IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN USA, INC., ALLERGAN HOLDINGS UNLIMITED COMPANY, and EDEN BIODESIGN, LLC., Plaintiffs, v. MSN LABORATORIES PRIVATE LIMITED, MSN PHARMACEUTICALS INC., and SUN PHARMACEUTICAL INDUSTRIES LIMITED, Defendants.	Civil Action No. 19-1727-RGA (consolidated)
ALLERGAN USA, INC., ALLERGAN HOLDINGS UNLIMITED COMPANY, ALLERGAN PHARMACEUTICALS and JANSSEN PHARMACEUTICA NV, Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LIMITED, Defendant.	Civil Action No. 20-1479-RGA

TRIAL OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Allergan brought this action against Sun Pharmaceutical Industries Limited ("Sun"), MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. (together, "MSN") for patent infringement under 35 U.S.C. § 271(e)(2)(A).

Allergan asserts Sun infringes U.S. Patent Nos. 11,007,179 (the "'179 patent"), 11,090,291 (the "'291 patent"), 11,160,792 (the "'792 patent"), 11,311,516 (the "'516 patent") and 7,741,356 (the "'356 patent"). (D.I. 469, ¶ 1; D.I. 461, ¶ 14; D.I. 414-1, Ex. 1, ¶ 113).[1] Sun contends the asserted claims of those patents are invalid. (D.I. 461, ¶¶ 3-4).

Allergan asserts MSN infringes U.S. Patent No. 11,229,627 (the "'627 patent") and the '291 patent. (D.I. 461, ¶ 16; D.I. 469, ¶ 2). MSN contends the asserted claims of the two patents are invalid. (D.I. 461, ¶ 3).

I held a three-day bench trial. (D.I. 457-459).

I have considered the parties' post-trial submissions. (D.I. 461, 462, 468, 469, 471, 477, 478). Having considered the documentary evidence and testimony, I make the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

I. BACKGROUND

Allergan holds New Drug Application ("NDA") No. 206940 for VIBERZI® eluxadoline[2] tablets. "VIBERZI® is approved for the treatment of irritable bowel syndrome with diarrhea ("IBS-D") in adults." (D.I. 414-1, Ex. 1, ¶ 81).

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[1] References to the docket are to C.A. 19-1727, unless otherwise noted.

[2] "Eluxadoline is the S,S configuration of the compound having the chemical name 5-({[2-Amino-3- (4-carbamoyl-2,6-dimethyl-phenyl)-propionyl]-[1-(4-phenyl-1H-imidazol-2-yl)-ethyl]-amino}- methyl)-2-methoxy benzoic acid." (D.I. 414-1, Ex. 1, ¶ 6).

Sun submitted Abbreviated New Drug Application ("ANDA") No. 213447 under § 355(j) of the Federal Food, Drug, and Cosmetic Act seeking FDA approval to engage in the commercial manufacture, market, and sell a generic version of Allergan's VIBERZI® eluxadoline tablets. (D.I. 414-1, Ex. 1, ¶ 107). In doing so, Sun filed "Paragraph IV" certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for U.S. Patent Nos. 9,675,587 (the "'587 patent") and 10,188,632 (the "'632 patent"). (*Id.*, Ex. 1, ¶¶ 107-08). Sun later filed a Paragraph IV certification for the '356 patent. (*Id.*, Ex. 1, ¶ 110).

MSN submitted ANDA No. 213576 under § 355(j) of the Federal Food, Drug, and Cosmetic Act seeking FDA approval to engage in the commercial manufacture, market, and sell a generic version of Allergan's VIBERZI® eluxadoline tablets. (*Id.*, Ex. 1, ¶ 90). In doing so, MSN filed Paragraph IV certifications for U.S. Patent Nos. 8,691,860 (the "'860 patent"), 9,115,091 (the "'091 patent"), 9,364,489 (the "'489 patent"), 9,789,125 (the "'125 patent"), and the '587 and '632 patents. (*Id.*, Ex. 1, ¶ 90).

Allergan filed its Complaint against MSN alleging infringement of the '860, '091, '489, '587, '125, and '632 patents. (D.I. 1 at 26). On that same day, Allergan filed its Complaint against Sun alleging infringement of the '587 and '632 patents. (*Id.*).

Over the course of the litigation in this case, Allergan filed continuation applications and prosecuted patents belonging to the patent family at issue. Allergan later obtained U.S. Patent Nos. 11,007,179 (the "'179 patent"), 11,090,291 (the "'291 patent"), and 11,160,792 (the "'792 patent"), 11,229,627 (the "'627 patent") and 11,311,516 (the "'516 patent") and asserted them against Sun and MSN as the patents issued. (*See* D.I. 414-1, Ex. 1, ¶¶ 94-106, 114-129). "The '587, '632, '179, '291, '792, '516, '627, and '356 patents have been listed for NDA No. 206940 in the Orange Book." (*Id.*, Ex. 1, ¶ 84).

Allergan filed a separate action alleging infringement of the '356 patent by Sun. (C.A. 20-1479, D.I. 1). That action was consolidated with this one. (D.I. 365).

Allergan and Sun stipulated that Sun would infringe the asserted claims of the '179, '291, '792, '516, and '356 patents if the claims are valid (D.I. 409; C.A. No. 20-1479-RGA, D.I. 53). Allergan and Sun stipulated to the dismissal of claims and counterclaims concerning the '587 and '632 patents. (D.I. 443).

At trial, the only issues between Allergan and Sun were whether the asserted claims of the '179, '291, '792, '516, and '356 patents are invalid. Sun argues the asserted claims of the '179, '291, '792, and '516 patents are invalid for lack of written description. (D.I. 462 at 5-13). If I were to find that the asserted claims have sufficient written description, then Sun argues the asserted claims of those patents are obvious. (*Id.* at 21-23). Sun contends that the asserted claim of the '356 patent is invalid for obviousness-type double patenting. (*Id.* at 23-25).

Allergan and Sun stipulated that claim 26 of the '516 patent and claim 7 of the '179 patent are representative of the asserted claims of the '179, '291, '792, and '516 patents. (D.I. 433 at 2).

The relevant claims from the '516 patent read as follows:

> 1. A pharmaceutical tablet comprising:
> about 75 mg of [eluxadoline],
> about 60-80% by weight filler;
> about 2-8% by weight disintegrant;
> about 10% by weight mannitol.

(JTX-006, cl. 1).

> 26. The pharmaceutical tablet of claim 1, comprising:
> about 75 mg of [eluxadoline];
> about 390 mg-450 mg 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.

(JTX-006, cl. 26).

The relevant claims of the '179 patent read as follows:

1. An abuse-deterrent, mono-phasic pharmaceutical tablet comprising:
about 75 mg of [eluxadoline],
about 60-80% by weight silicified microcrystalline cellulose;
crospovidone;
about 5-15% by weight mannitol; and
optionally, a glidant and/or lubricant.

(JTX-002, cl. 1).

3. The tablet of claim 1, comprising about 65-75% by weight silicified microcrystalline cellulose, and about 7.5-12.5% by weight mannitol.

4. The tablet of claim 3, comprising about 3-7% by weight crospovidone and a lubricant.

5. The tablet of claim 4, wherein the lubricant is magnesium stearate present in an amount of about 0.55-0.95% by weight.

6. The tablet of claim 5, comprising:
about 75 [eluxadoline];
about 390 mg-450 mg of silicified microcrystalline cellulose;
about 18 mg-42 mg crospovidone;
about 45 mg-75 mg of mannitol; and
about 3.3 mg-5.7 mg of magnesium stearate.

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.

(JTX-002, cl. 3-7).

Allergan and MSN stipulated to dismissal of the claims and counterclaims concerning the '860, '091, '489, '125, '356, '792, '179, '632, '516, and '587 patents. (D.I. 353; D.I. 452). Allergan

and MSN stipulated that MSN would infringe the asserted claims of the '291 and '627 patent if the claims are valid. (D.I. 408 at 2; 414-1, Ex. 1, ¶¶ 174-75).

At trial, the only issues between Allergan and MSN were whether the asserted claims of the '627 and '291 patents are invalid. MSN argues the asserted claims are invalid for lack of written description and lack of enablement. (D.I. 462 at 13-21). If I were to find the asserted claims have adequate written description and are enabled, then MSN argues the asserted claims are obvious. (*Id.* at 21-23).

Allergan and MSN stipulated that claim 27 of the '627 patent and claim 11 of the '291 patent are representative of all asserted claims against MSN. (D.I. 432 at 1-2).

Claim 27 of the '627 patent reads as follows:

> 27. A pharmaceutical tablet comprising:
> about 75 mg or about 100 mg of [eluxadoline];
> about 60-80% by weight filler;
> about 7.5-12.5% by weight mannitol;
> about 3-7% by weight disintegrant;
> colloidal silicon dioxide; and
> about 0.45-1 % by weight magnesium stearate.

(JTX-005, cl. 27).

Claim 11 of the '291 patent reads as follows:

> 11. An abuse-deterrent, mono-phasic pharmaceutical tablet comprising:
> about 75 mg of [eluxadoline];
> about 390 mg[-]450 mg filler;
> about 12 mg[-]48 mg disintegrant;
> about 60 mg of mannitol;
> colloidal silica; and
> magnesium stearate.

(JTX-003, cl. 11).

The asserted patents, except for the '356 patent, have a shared specification. (D.I. 469, ¶ 10).[3]

II. LEGAL STANDARDS

A. Written Description

The written description requirement contained in 35 U.S.C. § 112 requires that the specification "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (alteration in original). "In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* "When determining whether a specification contains adequate written description, one must make an 'objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.'" *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011) (quoting *Ariad*, 598 F.3d at 1351). The written description inquiry is a question of fact. *Ariad*, 598 F.3d at 1351.

B. Enablement

A patent's "specification must enable the full scope of the invention as defined by its claims." *Amgen Inc. v. Sanofi*, 143 S. Ct. 1243, 1254 (2023). For a patent claim to be enabled, the patent specification must "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same[.]" 35 U.S.C. § 112(a). "The enablement requirement is met where one skilled in the art,

[3] Unless otherwise noted, I cite only to the specification of the '179 patent (JTX-002) when referring to the patent specification of the asserted patents.

having read the specification, could practice the invention without 'undue experimentation.'" *Streck, Inc. v. Rsch. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) (citation omitted); *see also Amgen*, 143 S. Ct. at 1255 ("[A] specification may call for a reasonable amount of experimentation to make and use a patented invention. What is reasonable in any case will depend on the nature of the invention and the underlying art."). Factors for assessing whether a disclosure would require undue experimentation include:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

"Enablement is a question of law based on underlying facts." *Wyeth & Cordis Corp. v. Abbott Lab'ys,* 720 F.3d 1380, 1384 (Fed. Cir. 2013). The party challenging validity must prove lack of enablement by clear and convincing evidence. *Cephalon, Inc. v. Watson Pharms., Inc.,* 707 F.3d 1330, 1336 (Fed. Cir. 2013).

C. Obviousness

A patent claim is invalid as obvious under 35 U.S.C. § 103 "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07 (2007). "As patents are presumed valid, a defendant bears the burden of proving invalidity by clear and convincing evidence." *Shire, LLC v. Amneal Pharms., LLC*, 802 F.3d 1301, 1306 (Fed. Cir. 2015) (cleaned up). "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to

be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined." *KSR*, 550 U.S. at 406 (citations and quotation marks omitted).

A court is required to consider secondary considerations, or objective indicia of nonobviousness, before reaching an obviousness determination, as a "check against hindsight bias." *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1078-79 (Fed. Cir. 2012). "Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

D. Obviousness-Type Double Patenting

"Obviousness-type double patenting is a judicially-created doctrine designed to prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (internal quotation marks omitted). Under this doctrine, the court must determine "whether the claimed invention in the application for the second patent would have been obvious from the subject matter of the claims in the first patent, in light of the prior art." *In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985). In order to do so, the court applies a two-step analysis: "First, the court construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences. Second, the court determines whether those differences render the claims patentably distinct." *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1374 (Fed. Cir. 2014)

(internal quotation marks omitted). "A later claim that is not patentably distinct from ... an earlier claim is invalid for obviousness-type double patenting." *Id.* (internal quotation marks omitted).

For a patent to qualify as an obviousness-type double patenting ("ODP") reference, its expiration date must fall before that of the challenged patent. *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1215-17 (Fed. Cir. 2014). "ODP for a patent that has received [patent-term adjustment ("PTA")], regardless [of] 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." *In re Cellect, LLC*, ___ F.4th ____, 2023 WL 5519716, at *9 (Fed. Cir. Aug. 28, 2023).

III. WRITTEN DESCRIPTION (SUN)

A. Findings of Fact

1. A person of ordinary skill in the art (POSA) is a person who possesses a Ph.D. in chemistry, pharmaceutical sciences, or related disciplines and at least one year's experience formulating pharmaceutical products and the ability to operate independently on formulation development activities. (D.I. 461, ¶¶ 19-20; D.I. 469, ¶¶ 36-37). Alternatively, a POSA may have a lesser degree but would have more than one year of experience working in those fields, such that the total level of knowledge would be equivalent. (D.I. 461, ¶¶ 19-20; D.I. 469, ¶¶ 36-37). Furthermore, because drug development involves a multidisciplinary approach, a POSA may interface, consult, or work in a group with individuals having specialized expertise, for example, a physician with experience in the administration, dosing, and efficacy of drugs for the treatment of a particular disease state. (D.I. 461, ¶ 19-20; D.I. 469, ¶¶ 36-37).[4]

2. The priority date of the '179, '291, '792, and '516 patents is March 14, 2013. (D.I. 414-1, Ex. 1, ¶ 196).

3. A POSA would understand that the term "glidant" is a common category of excipient used in pharmaceutical formulations. (D.I. 469, ¶ 8; D.I. 461, ¶ 22; Tr. 197:11-23: (Gemeinhart)). A POSA would understand that a glidant is an agent used to improve the flow characteristics of a powder mixture. (D.I. 461, ¶ 26; D.I. 469, ¶ 8; Tr. 68:20-21, 69:6-

[4] Allergan's and Defendants' definitions of POSA differ slightly. "Both [Allergan's] and Defendants' experts agree that their opinions would be the same regardless of whether the Court adopts [Allergan's] or Defendants' definition of a POSA." (D.I. 469, ¶ 38; *see also* D.I. 461, ¶ 18). Therefore, while I adopt Defendants' definition, I note that adopting Allergan's definition instead would not change my conclusions.

8 (Costello); Tr. 101:22-102:2, 103:7-8 (Gemeinhart); JTX-023 (Ansel) at 36; JTX-060 (Remington) at 862; JTX-008 (Armstrong) at 7).

4. A POSA would understand that in some cases a glidant may be necessary. (JTX-008 (Armstrong) at 10); Tr. 247:10-18, 312:5-9 (Gemeinhart)). A POSA would understand that a glidant would be used when it is necessary. (Tr. 247:10-18 (Gemeinhart); JTX-008 (Armstrong) at 10). A POSA would not understand that a glidant is, "by definition," an optional excipient.

5. A POSA would recognize that colloidal silica and colloidal silicon dioxide are glidants. (Tr. 177:5-8 (Gemeinhart); Tr. 383:22-24 (Berkland)).

6. None of the formulations disclosed in the patent specification of the asserted patents are made without a glidant. (Tr. 141:13-142:13 (Gemeinhart); Tr. 421:1-18 (Berkland)).

7. The discussion in the patent specification regarding preparing a preformulation composition (JTX-002 ('179 patent) at col. 12:52-67) refers to an overview of the general manufacturing process of the invention, not a preliminary testing step. A POSA would not understand this paragraph to disclose that a glidant was optional or that the patentee was in possession of a glidant-optional formulation.

8. A POSA reading the patent specification would not have understood that a glidant was an optional excipient for practicing the invention.

9. A POSA reading the patent specification would not have understood the patentee to possess a formulation of eluxadoline in which a glidant is optional.

B. Conclusions of Law

Sun asserts there is no written description support for claims that do not require a glidant. (D.I. 462 at 5-13). Claim 26 of the '516 patent (JTX-006 ('516 patent), cl. 26) and claim 7 of the '179 patent do not list a glidant as a limitation. Claim 7 of the '179 patent depends from an independent claim that recites a glidant-optional limitation. (*See*, JTX-002 ('179 patent), cl. 1, 3-7).

A glidant is an agent that is used to improve the flow characteristics of a powder mixture. (D.I. 461, ¶ 26; D.I. 469, ¶ 8; Tr. 68:20-21, 69:6-8 (Costello); Tr. 101:22-102:2, 103:7-8 (Gemeinhart)). "[W]ithout that ability to flow, you won't have a good final product." (Tr. 101:2-4

(Gemeinhart); *see generally* Tr. 100:16-101:16 (Gemeinhart); Tr. 363:19-364:3, 366:3-16 (Berkland)).

Sun contends that because the specification only discloses formulations that contain a glidant and "nothing in the specification describes, or even suggests, that the inventors possessed a formulation without a glidant" (D.I. 462 at 6), the claims are invalid for lack of written description. Sun argues that this case is analogous to *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368 (Fed. Cir. 2009). (D.I. 462 at 6). I agree.

As of the priority date, eluxadoline, as a compound, was already known in the art. (*See* JTX-024 (Breslin) at 96; Tr. 172:8-22 (Gemeinhart); 472:14-473:6 (Berkland)). The inventions of the asserted patents are oral formulations of eluxadoline and the processes for preparing and administering those formulations. (*See, e.g.*, JTX-002 ('179 patent) at col. 1:23-28). The patent specification, however, only discloses a relatively narrow group of eluxadoline formulations. (Tr. 421:1-3 (Berkland)). In each of those formulations, a glidant (e.g., colloidal silica) is used. (Tr. 142:3-9 (Gemeinhart); *see, e.g.*, JTX-002 ('179 patent) at col. 11:23-12:3, 13:1-56, 16:10-17:40). The patent specification does not disclose that the patentee possessed a formulation of eluxadoline that either lacks a glidant or signaled to a POSA that the inclusion of a glidant in those formulations is optional (e.g., that the formulation(s) would have sufficient flow without a glidant).

I agree with Sun that this case is analogous to *ICU Med.*, 558 F.3d 1368. In *ICU Med.*, the patent specification only described medical valves with spikes, but the patent claimed medical valves without spikes (i.e., spikeless medical valves or "spike-optional" medical valves). *Id.* at 1377. The Federal Circuit reasoned that a POSA "would not understand the . . . patents to have invented the spikeless medical valve" because "the specification describes only medical valves with spikes." *Id.* at 1378. Just as spikeless claims in *ICU Med.* lacked adequate written description

because the specification failed to disclose a spikeless valve, the asserted claims here lack written description because the specification fails to disclose a formulation that does not have a glidant or where a glidant would be understood as optional.

For all the formulations disclosed in the patent specification, a glidant is used without any indication that it was not required to practice the invention. For example, there is nothing to signal to a POSA that without a glidant the formulations would have sufficient flow characteristics. Of course, patents are not limited to the specific embodiments disclosed in the specification. But the specification here fails to show that the patentee was in possession of a formulation in which the inclusion of the glidant was optional. Therefore, I find that a POSA would not understand the specification to indicate that a glidant is optional.

Allergan counters with three arguments. I address each one in turn.

First, Allergan argues that a POSA would understand that a glidant, "by definition" (D.I. 469, ¶ 43), is optional, and therefore the patent specification does not need to explicitly disclose that a glidant is optional (*see* D.I. 468 at 12 ("The shared specification need not have explained to a POSA that glidants are optional manufacturing aids; that was already a well-known fact."); *see also* D.I. 468 at 10-12). I understand Allergan to be arguing that a POSA would presume that a glidant is not required to practice the invention. Allergan cites for support a pamphlet of PROSOLV SMCC, which discloses that a glidant is typically not required when PROSOLV SMCC is used (D.I. 468 at 10; D.I. 469, ¶ 39 (citing (JTX-025 at 3)), and Desai, which discloses that silicified microcrystalline cellulose (SMCC) has "superior flow properties" without the addition of a glidant (D.I. 468 at 10; D.I. 469 ¶ 39 (citing JTX-011 (Desai) at 6)). The asserted claims against Sun recite using SMCC as a claim limitation. (JTX-006 ('516 patent), cl. 26; JTX-

002 ('179 patent), cl. 7). Allergan maintains that a POSA would possess this knowledge and a POSA would understand from this knowledge that a glidant is optional in the invention.

I disagree with Allergan that a POSA would understand that a glidant, by definition, is an optional excipient. While a glidant may not be required to produce all pharmaceutical formulations, a POSA would understand that a glidant can be necessary in some instances and, more importantly, that a glidant is used when it is necessary. (JTX-008 (Armstrong) at 10 ("Almost invariably a lubricant must be added, and a glidant and a disintegrating agent included when necessary.")). While Dr. Berkland testified that a glidant is not required for a formulation to form (Tr. 364:18-21, 365:5-6), he qualified his answer by explaining that "as long as all the ingredients mix well, you would not need to add [a glidant]" (Tr. 365:5-8). This is consistent with Dr. Gemeinhart's testimony (Tr. 312:5-9), as well as Armstrong (JTX-008 at 7, 10). I find a POSA 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 POSA would understand that using a glidant in a formulation would be a signal that it was necessary in order to achieve sufficient flow properties, unless noted otherwise.

I do not think the PROSOLV SMCC pamphlet (JTX-025), nor Desai (JTX-011) discloses that a glidant is optional "by definition." The PROSOLV SMCC pamphlet is not cited to nor incorporated into the patent specification. Even if it were, the PROSOLV SMCC pamphlet merely discloses that a glidant is not needed under typical uses, not that a glidant is never required when PROSOLV SMCC is used. (JTX-025 at 3 (listing "No additional CSD/glidants needed" as a "typical" reduction in excipient when used); Tr. 439:2-12 (Berkland)). Similarly, Desai just discloses that SMCC has enhanced flow properties without the addition of a glidant (JTX-011 at 6 ("Controlled optimal particle size and particle-size distribution ensures superior flow properties

of coprocessed excipients without the need to add glidants.")), but it does not state that a glidant is never required when SMCC is used. (JTX-011 (Desai) at 6; Tr. 244:13-20 (Gemeinhart)). Therefore, I disagree that a POSA's knowledge about SMCC would lead a POSA to understand that a glidant is optional "by definition," let alone optional in the claimed invention.

Allergan seems to equate something that is sometimes necessary as being optional, but those conditions do not mean the same thing. As discussed above, in instances where the flow is not sufficient, a glidant is necessary, not optional. Therefore, I do not think Allergan's first argument demonstrates that a POSA would understand a glidant to be optional for practicing the claimed invention.

Second, Allergan argues that a glidant is not essential to the invention and that a POSA would understand that whether a glidant is included in the formulation is not important to the invention. (D.I. 468 at 8-10). Allergan cites *In re Peters*, 723 F.2d 891 (Fed. Cir. 1983), to argue that a formulation without a glidant does not need to be described because the inclusion of a glidant is not essential to practicing the invention. Allergan contends the present case is analogous to *Peters* because "no prior art was distinguished or rejection overcome by relying on a glidant as a feature, and a POSA would understand that a glidant was unimportant to the invention." (D.I. 468 at 10).

But *Peters* is distinguishable. In *Peters*, the Federal Circuit determined that there was adequate written description for a display device that did not have tapered tips, despite the specification only providing examples with tapered tips. The Federal Circuit determined that the claims that lacked the tapered tip limitation omitted an "unnecessary limitation." *Peters*, 723 F.2d at 893. The Federal Circuit explained, "Most importantly, one skilled in the art would readily

understand that in practicing the invention it is unimportant whether the tips are tapered, and the board erred in determining the contrary." *Id.* The Federal Circuit further elaborated,

> What is important, says the patent, is that the tips withstand forces of atmospheric pressure loading. The teaching of the patent that metal tips permit a less thick support member than is possible with the glass support walls of the prior art is not affected by whether the metal tips are tapered.

Id. at 894. *Peters* is distinguishable because the knowledge of a POSA and the specification supported the reasoning that tapered tips were unnecessary.

As discussed above, I do not believe that a POSA would "readily understand" that including a glidant is unimportant in pharmaceutical formulations. Furthermore, the specification in *Peters* explained what was required of the tips (i.e., withstanding forces of atmospheric pressure loading) and that the disclosure of tapered metal tips was an example to satisfy that requirement. In the present case, however, the specification makes no disclosure about whether the use of a glidant is unimportant or just an optional component to include in the disclosed formulations. *See infra* Section III.B.1-2. While a POSA would understand that a formulation needs to have sufficient flow, a POSA would not understand that the formulations of the claimed invention would have sufficient flow without a glidant based on the disclosure of the patent specification. Therefore, I find *Peters* to be inapposite and I reject Allergan's second argument.

Third, Allergan contends that the specification describes that a glidant is optional. (D.I. 468 at 13-14). Allergan cites a paragraph it characterizes as "the description of the 'general process'" (JTX-002 ('179 patent) at col. 12:52-67) and a discussion in the background section that describes embodiments that include eluxadoline and only one other excipient (JTX-002 ('179 patent) at col. 4:4-5:33). (D.I. 468 at 12).

1. Preformulation Process Description

The first paragraph Allergan relies upon recites,

> For preparing formulations of the present disclosure, such as tablets, [eluxadoline] is mixed with one or more pharmaceutical excipients to form a solid preformulation composition containing, in preferred embodiments, a homogeneous mixture of the excipient(s) with the active ingredient. When referring to these preformulation compositions as "homogeneous," it is meant that the active ingredient are [sic] dispersed evenly throughout the composition so that the composition may be readily subdivided into equally effective unit dosage forms such as tablets or capsules. This solid preformulation is then subdivided into unit dosage forms of the type described above containing from, for example, about 10 to about 200 milligrams of the active ingredient.

(JTX-002 ('179 patent) at col. 12:52-67). The parties dispute the meaning of the term "preformulation" in this paragraph, which is relevant to interpreting what this paragraph is describing. Before addressing whether this paragraph provides written description of a glidant-optional formulation, I must first determine what "preformulation" means in this context.

a. Meaning of "Preformulation"

Allergan argues that this paragraph describes the general process for preparing the formulations of eluxadoline. Allergan cites to Dr. Gemeinhart's testimony that this paragraph "describes generally preparing formulations of the present disclosure." (D.I. 468 at 13 (citing Tr. 227:19-228:4)).

Sun contends that this paragraph does not describe the process of making formulations generally, but instead describes "early-stage research to test whether excipients are compatible with the drug." (D.I. 462 at 7). Sun cites to Dr. Gemeinhart's testimony (Tr. 309:18-310:9) and Lieberman (JTX-033 at 21) to show that, to a POSA, the term "preformulation" refers to an initial stage of research, not the first step in the manufacturing process.[5]

[5] Dr. Berkland offered testimony at trial regarding the meaning of "preformulation" in this paragraph. I separately struck that testimony. (D.I. 480).

I agree with Allergan that this paragraph is describing the general process of making formulations, and not an early-stage test. I credit Dr. Gemeinhart's testimony that a POSA would normally understand "preformulation" as an early-stage research test. I, however, think the plain language of the specification and the context of this paragraph show that "preformulation" is not used in the normal way.

First, the paragraph recites, "For preparing formulations of the present disclosure. . . ." (JTX-002 ('179 patent) at col. 12:52). This phrase indicates the paragraph is describing a process for making the invention, not testing. Second, "preformulation" in this paragraph refers to the mixture of eluxadoline with excipients (*see id.* at col. 12:57-64), not to "preformulation testing" or a "preformulation step." Third, I think this paragraph must be considered in context with the paragraphs that follow. The paragraphs that follow provide specific examples of preparing eluxadoline formulations. (*Id.* at col. 13:1-56). I think a POSA would, therefore, read this paragraph as a general overview, and the succeeding paragraphs as specific examples of different types of preparation processes.

Therefore, I agree with Allergan that this paragraph describes the general manufacturing process of the invention, not a preliminary testing step.

b. The Cited Paragraph Does Not Provide Sufficient Written Description

Allergan argues that because the paragraph describes mixing eluxadoline with one or more excipients, it presents the possibility that a formulation does not include a glidant or that a glidant is an optional excipient.(D.I. 468 at 13). Therefore, Allergan contends, this paragraph provides written description for a formulation where a glidant is optional or not included.

Sun contends that this paragraph does not disclose a "manufacturing process (preformulation or otherwise) where the glidant colloidal silica is optional." (D.I. 462 at 8).

The hallmark for written description is whether a POSA would understand the patentee to possess the claimed invention. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) ("[T]he specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed."). I find that a POSA would not understand the paragraph to disclose that a glidant is optional nor that the patentee possessed formulations in which a glidant is optional or not included.

Allergan's position that this paragraph provides sufficient written description goes too far. Allergan's interpretation of this paragraph implies that because the paragraph states the invention in the broadest possible terms, that is, eluxadoline and any possible combination of excipients, the paragraph provides written description for any formulation that is more than pure eluxadoline. The content, or the lack thereof, of this paragraph does not support possession of such a broad invention. This paragraph just outlines the basic idea of mixing eluxadoline with excipients and then subdividing the mixture into dosage amounts in some form. (Tr. 227:15-228:15 (Gemeinhart)). There is no disclosure of specific combinations or proportions of excipients used. As the Federal Circuit has explained, "'[T]he appearance of mere indistinct words in a specification or a claim, . . . , does not necessarily satisfy' § 112, ¶ 1 because it may not both put others on notice of the scope of the claimed invention and demonstrate possession of that invention." *Nuvo Pharms. (Ireland) Designated Activity Co. v. Dr. Reddy's Lab'ys Inc.*, 923 F.3d 1368, 1380 (Fed. Cir. 2019) (quoting *Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d 956, 968-69 (Fed. Cir. 2002)). This paragraph fails to do both.

At most, this paragraph may render making a formulation without a glidant obvious, but "a description that merely renders the invention obvious does not satisfy the [written description] requirement." *Ariad*, 598 F.3d at 1352. It is the paragraphs that follow the cited paragraph that

provide an adequate written description for the invention. And those paragraphs uniformly disclose eluxadoline formulations with a glidant. (JTX-002 ('179 patent) at col. 13:1-56). The cited disclosure is not sufficient to demonstrate that the patentee possessed a formulation of eluxadoline, or a process for creating a formulation of eluxadoline, where a glidant is optional or not included.

2. Background of Invention Section

Allergan argues that Columns 4 and 5 disclose that a glidant is optional. (D.I. 468 at 14 (citing JTX-002 ('179 patent) at col. 4:4-5:33). A sample portion of the specification recites,

> One embodiment of the disclosure provides a solid pharmaceutical formulation comprising [eluxadoline] and an inert ingredient selected from silicified microcrystalline cellulose, colloidal silicon dioxide,[6] crospovidone (polyvinylpolypyrrolidone; highly cross-linked polyvinylpyrrolidone (PVP)), mannitol, and magnesium stearate. In a specific embodiment, this pharmaceutical formulation may be substantially or completely free of a separate opioid antagonist, such as naloxone. A related embodiment provides a pharmaceutical formulation consisting of [eluxadoline] and an inert ingredient selected from silicified microcrystalline cellulose, colloidal silicon dioxide, crospovidone, mannitol, and magnesium stearate.

(JTX-002 ('179 patent) at col. 4:4-21).

Allergan contends that this paragraph, as well as the similar ones that follow, demonstrates that a glidant is optional because it describes an embodiment where eluxadoline and only one other ingredient, which does not have to be a glidant (i.e., colloidal silicon dioxide), is disclosed. I find this paragraph and the ones that follow (JTX-002 ('179 patent) at col.4:4-5:33) are insufficient to meet the written description requirement for the same reasons as the preformulation paragraph. This paragraph just outlines the basic idea to create a formulation of eluxadoline with some combination of excipients in some proportions. (*See* Tr. 113:9-16 (Gemeinhart); Tr. 443:8-20

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[6] "Colloidal silicon dioxide" and "colloidal silica" are both glidants and the terms are used interchangeably for each other. (Tr. 177:5-8 (Gemeinhart); Tr. 383:22-24 (Berkland); *see also* D.I. 140 at 14).

(Berkland)). That is not sufficient to demonstrate possession of a formulation where a glidant is optional or not included.

Allergan contends that the specification must be read as a whole, and that these paragraphs read with the remaining parts of the specification provides written description for a formulation in which a glidant is optional or not included. (D.I. 468 at 14). I disagree. The specification discloses examples of formulations that contain a glidant. Actual 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. *See Ariad*, 598 F.3d at 1352. The patent specification does not disclose that a formulation would have sufficient flow characteristics or work without a glidant. I do not think that these generic descriptions of mixing eluxadoline with excipients demonstrate that the patentee possessed a formulation where a glidant is optional or not included.

For these reasons, I find that the Sun has shown by clear and convincing evidence that the asserted claims of the '179, '291, '792, and '516 patents are invalid for lack of written description.

IV. WRITTEN DESCRIPTION (MSN)

A. Findings of Fact

1. The priority date of the '627 and '291 patents is March 14, 2013. (JTX-003 ('291 patent); JTX-006 ('627 patent); D.I. 461, ¶ 103; D.I. 469, ¶ 28).

2. A POSA would understand that terms "diluent" and "filler" are interchangeable. (Tr. 215:15-16 (Gemeinhart); Tr. 360:14-19 (Berkland)).

3. A POSA would understand that the term "filler" is a common category of excipient used in pharmaceutical formulations. (D.I. 469, ¶ 8; D.I. 461, ¶ 22; Tr. 97:19-98:5 (Gemeinhart)). A POSA would understand that a filler is an inert substance that creates the bulk of a dosage form. (D.I. 461, ¶ 23; D.I. 469, ¶ 8). A POSA would be able to recognize examples of fillers. (Tr. 215:23-216:22 (Gemeinhart); Tr. 357:18-358:1 (Berkland)).

4. A POSA would understand that the term "disintegrant" is a common category of excipient used in pharmaceutical formulations. (D.I. 469, ¶ 8; D.I. 461, ¶ 22; Tr. 97:19-98:5 (Gemeinhart)). A POSA would understand that a disintegrant is a substance added to a tablet to facilitate its breakup or disintegration after administration. (D.I. 461, ¶ 25; D.I. 469, ¶ 8). A POSA would be able to recognize examples of disintegrants. (Tr. 215:23-216:22 (Gemeinhart); Tr. 357:18-358:1 (Berkland)).

5. A POSA would understand that "U.S. Patent No. 7,741,356 to Breslin, et al." is incorporated by reference in its entirety. (JTX-002 ('179 patent) at col. 2:7-8). PCT. Application No. WO 2005/090315 (JTX-024) (hereinafter, "Breslin") and "U.S. Patent No. 7,741,356 to Breslin, et al." share the same description. (D.I. 461 at 11 n.2; D.I. 469 at 6 n.3; Tr. 208:21-209:8 (Gemeinhart)). Breslin provides examples of fillers and disintegrants that are commonly used in pharmaceutical formulations. (JTX-024 at 64-65).

6. The patent specification only discloses formulations of eluxadoline that use mannitol, silicified microcrystalline cellulose (SMCC), crospovidone, and a glidant. (D.I. 468 at 23; D.I. 462 at 14; Tr. 147:8-23 (Gemeinhart); Tr. 464:3-465:8 (Berkland)).

7. A POSA would understand the "Function" column of Table 1 in the patent specification to describe the role an excipient is performing in the formulation (JTX-002 ('179 patent) at col. 16:28-56), not that any other member of the same functional category could be substituted for the excipient. (Tr. 153:4-154:19, 155:7-23 (Gemeinhart)).

8. The claimed genus covers dozens to hundreds of combinations of fillers and disintegrants. (*See, e.g.*, JTX-024 (Breslin) at 64-65; JTX-026 (Ansel) at 35-36; JTX-057 (Lachman) at 30).

9. The state of the art of creating formulations of eluxadoline with different fillers and disintegrants on March 14, 2013, was not so predictable such that disclosing one representative species is sufficient for meeting the written description requirement.

10. A POSA reading the specification would not understand the patentee to have invented a formulation that includes using fillers other than mannitol and SMCC.

11. A POSA reading the specification would not understand the patentee to have invented a formulation that includes using a disintegrant other than crospovidone.

12. The patent specification lacks adequate written description for claims covering formulations using any filler and any disintegrant.

B. Conclusions of Law

MSN argues that the asserted claims of the '291 and '627 patents are invalid for lack of written description. (D.I. 462 at 13-19; D.I. 471 at 8-12). Allergan contends the asserted claims have adequate written description. (D.I. 468 at 18-29).

1. Incorporation of Breslin into the Patent Specification

The patent specification incorporates "U.S. Patent No. 7,741,356 to Breslin, et al." by reference. (JTX-002 ('179 patent) at col. 2:7-8;7 D.I. 469, ¶ 61; D.I. 462 at 16). Incorporation by reference is "a method for integrating material from various documents into a host document[] . . . by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein." *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 906 (Fed. Cir. 2018) (alteration in original) (quoting *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000)).

Both parties agree that PCT. Application No. WO 2005/090315 (JTX-024) (hereinafter, "Breslin") and "U.S. Patent No. 7,741,356 to Breslin, et al." share the same description. (D.I. 461 at 11 n.2; D.I. 469 at 6 n.3; Tr. 208:21-209:8 (Gemeinhart)). The parties dispute the scope of incorporation. (D.I. 462 at 16-17; D.I. 468 at 25). Because the test for written description "requires 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), I must first determine which parts of Breslin are incorporated into the patent specification.

"To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found

[7] The '179 patent (JTX-002) is not one of the patents asserted against MSN. As noted above, the asserted patents against MSN share a specification with the '179 patent. (*See supra* n.3).

in the various documents." *Advanced Display*, 212 F.3d at 1282. "[T]he standard of one reasonably skilled in the art should be used to determine whether the host document describes the material to be incorporated by reference with sufficient particularity." *Paice*, 881 F.3d at 907 (alteration in original) (quoting *Advanced Display*, 212 F.3d at 1283).

The patent specification incorporates Breslin with the following sentence,

> [Eluxadoline] is an opioid receptor modulator that effects simultaneous agonism of the μ opioid receptor (MOR) and antagonism of the δ opioid receptor (DOR) and may be useful in the treatment and prevention of various mammalian disease states, for example pain and gastrointestinal disorders such as diarrheic syndromes, motility disorders including post-operative ileus and constipation, and visceral pain including post-operative pain, irritable bowel syndrome and inflammatory bowel disorders (for example, see U.S. Pat. No. 7,741,356 to Breslin, et al., which is incorporated herein in its entirety).

(JTX-002 ('179 patent) at col. 1:63-2:8).

The disputed portion of Breslin recites,

> For preparing solid pharmaceutical compositions such as tablets, the principal active ingredient is mixed with a pharmaceutical carrier, e.g. conventional tableting ingredients such as diluents, binders, adhesives, disintegrants, lubricants, antiadherents and gildants [sic]. Suitable diluents include, but are not limited to, starch (i.e. corn, wheat or potato starch, which may be hydrolized [sic]), lactose, . . . , sucrose, sucrose-based diluents . . . , dextrose, inositol, mannitol, sorbitol, microcrystalline cellulose . . . , dicalcium phosphate, calcium sulfate dihydrate, calcium lactate trihydrate and the like. . . . Suitable disintegrants include, but are not limited to, starches (corn, potato, etc.), . . . , sodium starch glycolates, pregelatinized starches, clays (magnesium aluminum silicate), celluloses . . . , alginates, pregelatinized starches (i.e. corn starch, etc.), gums . . . , cross-linked polyvinylpyrrolidone and the like.

(JTX-024 (Breslin) at 64-65).

MSN argues that, based on the context in which Breslin is cited in the specification, "a POSA would understand Breslin to be incorporated only for its discussion about how eluxadoline can be used to treat gastrointestinal disorders along with the identification of the eluxadoline molecule and its mechanism of action." (D.I. 462 at 16). MSN contends that a POSA would not

understand Breslin's discussion of diluents (i.e., fillers) and disintegrants to be incorporated by reference. (*Id.*).

Allergan argues that the excerpted portion of Breslin is incorporated into the patent specification because the specification states that Breslin is incorporated in its entirety. (D.I. 468 at 25; *see* JTX-002 ('179 patent) at col. 1:63-2:8). I agree.

The specification recites, "for example, see U.S. Pat. No. 7,741,356 to Breslin, et al., which is incorporated in its entirety." (JTX-002 ('179 patent) at col. 2:7-8). The Federal Circuit has interpreted similar language as being "broad and unambiguous" that a reference is incorporated in its entirety. *See Paice*, 881 F.3d at 907 (interpreting "which is incorporated herein by this reference" to incorporate a patent in its entirety). The sentence here identifies Breslin as the specific material to be incorporated (i.e., the entirety of U.S. Pat. No. 7,741,356 to Breslin, et al.) and where the material can be found (i.e., in U.S. Pat. No. 7,741,356 to Breslin, et. al). "Such language is plainly sufficient to incorporate [Breslin] in its entirety." *Id.*

MSN is correct that the incorporation clause must be read in the context of the specification. *See Paice*, 881 F.3d at 909. But I disagree that the context of the specification limits the scope of incorporation. MSN's argument seems to be that Breslin's discussion of disintegrants and fillers should not be incorporated because the specification does not explicitly reference that discussion or apply it to the claims of the invention. (D.I. 462 at 16; D.I. 471 at 11). The Federal Circuit, however, has cautioned, "The applicability of a document's disclosed features and the incorporation of the document itself are distinct concepts, and one does not imply the other." *Paice*, 881 F.3d at 908. I think MSN is improperly conflating the two concepts.

Starting with the incorporation of Breslin, there is nothing in the specification that would limit the scope of incorporation. *See, e.g.*, *id.* at 907-08. Statements that limit the extent of

incorporation are typically clearer. *See Zenon Env't, Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1379 (Fed. Cir. 2007) (finding the phrase "[two identified references], the relevant disclosures of each of which are included by reference thereto as if fully set forth herein" as limiting incorporation to only relevant disclosures and not the entire documents); *Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1375–76 (Fed. Cir. 2006) (limiting extent of incorporation to one specific procedure when the specification stated "the procedure for preparing intestinal submucosa" was incorporated by reference).

Furthermore, Dr. Gemeinhart testified that a POSA would understand the entirety of Breslin to be incorporated into the patent specification. (Tr. 208:21-210:10). While Dr. Gemeinhart also testified that the context in which Breslin is cited in the specification would lead a POSA to read Breslin for its disclosure of eluxadoline as a treatment option (Tr. 320:24-324:8), I think that testimony is relevant to the applicability of Breslin's disclosures, not its scope of incorporation. *See Paice*, 881 F.3d at 907-08. Therefore, I find that Breslin is incorporated in its entirety.

Turning to the issue of whether Breslin's discussion of disintegrants and fillers applies to the claimed invention, I find that it does. Breslin's disclosure of fillers and disintegrants is consistent with how a POSA would understand these terms. (*See* Tr. 215:17-216:22 (Gemeinhart); Tr. 357:18-358:1 (Berkland)). Incorporating Breslin's discussion does not improperly expand the scope of the claims nor is it contrary to other parts of the specification. *Cf. Fifth Generation Computer Corp. v. Int'l Bus. Machines Corp.*, 416 F. App'x 74, 80 (Fed. Cir. 2011) ("In light of such clear claim language, it is inappropriate to look to the incorporated references to arrive at a stretched reading of those claim limitations."); *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1553 (Fed. Cir. 1996) (declining to import a definition from an incorporated reference when it was contradicted by other intrinsic evidence), *abrogated by Festo Corp. v. Shoketsu*

Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000). I am not persuaded by Dr. Gemeinhart's testimony that a POSA would read Breslin only for its discussion of eluxadoline (Tr. 320:24-324:8) because, as discussed, Breslin's disclosure aligns with the patent specification and a POSA's understanding of the claim terms.

Therefore, in evaluating whether there is adequate written description, I will treat Breslin (JTX-024) in its entirety as part of the specification.

2. Lack of Written Description

As discussed above, eluxadoline was already known as of the priority date of the asserted patents. (*See* JTX-024 (Breslin) at 96; Tr. 172:8-22 (Gemeinhart); 472:14-473:6 (Berkland)). The asserted patents cover oral formulations of eluxadoline and the processes for preparing and administering those formulations. (*See, e.g.*, JTX-002 ('179 patent) at col. 1:23-28). The asserted claims against MSN cover formulations of eluxadoline that use a "filler" and a "disintegrant" at specific amounts or weight percentages. (*See* JTX-005 ('627 patent), cl. 27; JTX-003 ('291 patent), cl. 11; D.I. 462 at 13; D.I. 468 at 18-19). Thus, the asserted claims cover formulations of eluxadoline using any filler and any disintegrant with the claimed amounts, which is a broad genus.

"[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." *Regents of the Univ. of Minnesota v. Gilead Scis., Inc.*, 61 F.4th 1350, 1356 (Fed. Cir. 2023).

The specification here only discloses formulations made with the same disintegrant (crospovidone) and fillers (mannitol and SMCC). (D.I. 468 at 13; D.I. 462 at 14; Tr. 147:8-23 (Gemeinhart); Tr. 464:3-465:8 (Berkland)). Indeed, the specification is explicit about using these

specific excipients, not functional groups, as it repeatedly recites using SMCC and crospovidone. For example, the Summary of Disclosure section of the specification describes 11 different embodiments and each one recites SMCC and crospovidone as potential ingredients. (JTX-002 ('179 patent) at col. 4:4-5:46). The specification also discloses five embodiments for preparing formulations of eluxadoline. (*Id.* at col. 13:1-60). Each one uses SMCC and crospovidone. (*Id.*). None of them discuss using other fillers (except for mannitol[8]) or other disintegrants. (*Id.*).

The specification further describes "[a]buse deterrent formulations of the present invention" as including eluxadoline, a glidant, SMCC, mannitol, and crospovidone. (JTX-002 ('179 patent) at col. 11-23-12:3)). In describing the present invention, the patentee referred to using a glidant, a common functional category (D.I. 469, ¶ 8; D.I. 461, ¶ 22; Tr. 197:11-23: (Gemeinhart)), and then provided colloidal silica as a preferred embodiment. (JTX-002 ('179 patent) at col. 11:47-52). Thus, this description of the present invention implies that the patentee would refer to functional categories explicitly, instead of through examples, when they intended to do so. In contrast to glidant, the patentee did not use a similar descriptive framework for filler and disintegrant (e.g., listing "disintegrant" and then providing crospovidone as a preferred embodiment). The patentee, instead, specified using SMCC and crospovidone. (*Id.* at col. 11:38-46; 11:58-64). I think this supports the conclusion that a POSA would read the specification to only disclose a formulation with SMCC and crospovidone, not a formulation using any filler and any disintegrant.

[8] Mannitol is listed as a separate claim limitation. (JTX-003 ('291 patent), cl. 11; JTX-005 ('627 patent), cl. 27).

In short, the specification discloses many "embodiments" and each one uses, or lists, SMCC and crospovidone as excipients. None of the embodiments recite using fillers or disintegrants generally.

Allergan, however, maintains there is adequate written description because the patent specification discloses both common structural features of the claimed genus and a representative number of species within the scope of the genus. (D.I. 468 at 19). I disagree.

a. Common Structural Features

The specification does not disclose common structural features for fillers and disintegrants. As discussed above, the specification only discloses formulations of eluxadoline using SMCC, mannitol, crospovidone, and a glidant. Nowhere does the specification inform a POSA what structural or chemical properties permits excipients to be viable fillers or viable disintegrants, let alone a viable combination of the two, in the claimed invention. Neither does the specification disclose that SMCC or crospovidone could be substituted with other fillers and disintegrants, respectively.[9] I find that a POSA would not understand the patentee to possess the broad genus of formulations of eluxadoline that could be made with any filler and any disintegrant based on the limited disclosure of the specification.

[9] Claims reciting "filler" and "disintegrant" were not part of the original patent that issued. The '291 and '627 patents were filed on February 21, 2021, and October 21, 2021, respectively. They are both continuations of patent applications that trace back to patent application No. 13/829,984, which was filed on March 14, 2013. Patent application No. 13/829,984 eventually issued as the '587 patent. The claims of the '587 patent recite SMCC and crospovidone, not "filler" and "disintegrant," as limitations. ('587 patent, cls.1-17). While the '587 patent is not part of the trial record, I take judicial notice of its content. *Anderson v. Kimberly-Clark Corp.*, 570 F. App'x 927, 932 n.3 (Fed. Cir. 2014) ("It is also well-established that a court may take judicial notice of patents or patent applications.").

Allergan raises two arguments that common structural features are sufficiently disclosed. I address each in turn.

i. Disclosure of Excipient "Functions" in Table 1

Allergan cites Table 1 in the specification. (JTX-002 ('179 patent) at col. 16:28-56). Allergan argues "a POSA would understand the terms 'filler' and 'disintegrant,' as used in Table 1 of the specification, to reference their respective excipient categories." (D.I. 468 at 21). Allergan contends a POSA would read Table 1 to indicate that other excipients belonging to these functional categories could be used to practice the invention. Allergan cites for support Dr. Berkland's testimony and comments from the patent examiner of the '291 patent, who came to the same conclusion. (*Id.* at 22-23). I disagree that a POSA would read Table 1 this way.

First, Dr. Gemeinhart testified that a POSA would read the "Function" column in Table 1 as stating the function of the corresponding component in the formulation, not that any excipient that performs that function could be used or substituted for the specific excipient listed. (Tr. 153:4-154:19, 155:7-23).

Second, while Dr. Berkland testified to the contrary (Tr. 375:21-376:12), I think other parts of his testimony undercuts his, and Allergan's, position.

At trial, I asked Dr. Berkland if a POSA would read Table 1 to provide written description support for a claim that, instead of reciting any specific excipients, just recited the generic functional categories (e.g., replacing "mannitol" in the claim with "filler"). (Tr. 482:17-483:5). As part of his answer, Dr. Berkland testified that mannitol has specific characteristics such as that it "help[s] with the breakup of the tablet," that it is a soluble filler, and that it contributes to the disintegrating properties of the formulation. (Tr. 483:6-10). I asked Dr. Berkland whether the "special characteristics" of mannitol, as opposed to SMCC, "might make it not subject to just being

the category." (Tr. 485:13-16). Dr. Berkland testified that was a "fair" statement. (Tr. 485:17). Dr. Berkland further elaborated, "You could potentially select another filler that behaves like mannitol, but mannitol really does the job nicely." (Tr. 485:17-19).

I think Dr. Berkland's testimony about mannitol is inconsistent with his testimony about how a POSA would understand Table 1. Mannitol and SMCC are both identified as "Filler" in the "Function" category of Table 1. (JTX-002 ('179 patent) at col. 16:37, 16:43). Dr. Berkland testified a POSA would read the "Filler" label for SMCC to mean that other fillers could be used in its place. (Tr. 375:21-376:12). But he indicated that a POSA would not read the "Filler" label for mannitol as referring to the fact that other fillers could be used in place of mannitol because of mannitol's special characteristics. (Tr. 485:13-19). Dr. Berkland further testified that, mannitol could potentially be substituted with "another filler that behaves like mannitol." (Tr. 485:17-29). The genus of fillers like mannitol seems narrower than the genus of fillers generally, given mannitol's "special characteristics." (Tr. 485:13-17 (Berkland)).

Thus, Dr. Berkland's testimony seems to be that a POSA would read the "Filler" label for SMCC to indicate that any filler could be used to replace SMCC, but a POSA would not read "Filler" to mean the same thing for mannitol. I don't think Dr. Berkland's testimony on how a POSA would read the labels in Table 1 is credible given the inconsistency as to how he is interpreting identical labels in the "Function" column for the different excipients. I think, instead, his testimony supports that a POSA would read Table 1 as describing the functions of the different excipients listed as this would align with his testimony regarding mannitol. (*See* Tr. 485:13-19).

The patent examiner who examined the '291 patent considered how to read Table 1 and reached the opposite conclusion. (JTX-050 at 393-94). While a patent examiner is "deemed to have experience in the field of the invention" and "act from this viewpoint," *In re Sang Su Lee*,

277 F.3d 1338, 1345 (Fed. Cir. 2002), the examiner's determination is not dispositive. At most, it may be persuasive. *See Cooper Notification, Inc. v. Twitter, Inc.*, 867 F. Supp. 2d 485, 492 (D. Del. 2012); *TecSec, Inc. v. Int'l Bus. Machines Corp.*, 763 F. Supp. 2d 800, 817 (E.D. Va. 2011), *aff'd*, 466 F. App'x 882 (Fed. Cir. 2012). I think the testimony of Drs. Gemeinhart and Berkland make it clear that a POSA would read Table 1 to describe the function of the individual excipients listed, not that other members of the different functional categories could be used. In weighing the patent examiner's comments against the testimony of both experts, I credit the expert testimony. I therefore disagree with the patent examiner's conclusion. I find a POSA would not read the "Function" column of Table 1 to indicate that other excipients of the same functional category could be used. I find a POSA, instead, would read the "Function" column of Table 1 only to indicate the function performed by the listed excipient.

Therefore, I find that Table 1 in the specification does not provide adequate written description for using any filler and any disintegrant.

ii. Disintegrant and Filler Are Terms of Art

Allergan argues there is adequate written description because "filler" and "disintegrant" are well-known terms of art and a POSA would be able to recognize the members of the two categories. (D.I. 468 at 20-22). Allergan contends the specification indicates that the invention is not limited to the examples. (D.I. 468 at 27; *see, e.g.*, JTX-002 ('179 patent) at col. 16:3-8 ("The examples are not intended to limit the disclosure, ...")).

Both parties, and their experts, agree that a POSA would understand "filler" and "disintegrant" to be terms of art and a POSA would be able to recognize members of both genera. (D.I. 462 at 14; D.I. 468 at 20-21; Tr. 215:17-22 (Gemeinhart); Tr. 359:19-360:11, 361:17-362:19

(Berkland)). In addition, the specification, by incorporating Breslin by reference, recites numerous examples of both types of excipients. *See* Section IV.B.1 *supra*.

I, however, think Allergan's argument misses the mark. The relevant genus here is neither fillers nor disintegrants, but formulations of eluxadoline using any filler and any disintegrant. A POSA would know what a filler and a disintegrant refers to, but the question here is whether a POSA would recognize that the patentee possessed such a broad genus of formulations from the specification. I think not.

"[T]he hallmark of written description is disclosure." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). The written description requirement does not demand "that the specification recite the claimed invention *in haec verba*," *id.* at 1352, but "the specification must describe an invention understandable to [a] skilled artisan and show that the inventor actually invented the invention claimed," *id.* at 1351. The specification does not teach which properties of fillers and disintegrants would permit other excipients, including combinations of fillers and excipients, to be used to practice the invention.

This Court addressed a similar issue in *Lipocine Inc. v. Clarus Therapeutics, Inc.*, 541 F. Supp. 3d 435 (D. Del. 2021). In that case, for a subset of the claims at issue, Lipocine argued the written description requirement was satisfied because the claims included "particular classes of excipients" like "solubilizer" and "dispersant." *Id.* at 466, 466 n.20. The Court rejected this argument because "there [was] nothing in the specification to indicate that compositions containing those particular excipients in varying amounts and in combination with various other excipients c[ould] achieve the PK parameters recited by the claims." *Id.* The Court explained,

> The underlying problem with the claims that require different combinations of excipients is that there is no basis from which to conclude that the functional limitations of any of those claims will be satisfied, except with respect to the few

> specific formulations that were the subjects of the clinical tests and simulations reported in the Data Examples.

Id. at 467.

I think the specification here is deficient for similar reasons. Allergan relies on the knowledge of a POSA, rather than what is disclosed in the specification, to recognize the common structural features of viable fillers and viable disintegrants and understand that they would work in place of SMCC and crospovidone, respectively. The specification indicates that the invention is not limited to the examples disclosed and that a POSA would recognize other techniques and methods could be used (JTX-002 ('179 patent) at col. 16:3-8), but the specification does not disclose that SMCC, as a filler, can be substituted with other fillers and that crospovidone, as a disintegrant, can be substituted with other disintegrants. I do not think the "not limited" statement is enough to show possession of such a broad genus.

Breslin, which is incorporated by reference, discloses that active ingredients, generally, can be mixed with excipients, including disintegrants and fillers. (JTX-024 at 64). I do not find this disclosure provides adequate written description for using any filler or any disintegrant in the claimed invention. The portion from Breslin discusses the general idea of mixing an active pharmaceutical ingredient with excipients. (*Id.*). Neither Breslin nor the patent specification indicate the patentee possessed formulations where any of the other fillers and disintegrants could be used in place of SMCC or crospovidone. *See Lipocine*, 541 F. Supp. 3d at 463 ("What is lacking in the list of excipients is the critical step of showing which of those excipients, in combination with other components of the [] formulations, will satisfy the [] limitations of the claims."). The patent specification, with Breslin, may make using, or attempting to use, other fillers and disintegrants obvious, but "a description that merely renders the invention obvious does not satisfy

the [written description] requirement." *Ariad*, 598 F.3d at 1352. I do not find Breslin's disclosure sufficient to provide common structural features.

Therefore, I find that the patent specification does not disclose common structural features to provide adequate written description for the asserted claims.

b. Representative Number of Species

i. There Is Only One Representative Species

Allergan argues that the written description requirement is satisfied because Breslin (JTX-024), which is functionally part of the specification, *see Paice*, 881 F.3d at 906, discloses a variety of examples of both fillers and disintegrants. Allergan contends this disclosure provides a representative number of species of the filler and disintegrant categories. (D.I. 468 at 24-25).

I agree with Allergan that Breslin gives examples of fillers and disintegrants. (JTX-024 (Breslin) at 64-65). That Breslin gives multiple examples of fillers and disintegrants, however, does not mean it gives multiple examples of the claimed species (i.e., the combinations of fillers and disintegrants that can be used to make formulations of eluxadoline). Breslin says nothing about examples of viable combinations of fillers and disintegrants. *See Lipocine*, F. Supp. 3d at 463. The examples of formulations of eluxadoline in the specification all use SMCC as a filler and crospovidone as a disintegrant. Therefore, I find that the patent specification discloses one representative species.

ii. One Representative Species Is Not Sufficient

Allergan contends that disclosure of one representative species is sufficient to satisfy the written description requirement. (D.I. 468 at 23-24). Allergan cites a handful of cases that found one representative species to be sufficient. (D.I. 469 at 24 (citing *Allergan Sales, LLC v. Sandoz, Inc.*, 717 F. App'x 991, 995 (Fed. Cir. 2017); *Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d

1357 (Fed. Cir. 2018); *In re Herschler*, 591 F.2d 693, 695, 687-98, 700-02 (C.C.P.A. 1979); *In re Smythe*, 480 F.2d 1376, 1383 (C.C.P.A. 1973))).

Those cases, however, do not stand for the rule that one representative species is always sufficient. The level of detail or number of representative species that must be disclosed varies with the particular facts of the case. *See Ariad*, 598 F.3d at 1351-52. The Federal Circuit has "set forth a number of factors for evaluating the adequacy of the disclosure, including 'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.'" *Id.* at 1351.

The facts of the cases Allergan cites, which Allergan does not discuss, illustrate why this is not a case where the disclosure of one representative species is sufficient. For example, the claimed genus was relatively narrow in *Allergan Sales*, 717 F. App'x at 995 (finding disclosure of a single species sufficient when genus covered six species), and *Herschler*, 591 F.2d at 701 (finding disclosure of a single steroid sufficient to describe the subgenus of steroids when the great-grandparent application disclosed a broader array of example materials of the larger genus and steroids were chemically similar). *See Ariad*, 598 F.3d at 1351 ("Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology."). In *Hologic*, the art was well understood and not unpredictable. 884 F.3d at 1361-62. And in *Smythe*, the C.C.P.A. found sufficient written description because the specification disclosed information about the properties and functions of the claimed genus in the specification. 480 F.2d at 1382-83.

In *Lipocine*, the Court addressed a similar issue. One of the asserted claims recited a formulation comprised "a solubilizer in an amount from about 50-86% by weight of the formulation." *Lipocine*. F. Supp. 3d at 459. The Court determined the claim lacked written

description "because the universe of solubilizers is immense, . . . , and the Data Examples demonstrate only that a formulation containing two such solubilizers," and a broader category of solubilizers, could produce the functional limitation of the claims. *Id.* I think the present case is more similar to *Lipocine* than the cases Allergan cites.

In the present case, the genus is broad. Allergan contends there are 63 possible combinations based on Ansel (JTX-026 at 35-36) (disclosing nine fillers and seven disintegrants). (D.I. 468 at 30). MSN argues there are dozens to hundreds of combinations. (D.I. 462 at 14). Breslin, by itself, discloses 12-17 examples of fillers and 9-15 examples of disintegrants, while also indicating that those lists are not comprehensive. (JTX-024 at 64-65). Breslin supports MSN's characterization that the genus covers dozens to hundreds of combinations. Therefore, I find this is hardly a narrow genus.

In the present case, the art is not so predictable that one representative species is sufficient to show possession of the broader genus. The patent specification cautions that "formulations for every [eluxadoline] are different and different formulations containing the same [eluxadoline] may have very different stability and drug delivery (e.g., pharmacokinetic) properties." (JTX-002 ('179 patent) at 1:53-62). Indeed, Dr. Gemeinhart testified this part of the specification would inform a POSA that different formulations would have different properties and that "it's an early field." (Tr. 111:8-18, 145:16-146:9, 225:2-8).

Allergan contends this description in the specification informs a POSA that "[e]ntirely different formulation strategies will result in varying characteristics; here, however, there is a single limited formulation strategy." (D.I. 468 at 24 n.9). I take Allergan to be arguing that any formulation adhering to the claims would not have varying characteristics. I disagree. I think the plain words of the specification would apply to formulations that use different excipients than

those disclosed in the specific examples in the specification (e.g., formulations using different fillers, disintegrants, or both). Dr. Gemeinhart's testimony supports this interpretation. (Tr. 111:8-18, 145:16-146:9, 225:2-8). Dr. Gemeinhart further testified that substituting fillers and disintegrants could have an effect on the manufacturing process as well. (Tr. 157:4-22).

Allergan maintains that substituting members of functional categories for each other is known and their ability to be substituted is predictable. (D.I. 468 at 21-22, 27; D.I. 469, ¶ 59). Allergan cites to Babul (JTX-021 at 77) and the testimony of Drs. Gemeinhart (Tr. 282:21-283:23) and Berkland (Tr. 357:9-358:1) to argue that a POSA would know that members of the same functional category can be substituted for each other.

I think Allergan's argument goes too far. While this may not be the most unpredictable of chemical and pharmaceutical arts, I think a POSA would consider the patent specification's warning (JTX-002 ('179 patent) at 1:53-62), would understand that different formulations can have different properties, and would be aware that using different excipients could affect the manufacturing process. (Tr. 111:8-18, 145:16-146:9, 225:2-8 (Gemeinhart)). I do not think a POSA would understand the outcome of replacing multiple excipients to be so predictable that disclosure of a single combination of ingredients—a formulation using SMCC as a filler and crospovidone as a disintegrant—is sufficient. Therefore, I find the art of substituting fillers and disintegrants in formulations of eluxadoline is not so predictable that one representative species is sufficient.

Given the breadth of the genus and level of predictability of the art, I think more than one representative species is required to claim the broad genus of formulations of eluxadoline made with any disintegrant and any filler. *See Lipocine*, 541 F. Supp. 3d at 459. Because only one

representative species is disclosed, I find the patent specification does not disclose a representative number of species to provide adequate written description for the asserted claims.

For these reasons, I find that MSN has met its burden of showing the asserted claims are invalid for lack of written description.

V. ENABLEMENT (MSN)

MSN argues that the asserted claims are invalid under 35 U.S.C. § 112 for lack of enablement. Because I have determined that the asserted claims are invalid under § 112 for lack of written description, I do not address this argument.

VI. OBVIOUSNESS (SUN AND MSN)

Sun and MSN argue that if I were to find the asserted claims have adequate written description and are enabled, then the asserted claims are obvious. (D.I. 462 at 21-23). Because I have found the asserted claims are invalid under § 112 for lack of written description, I do not address this argument.

VII. OBVIOUSNESS-TYPE DOUBLE PATENTING (SUN)

A. Findings of Fact

1. U.S. Patent Nos. 8,344,011 (the "'011 patent") and 8,608,709 (the "'709 patent") and the '356 patent are commonly owned by and assigned to Janssen Pharmaceutica NV. (D.I. 414-1, Ex. 1, ¶ 210). "The '709 Patent is a continuation of the '011 Patent, which is a divisional of U.S. Patent No. 7,786,158, which is a continuation of the '356 Patent." (*Id.*, Ex. 1, ¶ 204).

2. The '356, '011, and '709 patents are part of the same family with the same priority date. The '356 patent issued before the '011 and '709 patents. (*Id.*, Ex. 1, ¶ 211).

3. The '011 and '709 patents expire on March 14, 2025. (*Id.*, Ex. 1, ¶ 2215).

4. The '356 patent was awarded PTA under 35 U.S.C. § 154(b). (*Id.*, Ex. 1, ¶ 205). "The '356 [p]atent is entitled to 467 days of [PTA] for Patent Office delays, which when added to March 14, 2025, would cause the '356 [p]atent to expire on June 24, 2026." (*Id.*).

5. The '356 patent was issued before the other two patents, but expires after them due to the PTA.[10] (*Id.*, Ex. 1, ¶¶ 205, 215).

6. "Claim 40 of the '356 [p]atent covers eluxadoline, as well as 7 other compounds." (*Id.*, Ex. 1, ¶ 207).

7. "Claim 33 of the '011 [p]atent discloses a method of administering eluxadoline." (*Id.*, Ex. 1, ¶ 208).

8. "Claim 5 of the '709 [p]atent covers eluxadoline." (*Id.*, Ex. 1, ¶ 209).

9. Claim 40 of the '356 patent, claim 5 of the '709 patent, and claim 33 of the '011 patent are not patentably distinct from each other. (*Id.*, Ex. 1, ¶¶ 207-09; D.I. 462 at 24; *see* D.I. 468 at 38-40 (failing to argue the claims are patentably distinct).

10. Claim 40 of the '356 patent is invalid.

B. Conclusions of Law

The issue here is a legal one: whether the fact the '356 patent expires after the '011 and '709 patents makes it invalid for obviousness-type double patenting over those two patents.

The Federal Circuit recently addressed the issue of how ODP is applied to a patent that has received PTA. "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." *In re Cellect*, 2023 WL 5519716, at *9. Allergan argues the present case is distinguishable from *In re Cellect* as this case involves a "first-filed, first-issued patent having a [PTA]." (D.I. 482 at 1). Allergan maintains that the distinct facts of this case do not raise the same equitable concerns present in *In re Cellect*, namely the risk of separate ownership or potential for

[10] "The '356 [p]atent is also entitled to 1,068 days of Patent Term Extension under 35 U.S.C. § 156, which addresses delays in FDA approval of a claimed drug product. Sun does not contend that obviousness-type double patenting applies to shorten Patent Term Extension." (D.I. 414-1, Ex. 1, ¶ 206).

gamesmanship, and I should therefore conclude that ODP does not invalidate claim 40 of the '356 patent. (*Id.* at 2-6).

The "first-filed, first-issued" distinction is immaterial. When analyzing ODP, a court compares patent expiration dates, rather than filing or issuance dates. *Gilead*, 753 F.3d at 1215-17; *In re Cellect*, 2023 WL 5519716, at *9. Allergan nevertheless proposes that I consider these dates, among other facts, as part of a case-by-case review of equitable considerations to determine if a patent owner received an unjust time extension and ODP should therefore invalidate a challenged claim. (D.I. 482 at 5-6). The court in *In re Cellect* rejected such analysis, holding that ODP depends solely on patent expiration dates and should not influenced by equitable concerns. "[A]ny extension past [the ODP reference patent's expiration] date constituted an inappropriate timewise extension for the asserted claims of the challenged patents." *In re Cellect*, 2023 WL 5519716, at *10. "An applicant's ability to show that it did not engage in gamesmanship in obtaining a grant of PTA is not sufficient to overcome a finding that it has received an unjust timewise extension of term. *Id.* at *11. *In re Cellect* recognizes no exception to the rule it announced, whether for first-filed, first-issued claims or otherwise. I am bound by the Federal Circuit's holding. I have reviewed Allergan's remaining arguments and find them unpersuasive. As a result, I apply the rule dictated in *In re Cellect*.

As stated above, claim 40 of the '356 patent is not patentably distinct from the asserted claims of the '011 and '709 patents. The expiration date of the '356 patent, after addition of PTA, falls after the expiration dates of the '011 and '709 patents. ODP therefore invalidates the challenged claim.

For these reasons, I find claim 40 of the '356 patent is invalid.

VIII. CONCLUSION

For the foregoing reasons, I find the asserted claims of the '627, '291, '179,'792, and '516 patents invalid for lack of written description. I find the asserted claim of the '356 patent to be invalid for obviousness-type double patenting. The parties shall submit a final judgment consistent with this memorandum opinion within one week.