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

2024-1061

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

Decided: August 13, 2024

ERIC WILLIAM DITTMANN, Paul Hastings LLP, New York, NY, argued for plaintiffs-appellants. Also represented by PETER E. CONWAY, MELANIE R. RUPERT; STEPHEN BLAKE KINNAIRD, Washington, DC; JAMES YI LI, LISA BARONS PENSABENE, HASSEN A. SAYEED, O'Melveny &

Myers LLP, New York, NY.

CHARLES B. KLEIN, Winston & Strawn LLP, Washington, DC, argued for defendant-appellee Sun Pharmaceutical Industries Limited. Also represented by JOVIAL WONG; EIMERIC REIG-PLESSIS, San Francisco, CA.

RONALD M. DAIGNAULT, Daignault Iyer LLP, Vienna, VA, for defendants-appellees MSN Laboratories Private Ltd., MSN Pharmaceuticals, Inc. Also represented by RICHARD JUANG, TEDD W. VAN BUSKIRK.

Before LOURIE, DYK, and REYNA, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE.

Opinion concurring-in-part and dissenting-in-part filed by *Circuit Judge* DYK.

LOURIE, *Circuit Judge*.

Allergan USA, Inc., Allergan Holdings Unlimited Co., Allergan Pharmaceuticals International Ltd., Janssen Pharmaceutica NV ("Janssen"), and Eden Biodesign, LLC (collectively, "Allergan") appeal from the final judgment of the United States District Court for the District of Delaware. Following a three-day bench trial, the district court determined that claim 40 of U.S. Patent 7,741,356 ("the '356 patent"), asserted against Sun Pharmaceutical Industries Limited ("Sun"), is invalid under the doctrine of obviousness-type double patenting. *Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, 694 F. Supp. 3d 511, 541 (D. Del. 2023) ("*Decision*"). The district court also determined that the claims of U.S. Patents 11,007,179 ("the '179 patent"), 11,090,291 ("the '291 patent"), 11,160,792 ("the '792 patent"), and 11,311,516 ("the '516 patent") asserted against

Sun are invalid under 35 U.S.C. § 112 for lack of written description. *Id.* at 529.[1]

For the following reasons, we reverse the district court's determination that asserted claim 40 of the '356 patent is invalid for obviousness-type double patenting. We also reverse its determination that the asserted claims of the '179, '291, '792, and '516 patents lack written description.

BACKGROUND

I

In 2015, the U.S. Food and Drug Administration ("FDA") approved the New Drug Application ("NDA") for eluxadoline tablets, which Allergan markets and sells under the brand name Viberzi®. Eluxadoline is a mu- and kappa-opioid agonist and a delta-opioid antagonist that mitigates the symptoms of irritable bowel syndrome with diarrhea, *i.e.*, IBS-D. The drug compound and compositions thereof are protected by a number of patents, including each of those asserted here, which were timely listed in the Orange Book.

A. The '356 Patent

The first-ever patent application to cover eluxadoline was filed on March 14, 2005, and assigned to Janssen. The '356 patent issued from that application on June 22, 2010.

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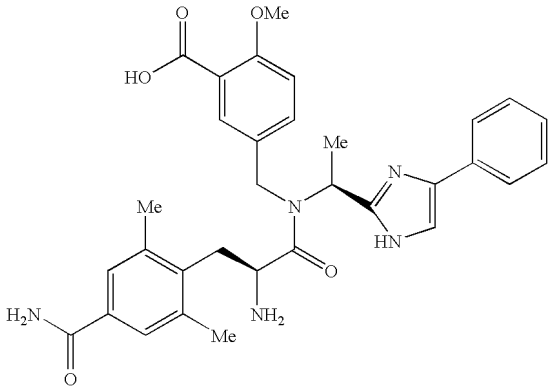
[1] The district court further determined that all claims asserted against MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc. are invalid for lack of written description. *Id.* at 529–39. Allergan does not appeal from, so we do not disturb, the district court's judgment in favor of MSN.

Asserted claim 40 of the '356 patent recites eight chemical compounds, including eluxadoline:



'356 patent at col. 143, l. 49–col. 146, l. 20. To account for delay in prosecution, the '356 patent received a patent term adjustment ("PTA") of 1,107 days pursuant to 35 U.S.C. § 154(b). J.A. 14485. However, in the process of securing patent term extension ("PTE") for delays in FDA approval under 35 U.S.C. § 156, Janssen disclaimed all but 467 days of the awarded PTA. Allergan Br. at 5. Accordingly, after accounting for PTA (but not PTE), the '356 patent will expire on June 24, 2026.[2]

Janssen filed a number of continuing applications that each claim priority from the March 14, 2005 filing date of the '356 patent. Relevant here are U.S. Patents 8,344,011 ("the '011 patent") and 8,609,709 ("the '709 patent").

The application leading to the '011 patent was filed on July 19, 2010, as a divisional of U.S. Patent 7,786,158, which is a continuation of the '356 patent. The '011 patent

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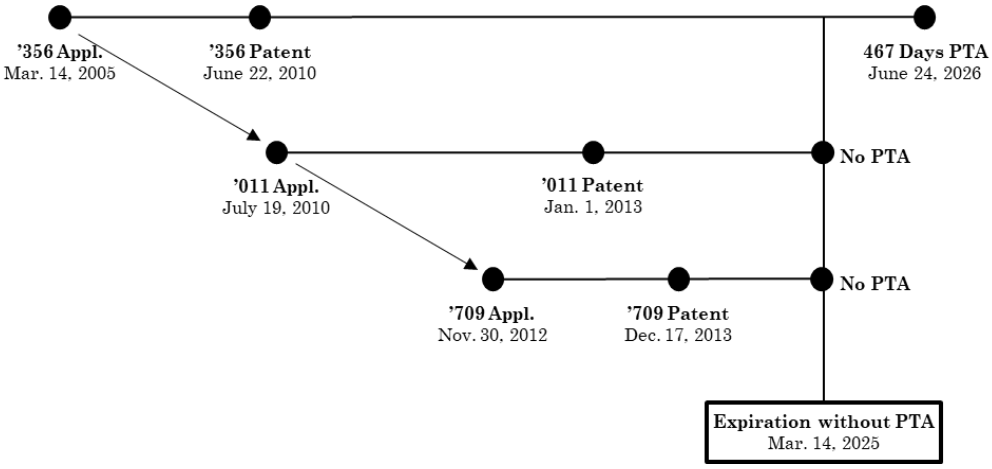
[2] The expiration date of the '356 patent after the addition of PTE is irrelevant to this appeal. *See Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1372 (Fed. Cir. 2018) ("*Ezra*") (holding that obviousness-type double patenting does not invalidate an otherwise validly obtained PTE).

issued on January 1, 2013. Claim 33 recites a method for treating pain or gastrointestinal disorder comprising administering to a patient in need thereof eluxadoline or one of seven other compounds. '011 patent at col. 111, l. 31–col. 113, l. 30. Because there was no delay in prosecution, the '011 patent did not receive any PTA and will expire on March 14, 2025, *i.e.*, twenty years from its priority date.

The application leading to the '709 patent was filed on November 30, 2012, as a continuation of the '011 patent. The '709 patent issued on December 17, 2013, and is subject to a terminal disclaimer over the '356 patent. Claim 5 directly claims the eluxadoline compound. '709 patent at col. 110, ll. 20–37. Because there was no delay in prosecution, the '709 patent did not receive any PTA and, like the '011 patent, will expire on March 14, 2025, *i.e.*, twenty years from its priority date.

The relationship between the filing, issuance, and expiration dates of each of the '356 patent, the '011 patent, and the '709 patent is depicted in the following figure:[3]



[3] For the sake of simplicity and clarity, we refer to the applications leading to each patent by the associated

Because all three patents share a priority date, all would expire on the same day but for the PTA awarded to the '356 patent.

B. The '179, '291, '792, and '516 Patents

Each of the '179, '291, '792, and '516 patents is generally directed to formulations of eluxadoline. The patents share a common specification and priority date of March 14, 2013. The parties agree that claim 7 of the '179 patent and claim 26 of the '516 patent are representative of the asserted claims.

Claim 7 of the '179 patent recites:

> 7. The tablet of claim 6, comprising:
>
> about 75 mg of [eluxadoline];
>
> about 390 mg–450 mg of silicified microcrystalline cellulose;
>
> about 30 mg of crospovidone;
>
> about 60 mg of mannitol; and
>
> about 4.5 mg of magnesium stearate.

'179 patent at col. 37, ll. 1–10. Claim 7 ultimately depends from independent claim 1, which recites:

> 1. An abuse-deterrent, mono-phasic pharmaceutical tablet comprising:
>
> about 75 mg of [eluxadoline];
>
> about 60-80% by weight silicified microcrystalline cellulose;

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patent number rather than by the application number. For example, the application leading to the '011 patent is referred to as "the '011 application."

> crospovidone;
>
> about 5-15% by weight mannitol; and
>
> *optionally, a glidant* and/or lubricant.

Id. at col. 36, ll. 33–43 (emphasis added).

Similarly, claim 26 of the '516 patent recites:

> 26. The pharmaceutical tablet of claim 1, comprising:
>
> about 75 mg of [eluxadoline];
>
> about 390 mg–450mg silicified microcrystalline cellulose;
>
> about 30 mg crospovidone;
>
> about 60 mg mannitol;
>
> about 4.5 mg magnesium stearate; and
>
> about 18 mg of a film coating,
>
> wherein the nominal weight of the tablet without the film coating is about 600 mg and the total weight of the tablet is about 618 mg.

'516 patent at col. 36, ll. 1–14. Independent claim 1, from which claim 26 depends, recites a pharmaceutical tablet comprising about 75 mg of eluxadoline with various percentage weights of a filler, disintegrant, and mannitol. *Id.* at col. 34, ll. 12–48. Claim 1 of the '516 patent is silent as to any glidant.

II

In July 2019, Sun submitted an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market and sell a generic version of Viberzi. To comply with its statutory obligations under the Hatch-Waxman Act, Sun made a Paragraph IV certification pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV), contending that the claims of the '356 patent are invalid or would not be infringed by the manufacture, use, or sale of Sun's generic product. Sun gave Allergan notice of that certification in a letter dated October 8, 2020. Three weeks later, Allergan sued Sun under 35 U.S.C. § 271(e)(2)(A), alleging that the filing of Sun's ANDA directly infringed claim 40 of the '356 patent. *Allergan USA, Inc. v. Sun Pharm. Indus. Ltd.*, No. 20-1479 (D. Del. filed Oct. 29, 2020) (consolidated with *Allergan USA, Inc. v. Sun Pharm. Indus. Ltd.*, No. 19-1727 (D. Del. filed Sept. 13, 2019)).

Separately, on May 18, 2021, while proceedings on the '356 patent were pending, the '179 patent issued. Allergan filed a new complaint against Sun, alleging that the submission of Sun's ANDA infringed various claims of that newly-issued patent. *Allergan USA, Inc. v. Sun Pharm. Indus. Ltd.*, No. 21-1065 (D. Del. filed July 23, 2021) (consolidated with *Allergan*, No. 19-1727). Issuance of each of the '291 patent, the '792 patent, and the '516 patent soon followed and, with each issuance, Allergan amended its complaint to add new claims of infringement. Again complying with its statutory obligations, Sun timely made Paragraph IV certifications contending that the claims of each of those patents are invalid or would not be infringed by the manufacture, use, or sale of Sun's generic product, and gave notice of those certifications to Allergan.

Following discovery and ahead of trial, the parties stipulated that Sun would infringe all the asserted claims if those claims were valid. *Decision*, 694 F. Supp. 3d at 518. Accordingly, the only issues before the court in the three-day bench trial were of the asserted claims' validity; namely: (1) whether claim 40 of the '356 patent is invalid for obviousness-type double patenting ("ODP"), and (2) whether the asserted claims of the '179, '291, '792, and

'516 patents are invalid for lack of written description. *See id.* at 518–19.[4]

A

Sun argued that claim 40 of the '356 patent is invalid for ODP over claim 33 of the '011 patent and claim 5 of the '709 patent because the claims are not patentably distinct and because claim 40, having been awarded 467 days of PTA, expires after the reference claims of the '011 and '709 patents. *See id.* at 519, 540. In response, Allergan argued that because the '356 patent was the first patent claiming eluxadoline to be filed and the first patent to issue, claim 40 is not subject to ODP over the later-filed, later-issued claims of the reference patents. *See id.* at 540. Allergan did not contest Sun's argument that claim 40 is not patentably distinct from the reference claims. *Id.*

The district court agreed with Sun, finding Allergan's "first-filed, first-issued" distinction "immaterial." *Id.* It stated that "[w]hen analyzing ODP, a court compares patent expiration dates, rather than filing or issuance dates." *Id.* (citing *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1215–17 (Fed. Cir. 2014), and *In re Cellect, LLC*, 81 F.4th 1216, 1228–29 (Fed. Cir. 2023)). It construed Allergan's argument as one urging the court to consider filing and issuance dates "as part of a case-by-case review of equitable considerations to determine if a patent owner received an unjust time extension," an analysis it deemed "rejected" by this court in *Cellect*. *Id.* (citing 81 F.4th at

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[4] Sun also argued at trial that, if the asserted claims were found to have adequate written description, they would have been obvious under 35 U.S.C. § 103. *Id.* at 519. Because the district court determined that the claims lacked a sufficient written description, it did not reach that issue. *Id.* at 539. Therefore, obviousness of the claims under § 103 is not before us in this appeal.

1229). Therefore, because it read *Cellect* and our prior case law as binding it to consider expiration dates alone in the ODP analysis, the district court concluded that claim 40 of the '356 patent is invalid.

B

As for the '179, '291, '792, and '516 patents, Sun argued that the asserted claims are invalid under 35 U.S.C. § 112 for lack of written description because there is no support in the specification for a pharmaceutical tablet that does not include a glidant, *e.g.*, colloidal silica.[5] *Id.* at 523. Allergan countered with arguments that (1) a person of ordinary skill in the art would have understood that a glidant, by definition, is optional such that the specification need not explicitly disclose as such; (2) a glidant is not essential to the invention such that a person of ordinary skill would recognize that its inclusion in the formulation was not necessary; and (3) the specification describes that a glidant is optional. *See id.* at 524–26.

The district court again agreed with Sun, finding that "[f]or all the formulations disclosed in the patent specification, a glidant is used without any indication that it was not required to practice the invention." *Id.* at 524. It explained that "[a]ctual reduction to practice of a formulation in which a glidant is optional or not included is not required, but the specification must at least provide constructive reduction to practice of a formulation in which a glidant is optional or not included." *Id.* at 528–29. But because, in the district court's view, "[t]he patent specification does not disclose that a formulation would have sufficient flow characteristics or work without a glidant," it found that the patentee had not demonstrated possession

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[5] The patent specification uses the term "colloidal silica" interchangeably with "colloidal silicon dioxide." Those two terms refer to the same ingredient.

of "a formulation where a glidant is optional or not included." *Id.* at 529. The court therefore held the asserted claims invalid for lack of written description.

* * *

Allergan timely appealed from the district court's entry of final judgment. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

"Obviousness-type double patenting is an issue of law premised on underlying factual inquiries." *Ezra*, 909 F.3d at 1372 (citation omitted). We therefore review the district court's ultimate conclusion on ODP *de novo*, and its predicate findings of fact for clear error. *Id.* Here, where Allergan concedes that the asserted claim is not patentably distinct over the reference claims, the only question before us is one of law. Namely, 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? We hold that it cannot.

A

"The prohibition against double patenting is a longstanding doctrine of patent law." *Gilead*, 753 F.3d at 1212. The judicially-created doctrine stems from 35 U.S.C. § 101, which provides that an inventor may obtain "a patent" (*i.e.*, a single patent) for an invention. *E.g.*, *Cellect*, 81 F.4th at 1226 (citing *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997)). The doctrine's primary goal is to prevent an unjustified timewise extension of patent exclusivity beyond the life of a patent. That goal is grounded in the principle that:

> [t]he public should . . . be able to act on the assumption that upon expiration of the patent it will be free to use not only the invention claimed in the

> patent but also any modifications or variants thereof which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill of the art and prior art other than the invention claimed in the issued patent.

In re Zickendraht, 319 F.2d 225, 232 (CCPA 1963) (Rich, J., concurring).

Until 1995, a patent's term was measured from its issuance date. *See* Neel U. Sukhatme, *Regulatory Monopoly and Differential Pricing in the Market for Patents*, 71 Wash. & Lee L. Rev. 1855, 1894–95 n.146 (2014) ("Since the Patent Act of 1790, when Congress established a term of fourteen years from issuance, the baseline term for a patent has changed only three times: in 1836 (increased to twenty-one years from patent issuance), 1861 (decreased to seventeen years from issuance), and 1995 (changed to twenty years from application filing date)."). Before 1995, then, issuance dates and expiration dates were inextricably intertwined. Accordingly, courts traditionally looked to the issuance dates of commonly-owned, patentably-indistinct patents to determine whether ODP applied. *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1362 (Fed. Cir. 2018) ("*Breckenridge*") (citing *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 196–97 (1894) and *Suffolk Co. v. Hayden*, 70 U.S. 315, 319 (1865)).

Congress's passage of the Uruguay Round Agreements Act of 1994, Pub. L. No. 103-465, 108 Stat. 4809 ("URAA") changed how patent terms were determined. Instead of measuring from issuance date, a patent's term is now measured from its effective filing, or priority, date, *i.e.*, the earlier of (1) the filing date of the application and (2) the filing date of an application from which the patent claims priority. 35 U.S.C. § 154(a)(2). In many cases, this means that, post-URAA, there is little risk of an unjustified extension of term subject to ODP because all patents to an

invention that share a priority date are expected to expire on the same day. *See In re Fallaux*, 564 F.3d 1313, 1318 (Fed. Cir. 2009) (explaining that the "unjustified patent term extension justification for obviousness-type double patenting has limited force" post-URAA); *see also Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014) ("Although this court has recognized that the doctrine of [ODP] is less significant in post-URAA patent disputes, we have also recognized its continued importance."). But as we alluded in *Abbvie*, a common priority date does not always guarantee a common expiration date.

Soon after passing the URAA, Congress sought to account for patent term lost due to delays in prosecution, which, of course, had not been a concern when term was measured from issuance date. *See* Patent Term Guarantee Act of 1999, Pub. L. No. 106-113, § 4402, 113 Stat. 1501, 1501A-557 (codified as amended at 35 U.S.C. § 154(b)). To achieve that goal, Congress codified PTA to adjust a patent's term for, *inter alia*, any delay due to the failure of the U.S. Patent and Trademark Office ("PTO") to timely examine the application. 35 U.S.C. § 154(b)(1)(A)–(B); *see Intra-Cellular Therapies, Inc. v. Iancu*, 938 F.3d 1371, 1374–75 (Fed. Cir. 2019) (summarizing congressional rationale for PTA). As a result, two commonly-owned patents that would otherwise expire on the same day due to a shared priority date may nevertheless have different expiration dates due to an award of PTA. *See Abbvie*, 764 F.3d at 1373. Any concern of ODP in those circumstances (*i.e.*, where the two patents claim patentably indistinct inventions) is commonly obviated by the filing—whether voluntarily or upon receipt of a rejection from an examiner—of a terminal disclaimer that ties the expiration date (and ownership) of the later-filed application to the expiration date of the earlier-filed application. *See Boehringer Ingelheim Int'l GmbH v. Barr Lab'ys, Inc.*, 592 F.3d 1340, 1346 (Fed. Cir. 2010). In such case, the patent subject to the terminal

disclaimer cannot expire on any date later than the patent over which that disclaimer was filed, even if it receives the benefit of PTA. *Id.*; *see* 35 U.S.C. § 154(b)(2)(B) ("No patent the term of which has been disclaimed beyond a specified date may be adjusted . . . beyond the expiration date specified in the disclaimer.").

But as we recently saw in *Cellect*, this system is not infallible. There, the patent owner had obtained a number of interrelated patents to admittedly patentably indistinct subject matter which each claimed priority from a single application. 81 F.4th at 1219. Accordingly, but for individual grants of PTA awarded to each patent, each would have expired on the same day. *Id.* For one reason or another, none of the asserted patents was subject to a terminal disclaimer, and all the patents had expired. *Id.* In reexamination proceedings, it was determined that the claims of the since-expired asserted patents were invalid for ODP because the various awards of PTA had resulted in the patent owner receiving an unjustified timewise extension of patent term (up to 759 days) on patentably indistinct inventions. *See id.* at 1221. On appeal, we affirmed the asserted patents' invalidity, holding that "ODP for a patent that has received PTA, regardless whether or not a terminal disclaimer is required or has been filed, must be based on the expiration date of the patent *after* PTA has been added." *Id.* at 1229 (emphasis added). Accordingly, *Cellect* established a rule that, when it comes to evaluating ODP on a patent that has received PTA, the relevant expiration date is the expiration date including PTA—not the original expiration date measured twenty years from the priority date.

With this background in mind, we proceed to the merits.

B

Here, the district court found itself bound by *Cellect* and held that because claim 40 of the '356 patent expired

after the reference claims of the '011 and '709 patents due to PTA, it was invalid for ODP. *See Decision*, 694 F. Supp. 3d at 540–41 ("*In re Cellect* recognizes no exception to the rule it announced. . . . I am bound by the Federal Circuit's holding. . . . As a result, I apply the rule dictated in *In re Cellect*."). The problem with that result, however, is that *Cellect* answered a different question than that at issue here. Our holding in *Cellect* is only controlling in this case to the extent that it requires us to consider, in our ODP analysis, the '356 patent's June 24, 2026 expiration date (*i.e.*, the expiration date after the addition of PTA), not the March 24, 2025 expiration date that it would have shared with the '011 and '709 reference patents in the absence of a PTA award. It does not follow, however, that the '356 patent *must* be invalidated by the '011 and '709 reference patents simply because it expires later. Indeed, *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—and therefore has little to say on the precise issue before us.[6]

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[6] Sun argues that, in *Cellect*, we "confirmed" that an earlier-filed, earlier-issued, later-expiring claim can be invalidated for ODP based on a later-filed, later-issued, earlier-expiring claim. Sun's Br. at 21–27. We disagree. *Cellect* did not involve the situation presented here of ODP with respect to a first-filed, first-issued patent. In any event, the patent owner in *Cellect* did not challenge whether the reference claims used to invalidate the asserted claims were proper ODP reference claims. Therefore, under the principle of party presentation, the court did not consider that issue. *Greenlaw v. United States*, 554 U.S. 237, 243 (2008) ("[W]e rely on the parties to frame the issues for decision and assign to courts the role of

Here, we conclude that the claims of the '011 and '709 reference patents are not proper ODP references that can be used to invalidate claim 40 of the '356 patent. That is the only conclusion consistent with the purpose of the ODP doctrine, which 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. *See Miller*, 151 U.S. at 198 ("[T]he power to create a monopoly is exhausted by the first patent . . . a new and later patent for the same invention would operate to extend or prolong the monopoly beyond the period allowed by law."); *Abbvie*, 764 F.3d at 1373 (citing *Miller* for the "crucial purpose" of ODP: "prevent[ing] an inventor from securing a second, later expiring patent for the same invention"); *Cellect*, 81 F.4th at 1226 ("A crucial purpose of ODP is to prevent an inventor from securing a second, later-expiring patent for non-distinct claims."). Sun's contrary position would require us to conclude that the '356 patent—the first-ever patent covering eluxadoline—extends Allergan's period of exclusivity to the subject matter claimed in the '011 and '709 continuation patents simply because it expires later. That position is antithetical to the principles of ODP.

The '356 patent is undoubtedly the "first" patent to cover eluxadoline, whether we measure by filing date or by issuance date. And each of the '011 and '709 patents is unquestionably "second" to that patent; neither of the applications leading to those patents was even filed until after the '356 patent issued. Indeed, each of the '011 and '709

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neutral arbiter of matters the parties present."). Whatever merit Sun's argument may have as a matter of fact, *Cellect* cannot be read as "confirming," much less holding, that a later-filed, later-issued, earlier-expiring claim is a proper ODP reference against a first-filed, first-issued, later-expiring claim having a common priority date.

patents claims priority from the application that led to the '356 patent—the first patent to ever be filed, and to ever issue, with claims to eluxadoline. Applying the fundamental purposes of ODP to these undisputed facts, the claims of the '356 patent do not "extend or prolong the monopoly [on eluxadoline] beyond the period allowed by law," *Miller*, 151 U.S. at 198, and therefore are not subject to ODP over the '011 and '709 patents. Put otherwise, the fact that the '356 patent expires later is of no consequence here because it is not a "*second*, later expiring patent for the same invention." *Abbvie*, 764 F.3d at 1373 (emphasis added). As the first-filed, first-issued patent in its family, it is the patent that sets the maximum period of exclusivity for the claimed subject matter and any patentably indistinct variants. We therefore hold 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.

Despite Sun's assertions to the contrary, our conclusion is consistent with our case law. *E.g.*, *Cellect*, 81 F.4th at 1230 ("We do, however, note that the non-asserted claims in the challenged patents are entitled to their full term, including the duly granted PTA, unless they are found to be later-filed obvious variations of earlier-filed, commonly owned claims."); *Ezra*, 909 F.3d at 1374 (noting that "the traditional concern with obviousness-type double patenting" is not raised where "it is the earlier-filed, earlier issued . . . patent, not the later-filed, later-issued . . . patent, that has the later expiration date"); *see Breckenridge*, 909 F.3d at 1366 ("In this particular situation where we have 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, we decline to invalidate the challenged pre-URAA patent by finding the post-URAA patent to be a proper obviousness-type double patenting reference.").

Sun places its stock in our holding in *Gilead*. And taken on its face, we can understand why. But that case too is not inconsistent with our holding today.

In *Gilead*, we recognized that use of issuance date alone, post-URAA, to determine whether a patent was invalid for ODP had "several shortcomings." 753 F.3d at 1215. For example, such an analysis could allow for patents to be "subject to significant gamesmanship during prosecution." *Id.* In that case, the patent owner had crafted a separate chain of applications, not tied to the priority date of an earlier-filed patent that claimed patentably indistinct subject matter. *Id.* at 1210. Because the later-filed, earlier-issued asserted patent did not claim priority from the earlier-filed, later-issued patent, it did not share an expiration date with that patent, and instead expired twenty years from its own, later filing date. *Id.* This resulted in the asserted claim having nearly two years of additional term as compared to the patentably indistinct reference claim. *Id.* Under those circumstances, we observed that, between issuance date and expiration date, the latter serves as the better benchmark in determining the application of ODP post-URAA. *Id.* at 1216. Accordingly, we held that a later-issued but earlier-expiring patent can qualify as a ODP reference to invalidate an earlier-issued but later-expiring patent. *Id.* at 1211–12.

We acknowledge Sun's position that our holding in *Gilead* appears to apply here, where the later-issued, earlier-expiring claims of the '011 and '709 patents are relied upon as ODP references to invalidate the earlier-issued but later-expiring claim of the '356 patent. But the court in *Gilead*, guided by the parties' arguments, focused its inquiry only on whether issuance dates should remain the most relevant benchmark for evaluating ODP post-URAA. *See id.* at 1214–15. It did not address the role of filing dates. And most importantly, our holding in *Gilead*, which was expressly limited to the "circumstances of [that] case," *id.* at 1212, was not pronounced in a vacuum. 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 resulted in an unwarranted extension of patent term for an invention that had already been the subject of an earlier-filed, earlier-expiring claim. In contrast, claim 40 of the '356 patent was filed before, shares a priority date with, and issued before the reference claims of the '011 and '709 patents. Because 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.

For similar reasons, we are unpersuaded by Sun's reliance on *Abbvie*, in which the asserted claims were filed later, claimed a later priority date, issued later, and expired later than the patentably indistinct reference claims. As we have recognized, *Abbvie* "is a prime example of the post-URAA scenario we contemplated in *Gilead* where an inventor, seeking to prolong his exclusivity rights over his invention, applies for a second patent on an obvious variant of his invention protected by a first patent" and achieves a later expiration date by choosing a different, later priority date than the one relied upon for the first patent. *Breckenridge*, 909 F.3d at 1365. For the reasons already explained, that is not the case here.

To borrow language from *Breckenridge*, in many ways this case is "a prime example" of when ODP does not apply. *See id.* When seeking patent protection, it is not atypical for a patent applicant to first seek to protect the most valuable inventive asset (*e.g.*, a pharmaceutical genus claim) before filing continuing applications on enhancements or modifications to that inventive asset (*e.g.*, a particular compound in that genus, a method of using the compounds of that genus, etc.). And it is unsurprising that prosecution of a first-of-its-kind invention can be protracted, requiring greater time and effort by the applicant and examiner alike, such that any eventual patent on that invention is awarded some amount of PTA. Nor is it surprising that,

for one reason or another (*e.g.*, the examiner's newfound familiarity with the subject matter), a subsequently filed continuing application claiming the same priority date and covering a modification of that invention proceeds much more efficiently through prosecution such that any patent awarded to that modification receives little to no award of PTA. As a result, that later-filed, later-issued continuing, or "child," patent, whether subject to a terminal disclaimer over the parent or not, generally expires no later than the parent patent. That child patent does not, then, result in any extension of patent term of the invention claimed in the parent patent given that it expires first. Nor can the parent patent be said to result in an extension of 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.

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. That is because such a holding would require patent owners, in order to preserve the validity of the parent patent, to file a terminal disclaimer disclaiming any term of the parent that extends beyond that of the child, which, given that the patents share a priority date, would amount to the disclaimer of *only* PTA. That parent patent, then, would not receive the benefit of its congressionally guaranteed patent term, *see* 35 U.S.C. § 154(b), and would instead be limited to the, presumably shorter, term of its own child. Such a result would be untenable.

Accordingly, claim 40 of the '356 patent is not invalid for ODP over claim 33 of the '011 patent or claim 5 of the '709 patent.

II

We turn now to whether the asserted claims of the '179, '291, '792, and '516 patents, none of which require the inclusion of a glidant, satisfy the written description requirement of 35 U.S.C. § 112. Recall, the district court concluded that they did not, finding that a person of ordinary skill in the art would not understand the inventors to have possessed a formulation that lacked a glidant.

A

At the outset, we note that this is not a typical written description case. It is not a "blaze marks" case in which the claims recite a species where the specification describes only a genus. *See Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326–27 (Fed. Cir. 2000) ("[O]ne cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure."); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996) ("[S]imply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses."). Nor is it a case in which a patentee attempts to claim broadly that which the specification describes only narrowly. *See Regents of the Univ. of Minnesota v. Gilead Scis., Inc.*, 61 F.4th 1350, 1356 (Fed. Cir. 2023) ("[W]ritten description of a broad genus requires description not only of the outer limits of the genus but also of either a representative number of members of the genus or structural features common to the members of the genus, in either case with enough precision that a relevant artisan can visualize or recognize the members of the genus.").

Here, the asserted claims are essentially picture claims to a particular pharmaceutical tablet comprising eluxadoline and various inert ingredients. The claims are narrow,

not only in that they recite specific amounts of the ingredients (in most cases, not even ranges), but also in that they recite specific ingredients—silicified microcrystalline cellulose, crospovidone, mannitol, and magnesium stearate—not classes of ingredients, *e.g.*, filler, disintegrant, preservative, etc. For example, the asserted claims recite, in part, "about 60 mg mannitol." That limitation is undisputedly narrow, and much narrower than a limitation that would recite, for example, "about 5-15% by weight filler." *See* '179 patent at Table 1, col. 16, ll. 27–56 (identifying mannitol as a "filler").

Moreover, the written description generally matches the scope of the claims. *GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 731 (Fed. Cir. 2014) ("We have not required more for an adequate written description that matches claim scope."). The claims do not recite an embodiment that is arguably undisclosed. Indeed, it is undisputed that each of the claimed limitations, *i.e.*, each of the expressly recited ingredients and its recited amount, is adequately disclosed in the specification. J.A. 5970, 5973–74 (Sun's expert testifying that a person of ordinary skill in the art could "pick out th[e] embodiment" recited in claim 26 of the '516 patent).

The issue before us, then, is not whether the inventors had possession of the formulation that is expressly claimed. That question answers itself. Rather, the issue is whether the inventors had possession of a formulation that lacked a component that is *not* claimed, or only optional. In the district court's view, they did not. We disagree.

B

To resolve this issue, we must make "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). "Whether a claim satisfies the written description requirement is a question of fact that, on

appeal from a bench trial, we review for clear error." *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014). "A factual finding is clearly erroneous when, despite some supporting evidence, we are left with a definite and firm conviction that the district court was in error." *Id.* at 1186. A district court's interpretation of precedent regarding the written description requirement is reviewed without deference. *Id.* at 1190.

"The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991) (emphasis omitted). "A specification adequately describes an invention when it 'reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.'" *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1335 (Fed. Cir. 2021) (quoting *Ariad*, 598 F.3d at 1351).

Based on its review of the patent specification and supporting expert testimony, the district court found that the asserted claims of the '179, '291, '792, and '516 patents are invalid for lack of written description because "the specification . . . fails to show that the patentee was in possession of a formulation in which the inclusion of the glidant was optional." *Decision*, 694 F. Supp. 3d at 524. Specifically, the district court determined that the specification discloses only a narrow group of eluxadoline formulations, all of which include a glidant. *Id.* at 523. Moreover, it found that the specification provides no "indication that [a glidant] was not required to practice the invention." *Id.* at 524; *see id.* at 529 ("The patent specification does not disclose that a formulation would have sufficient flow characteristics or work without a glidant."). That was clear error.

First, the word "optional" does not indicate a component that must be specifically described, for § 112 purposes, or included in an accused composition, for infringement purposes. It denotes the opposite, something

that need not be present. There are only two options, present or absent, and the very word itself describes both possibilities.

Moreover, the specification describes at least two embodiments in which a glidant is not required. First, it discloses an embodiment in which the formulation comprises eluxadoline "and *an* inert ingredient selected from silicified microcrystalline cellulose, colloidal silicon dioxide [*i.e.*, a glidant], crospovidone (polyvinylpolypyrrolidone; highly cross-linked polyvinylpyrrolidone (PVP)), mannitol, and magnesium stearate." '179 patent at col. 4, ll. 4–12 (emphasis added). Second, it discloses an embodiment in which the embodiment *consists* of eluxadoline "and *an* inert ingredient selected from silicified microcrystalline cellulose, colloidal silicon dioxide, crospovidone (polyvinylpolypyrrolidone; highly cross-linked polyvinylpyrrolidone (PVP)), mannitol, and magnesium stearate." *Id.* at col. 4, ll. 14–21 (emphasis added). Those embodiments plainly require only eluxadoline and *some* other ingredient. They do not require, however, any one of the inert ingredients, so long as at least one of those inert ingredients is present. *See ABS Glob., Inc. v. Cytonome/St, LLC*, 84 F.4th 1034, 1040 (Fed. Cir. 2023) (collecting cases and explaining that, unless context sufficiently indicates otherwise, the use of "a" or "an" before a noun naming an object means "one or more"); *see also* '179 patent at col. 10, ll. 20–23 ("As used herein, the singular forms 'a,' 'and' and 'the' include plural referents unless the content and context clearly dictate otherwise."). Accordingly, those embodiments contemplate a formulation that both includes and does not include a glidant. Stated otherwise, they contemplate a formulation in which a glidant is optional.

Further, claim 1 of the originally filed patent application from which the asserted patents claim priority recited:

> 1. A solid pharmaceutical dosage formulation comprising [eluxadoline] and an inert ingredient

> selected from silicified microcrystalline cellulose, colloidal silicon dioxide, crospovidone, mannitol, and magnesium stearate.

U.S. Patent Application 13/829,984 (filed Mar. 14, 2013). Originally filed claims have long been held to be part of the specification to be considered in any § 112 analysis. *In re Gardner*, 480 F.2d 879, 879 (CCPA 1973). Thus, that application disclosed formulations without a glidant.

Consider a scenario in which Allergan had successfully obtained a patent including the originally filed claim. That claim, which does not require colloidal silica, *i.e.*, a glidant, would undoubtedly have satisfied the written description requirement of § 112 (though it could face challenges on other questions of patentability) because it would be directly supported *in haec verba* by the disclosure. *See* '179 patent at col. 4, ll. 4–12; *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (noting that "the exact terms need not be used *in haec verba*, so long as the specification "contain[s] an equivalent description of the claimed subject matter"); *see also ScriptPro LLC v. Innovation Assocs., Inc.*, 833 F.3d 1336, 1341 (Fed. Cir. 2016) (reversing district court's grant of summary judgment of invalidity where the originally filed claims supported written description of an invention that was "not limited to the embodiment or purpose that [was] the focus of the specification"). It therefore cannot be, as the district court found, that the inventors did not have possession of a formulation in which a glidant was not required. They did have such possession as they disclosed it in an original claim, whether that claim remained or not.

To be sure, the specification does largely focus on more detailed formulations that include a glidant. For example, one such embodiment discloses that the formulation contains "from about 0.45-1.0% by weight of a glidant, e.g., colloidal silica." '179 patent at col. 11, ll. 47–52. And further provided are examples including a glidant in specific

amounts. *See id.* at col. 16, ll. 13–55 (providing example formulations including 4.5 mg (in a 75 mg tablet) or 6 mg (in a 100 mg tablet) of colloidal silica as a glidant). However, those disclosures, as the district court correctly understood, do not limit the scope of the invention. *Decision*, 694 F. Supp. 3d at 524 ("Of course, patents are not limited to the specific embodiments disclosed in the specification."); *see ScriptPro LLC*, 833 F.3d at 1341 ("[A] specification's focus on one particular embodiment or purpose cannot limit the described invention where that specification expressly contemplates other embodiments or purposes."). But despite understanding this principle, the district court nevertheless limited the validity of the claims to only those that expressly recite a glidant, finding that the disclosures at column 4 (and the original claims) "just outline[] the basic idea to create a formulation of eluxadoline with some combination of excipients in some proportions." *Decision*, 694 F. Supp. 3d at 528.

As noted above, however, this is not a case in which the disclosure provides only a "broad outline of a genus's perimeter," and claims a species within that broad outline. *See Regents of the Univ. of Minnesota*, 61 F.4th at 1356. Nor do the disclosures at column 4 and the original claims provide "thousands" of possible formulations from a "laundry list of ingredients," as Sun contends. Sun Br. at 44–45. Rather, those embodiments recite a specific active ingredient—eluxadoline—in combination with one or more of just five specific inert ingredients, which may or may not be a glidant. As the "hallmark" of written description, *see Ariad*, 598 F.3d at 1351, the disclosure must be considered as a whole, as the person of ordinary skill in the art would read it, to determine if it *reasonably* conveys possession. Here, the specification as a whole shows possession through its description of a formulation without a glidant.

In reaching its conclusion, the district court found instructive our decision in *ICU Medical, Inc. v. Alaris*

Medical Systems, Inc., 558 F.3d 1368 (Fed. Cir. 2009). But that case is distinguishable.

ICU Medical is a medical device case involving claims to valves used in IVs. 558 F.3d at 1372. The specification "repeatedly and uniformly" described the inventive valves as including a spike, which was included "for the purpose of piercing a seal inside the valve." *Id.* at 1374–75 (citations omitted). Although the patentee had obtained various claims to a valve comprising a body, a seal, and a spike, the asserted claims recited a valve comprising only a body and a seal. *Id.* at 1377. They did not recite any spike limitation. *Id.* We therefore referred to the invention of those claims as "spikeless" (or "spike-optional") valves because, although they did not *exclude* the preferred embodiment of a valve with a spike, they did not *require* a spike. *Id.* We held these "spikeless" claims invalid for lack of adequate written description because "the specification describe[d] only medical valves with spikes." *Id.* at 1378. The inventor therefore did not possess a medical valve that operated without a spike. *Id.*

This case is different from *ICU Medical* in at least two material aspects. First, the entirety of the specification in *ICU Medical* described *only* medical valves having spikes. That is different from the specification here where, as discussed above, it discloses at least two embodiments in which the formulation does not necessarily include the unclaimed glidant. Second, the specification in *ICU Medical* attributed a particular function to the spike—piercing a seal inside the valve—that could not be accomplished without a spike. That is different from the situation here where the specification attributes no particular function or significance to the glidant. The very fact that a glidant is not necessarily present in every embodiment indicates that it is optional, regardless whether the inventors expressly described it as "optional." *Lockwood*, 107 F.3d at 1572 ("[T]he exact terms need not be used *in haec verba*[.]"). And there is no disclosure to suggest that the glidant is essential or

otherwise necessary to the invention. *See In re Peters*, 723 F.2d 891, 893–94 (Fed. Cir. 1983) (finding no lack of written description for claim omitting a tapered tip where there was no evidence, intrinsic or extrinsic, that a tapered tip was essential to the invention).

In that regard, the district court relied on expert testimony to find that "a [person of ordinary skill in the art] would generally understand that a glidant can be necessary for some formulations (*e.g.*, those that have insufficient flow characteristics or do not mix well) and a [person of ordinary skill in the art] would understand that using a glidant in a formulation would be a signal that it was necessary in order to achieve sufficient flow properties." *Decision*, 694 F. Supp. 3d at 524–25. But that a glidant *may* be necessary does not mean that the inventors did not possess a formulation in which it *was not* necessary. So, just as "[t]he patent specification does not disclose that a formulation would have sufficient flow characteristics or work without a glidant," as the district court found, *id.* at 529, neither does it disclose that a formulation would *not* have sufficient flow characteristics or work without a glidant. Similarly, just as the specification provides no "indication that [a glidant] was not required to practice the invention," *id.* at 524, neither does it provide any indication that a glidant *was* required to practice the invention. Again, these facts distinguish this case from *ICU Medical*, where the unclaimed feature had a particular function necessary to the disclosed invention.

Nothing in our analysis should be read as limiting the written description inquiry to *only* the four corners of the specification, to the exclusion of expert testimony. Our inquiry is, and has always been, an "objective" one "into the four corners of the specification *from the perspective of a person of ordinary skill in the art*." *Ariad*, 598 F.3d at 1351 (emphasis added). It therefore was not error, especially during a bench trial, for the district court to have relied on expert testimony when evaluating written description.

E.g., *id.* at 1355–56 (crediting expert testimony regarding satisfaction of the written description requirement); *Nalpropion Pharms., Inc. v. Actavis Lab'ys FL, Inc.*, 934 F.3d 1344, 1349 (Fed. Cir. 2019) (same). But the proper inquiry must be into the specification first and then *guided* by expert testimony. Here, for example, there is no concern if an expert testifies that a person of ordinary skill in the art would understand that a glidant is an agent used to improve the flow characteristics of the composition. *See Decision*, 694 F. Supp. 3d at 523. But without *some* basis in the specification that the invention would be understood to *require* a glidant, expert testimony cannot be used to fill that gap. Reliance on such testimony, untethered to the inventors' own description of the invention, would improperly take the written description inquiry outside the four corners of the specification.

One final cautionary point. Whether a claimed invention would "work," or whether it is operable, goes more directly to the utility requirement or the enablement requirement, not the written description requirement. Certainly, in cases like *ICU Medical*, where the invention is only described as including a feature that provides a particular, necessary function to the invention, the inquiries may overlap. But a claimed invention need successfully operate only to some limited degree. It "need not be the best or the only way to accomplish a certain result, and it need only be useful to some extent and in certain applications." *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180 (Fed. Cir. 1991). So, although a formulation without a glidant may not flow as well as a formulation with a glidant, that does not mean that the formulation would not "work" without a glidant, as the district court found.

We therefore hold that the district court clearly erred in finding that the specification does not reasonably convey to a person of ordinary skill in the art that the inventors had possession of a formulation without a glidant, and reverse the district court's conclusion that the asserted

claims of the '179, '291, '792, and '516 patents are invalid under 35 U.S.C. § 112 for lack of written description.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we reverse the district court's judgment of invalidity of the asserted claims under 35 U.S.C. § 112 and obviousness-type double patenting. Upon receipt of the mandate, the district court can, and should, address any other grounds of invalidity raised by the parties at trial that are adequately supported by the record.

REVERSED

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

2024-1061

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

DYK, *Circuit Judge*, concurring-in-part and dissenting-in-part.

I join Part I of the majority's opinion concerning double patenting. However, I respectfully dissent from Part II of the majority's opinion concerning written description. The issue is whether there is adequate written description support for "[a] pharmaceutical tablet comprising" ingredients

not including a glidant, and for "[a]n abuse-deterrent, mono-phasic pharmaceutical tablet comprising . . . optionally, a glidant and/or lubricant," formulations that are covered by the challenged claims.[1] '516 patent at col. 34, ll. 12–48; '179 patent at col. 36, ll. 33–43. A glidant is an inert ingredient commonly added to tablet formulations to ensure that the mixture of the drug and the other ingredients flows adequately. The formulation patents as initially allowed by the examiner claimed only compositions that included a glidant.[2] After litigation commenced, Allergan filed new continuation applications claiming formulations that do not require a glidant or wherein a glidant is optional and, once they issued as patents, asserted them against Sun. The question on appeal is whether these new glidant-optional claims have adequate written description support.

I

Written description is a question of fact that, on appeal from a bench trial, we review for clear error. *Biogen Int'l GMBH v. Mylan Pharms. Inc.*, 18 F.4th 1333, 1340–41

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[1] *I.e.*, claims 7 and 18 of the '179 patent, claims 7 and 19 of the '291 patent, claims 6 and 16 of the '792 patent, and claims 26 and 29 of the '516 patent.

[2] *See, e.g.*, U.S. Patent No. 10,188,632 at claim 1 ("A solid pharmaceutical dosage formulation comprising . . . about 0.55-0.95% by weight of colloidal silicon dioxide [a glidant] . . . ."); *id.* at claim 14 ("A pharmaceutical composition comprising . . . about 4.5 mg of colloidal silica [a glidant] . . . ."); U.S. Patent No. 9,675,587 at claim 1 ("An abuse deterrent, mono-phasic pharmaceutical composition . . . consisting essentially of . . . from about 0.55-0.95% by weight of colloidal silica . . . ."); *id.* at claim 7 ("An abuse deterrent, mono-phasic pharmaceutical composition . . . consisting essentially of . . . about 6 mg of colloidal silica . . . .").

(Fed. Cir. 2021). The written description question is to be answered from the perspective of a person of ordinary skill in the art. *In re Peters*, 723 F.2d 891, 894 (Fed. Cir. 1983). Accordingly, district courts may rely on expert testimony when interpreting a specification. *See, e.g.*, *Biogen*, 18 F.4th at 1343 (crediting expert testimony that the claims lacked written description support because the specification failed to link a disclosed dose to the claimed therapeutically effective amount).

Here, there was extensive expert testimony on written description. Both sides agreed that "[g]lidants are typically used in solid oral dose formulation" and that "[a] glidant is generally used in almost every formulation." J.A. 5784 (inventor testimony); *see also* J.A. 15–16 (collecting evidence). Expert testimony offered by Sun established that there was "no evidence within the specification" that the inventors possessed a formulation without a glidant. J.A. 5856. Significantly, the specification calls out the ingredients that the inventors considered optional, such as coloring agents, preservatives, anti-oxidants, buffers, and dissolution-rate modifying agents, but it made no mention of a glidant's being optional. *See, e.g.*, '179 patent at col. 12, ll. 38–51; *id.* at col. 4, ll. 12–14; J.A. 5834 ("There's no description of colloidal silica [a glidant] being optional here."). Based on this expert testimony, the district court concluded that a person of ordinary skill would understand that a glidant is not optional.

This case is quite similar to *ICU Medical, Inc. v. Alaris Medical Systems, Inc.*, a case where we found written description lacking. 558 F.3d 1368, 1379 (Fed. Cir. 2009). There, as here, the patentee attempted to broaden its claims by removing a limitation that was present in every disclosed embodiment (there, a spike designed to pierce a medical valve). *Id.* at 1378. That is, the patentee claimed "spike-optional" embodiments despite the lack of a corresponding disclosure in the specification. *Id.* at 1377. We affirmed a judgment of invalidity because the evidence did

not establish that a person of ordinary skill in the art would recognize that the inventor had possession of "a medical valve that operated without a spike." *Id.* at 1378. Likewise, the expert testimony here established that a person of ordinary skill in the art would not understand Allergan to have invented a formulation without a glidant. The district court's factual findings are not clearly erroneous, and there is no contention that those findings were not supported by the expert testimony.

II

In reversing the district court and finding the written description requirement met, the majority exclusively relies on the original claims before they were amended to require a glidant and on the specification's disclosure of a pharmaceutical formulation with "*an* inert ingredient selected from" a list that includes colloidal silicon dioxide (a glidant). Maj. Op. 24 (quoting '179 patent at col. 4, ll. 8–12 (emphasis added); *id.* at col. 4, ll. 14–21 (emphasis added)). The majority reasons that, because this particular glidant is optional, all glidants are optional, and the specification therefore describes a glidant-free formulation. That conclusion does not follow. While the specification indicates that colloidal silicon dioxide is optional, nothing in the disclosure teaches that the use of some form of glidant is optional. Rather, every complete formulation disclosed in the specification uses a glidant. The majority admits that "the specification does largely focus on more detailed formulations that include a glidant." Maj. Op. 25.

The unrebutted expert testimony was that a person of ordinary skill in the art would normally use a glidant and that, absent a teaching to the contrary, he would interpret the specification to show that the inventor possessed only formulations that include a glidant. The disclosures relied on by the majority did not suggest a contrary conclusion. Because ample expert testimony supports the district

court's factual finding, I would affirm the district court's well-reasoned opinion as to written description.