These attempts fail.

Many of Appellants' arguments rely on the false premise that an unjustified extension of patent term is the sole justification underlying the ODP doctrine. As already discussed, this Court's precedent in *Fallaux*, *Hubbell*, *Van Ornum*, and *Cellect* make clear that the risk of harassment by multiple assignees is a second and independent basis justifying ODP.

Appellants argue that, under this Court's decision in *Allergan*, the '019 application has an earlier priority date than those of the reference patents, making the '019 application "first-filed" and one that cannot extend the term of a patent. Therefore, Appellants argue, the reference patents do not qualify as ODP references for the '019 application. Br. at 25-27 (citing *Allergan,* 111 F.4th at 1369). Appellants' reliance on *Allergan* is inapt.

As a factual matter, the '019 application is not "first" in its own family—there are several earlier-filed applications and earlier-issued patents that each have the same priority claim.[5] *See* Appx4802. The '019 patent *application* is also not the first-filed, first-issued *patent*, like the patent at issue in *Allergan*. 111 F.4th at 1362. Accordingly, on the facts, the '019 application is not analogous to the first-filed, first-issued patent subject to the ODP allegation in *Allergan*, which was "the first patent claiming eluxadoline to be filed." 111 F.4th at 1364-65.

As a legal matter, *Allergan* does not address the situation here. In *Allergan*, the Court established a narrow shield to ODP, holding that "a first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date." *Id.* at 1369. As

[5] It is also not first compared to five of the six reference patents, which issued from applications actually filed earlier. *See* Br. at 7-9; Appx3625; Appx3816; Appx4121; Appx3978; Appx4714; Appx4209.

noted above, the '019 application is not first-filed. Appellants incorrectly equate "earlier" with "first"—arguing the '019 application is "first" because it has an earlier patent-term filing date—to try to use *Allergan* to avoid ODP. Br. at 25-27. But that was not this Court's decision in *Allergan*. Instead, this Court in *Allergan* repeatedly distinguished between "first filed"—meaning its actual filing date—and patent-term filing date, which it equated with "priority date." *See, e.g.,* 111 F.4th at 1367 (explaining that a patent's term is measured from its priority date); *see also id*. at 1369 (distinguishing "first-filed" claim and "later-filed" claim where the claims have "a common priority date").

This distinction between actual filing date and patent-term filing date underlies the reasoning of *Allergan*, which focused on protecting the patent that was the first to *claim* the distinct subject matter, and which protects against an ODP charge based on a later-filed, later-issued continuation patent having a common priority date. *Id*. at 1371 (distinguishing first-filed applications seeking to claim the "most valuable inventive asset" from "subsequently filed continuing application[s]" with the same priority date that "cover[] a modification of that invention"). As *Allergan* explained, a patent-term filing date is relevant to a patent's expiration date, and considering a patent's expiration date is not the same as addressing the role of filing dates. *Id*. at 1367, 1370. And nothing in *Allergan* supports Appellants' attempt to craft a new rule for what is "first" between

different patent families. *See* Br. at 25-28. To the contrary: equating "first-filed" with an earlier patent-term filing date removes the role of filing dates established by *Allergan*. 111 F.4th at 1370. Indeed, under Appellants' reading of *Allergan*, both the challenged patent and reference patent in that case would be "first," as they have the same patent-term filing date. *Id*. at 1364.

Accordingly, the only patent protected under the *Allergan* shield is the first-filed, first-issued patent covering a patentably distinct invention from a later continuation application sharing a common priority date. 111 F.4th at 1369. Appellants' '019 application is not "first-filed," "first-issued," and it does not "ha[ve] a common priority date" with the reference patents. *Allergan* simply does not shield a later-filed continuation application from an ODP rejection, including rejections relying on patents from another patent family, as is the situation for the '019 application here. And while Appellants cry foul at the lack of protection for "foundational" technology (*see* Br. at 37), that assertion overlooks that the '019 application is not the first application to claim such technology and Appellants' possession of several already-granted patents covering patentably indistinct inventions.[6]

[6] As noted, Appellants have also filed terminal disclaimers over earlier-filed, earlier-issued patents that are within the same family as the '019 application. Appx3303-3305; Appx3457-3459. Clearly, the '019 application is not "first."

Appellants' attempt to analogize their facts to *Ezra* and *Gilead*, arguing that reference patents having a later patent-term filing date do not qualify as ODP references, fares no better. Br. at 27-28. As the Board explained, those cases involved fact-specific holdings that are not applicable to this case. Appx7-8.

In *Ezra*, the Court relied on patent term extension (PTE) granted under 35 U.S.C. § 156 to determine that ODP does not invalidate a patent with validly obtained PTE. 909 F.3d at 1373-75. True, the Court mentioned that the scenario in *Ezra* permitted an earlier-filed, earlier-issued patent to extend patent term beyond the patentably indistinct patent, but the Court held that, under the Patent Act, PTE granted under § 156 has a distinct purpose that terminal disclaimers cannot cut short. *Id*.; *see also, e.g.*, *Cellect*, 81 F.4th at 1227 (holding that *Ezra*'s narrow application of ODP on patents with validly obtained PTE under § 156 does not extend to patents with patent term adjustment granted under 35 U.S.C. § 154 due to the differences in the statutory provisions).

Appellants' reliance on *Gilead* is also unavailing. Appellants argue that, under *Gilead*, ODP should be based on patent-term filing date, not issue date, and that the Board's approach contravenes *Gilead* by focusing on which patent issued first. Br. at 27-28. That is not what *Gilead* held and that is not what the Board did here. As the Board explained, *Gilead* narrowly held that a patent that is later-issuing and earlier-expiring can qualify as an ODP reference. Appx7-8 (citing

Gilead, 753 F.3d at 1211-12, 1217). It did not foreclose a later-expiring patent from qualifying as an ODP reference under the harassment rationale. *See id*. And the Board here did not focus on issue dates; it simply analogized to *Fallaux* and relied on the anti-harassment justification of ODP (while also noting the '019 application was actually filed over six years after the earliest reference patent was filed). Appx7-9; Appx12.

Appellants next argue that there is no evidence of gamesmanship resulting in an undue extension of patent term. Br. at 28. But there is no requirement that the Board make such a finding to conclude that Appellants' pending claims are unpatentable under ODP. *See Cellect*, 81 F.4th at 1230 (determining that "there is no basis for an examiner to inquire into the intent of an applicant, or credit it" in making an ODP rejection); *Fallaux*, 564 F.3d at 1317 (rejecting relevance of "proof of nefarious intent" in determining whether two-way test applies in ODP analysis). And again, Appellants' argument ignores that the Board relied on the anti-harassment justification for ODP.

Appellants also assert that the Court's decisions in *Allergan*, *Ezra*, and *Breckenridge* show that the anti-harassment justification alone is not sufficient to find that a patent qualifies as an ODP reference because, otherwise, every patent would qualify against a challenged patent or application. Br. at 31. First, not every patent would qualify as an ODP reference under the second justification—an

Examiner would still need to show, e.g., that the reference claims and application claims are patentably indistinct, and have a common assignee, common inventor, or are subject to a joint research agreement. *See* MPEP § 804 (9th ed. Rev. 01.2024). Second, as largely discussed above and as explained by the Board, *Allergan, Ezra*, and *Breckenridge* involve narrow fact-specific limitations on ODP that are not pertinent to the facts of this case and do not answer the question of whether the risk of harassment alone justifies ODP. Appx7-8 (e.g., finding that *Breckenridge*, 909 F.3d at 1366, involved a "particular situation" involving "an earlier-filed, earlier-issued, pre-URAA patent that expires after the later-filed, later-issued, post-URAA patent due to a change in statutory patent term law."). By contrast, other cases like *Fallaux* and *Hubbell* expressly affirmed ODP rejections based solely on the anti-harassment justification. *See* above § IV.B.1

Appellants finally argue that the availability of the two-way test confirms that the risk of harassment alone is not a sufficient basis to establish that a reference qualifies as an ODP reference. Br. at 31-33. As a general matter, the two-way test is a narrow exception to the general rule of the one-way test, in which the Examiner asks whether the application claims are obvious over the reference claims. Appx11 (citing *Fallaux*, 564 F.3d at 1316). Under the two-way test, the Examiner also asks whether the reference claims are obvious over the application claims. *Id*. But the two-way test is "only appropriate in the unusual circumstance

where, inter alia, the United States Patent and Trademark Office (PTO) is *solely* responsible for the delay in causing the second-filed application to issue prior to the first." *Id.*

Here, Appellants do not dispute that the claims of the '019 application could have been filed in an earlier application in the family that preceded the patent-term filing dates of the reference patents, and thus were responsible for any delay in those claims being examined. Appx12 (finding "Appellant chose to delay the filing of the instant application until more than nine years after the [first] application was filed."). So as a practical matter, the two-way test is not applicable to the facts of this case, as the Board correctly found. Appx11-13. Further, *Fallaux* and *Hubbell* both rejected applying a two-way test under almost identical factual circumstances present here, where applicant admitted it could have filed the pending claims in an earlier application. *Fallaux*, 564 F.3d at 1318; *Hubbell*, 709 F.3d at 1149-50, n.7 (rejecting extending the reasoning from *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991) to apply the two-way test given applicant's concession delaying prosecution of its claims).

3. Appellants' policy arguments are foreclosed by this Court's precedent.

Appellants assert that the Board's decision was an "extension" of the ODP doctrine and offer policy arguments against that result. Br. at 37-39. The Board did not extend ODP but simply found the facts of this case similar to those in this

Court's binding precedent (notably *Fallaux*) and affirmed. Appx8-9. Whatever the merits of those policy arguments, the Board faithfully applied this Court's binding precedents. *Deckers Corp. v. United States*, 752 F.3d 949, 964 (Fed. Cir. 2014); Fed. Cir. IOP #13.

V. CONCLUSION

Appellants admit they seek claims that are patentably indistinct from claims already issued to them across six patents. The Board therefore correctly affirmed the rejection of the pending claims of the '019 patent application for ODP based on the multiple-assignee harassment rationale underlying ODP. The Court should affirm.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief complies with the type-volume limitation in Fed. Cir. R. 32(b). The total number of words in the foregoing brief is 6,241 words, as calculated by Microsoft Word.

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