24-1061

United States Court of Appeals for the Federal Circuit

ALLERGAN USA, INC., ALLERGAN HOLDINGS UNLIMITED CO., ALLERGAN PHARMACEUTICALS INTERNATIONAL LTD., JANSSEN PHARMACEUTICA NV, EDEN BIODESIGN, LLC,

Plaintiffs-Appellants,

– v. –

MSN LABORATORIES PRIVATE LTD., MSN PHARMACEUTICALS, INC., SUN PHARMACEUTICAL INDUSTRIES LIMITED,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Delaware in Nos. 1:19-cv-01727-RGA, 1:21-cv-01064-RGA, 1:21-cv-01065-RGA and 1:20-cv-01479-RGA, Honorable Richard G. Andrews, Judge

RESPONSE TO DEFENDANT-APPELLEE'S PETITION FOR REHEARING OR REHEARING EN BANC

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November 8, 2024

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CERTIFICATE OF INTEREST

Counsel for Allergan USA, Inc., Allergan Holdings Unlimited Co., Allergan Pharmaceuticals International Ltd., Janssen Pharmaceutica NV, and Eden Biodesign, LLC certifies the following:

1. Provide the full names of all entities represented by undersigned counsel in this case.	2. 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.	3. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.
Allergan USA, Inc., Allergan Holdings Unlimited Co., Allergan Pharmaceuticals International Ltd., Janssen Pharmaceutica NV, and Eden Biodesign, LLC	AbbVie Inc. as real party in interest for Allergan Holdings Unlimited Co. with respect to New Drug Application No. 206940 for Viberzi® brand eluxadoline tablets	AbbVie Inc. (for Allergan USA, Inc., Allergan Holdings Unlimited Co., Allergan Pharmaceuticals International Ltd., and Eden Biodesign, LLC) Johnson & Johnson (for Janssen Pharmaceutica NV)

1. The names of all law firms and the partners or associates that appeared for the party now represented for the entities in the originating court or agency or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP: Jack B. Blumenfeld, Jeremy A. Tigan

O'MELVENY & MYERS LLP: Daniel O'Boyle, Carolyn S. Wall, Mark A. Hayden, Amy Jing Ying Zhao

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2. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b).

None

3. Information required by Federal Rule of Appellate Procedure 26.1(b) and (c) that identifies organizational victims in criminal cases and debtors and trustees in bankruptcy cases.

Not Applicable

Respectfully submitted,

Dated: November 8, 2024

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INTRODUCTION

This Court should reject the rehearing petition of Sun Pharmaceutical Industries Limited. Sun's challenge to the panel's reversal on written description misconstrues the panel's analysis as conflicting with legal precedent. No such conflict exists. Based on the intrinsic record, the panel determined that the district court's factual findings were clearly erroneous. This does not warrant rehearing.

Sun likewise fails to justify rehearing on the panel's obviousness-type double patenting ("ODP") holding. The panel correctly held that, in a family sharing the same priority date, later continuation patents cannot serve as ODP reference patents to the first-filed, first-issued patent. Precedents of this Court and the Supreme Court declare that the original grant of exclusivity defines the respective rights of the inventor and the public. In contrast, no precedent supports Sun's position that a later-filed, later-issued child patent—which did not even exist when the parent patent issued—qualifies as an ODP reference patent. Indeed, the panel recognized that "this case is a 'prime example' of when ODP does not apply." Op. 19.

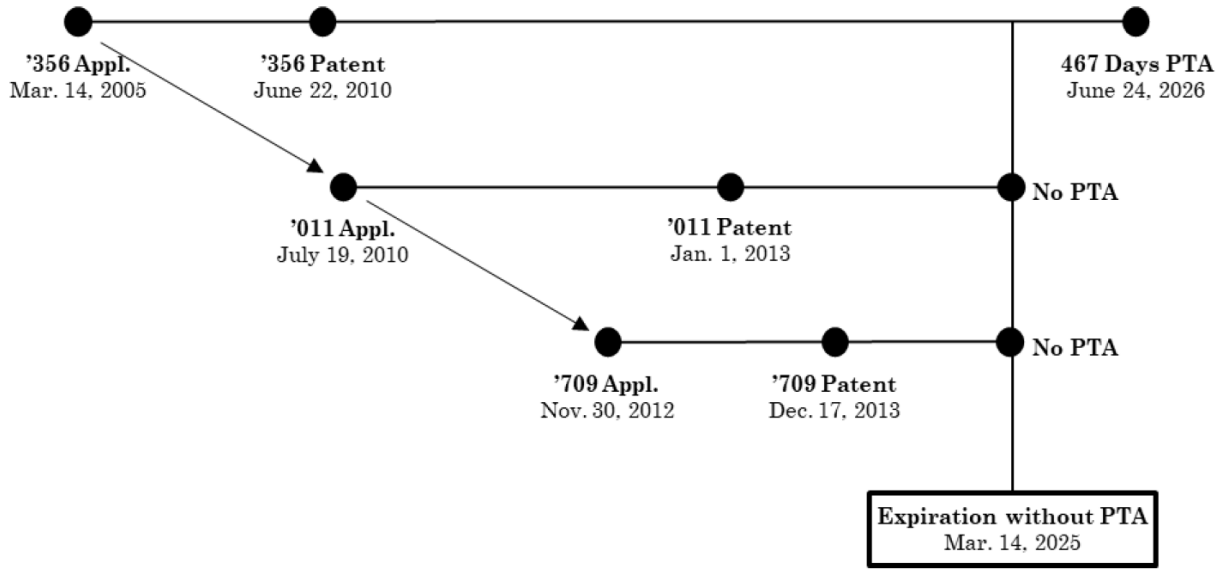
Amici curiae (not Sun) contend that the panel opinion would allow split ownership of patents having patentably indistinct claims and purportedly open the door to potential harassment through multiple infringement lawsuits. But ODP prohibits only the *issuance* of a *second* patent with patentably indistinct claims,

absent a terminal disclaimer disavowing its enforceability when not commonly owned with the first patent. The first-filed, first-issued patent, as the original grant, is never invalid for ODP over later-filed family members.

STATEMENT OF THE CASE

1. Patents-in-Suit. This appeal concerns two sets of patents. The first family claims the compound eluxadoline and methods of administering eluxadoline to treat pain or gastrointestinal disorders. The first-filed, first-issued patent in the family is U.S. Patent No. 7,741,356 ("the '356 patent"), which claims eluxadoline. Op. 3-4. The '356 patent was filed on March 14, 2005, and issued on June 22, 2010. *Id*. 3. Two continuation patents claiming priority to the '356 patent application, U.S. Patent Nos. 8,344,011 ("the '011 patent") and 8,609,709 ("the '709 patent"), were filed after the '356 patent had already issued and have patentably indistinct claims. *Id*. 4-5.

Due to PTO delay during prosecution, the '356 patent received a 1,107-day patent term adjustment ("PTA") under 35 U.S.C. § 154(b). *Id*. 4. The patentee later disclaimed all but 467 days of the PTA, resulting in a June 24, 2026 expiration date. *Id*. The two continuation patents did not experience PTO delay during prosecution, and therefore expire on March 14, 2025 (*i.e.*, more than 15 months before the '356 patent). *Id.* 5-6.



The second patent family claims eluxadoline formulations. *Id*. 6. "[T]he asserted claims are essentially picture claims to a particular pharmaceutical tablet comprising eluxadoline and various inert ingredients," narrowly reciting "specific ingredients" in "specific amounts." *Id*. 21-22. None of these claims recites a "glidant" (an ingredient that can be used to facilitate powder flow during commercial tablet manufacturing). Certain claims state that a glidant is optional, while others are entirely silent about glidants. *Id*. 6-7.

There is no dispute that the specification describes formulations having the claimed ingredients in the specified amounts. *Id*. 22. The specification neither states that glidants are necessary to the invention nor discusses powder flowability during manufacturing. Instead, the specification expressly describes formulations without glidants. For example, the "Summary of Disclosure" states that the

inventive formulation can be composed of eluxadoline and only one (or more) of five identified inert ingredients. *Id*. 24. The specification also discloses that the solid mixture that is eventually pressed into tablets may contain one or more excipients, none of which need be a glidant. Appx194; Appx5975. Likewise, the originally filed claims, which are part of the specification, do not require a glidant. Op. 24-25.

2. District Court Proceedings. In 2015, the FDA approved the eluxadoline drug marketed as Viberzi®. *Id*. 3. After Sun and another generic drug company filed Abbreviated New Drug Applications to develop generic versions of Viberzi®, Plaintiffs commenced a Hatch-Waxman action alleging infringement of the patents-in-suit. *Id*. 7-8.

Following a bench trial, the district court invalidated the patents challenged by Sun. The '356 patent was invalidated for ODP over the later-filed, later-issued '011 and '709 continuation patents. The court viewed *In re Cellect*, 81 F.4th 1216 (Fed. Cir. 2023), *cert. denied*, *Cellect v. Vidal*, No. 23-1231 (Oct. 7, 2024), as mandating a mechanical comparison of expiration dates, without exception. Op. 9-10. The court also invalidated the asserted formulation claims for lack of written description because "'the patent specification does not disclose that a formulation would have sufficient flow characteristics or work without a glidant.'" *Id*. 10-11 (quoting district court).

3. Panel Opinion. A panel of this Court reversed. On ODP, the panel unanimously held 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.* 11. The panel (Judges Lourie, Dyk, and Reyna)—the same panel that decided *Cellect*—held that *Cellect* did not mandate a contrary rule. The panel observed that *Cellect* "does not address, let alone resolve, any variation of the question presented here—namely, under what circumstances can a claim properly serve as an ODP reference." *Id.* 15. Indeed, "*Cellect* did not involve the situation presented here of ODP with respect to a first-filed, first-issued patent," and there was no ODP reference challenge on appeal. *Id.* 15-16 n.6.

The panel concluded that the two continuation patents "are not proper ODP references that can be used to invalidate claim 40 of the '356 patent." *Id.* 16. ODP "prevent[s] patentees from obtaining a second patent on a patentably indistinct invention to effectively extend the life of a first patent to that subject matter." *Id.* (citing *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 193 (1894), and *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014)). "The '356 patent is undoubtedly the 'first' patent to cover eluxadoline, whether we measure by filing date or by issuance date." *Id.* Because "the first-filed, first-issued patent in its family … sets the maximum

period of exclusivity for the claimed subject matter and any patentably indistinct variants," it "cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date." *Id.* 17. The Court noted that this conclusion comports with precedent, including *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), and *AbbVie*. Op. 17-19.

The panel further observed that a first-filed, first-issued patent, even if it expires later because of PTO delay, does not extend the "patent term of the invention claimed in the child patent when, as here, the claims in the child patent did not even exist until after the parent patent issued." *Id.* 20. A contrary result would "effectively abrogate the benefit Congress intended to bestow on patentees when codifying PTA" by denying the parent "its congressionally guaranteed patent term." *Id.*

The panel also found "clear error" in the district court's written description ruling, because, *inter alia*, "the specification describes at least two embodiments in which a glidant is not required." *Id*. 23-24. Further, the original application claims, which are part of the specification, disclosed formulations without a glidant. *Id*. 24-25. Thus, "the specification as a whole shows possession through its description of a formulation without a glidant," *id*. 26, and does not disclose that a glidant was necessary to the invention, *id*. 28. Because expert testimony cannot be relied upon to require a glidant without some basis in the specification,

"the district court clearly erred in finding" inadequate written description. *Id.* 29-30.

Judge Dyk dissented from the written description ruling, opining that "ample expert testimony supports the district court's factual finding." Op. of Dyk, J., concurring-in-part and dissenting-in-part, at 4-5.

ARGUMENT

I. The Panel's Written Description Decision on the Formulation Patents Does Not Warrant Rehearing

Sun's primary argument for rehearing focuses on the panel's written description ruling. Pet. 11-15. That ruling was correct—the panel assessed the specification disclosure and concluded that the District Court clearly erred in finding lack of written description. At a minimum, Sun fails to justify rehearing.

Sun fails to identify any issue that the panel overlooked or misapprehended. Fed. R. App. P. 40. Instead, Sun simply disagrees with the panel's analysis, Pet. 10-11, which does not suffice.

Sun also falls short of meeting the exacting standards for *en banc* review. For instance, Sun does not argue that whether these patent claims are adequately described is exceptionally important. Fed. R. App. P. 35(b)(1)(B). Nor does Sun identify any legal conflict with this Court's or Supreme Court precedent on either of the two written description questions presented. Fed. R. App. P. 35(b)(1)(A).

First, the panel confirmed written description based on its assessment of the specification, including the text, embodiments, and original claims, which is precisely what *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010), requires. Sun fails to identify any precedent stating a different rule of law than the panel applied here. Pet. vi. Mere disagreement on the application of the legal written description standard to factual determinations does not justify *en banc* intervention. Sun fails to establish error, much less conflict with precedent.

Contrary to Sun's contention, Pet. 12, this "is not a 'blaze marks' case in which the claims recite a species where the specification describes only a genus," Op. 21. What Sun identifies as a "species"—eluxadoline tablet claims comprising mannitol, magnesium stearate, crospovidone, and silicified micro-crystalline cellulose in specified amounts—is described in the specification. Accordingly, this is not a case where the specification describes only a broader genus, and not the claimed invention. Indeed, as the panel stated, this was "undisputed"; Sun's expert acknowledged that formulations having each claim element are described in the specification. *Id*. 22. The only issue on appeal was whether the claims nonetheless lack written description because they do not require a glidant, which is unrelated to a blaze-marks analysis.

Moreover, the panel did not contravene *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997), which provides that written description is not satisfied merely because an undescribed element would have been obvious. Pet. 11-12. The panel nowhere relied on obviousness and, unlike in *Lockwood*, the specification here expressly describes every limitation, as Sun's expert admitted. Op. 22. Contrary to Sun's contention, Pet. 11, this case is not analogous to *Novozymes A/S v. DuPont Nutrition Biosciences APS*, where the specification listed several structural modifications for potentially improving enzymes, but disclosed no enzyme that satisfied all of the claimed structural and functional limitations. 723 F.3d 1336, 1348 (Fed. Cir. 2013). In short, Sun attempts to generate legal conflict where none exists.

Second, there is no conflicting precedent on whether this Court "may … re-weigh the evidence" and decide the ultimate question of written description. Pet. vi-vii. The panel did not reweigh the evidence; it reviewed findings of fact for clear error, identified clear error, and reversed on that basis. Op. 23-24; *see also Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012). This is the proper province of this Court. Fed. R. Civ. P. 52(a)(6). The panel found "at least two embodiments in which a glidant is not required" described in the specification, as well as the original application claims, and thus held the written description requirement was satisfied. Op. 24-25. Identifying the district

court's clear error in misinterpreting the specification does not usurp the fact finder's prerogative and is not worthy of rehearing.

II. The Panel's Unanimous ODP Ruling Does Not Warrant Rehearing

Sun seeks rehearing of the panel's unanimous ODP ruling as an afterthought, devoting only three pages of argument to the issue. Pet. 15-18. Sun's potshots at the panel opinion and claims of legal conflict miss the mark.

Sun cites *Gilead* in arguing that the panel decision somehow violates the "'bedrock principle'" that, "*once … reference patents expire*, 'the public is free to use' obvious variants" because the only "'date that really matter[s] is 'patent expiration.'" Pet. 16 (quoting *Gilead*, 753 F.3d at 1214-16).[1] But Sun overlooks the central question decided by the panel: that a later-filed, later-issued continuation patent cannot serve as an ODP reference patent for the first-filed, first-issued patent in the family. Op. 16. Only if there is a proper reference patent does the Court then proceed to determine whether the challenged patent provides an unjust timewise extension or risks split ownership.

The panel correctly held that the asserted continuation patents are not proper reference patents. As this Court declared in *AbbVie*, discussing Supreme Court precedent, the public's right to practice the invention arises only "after the *original* period of monopoly expires." 764 F.3d at 1373. The first-filed,

[1] Emphasis is added unless otherwise noted.

first-issued patent for an invention defines the original grant of exclusivity: it "is the patent that sets the maximum period of exclusivity for the claimed subject matter and any patentably indistinct variants." Op. 17. Because the '356 patent established the original period of eluxadoline exclusivity, its claims, by definition, do "not extend or prolong the monopoly on eluxadoline beyond the period allowed by law, and therefore are not subject to ODP over the '011 and '709 patents." *Id.*

Indeed, Sun's proposed rule would create inconsistency between § 101 statutory double patenting and ODP, a judicial doctrine "grounded in" that provision. *AbbVie*, 764 F.3d at 1372. Section 101 never invalidates the original, first patent over a later patent claiming the same invention. *See, e.g.*, *Miller*, 151 U.S. at 198. Likewise, ODP should not invalidate the original patent based merely on a later patent claiming an obvious variant of that invention. *Id.* Thus, the panel correctly held 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." Op. 17.

Sun avers that this holding contradicts *Gilead*, but as the panel pointed out, that is untrue. Sun never acknowledges that *Gilead*: (i) embraced the principle that the original exclusivity period determines the reference patent, 753 F.3d at 1215; and (ii) held only that an *earlier-filed patent*, claiming an earlier priority

date, "can qualify" as a reference patent for a later-filed, later-expiring patent "under the circumstances [t]here," *id.* at 1217. In that case, the patentee "crafted a separate 'chain' of applications" having different priority dates. *Id.* at 1210. *Gilead* explained that, post-URAA, the original period of exclusivity depends on the earliest effective filing (or priority) date: "In the URAA, Congress clearly limited *the one period of exclusivity* an inventor can obtain for each of his inventions to twenty years *from the filing date of the earliest application* to which the inventor claims priority—with some limited exceptions." *Id.* at 1215; *see also id.* at 1212.[2] Thus, this Court held that a patent issuing from "the earliest application," *id.* at 1215, "qualifies as an [ODP] reference" with respect to an earlier-issued, later-expiring patent "having a later priority date," *id.* at 1210; *see also id.* at 1216-17 (noting that MPEP requires a terminal disclaimer only "for the later of" two co-pending applications). This is because the later-filed patent, even though earlier-issued, "extend[ed] the inventors' term of exclusivity on obvious variants of the invention claimed in the '375 patent." *Id.* at 1214.

As the panel explained, *Gilead*'s rationale has no application here. "Unlike here, the challenged claims of the asserted patent in *Gilead* were filed after, claimed a later priority date than, and expired after the reference claims, which

[2] Quoting *Odiorne v. Amesbury Nail Factory*, which discussed the public's "right to use the invention at the expiration of the term specified in the *original* grant." 18 F. Cas. 578, 579 (C.C.D. Mass. 1819) (adopted by *Miller*, 151 U.S. at 198).

resulted in an unwarranted extension of patent term for an invention that had already been the subject of an earlier filed, earlier-expiring claim." Op. 18-19. In contrast, "[b]ecause the '356 patent was the first patent in its family to be filed and to issue, it does not extend any period of exclusivity on the claimed subject matter." *Id.* 19. Not only does Sun fail to heed *Gilead*'s distinct facts and reasoning, it ignores the express limitation of *Gilead*'s holding to "the circumstances [of that case]." 753 F.3d at 1217; Op. 18. There is no conflict with *Gilead*.[3]

Moreover, Sun's position is inconsistent with this Court's decisions in *AbbVie* and *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1364-66 (Fed. Cir. 2018). Op. 19-20. In *AbbVie*, like *Gilead*, the earlier-filed, earlier-issued patent established an original exclusivity period and thus was a proper ODP reference. Therefore, a subsequent patent that expired later because of a different priority date was invalid for ODP, as it unduly extended that "original" term. 764 F.3d at 1372-73 (citing *Odiorne* and *Miller*). Nothing in

[3] Sun points to *Gilead*'s statement that identifying which patent came "first" is of "little import." Pet. 16. But *Gilead* was merely explaining that issuance date is no longer the sole benchmark post-URAA. *Id.* The original grant still must be identified, and the panel here pointed out that a first-filed, first-issued patent is "undoubtedly the 'first' patent to cover eluxadoline, whether we measure by filing date or by issuance date." Op. 16.

AbbVie supports Sun's perverse proposal that continuation patents can invalidate the first-filed, first-issued patent establishing the original exclusivity period.

In *Breckenridge*—which Sun nowhere addresses—this Court rejected the claim that ODP can be determined solely by comparing expiration dates, when (as here) the original statutory period of exclusivity would be truncated. 909 F.3d at 1364-66. While addressing a different question (*i.e.*, whether ODP invalidates a pre-URAA patent that expires after a post-URAA patent), *Breckenridge*'s reasoning squarely refutes Sun's position. The first-filed, first issued patent in *Breckenridge* had not "improperly captured unjustified patent term," *id.* at 1364, and the later-filed, later-issued post-URAA "patent [wa]s not a proper [ODP] reference" because it did not establish an original exclusivity period extended by the challenged patent, *id.* at 1366. Mechanically comparing expiration dates in that context would have improperly "truncate[d] the term statutorily assigned to the [earlier filed, earlier-issued] patent." *Id.* at 1358, 1366. So too, here, Sun's proposed rule would improperly truncate the original patent term, not prevent its unjust extension, demonstrating why "this case is a 'prime example' of when ODP does not apply." Op. 19-20.

Sun's position is not only irreconcilable with the ODP doctrine, but would undermine the statutory scheme. Parent patents, unlike child patents, often face PTO delays and may expire later. *Id*. But a later-expiring parent patent does not

extend the "patent term of the invention claimed in the child patent when, as here, the claims in the child patent *did not even exist* until after the parent patent issued." *Id*. 20; *see also Return Mail, Inc. v. United States Postal Service*, 139 S. Ct. 1853, 1859 (2019) (requiring proof that "the patent never should have issued in the first place" to establish invalidity under § 282). "To hold otherwise—that a first-filed, first-issued parent patent having duly received PTA can be invalidated by a later-filed, later-issued child patent with less, if any, PTA—would not only run afoul of the fundamental purposes of ODP, but effectively abrogate the benefit Congress intended to bestow on patentees when codifying PTA." Op. 20. Indeed, Congress contemplated truncating PTA only when patent term "*has been* disclaimed beyond a specified date" of an already-existing patent. 35 U.S.C. § 154(b)(2)(B). In other words, the provision requires the existence of a "first" (or some earlier) patent having a specific expiration date, to which a later-filed application can be terminally disclaimed and subsequently allowed to issue. Sun, having no answer to this analysis, ignores it.

Finally, Sun ironically argues that the panel's reading of *Cellect* is not "plausible." Pet. 18 (characterizing panel decision as "pretend[ing what] *Cellect* … held"). The same panel decided both this case and *Cellect*. *Cellect* decided a different question (*i.e.,* whether PTA was broadly immune from ODP), and did

not involve a first-filed, first-issued patent or any question of reference patent status. Op. 15 & n.6.

Amici curiae attempt to inject a new issue on rehearing—that the panel opinion contravenes the ODP prohibition against split ownership of a patented invention. AAM Br. 6-8; Alvogen Br. 10-11. That issue is not properly considered: Sun's principal brief before the panel conceded that "[t]here was no such risk" of "a split in ownership" here, Sun Br. 35, and did not raise the issue in its rehearing petition. An *amicus* cannot raise issues not raised by the parties, *BASR Partnership v. United States*, 795 F.3d 1338, 1347 (Fed. Cir. 2015), especially not on rehearing, *Haas v. Peake*, 544 F.3d 1306, 1307-08 (Fed. Cir. 2008).

Sun had good reason for not raising *amici*'s newfound split-ownership argument, as it utterly lacks merit. The original patent (here, the '356 patent) is never invalid for ODP over later family members. Instead, only later patents containing patentably indistinct claims would be invalid absent a terminal disclaimer promising not to divide ownership. Accordingly, the panel correctly held that the '356 patent is not invalid for ODP.

ODP "prevents an inventor from claiming *a second patent* for claims that are not patentably distinct from the claims of a first patent." *Cellect*, 81 F.4th at 1226. During prosecution, "the examiner asks whether the application claims are

obvious over the patent claims." *In re Hubbell*, 709 F.3d 1140, 1149 (Fed. Cir. 2013). To prevent both unjust term extension and split-ownership risk, this Court has required "as a condition of issuance" of the application claims a terminal disclaimer (i) surrendering any additional term beyond the first patent and (ii) covenanting that the second patent will be unenforceable if ownership is split. *See Simpleair, Inc. v. Google LLC*, 884 F.3d 1160, 1167 (Fed. Cir. 2018) (terminal disclaimer obviates ODP "in exchange for limiting the patent term *and alienability of the resulting continuation patent*, *see* 37 C.F.R. §§ 1.321(d)(3), 1.321(c)(3)"). "The risk of harassment by multiple assignment can be eliminated entirely" by a disclaimer limiting the second patent's enforceability to common-ownership periods with the first. *In re Van Ornum*, 686 F.2d 937, 944-45 (C.C.P.A. 1982).

The terminal disclaimer disavowing enforceability of an alienated second patent must be filed regardless of the relative expiration dates. As the CREATE Act legislative history cited by *amici* makes clear, "the disclaimer must be filed in the patent with the patentably indistinct claims and must reference the first-issued patent against which the disclaimer applies. Thus, the disclaimer only affects the ability to enforce the disclaimed patent … *while the first-issued patent's enforceability is unaffected*." 150 Cong. Rec. S7521 (daily ed. June 25, 2004) (statement of Sen. Hatch).

The panel opinion does not open the door to split ownership. To be validly issued in the first place, later-filed, later-issued continuation patents need to be terminally disclaimed to the first-filed, first-issued patent to ensure common ownership. Otherwise, the continuation patent itself is invalid for ODP over the first patent, as *its* issuance (not the first patent's issuance) created a split-ownership risk. Regardless, the first patent is never invalidated, even if no terminal disclaimer is filed.[4]

[4] This is not the first opinion allowing "common ownership of two patents with different expiration dates." Alvogen Br. 2. *Breckenridge* and the two-way ODP test, *see In re Braat*, 937 F.2d 589, 594 (Fed. Cir. 1991), are examples of that.

CONCLUSION

Sun's petition should be denied.

Respectfully submitted,

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Dated: November 8, 2024

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

Pursuant to Federal Rule of Appellate Procedure 27(d) and 32(g), I certify the following:

1. The attached response complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2)(A). The response contains 3,892 words, excluding the parts of the motion exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

2. This response complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 27(d)(1)(E). The response has been prepared in a proportionally spaced typeface using MS 365 in a 14 point Times New Roman font.

Date: November 8, 2024

/s/ Eric W. Dittmann
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