UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME CORP., MERCK SHARP & DOHME B.V., and ORGANON USA, INC.,
Petitioners,

v.

MICROSPHERIX LLC,
Patent Owner.

CASE NO: IPR2018-00602
U.S. PATENT: 8,821,835 B2

NOTICE OF APPEAL

Via PTAB E2E
Patent Trail and Appeal Board

Via Express Mail
Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
P.O. Box 1450
Alexandria, VA 22313-1450

Via CM/ECF
United States Court of Appeals for the Federal Circuit

Pursuant to 35 U.S.C. § 141 and 37 C.F.R. § 90.2, Petitioners Merck Sharp & Dohme Corp., Merck Sharp & Dohme B.V., and Organon USA, Inc. ("Merck" or "Petitioners") hereby provide notice that they appeal to the United States Court of Appeals for the Federal Circuit from the Final Written Decision entered July 8, 2019 (Paper 43) and from all underlying orders, decisions, rulings, and opinions adverse to them regarding U.S. Patent No. 8,821,835 ("the '835 patent") at issue in *Inter Partes* Review IPR2018-00602. A copy of the Final Written Decision is attached as Exhibit A.

In accordance with and for the purpose of providing the Director with the information requested pursuant to 37 C.F.R. § 90.2(a)(3)(ii), Petitioners anticipate that the issue(s) on appeal may include, but are not limited to the following, as well as any underlying findings, determinations, rulings, decisions, opinions, or other related issues:

- Whether the Board erred in determining that the challenged claims have not been shown to be unpatentable.
- Any and all explicit or implicit findings or determinations supporting or related to the above identified issues, and all other issues decided adversely to Petitioner in any order, decision, ruling, or opinion by the Board in this *Inter Partes* Review.

Simultaneous with this filing and in accordance with 35 U.S.C. § 142 and 37 C.F.R. § 90.2(a)(1), this Notice is being filed with the Director of the United States Patent and Trademark Office, and a copy of this Notice is being concurrently filed

with the Patent Trial and Appeal Board. In addition, a copy of this Notice along with the required docketing fees are being filed with the Clerk's Office for the United States Court of Appeals for the Federal Circuit via CM/ECF.

Dated: July 22, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that, in addition to being filed electronically through the Patent Trial and Appeal Board's End to End system (PTAB E2E), the foregoing Notice of Appeal was filed by Express Mail on July 19, 2019, with the Director of the United States Patent and Trademark Office, at the following address:

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
P.O. Box 1450
Alexandria, VA 22313-1450

The undersigned certifies that a copy of the foregoing Notice of Appeal, along with the required docket fee, was filed on July 19, 2019, with the Clerk's Office of the United States Court of Appeals for the Federal Circuit through the Court's CM/ECF filing system.

The undersigned certifies service pursuant to 37 C.F.R. § 42.6(e) of a copy of this Notice of Appeal by electronic mail on July 19 2019, on the counsel of record for Patent Owner:

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DATED: July 22, 2019

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EXHIBIT A

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Paper No. 43
Entered: July 8, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME CORP., MERCK SHARP & DOHME B.V., AND ORGANON USA, INC.,
Petitioner,

v.

MICROSPHERIX LLC,
Patent Owner.

Case IPR2018-00602
Patent US 8,821,835 B2

Before ULRIKE W. JENKS, TINA E. HULSE, and JAMES A. WORTH, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

On February 9, 2018, Merck Sharp & Dohme Corp., Merck Sharp & Dohme B.V., and Organon USA, Inc. (collectively, "Merck" or "Petitioner"), filed a Petition requesting an *inter partes* review of claims 1–4, 9–12, and 14–20 of U.S. Patent No. 8,821,835 B2 (Ex. 1001, "the '835 patent"). Paper 2 ("Pet."). Microspherix LLC ("Microspherix" or "Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp."). With our authorization, Petitioner filed a Reply to the Preliminary Response (Paper 11), and Patent Owner filed a Surreply (Paper 12). On July 23, 2018, we instituted an *inter partes* review of claims 1-4, 9–12, and 14–20 of the '835 patent. Paper 13 ("Dec. Inst."), 38.

Patent Owner filed a Response to the Petition. Paper 24 ("PO Resp."). Petitioner filed a Reply. Paper 27 ("Pet. Reply"). With our authorization, Patent Owner filed a Surreply (Paper 34, "PO Surreply"), and Petitioner filed a SurSurreply (Paper 37, "SurSurreply")).

Petitioner also filed a Motion to Exclude certain evidence (Paper 36, "Pet. MTE"), to which Patent Owner filed an Opposition (Paper 38, "PO MTE Opp'n"), and Petitioner filed a Reply (Paper 40, "Pet. MTE Reply").

An oral hearing was held on April 8, 2019, a transcript of which has been entered in the record. Paper 42 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42 .73.

For the reasons that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1–4, 9–12, and 14–20 of the '835 patent are unpatentable.

A. Related Matters

Petitioner identifies related litigation: U.S. District Court for the District of New Jersey: *Microspherix LLC v. Merck Sharp & Dohme Corp.*, Case No. 2:17-cv03984-CCC-JBC, filed on June 5, 2017. Paper 7, 1.

Petitioner also identifies as related matters IPR2018-00393 (U.S. Patent No. 9,636,402) and IPR2018-00402 (U.S. Patent No. 9,636,401). Pet. 4, n.2. We instituted *inter partes* review in both proceedings and enter Final Written Decisions in those proceedings concurrently with this Decision.

B. The '835 Patent (Ex. 1001)

The '835 patent issued from Application No. 13/916,916 ("the '916 application") claiming benefit to the filing date of several earlier filed applications and ultimately claiming benefit to Provisional Application No. 60/412,050, filed on Sep. 19, 2002, and Provisional Application No. 60/249,128, filed on Nov. 16, 2000.[1]

The '835 patent is titled "Flexible and/or Elastic Brachytherapy Seed or Strand" and relates to "imag[e]able implantable brachytherapy devices, and methods of use thereof." Ex. 1001, 1:26–27.

The Specification of the '835 patent describes disadvantages in prior art brachytherapy devices that were temporary, i.e., patients most often stayed in the hospital for the entire time that low dose rate radioactive sources were indwelling or between sessions if high dose rate radioactive sources were used. *Id.* at 3:27–30. The '835 patent discloses:

A brachytherapy strand that is elastic and/or flexible and

[1] Petitioner provides a visual diagram outlining the relationships between various applications in this patent family. Pet. 5.

> preferably biodegradable has been developed. A drug or other therapeutically active substance or diagnostic can be included in the strand in addition to, or as an alternative to, a radioistope. The rate of release in the implantation site can be controlled by controlling the rate of degradation and/or release at the implantation site, in the preferred embodiment, the strands also contain a radioopaque material or other means for external imaging.

Id. at 3:60–68. The '835 patent discloses that in order "to assist in tracking their proper placement using standard X-ray imaging techniques, seeds may contain a radiopaque marker." *Id.* at 2:24–26. The '835 patent discloses that "[d]iagnostic compounds can be magnetic (detectable by MRI), radiopaque (detectable by x-ray), fluorescent (detectable by fluorescent techniques) or ultrasound detectable." *Id.* at 9:63–66.

C. Illustrative Claim

Claim 1 of the '835 patent is illustrative and reproduced below, emphasis added:

> 1. A seed, for implantation into a subject, comprising: a marker component configured to allow for the determination of the position of the seed within a target tissue, the marker component having a length extending along a centerline of the marker component between a first end and a second end and having a substantially continuous wall bounding a hollow interior; and a therapeutic, prophylactic, and/or diagnostic agent, wherein the agent is disposed within the hollow interior, wherein the length of the marker component is greater than the diameter of the hollow interior and wherein the substantially continuous wall includes *at least one opening* adapted to allow the agent to pass out of the hollow interior.

Ex. 1001, 23:26–37 (emphasis added).

The other independent claims, claim 17 and 20, similarly recite openings in the seed. For example, claim 17 recites that the seed "includes *at least one opening* adapted to allow the agent to pass out of the hollow interior." Ex. 1001, 24:38–39 (emphasis added). Claim 20 recites that the seed contains a "marker component comprising *a tube having open ends, . . .* and wherein the seed further comprises a plurality of *openings that extend through the wall*, and wherein the plurality of openings facilitate the passing of the agent out of the hollow interior of the tube into the surrounding tissue." *Id.* 24:47–58 (emphasis added).

D. Instituted Grounds of Unpatentability

We instituted *inter partes* review of claims 1–4, 9–12, and 14–20 of the '835 patent on the following grounds.

Claims Challenged	**Basis**	**References**
1–4, 9–12, and 15–19	§ 102(a)	Zamora[2]
1–4, 9–12, and 14–20	§ 103(a)	Zamora alone and further in view of Brem[3]
1–4, 10, 14, 16–17 and 20	§ 103(a)	De Nijs[4] in view of Schopflin[5]
14 and 20	§ 103(a)	De Nijs and Schopflin in further view of Brem

[2] Zamora et al., US 6,575,888 B2, issued June 10, 2003 ("Zamora," Ex. 1003). As further explained below, Petitioner relies on Zamora as prior art under pre-AIA 35 U.S.C. § 102(e). Pet. 2. Zamora claims priority to U.S. Provisional Application No. 60/178,083, filed Jan. 25, 2000. Ex. 1026 ("the '083 provisional application" or "the Zamora Provisional").
[3] Brem et al., US 5,626,862, issued May 6, 1997 ("Brem," Ex. 1004).
[4] De Nijs, US 5,150,718, issued Sept. 29, 1992 ("De Nijs," Ex. 1005).
[5] Schopflin, US 4,012,497, issued Mar. 15, 1977 ("Schopflin," Ex. 1006).

Petitioner also relies on the Declaration of Robert S. Langer, Sc.D. (Ex. 1002) to support its assertions. Patent Owner relies on the Declaration of Dr. Patrick F. Kiser, Ph.D. (Ex. 2147) to support its opposition to the Petition.

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2017)[6]; *Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, 2142 (2016). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc*., 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner requests construction of the term "seed." Pet. 21–22. For purposes of this decision we provide a construction of the term "seed." Patent Owner requests construction of the term "pore." PO Resp. 11–12. Because we do not rely on this term in reaching our decision, we do not

[6] A recent amendment to this rule does not apply here, because the Petition was filed before November 13, 2018. *See* "Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board," 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42).

provide a construction for this term in this decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999) (Courts only construe claims to the extent necessary to resolve the dispute.).

Petitioner submits that the term seed "is an implant that has a size and shape suitable for passing through a needle, which includes 'seeds shaped into a cylinder (or rod) structure with a diameter of between about 0.8 to 3 millimeters and a length of up to 40 [millimeters].'" Pet. 21 (citing Ex. 1001, 14:31–34). Based on that portion of the specification, Petitioner submits that the broadest reasonable interpretation of "seed" includes an elongated cylinder (or rod) structure. Pet. 22. Patent Owner does not challenge Petitioner's construction in its Patent Owner Response. PO Resp. 11–12.

Given that the '835 patent has not expired, we use the broadest reasonable interpretation standard. Having considered the arguments and evidence presented at trial, we determine the broadest reasonable interpretation of "seed" that is consistent with the specification is an implant that includes the shape of a "cylinder (or rod) structure."

B. Level of Ordinary Skill in the Art

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al–Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu–Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

The parties generally agree that a person of ordinary skill in the art would have had at least a Master's degree in bioengineering or a related field

with several years of experience with biomedical implants. Pet. 20; *see also* PO. Resp. 11. On this record, we adopt the parties' definition of the level of skill in the art. We further note that the prior art itself demonstrates the level of skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (Explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown.") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985)).

C. Principles of Law

After institution of an *inter partes* review, the "reasonable likelihood" threshold standard no longer applies. As stated in our Trial Practice Guide, the "reasonable likelihood" standard applicable to an institution decision "is a somewhat flexible standard that allows the Board room to exercise judgment." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765 (U.S. Patent & Trademark Office Aug. 14, 2012); *see also Genzyme Therapeutic Prods. Ltd. P'ship v. Biomarin Pharma. Inc.*, 825 F.3d 1360, 1367 (Fed. Cir. 2016) ("The purpose of the trial in an *inter partes* review proceeding is to give the parties an opportunity to build a record by introducing evidence—not simply to weigh evidence of which the Board is already aware.").

In an *inter partes* review, the burden of persuasion is on the petitioner to prove "unpatentability by a preponderance of the evidence," 35 U.S.C. § 316(e), and that burden never shifts to the patentee. *Dynamic Drinkware, LLC v. National Graphics, Inc.*, 800 F.3d 1375, 1378 (2015).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966). In an *inter partes* review, Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Thus, to prevail Petitioner must explain how the proposed combinations of prior art would have rendered the challenged claims unpatentable. With these standards in mind, we address each challenge below.

D. Ground 1: Anticipation by Zamora

Petitioner contends that claims 1–4, 9–12, and 15–19 are unpatentable as anticipated by Zamora. Pet. 22– 38. Patent Owner opposes. PO Resp. 18–30.

1. Analysis

The parties dispute whether Zamora constitutes § 102(e) prior art. As explained further below, we find Petitioner has not satisfied its burden to establish that it is.

a. Legal Background Regarding § 102(e) Prior Art

Petitioner has the burden of persuasion to prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e) ("In an inter partes review . . . , the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence."). Where, as here, Petitioner asserts the challenged claims are unpatentable over a prior art reference because it is § 102(e) prior art, it is Petitioner's burden to prove that reference is entitled to the filing date of its provisional application. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

The Federal Circuit has made clear that determining whether a reference is § 102(e) prior art involves a burden-shifting framework. *Id.* at 1379. In *Dynamic Drinkware*, although the burden of persuasion to prove unpatentability never shifted from the petitioner, the burden of production regarding whether the Raymond reference was § 102(e) prior art shifted between the petitioner and patent owner. *Id.* The petitioner met the initial burden of production by arguing Raymond anticipated the challenged claims under § 102(e). *See id.* The burden then shifted to the patent owner to argue or produce evidence that Raymond did not actually anticipate the claims, or that the claims of the patent at issue were entitled to the benefit of a filing date before the filing date of Raymond. *Id.* at 1380. The patent owner produced evidence that the claimed invention was reduced to practice before the actual filing date of Raymond and thus was entitled to a date of invention before that of the Raymond patent. *Id.* As a result, the burden then shifted back to the petitioner to prove that the claimed invention was not reduced to practice, as argued by the patent owner, or that the Raymond patent was

entitled to the benefit of a filing date before the date of the patent owner's proposed reduction to practice. *Id.*

The Federal Circuit noted that 35 U.S.C. § 119(e)(1) addresses the requirements for a patent to claim priority from the filing date of its provisional application. *Id.* at 1378. Under § 119(e)(1), the specification of the provisional application 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," 35 U.S.C. § 112 ¶ 1, to enable an ordinarily skilled artisan to practice the invention claimed in the non-provisional application. *Id.* (quoting *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1294 (Fed. Cir. 2002)). In other words, "[a] reference patent is only entitled to claim the benefit of the filing date of its provisional application if the disclosure of the provisional application provides support for the claims in the reference patent in compliance with § 112, ¶ 1." *Id.* at 1381 (citing *In re Wertheim*, 646 F.2d 527, 537 (CCPA 1981)).

In *Dynamic Drinkware*, the Federal Circuit determined that the petitioner failed to compare the claims of the Raymond patent to the disclosure of its provisional application. *Id.* The petitioner had only compared the claims of the patent at issue with the disclosures of the Raymond patent and the Raymond provisional. *Id.* at 1381. That is insufficient. As *Dynamic Drinkware* makes clear, "[a] provisional application's effectiveness as prior art depends on its written description support for the claims of the issued patent of which it was a provisional." *Id.* at 1382.

b. Whether Zamora is § 102(e) Prior Art

Zamora was filed on January 24, 2001. Ex. 1003, [22]. Zamora claims priority to U.S. Provisional App. No. 60/178,083, which was filed on January 25, 2000 (Ex. 1026, "Zamora Provisional"). *Id.*, [60].

The '835 patent was filed on June 13, 2013. Ex. 1001, [22]. The '835 patent claims priority to a string of continuation and continuation-in-part applications, the earliest of which was filed May 18, 2001. *Id.*, [63]. The '835 patent also claims priority to two provisional applications: U.S. Provisional App. No. 60/249,128 (Ex. 2071, "the '128 Provisional"), which was filed on November 16, 2000, (Ex. 1001, [60]) and U.S. Provisional App. No. 60/412,050 (Ex. 1039, "the '050 Provisional"), which was filed on September 19, 2002 (Ex. 1001, [60]).

Thus, for Zamora to qualify as § 102(e) prior art, either one of the following must be shown:

(1) The '835 patent is not entitled to the filing date of the '128 Provisional, thereby making its earliest effective filing date May 18, 2001, which is after the filing date of Zamora; or

(2) If the '835 patent is entitled to the filing date of the '128 Provisional, then Petitioner must demonstrate that Zamora is also entitled to the filing date of the Zamora Provisional, which was filed January 25, 2000, which is before the earliest effective filing date of the '128 Provisional on November 16, 2000.

Petitioner has satisfied its initial burden of production by asserting the challenged claims of the '835 patent are unpatentable as anticipated over Zamora as § 102(e) prior art. Pet. 1–3; *see Dynamic Drinkware*, 800 F.3d at 1378. Petitioner also identifies where in the Zamora '083 Provisional it

contends there is written description support for claims 1 and 9 of Zamora. Pet. 2–3.

Because Petitioner satisfied its initial burden by asserting Zamora as § 102(e) prior art, the burden of production shifts to Patent Owner to show Zamora is not § 102(e) prior art. Patent Owner makes two arguments to satisfy its burden. First, Patent Owner contends that the '835 patent is entitled to the benefit of the filing date of the '128 Provisional. PO Resp. 18–20. Second, Patent Owner contends that Zamora is not entitled to the benefit of the filing date of the Zamora Provisional because Petitioner fails to show the relied-on disclosure is present in Zamora's provisional and because the Zamora Provisional fails to support key limitations of Zamora's claims. *Id.* at 21–26.

In response, Petitioner asserts the '835 patent cannot claim priority to any application before the '050 Provisional. Pet. Reply 24–25. Moreover, Petitioner asserts that each limitation of Zamora's claim 1 is supported in the Zamora Provisional, which "is all that the law requires." *Id.* at 25. And even if the law does require that the relied-upon disclosures are supported by the Zamora Provisional, Petitioner asserts that disclosure is supported by the Zamora Provisional. *Id.*

In its Surreply, Patent Owner asserts Zamora is not prior art because Petitioner has failed to show the challenged claims are not entitled to the benefit of the filing date of the '128 Provisional. PO Surreply 22–23. Patent Owner also asserts that Petitioner's argument fails because it did not show the relied-upon disclosures of Zamora were carried forward from the Zamora Provisional. *Id.* at 23.

We now turn to the first question of whether the '835 patent claims are entitled to the benefit of the earliest effective filing date of the '128 Provisional.

(1) Whether the '835 Patent Claims Are Entitled to the Benefit of the Earliest Effective Filing Date of the '128 Provisional

Patent Owner asserts that the '128 Provisional and all intervening applications fully support the challenged claims. PO Resp. 18–20 (citing Ex. 2147 ¶ 90). Petitioner disagrees. Pet. Reply 24–25. We find that claims 1–4, 9–12, and 14–20 of the '835 patent are supported by the disclosure of the '128 Provisional for the reasons stated by Patent Owner and as supported by its declarant, Dr. Kiser. We focus our discussion on the limitations whose priority is in dispute.

Petitioner argues that the '128 Provisional fails to provide written description support for the full scope of the term "seed" recited in the '835 patent claims. Pet. Reply 24–25. That is, Petitioner notes that Patent Owner asserts the De Nijs and Nexplanon implants, which are 40 mm long, constitute seeds, and that the '835 patent only recites seeds up to 10 mm long. *Id.* at 24 (citing EX. 1053). Petitioner argues that the '128 Provisional does not describe any implant longer than 10 mm, which is consistent with "traditional 'brachytherapy seeds'" described in the '128 Provisional. *Id.* (citing Ex. 2071, 3:3–13). Moreover, Petitioner asserts that Figures 5A and 5B of the '128 Provisional does not provide written description support for longer implants because it merely depicts "a plurality of brachytherapy seeds . . . conjoined into a chain [] using a plurality of spacers." *Id.* at 25 (quoting Ex. 2071, 29:3–13). Thus, Petitioner argues the inventor was not in

possession of the full scope of the claimed invention before the '050 Provisional. *Id.* at 24–25.

The test for written description support 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." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). "[T]here is no categorical rule that a species cannot suffice to claim the genus." *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1352 (Fed. Cir. 2011). Rather, "a sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350 (citation omitted). "Different claims of [a CIP] application may therefore receive different effective filing dates." *Augustine Med., Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1302–03 (Fed. Cir. 1999) (*cited in PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299 (Fed. Cir. 2008)).

We find Petitioner's arguments regarding the term "seed" for implantation in independent claims 1, 17, and 20 to be unconvincing. Here, each of the challenged claims of the '835 patent are silent as to the length of the seed with the exception of claim 2. Claim 2 recites a seed with a "marker component [that] has a maximum length of 10 mm." The '128 Provisional describes seeds of 2–10 mm with certain needles, and a preferred length of 4–6 mm with other needles. Ex. 2071, 15:3–17 Petitioner admits that the '128 Provisional teaches seeds that are 10 mm in length. Pet. Reply. 24.

The ’128 Provisional teaches “brachytherapy seeds shaped into a cylinder (or rod) having a diameter of between about 0.8 to 3 millimeters . . . and a length of between about 4 to 6 millimeters . . . are preferred.” Ex. 2071, 15:3–17. The ’128 Provisional also teaches an implant depicted in Figures 5A and 5B, which is reproduced below:

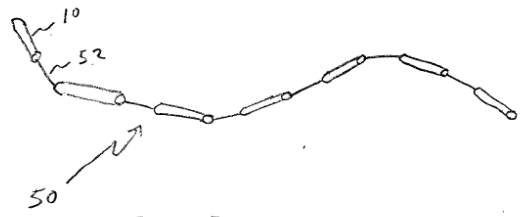

FIG. 5A

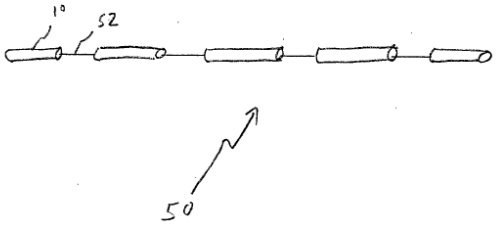

FIG. 5B

Figures 5A and 5B depict an implant where “a plurality of brachytherapy seeds 10 may be conjoined into a chain 50 using a plurality of spacers 52 to connect the plurality of seeds 10.” Ex. 2071, 29:3–5, Figs. 5A, 5B. Moreover, the ’128 Provisional teaches that spacers “can have any size suitable for use with brachytherapy seed 10” and that for many applications, the length will vary from “between about 0.5 mm to about 50 mm.” *Id.* at 29:6–9. Thus, we determine that the ’128 Provisional, and Figures 5A and

5B, provide sufficient written description support for the "seed" (i.e., elongated implant) recited in the '835 patent claims.

As we found in the Decision on Institution, the '128 Provisional discloses "a brachytherapy seed for implantation into a subject including a biocompatible component, a therapeutically active component, and a radiopaque marker." Ex. 2071, 6:1–3. The '128 Provisional discloses that microspheres of a radio-opaque polymer may be co-mingled with microspheres containing a biocompatible component. Ex. 2071, 26:10–15. The '128 Provisional discloses that component 12 can be a biodegradable polymer (Ex. 2071, 17:1–2) and that the biocompatible component may serve as a coating (*id.* at 31:6–7). The '128 Provisional discloses that "some versions of the seeds of the invention" "do not contain a radioisotope." Ex. 2071, 5:18–21. Accordingly, we determine that independent claims 1, 17, and 20 are sufficiently supported by the '128 Provisional.

Petitioner does not argue the remaining claims separately.

Petitioner contends that the addition of specific lengths of implants in the '050 Provisional "necessitated a Continuation in Part ('793 Application), which eventually matured into the '402 patent." Pet. Reply 24. But we are not persuaded that it was the addition of "a length of up to 40 millimeters" in the specification necessitated the filing of a continuation-in-part application. A cursory comparison of the figures of the '128 Provisional and the '050 Provisional makes clear that the '050 Provisional added more new matter than just the length of the implants. *Compare* Ex. 2071, Figs. 1–5B, *with* Ex. 1039, Figs. 1–5D (depicting different embodiments of strands and various applications of a strand for treatment of breast cancer). Thus, we find Petitioner's argument that the continuation-in-part was "necessitated"

because it added a description of the length of the implant to be unconvincing.

Petitioner argued during the oral hearing that Patent Owner is estopped from asserting Zamora is not prior art. Tr. 52:15–53:7. Petitioner's counsel admitted, however, that that argument was only made in the Reply to Patent Owner's *Preliminary Response*. *Id.* at 53:8–12. That is, Petitioner did not raise the argument in its Reply to Patent Owner's Response after trial was instituted. We, therefore, find that argument is waived and do not consider it here.[7] *See In re NuVasive*, 842 F.3d 1376, 1380–81 (Fed. Cir. 2016) (finding patent owner waived arguments made in Preliminary Response and not raised in Patent Owner Response); *cf.* Scheduling Order (Paper 14), 6 (cautioning patent owner that "any arguments for patentability not raised and fully briefed in the response will be deemed waived").

Accordingly, we determine that the '128 Provisional provides written description support for claims 1–4, 9–12, and 15–19 of the '835 patent.

Having found the effective filing date of claims 1–4, 9–12, and 15–19 of the '835 patent is November 16, 2000, we now turn to whether Zamora is entitled to claim the benefit of the January 25, 2000, filing date of the Zamora Provisional to antedate those claims of the '835 patent.

[7] Although Patent Owner addressed Petitioner's estoppel argument in its Patent Owner Response (PO Resp. 25), Petitioner did not respond to Patent Owner's argument in its Reply. We find this further supports waiver of Petitioner's argument, as Petitioner could have raised the estoppel issue by responding to Patent Owner's arguments in its Reply, but it chose not to.

(2) Whether Zamora is Entitled to the Benefit of the Earliest Effective Filing Date of the Zamora Provisional

The Petition asserts that Zamora is § 102(e) prior art and provides a claim chart identifying where the limitations of claims 1 and 9 of Zamora are supported by the written description of the Zamora Provisional. Pet. 1–3.

Patent Owner argues that the Zamora Provisional does not support the location of the radiopaque medium, which Patent Owner asserts must be on at least an "*external surface* of the tube." PO Resp. 26.

Claim 1 of Zamora recites that the radiopaque medium is "disposed either on at least a portion of an external surface of the tube, within at least [a] portion of a structure of the tube, or within the radioactive material." Ex. 1003, 14:19–22. In other words, claim 1 of Zamora functions as a *Markush* group with three possible ways to dispose the radiopaque medium relative to the device.

Petitioner relies on two different passages in the Zamora Provisional to support this limitation. First Petitioner relies on a passage in Zamora in which radiosensitization material coats an external surface. Ex. 1026, 8:10–17[8]. However, at oral argument, counsel for Petitioner conceded that radiosensitization material refers to "a drug that makes tissue sensitive to radiation," which is different than radiopaque material, as recited. Tr. 50:19–51:6. Therefore, this passage in Zamora does not disclose *radiopaque* material disposed *on an external surface* of the tube, as recited.

Second, Petitioner relies on a passage in the Zamora Provisional in which radiopaque material is "[a]dmixed into the seed core or the cylinder

[8] We refer to the page numbers of the application that constitutes the Zamora Provisional rather than to the Exhibit number.

walls is an X-ray contrast agent." Ex. 1026, 5:13. Radiopaque material admixed into the cylinder walls is not necessarily on an external surface of the tube. Further, the claim requires that the material be disposed on an external surface. At most, the Zamora Provisional might support radiopaque material disposed *in* a tube wall, but does not disclose radiopaque material *disposed on* an external surface of the tube, as recited.

As an initial matter, we must determine the meaning of the limitation disposed "on at least a portion of an external surface" of claim 1 of Zamora. Turning first to the claim language, Zamora distinguishes between radiopaque medium that is disposed "on at least a portion of an external surface of the tube" and radiopaque medium that is disposed "within at least [a] portion of a structure of the tube." Ex. 1003, 14:19–22. Consistent with that, Zamora teaches that the radiopaque medium can be incorporated into the device in several ways:

> The device may further include a radiopaque medium, which may be disposed on at least a portion of the external surface of the bioabsorbable polymeric housing, such as a tube, may be disposed within at least a portion of the structure of the bioabsorbable polymeric housing, such as a tube, or may be disposed within the radioactive material.

Ex. 1003, 4:19–24. Zamora also describes various embodiments for applying the radiopaque medium:

> In one embodiment, an iodine-based radiopaque agent is admixed with the other constituent elements forming complex 125 [sic, 126]. In another embodiment, a barium-based radiopaque agent is admixed with the other constituent elements forming complex 126. In yet another embodiment, the radiopaque agent forms a part of a coating over the device 110.

Id. at 12:31–37. Thus, Zamora teaches that admixing radiopaque material into the complex with disposing radiopaque medium "in" the structure. And Zamora teaches that coating radiopaque material over the device with disposing radiopaque medium "on" the structure. We also find this to be consistent with the plain meaning of the term "disposed on." We, therefore, determine the term disposed on "an external surface to include material coated on an external surface, but does not include material that is admixed into the complex.

The Zamora Provisional does not describe coating radiopaque material or any other means of disposing radiopaque material on the external surface of the tube. Moreover, although the Zamora Provisional teaches that radiosensitization agents "may be coated on the container" (Ex. 1026, 8:9–14), we are not inclined to combine that teaching with the teaching of an admixed radiopaque material, as Petitioner appears to suggest. Pet. Reply 25. That would be in the nature of an obviousness inquiry, which is not the standard for written description required here. *See Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571–72 (Fed. Cir. 1997) ("Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed."). Thus, we are not persuaded that the Zamora Provisional provides written descriptive support for the radiopaque medium being disposed "on at least [a] portion of a structure of the tube." As such, the Zamora Provisional only supports two out of three possible locations for radiopaque material in claim 1 of Zamora. The evidence of record does not establish that a person of ordinary skill in the art would have understood the inventor to have possessed the claim limitation, as recited. *See* Ex. 1043, 5:13, 8:13–17. We, therefore, find

Petitioner has not shown that the Zamora Provisional provides representative disclosures to support claim 1 of Zamora.[9] Petitioner does not argue written description support for any other independent claim of Zamora.

2. Conclusion

Having determined that the '835 patent is entitled to the filing date of the '128 Provisional, and that Zamora is not prior art, we find that Petitioner has not shown by a preponderance of evidence that claims 1–4, 9–12, and 15–19 are unpatentable as anticipated by Zamora.

E. Ground 2. Obviousness over Zamora and Brem

Petitioner contends that claims 1–4, 9–12, and 15–19 are unpatentable as obvious over Zamora alone, or claims 1–4, 9–12, and 14–20 over Zamora in view of Brem. Pet. 38–44. Patent Owner opposes. PO Resp. 30–44.

Having determined that Zamora is not prior art (*see above* II. D.1.b.2), we find that Petitioner has not shown by a preponderance of evidence that

[9] Petitioner also refers to claim 9 of Zamora in Petitioner's chart attempting to show written description support for a claim of the Zamora reference. Claim 9 is written in multiple dependent form and depends from claim 1 as well as other independent claims, i.e., claims 2, 4, and 6. *See* Pet 3; Ex. 1003, 15:8–10. Thus to show support for claim 9 in the Zamora Provisional, Petitioner would have to support the independent claim limitations which carry over to claim 9 from at least one of claims 1, 2, 4, and 6. Above, we determine that Petitioner has not shown support for the limitations of independent claim 1. Further, Petitioner does not explain how independent claims 2, 4, and 6 would have been supported by the Zamora provisional. We determine that Petitioner has not met its burden to show written descriptive support for claim 9 by virtue of its dependency from any of claims 1, 2, 4, and 6.

claims 1–4, 9–12, and 14–20 are unpatentable as obvious over Zamora alone or in combination with Brem.

F. Ground 3. Obviousness over De Nijs and Schopflin

Petitioner contends that claims 1–4, 10, 14, 16, 17, and 20 are unpatentable as obvious over De Nijs in view of Schopflin. Pet. 44–58. Patent Owner opposes. PO. Resp. 44–62.

1. Overview of De Nijs (Ex. 1005)

De Nijs is titled "Method of Contraception" and relates to "an implant of polymeric material which can release a contraceptive agent for a relatively long time when fitted subcutaneously or locally [and more specifically to] an implant of such small dimensions that it can be fitted subcutaneously with an ordinary hypodermic needle." Ex. 1005, 1:7–15. De Nijs identifies a problem with the prior art, i.e., the polymeric material of an implant often had to be charged with large amounts of a contraceptive agent to guarantee release for about 4 years. *Id.* at 1:23–27. This large amount of material leads to very large implants that could only be fitted surgically, or to several smaller implants that had to be fitted simultaneously. *Id.* at 1:27–30.

De Nijs discloses an implant characterized by a core of ethylene/vinyl acetate copolymer (EVA) having a molecular weight such that the melt index is higher than 10 grams per 10 minutes, and a vinyl acetate content of 20% by weight or more. *Id.* at 2:3–8. De Nijs discloses that the core material functions as a matrix for 3-keto-desogestrel, levonorgestrel or gestodene as active contraceptive substances, in a quantity that is sufficient for a long-lasting constant release of at least 15–30 μm of active substance

per day. *Id.* at 2:7–13. De Nijs further discloses a membrane having a layer thickness of 50–250 μm, which encases the core material and also consists of EVA material, but with such a molecular weight that the melt index is less than 10 grams per 10 minutes, and an acetate content of less than 20% by weight. *Id.* at 2:14–18. De Nijs discloses that the implant is completely or virtually completely cylindrical with a maximum external diameter of about 2 mm and a length that is smaller than about 5 cm. *Id.* at 2:18–22.

2. Overview of Schopflin (Ex. 1006)

Schopflin is titled "Drug Excipient of Silicone Rubber" and relates to organopolysiloxane molding composition drug excipients having a regular, uniform and prolonged drug dispensation rate. Ex. 1006, 1:16–19. Schopflin discloses that nonionic, lipid-soluble medicaments enclosed in organosiloxane elastomers and in organosiloxane-resin reinforced organopolysiloxane elastomers are released with a delay from the carrier material. *Id.* at 1:27–31. Schopflin explains that vulcanization of organopolysiloxane containing a drug is impossible due to heat instability, and two-component compositions often failed, *inter alia*, because they required saturation with a drug. *Id.* at 2:7–11, 2:62–68.

Schopflin discloses a vulcanizable composition capable of being catalytically cured with a platinum metal-based vulcanization catalyst in the presence of a pharmaceutically active amount of a nonionic, lipophilic drug to form a nontoxic elastomeric sustained release pharmaceutical composition. *Id.* at 3:33–38. Schopflin discloses that the vulcanizable composition consists essentially of: (a) a polydimethylsiloxane having vinyl groups on both ends; (b) a copolymer consisting essentially of SiO_2 units, $(CH_3)_3SiO_{0.5}$ units, and $Vinyl(CH_3)_2SiO_{0.5}$ units; and (c) a cross-linking Si-H

component, consisting essentially of $(CH_3)_3SiO_{0.5}$ units, $(CH_3)_2SiO$ units, and CH_3HSiO units. *Id.* at 3:40–47.

Schopflin further discloses that its drug excipients are suitable as vehicles for one or more nonionic, lipophilic drugs. *Id.* at 5:37–39. The drugs can be bound singly or in admixture and in pure form or with conventional additives. *Id.* at 5:47–50. The additives include lactose, magnesium stearate, highly dispersed barium sulfate with a particle size smaller than 4 µm, and silicon oil with a molecular weight of 300–20,000. *Id.* at 5:50–53. Schopflin discloses that for X-ray localization of the implant in the body a radiopaque amount of barium sulfate is incorporated in the active agent carrier. *Id.* at 7:41–43.

3. Analysis

Petitioner asserts that De Nijs teaches every limitation of the claims of the '835 patent except for the marker component. Pet. 45; Pet. Reply 4. Petitioner asserts that De Nijs discloses a seed that is "virtually cylindrical with a maximum section of about 2 mm" and a "length [that is] preferably between 1 and 4 cm" and, in one embodiment, the implant is a "coaxial filament" cut to a desired length. Pet. 47–48 (citing Ex. 1005, 1:62–66, 3:19–24, 5:55–66, 6:35–53, 7:11–24, and clm. 5), *id.* at 49 (citing Ex, 1002 ¶ 120); Pet. Reply 6. Petitioner further asserts that the De Nijs "implant is designed for 'subcutaneous fitting' into a patient via an 'ordinary hypodermic needle.'" Pet. 48 (citing Ex 1005, 1:67–2:2; Ex. 1002 ¶ 118).

Petitioner relies on Schopflin for teaching the inclusion of a marker component in a seed. Pet. 48 (citing Ex. 1006, (Example 3)); *see also* Pet. Reply 9 ("Schopflin specifically teaches that there is a need for "improved X-ray localization" of such implants"). Petitioner asserts that Schopflin

teaches the addition of a radiopaque amount of barium sulfate for the purpose of improved localization of the seed by X-ray. Pet. 48 (citing Ex. 1006, 7:37–43, 9:5–21; Ex. 1002 ¶ 119). Petitioner asserts that adding barium sulfate to either of the polymer layers of the coaxial filament taught by De Nijs results in the inclusion of a marker that extends the length of the seed. Pet. 48; *see also* Pet. Reply 9–10 ("The radiopacity imparted by the barium sulfate allows for more precise placement as well as another means to find the implant if lost during removal . . . which is consistent with the frequent inclusion of barium sulfate in prior art contraceptive implants." (citing Ex. 1002, ¶¶ 41-42; Ex. 2110, Ex 2107, and Ex. 2026)).

Petitioner's expert, Dr. Langer, testified that a person of ordinary skill would have had a reasonable expectation of success in combining the teachings of De Nijs and Schopflin because they both rely on similar hormones. Ex. 1002 ¶ 116.

> A POSA would also have had a reasonable expectation that the teachings of De Nijs and Schopflin could be successfully combined because they disclose implants with features that overlap heavily. De Nijs and Schopflin both teach cylindrical implants about 2 to 2.5 mm in diameter and 1 to 4 cm in length. *Compare* De Nijs at 1:62-67, 2:3-27 *with* Schopflin at 8:62-9:2. Both teach the use of contraceptive hormones as the drug inside the implant. *Compare* De Nijs at 2:3-29 with Schopflin at 5:54-67, 7:16-24. Both teach the use of a polymeric coating to cover the implant. *Compare* De Nijs at 1:34-36, 2:3-20, 3:34-36 with Schopflin at 1:21-26, 5:31, 7:2-4. Given the substantial overlap, a person of ordinary skill would have an expectation that these references could be successfully combined to create a radiopaque device.

Ex. 1002 ¶ 116; *see* Pet. 46.

Patent Owner contends that Petitioner has not made a prima facie case of obviousness. PO Resp. 44–62. Specifically, Patent Owner contends that Petitioner has not articulated a sufficient reason why one of ordinary skill would look to add a marker component to De Nijs in the first place (*see* PO Resp. 53–55), "provides no motivation to use a marker with contraceptive implants like De Nijs" (*see id.* at 55), and even if there were a reason to add such a marker there is no reasonable expectation of success in adding a barium sulfate marker because this would affect release rate of the drug (*see id.* at 55–62). Patent Owner further argues that Petitioner is estopped from making the unpatentability arguments as proposed because these arguments are opposite to prior arguments made during the prosecution of one of Petitioner's own patents. *See id.* at 45–48. We address these arguments below, starting with judicial estoppel:

A. Judicial Estoppel

Patent Owner argues that Petitioner's current position – that the addition of marker material to De Nijs's implant is obvious – is "the exact opposite [of the position taken] to obtain its own patent and [Petitioner] is estopped from reversing itself now. During prosecution of Merck's patent, the Examiner argued (as Merck does now) that adding a marker to De Nijs was obvious." PO Resp. 45 (citing Ex. 2062, 8). According to Patent Owner:

> The doctrine of estoppel prevents Merck from changing positions just because its interests have changed. *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001). Estoppel applies both in federal courts and in proceedings before administrative agencies, including the PTAB, and "protect[s] the integrity of the judicial process by prohibiting parties from deliberately changing positions according to the exigencies of the moment."

> *New Hampshire*, 532 U.S. at 743; *Data Gen. Corp. v. Johnson*, 78 F.3d 1556, 1565 (Fed. Cir. 1996).

PO Resp. 47–48.

Petitioner contends that estoppel does not apply because "Merck's arguments were not accepted by the Examiner in that prosecution, which is necessary for the doctrine of judicial estoppel to apply." Pet. Reply 16. "Merck only obtained allowance of the '037 patent ["Veenstra patent" (Ex. 2002)] claims through repeated amendment, ultimately reciting that the barium sulfate be 'encapsulated' within the microstructure of the polymer matrix '***and not*** in the crystalline desogestrel or 3-ketodesogestrel,' a surprising result it supported with experimental evidence demonstrating such microencapsulation." Pet. Reply 18 (citing Ex. 2002, claim 1, 8:40–9:25, Fig. 10).

Having considered the arguments and evidence presented at trial, we agree with Petitioner that significant amendments were made during the prosecution of the Veenstra patent (Ex. 2002) in order to address the examiner's concern regarding the toxicity of barium sulfate. For example, in the notice of allowance of the Veenstra patent, the examiner explained that barium sulfate is known to be toxic and care must be taken to ensure that barium sulfate does not leach out of an implant device.

> Priewe (US 2003/0010929), newly cited, discloses that barium sulfate can be used as an X-Ray visible elements only as long as it is sufficiently and permanently encapsulated as barium ions are very toxic and despite the low solubility of barium iron, toxic effects can be expected in the case of long-term implantation (0010 and 0034]. Priewe teaches that when barium sulfate is used in the polymeric structure, it should be further coated with a non-resorbable polymer, in order to prevent the barium sulfate from being released in the body of a patient in the long term

> [0027], [that] however, Priewe does not suggest the use of barium sulfate in contraceptive implant or in combination with hormonal drugs, particularly desogestrel and 3-ketodesogestrel.

Ex. 2070, 4. The examiner's notice of allowance makes clear that the addition of the "encapsulating barium sulfate limitation," something that is not found in prior art, was a necessary amendment in order for the claim to reach allowance.

We agree with Petitioner's position that the examiner did not accept the relevant arguments made during the prosecution of the Veenstra patent with respect to the cited art, the combination of De Nijs and Miller. *See* Pet. Reply 18. During prosecution of the Veenstra patent Merck took the position that "it was not obvious how to incorporate a radio-opaque material into a controlled-release contraceptive implant without affecting the hormone release profile, while also ensuring that the radio-opaque material does not migrate outside of the implant in undesired amounts, particularly wherein the implant is a rod having open ends." Ex. 2063, 44. This argument, however, was ultimately not adopted by the examiner.

Instead, Merck relied on the unexpected finding that when mixing barium sulfate, the radiopaque component, with the hormone crystals, and EVA polymer (*see* Ex. 2002, 5:5–38) the barium sulfate did not localize with the hormone component. *Compare* Ex. 2003, 7–8, with Ex. 2070, 4.

> Applicants [Merck] believe that having almost all the radio-opaque material encapsulated within the polymer and hardly any radio-opaque encapsulated in the hormone crystals contributes in allowing the device to demonstrate two unexpected features; (1) prevents the radio-opaque material from leaching out of the device and (2) enables the radio-opaque material to not affect the release rate of the desogestrel or 3-ketodesogestrel as compared to the same device without a radio opaque material.

Ex. 2003, 7–8 (citing Ex. 2002, 3:62–4:9). According to the applicants, that barium sulfate is encapsulated in the polymer at a location separate from the hormone is a surprising finding as described in the Veenstra patent prosecution.

> When evaluating where the radio-opaque component was located in the implant after production thereof, it was surprisingly found that almost all of the radio-opaque component was encapsulated within the polymer component and hardly any radio-opaque component was encapsulated in the hormone crystals. This was unexpected in view of the fact that the polymer component represents only about 36 wt % of the implant whereas the hormone component comprises about 52.5 wt % of the implant. As a result of the encapsulation within the polymer component, the radio-opaque component crystals could not migrate out of the implant through the open ends of the implant in undesired amounts. Had the radiopaque component been present in the hormone crystals, it may have been able to migrate outside of the implant is case where the hormone crystals are inter-connected.

2002, 3:62–4:9.

Based on this record, we agree with Petitioner that its prior arguments were not relied on by the examiner during the prosecution of the unrelated Veenstra patent and, for at least this reason, do not give rise to judicial estoppel. *See ScanDisk Corp. v Memorex Products, Inc., 415 F.3d 1278, 1290–91* (Fed. Cir. 2005) (discussing *New Hampshire v. Maine*, 532 U.S. 742, 750–51 (2001) (finding several factors inform the decision whether to apply the doctrine of judicial estoppel including whether a party's later position is "clearly inconsistent" with its earlier position; whether the party has "succeeded in persuading a court to adopt the earlier position;" and whether the party would derive an "unfair advantage.").

We recognize that Petitioner's current position is the same as that of the examiner during the prosecution of the Veenstra patent. We note, however, that the claims in the prosecution of the unrelated Veenstra patent only reached allowance after incorporation of language that captured Veenstra's unexpected results as set out the specification. In other words, Merck's position during the prosecution of the Veenstra patent were not successful. Because, Merck did not succeed "in persuading a court[10] to accept that party's earlier position" we do not find that estoppel applies to Petitioner in this proceeding. *New Hampshire*, 532 U.S. at 750–51. Accordingly, we do not agree with Patent Owner's position that Petitioner is judicially estopped from arguing that the addition of a marker disclosed in Schopflin to De Nijs's implant is obvious.

B. Reason to Combine the De Nijs and Schopflin

The parties dispute whether a person of ordinary skill in the art would have had a reason to add an X-ray detectable marker into a contraceptive implant in the first place. Pet. 46 (citing Ex. 1002 ¶ 115 (teaching of difficult removal would have motivated a POSA "to include a radiopaque material . . . to make it easier to locate the implant within a patient's body"); Ex. 1021, 224); PO Resp. 55 (citing Ex. 1021, 223 ("*rare* problem of difficult localization"). We recognize that there may be multiple techniques to improve the localization of implanted material for later retrieval purposes.

[10] The Federal Circuit does not limit the application of judicial estoppel to courts and has applied it to other administrative agencies. *See Data Gen. Corp. v. Johnson*, 78 F.3d 1556, 1565 (Fed. Cir. 1996) ("Although the Board [i.e., the General Services Administration Board of Contract Appeals] is not a court, we assume it has authority by analogy to apply the doctrine in an appropriate case.").

See e.g., Ex. 1021, 227 ("use of ultrasound to locate in situ NORPLANT® rods"), 224–25 ("When devices are implanted within the body . . . careful attention must be given to both the clinical and programmatic aspects of their eventual removal"). One known solution for improving localization of an implant is to include a radiopaque marker with the device. Ex. 1006, 7:37–43 ("[F]or improved X-ray localization in the body, the active agent carrier can contain a radiopaque amount of barium sulfate"); Ex. 1002 ¶ 127) (cited in Pet. 52). Petitioner's position is that Schopflin teaches the inclusion of 5% by weight barium sulfate to an implant for improved localization, a sufficient teaching for the inclusion of a marker. Pet. Reply 9–10 (citing Ex. 1006, 7:41–43, Example 3). Petitioner, additionally, directs our attention to intrauterine devices (IUDs), a contraceptive device, that are known to incorporate barium sulfate to support the position that adding barium sulfate to an implanted device would be obvious. *Id.* at 10 (citing Ex. 2110, Ex. 2107, Ex. 2026).

We consider the parties' respective arguments in two parts. First, we consider whether a person of ordinary skill in the art would have had a reason to use a marker component for localization generally. Then, we consider whether a person of ordinary skill in the art would have had a reason to use barium sulfate for localization specifically.

(1) Using a Marker Component for Localization Generally

Based on the evidence presented, we find that Petitioner has shown by a preponderance of the evidence that the teaching of a retrieval or localization problem with an implant is sufficient motivation to improve the visualization of the implanted device. *See* Ex. 1002, ¶ 115; Ex. 1021, 244–25. We, therefore, disagree with Patent Owner's assertions to the contrary.

PO Resp. 55. Here, Schopflin teaches that X-ray localization of an implant can be achieved with the incorporation of barium sulfate into the implant matrix. Ex. 1006, 7:41–43. We find that this teaching in Schopflin in conjunction with the knowledge in the prior art that it can be difficult to locate a Norplant implant in a patient, is sufficient motivation for one of ordinary skill in the art to consider incorporating a marker with an implant device. *See* Ex. 1002 ¶¶ 114–115, Ex. 1021, 224–25. This identified retrieval problem is especially pertinent for implants such as the birth control implants, taught by De Nijs and Schopflin, that are intended to reside within a patient for years.

We, therefore, accept Petitioner's position that the difficulty of locating an implant, provides sufficient motivation to incorporate a general radiopaque marker to facilitate retrieving the implant using X-ray.

(2) Selecting Barium Sulfate as the Marker

The question now turns on whether one of ordinary skill in the art would have been motivated to incorporate a radiopaque marker known to be toxic into an implant. The ordinary skilled artisan is not limited to only considering the teaching in the references themselves but would also consider the knowledge in the prior art as a whole. *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1374–75 (Fed.Cir.2011) ("Through the lens of one of ordinary skill in the art, even when all claim limitations are found in prior art references, the fact-finder must not only determine what the prior art teaches, but whether prior art teaches away from the claimed invention and whether there is a motivation to combine teachings from separate references.").

Because the implants relied on by Petitioner in making their unpatentability arguments are intended for long-term use in the patient's body, we agree with Patent Owner that a person of ordinary skill in the art would understand that these implants would need to be made of materials that are not known to be toxic to the patient.[11] *See* Ex. 1005, 1:8–13 (De Nijs stating "[t]he invention relates to an implant of polymeric material which can release a contraceptive agent for a relative long time"); Ex. 2147 ¶ 156; PO Resp. 50–60. In other words, one of ordinary skill would not look to incorporate marker material that is known to be toxic and susceptible to leaching from a matrix. Ex. 2147 ¶ 156. Patent Owner directs us to evidence in the art that barium sulfate, the only radiopaque material contemplated in Schopflin, is toxic.

> [T]he prior art is replete with evidence [that] barium sulfate "gradually leached out" of polymer matrices causing the "release of heavy metal toxins" (EX 2130, 2:13-15), and was "toxic to tissues." (EX. 2143, 1:30-33.) Merck's expert admits as much, agreeing a circa-2000 POSA developing a De Nijs-like implant

[11] We note that the contraceptive IUDs, cited by Petitioner (*see* Pet. Reply 10 (citing Ex. 2110, Ex. 2107, Ex. 2026)), are not implanted into target tissue, as claimed in the '835 patent. Instead, IUDs are place into a body cavity. Furthermore, there is evidence that leaching of material into the uterine cavity does not necessarily result in systemic uptake of that material. "The copper released from the [intra uterine] devices [(IUD)] induces a local sterile inflammatory response in the endometrium, thereby preventing implantation of the fertilized egg. Furthermore, there is a direct toxic effect on the sperm and egg, and the mucus of the cervix is densified, impairing sperm penetration. Copper is not absorbed to a measurable extent from the uterus into the systemic circulation." Ex. 2026, 2. Also, Progesterone released from IUD does not reach systemic circulation while levonorgestrel is systemically absorbed. *Id.* at 3. Additionally, there is also no evidence that the IUD devices are open ended devices with embedded barium sulfate.

> with barium sulfate would have concerns about leakage out of the unsealed ends in an undesired amount, potentially resulting in adverse effects. (EX 2142, 81:7-16, 83:2-5.).

PO Resp. 60. Patent Owner argues that person of ordinary skill in the art would not have "been motivated to add, or expected success in adding, a marker component [like barium sulfate] to an open-ended implant's core with the drug itself for fear of impacting drug release rate or causing the [toxic] marker to leach out." *Id.* at 44–45. Patent Owner argues that it was not obvious to combine De Nijs and Schopflin because a person of ordinary skill in the art would not have expected to succeed in adding a "marker component" in the "hollow interior" with the drug "agent" at the same time. *Id.* at 50. Patent Owner argues that "even if POSAs were to look to De Nijs to add an opening to an implant with drug, it would not be obvious to then add potentially toxic marker material, which could escape through that opening." *Id.* at 52–53 (citing Ex. 2063, 15 [sic][12]).

Petitioner also asserts that Schopflin functions as an open container, because "[t]he entire thing [is] uncoated. So you can think of the entire thing as open." Tr. 12:5–11. However, Petitioner's expert does not provide support for the understanding that barium sulfate would function in the same manner in De Nijs's system.

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[12] We assume Patent Owner intended to cite page 44 of Exhibit 2063, in which Merck, during the prosecution of the unrelated Veenstra patent (discussed above *see II.F.3.A*) argued "that at the time of invention it was not obvious how to incorporate a radio-opaque material into a controlled-release contraceptive implant without affecting the hormone release profile, while also ensuring that the radio-opaque material does not migrate outside of the implant in undesired amounts, particularly wherein the implant is a rod having open ends." Ex. 2063, 44.

The preponderance of evidence of record shows that at the time the invention was made, barium sulfate was known to leak out of matrices and this was of concern because it was known to be toxic. *See* Ex. 2131 ¶¶ 10 (stating barium is toxic if "not sufficiently encapsulated"), 27 (warning barium sulfate, "which has a toxic effect" must be coated to prevent "being released in the body of a patient.")); Ex. 2147 ¶¶ 157, 219, 276; Ex. 1054, 132:13–133:12 (barium sulfate "not completely insoluble"); Ex. 2143, 1:20–33 (footnote omitted) ("Current methods of rendering objects radio-opaque involve compounding materials like barium sulfate (i.e., BaSO) into the objects. . . . In particular, medical devices treated with the current methods have low biocompatibility and may be toxic to tissues."); Ex. 2130, 2:13–15("The [barium] salt gradually leached out of the matrix causing discoloration of the polymer and release of heavy metal toxins"). Thus, we agree with Patent Owner that a person of ordinary skill in the art at the time of the invention would have known that barium sulfate is toxic, and would have looked to encapsulate barium sulfate in order to ensure that it would not leach out of an implant especially when the implant is intended for long-term use in the body.

Given that barium sulfate leaching is a known problem, we find that Petitioner has not provided a sufficient reason that would have prompted a person of ordinary skill in the art to consider adding barium sulfate to any of the De Nijs devices, let alone the device having open ends. Petitioner does not explain how to successfully combine De Nijs and Schopflin to ensure that the known leaching issue of barium sulfate is controlled. Pet. 46 (citing Ex. 1002 ¶ 116). We agree with Patent Owner that Petitioner has not established by a preponderance of evidence that, given the knowledge that

barium sulfate is toxic and is known to leach out of polymer matrices, a skilled artisan would have contemplated using barium sulfate as the marker in a long term implantable device. Here, the weight of the evidence is such that one of skill would have known to encapsulate any barium sulfate in order to prevent any toxic side effects. We, therefore, agree with Patent Owner, on this record, that a skilled artisan would not have selected barium sulfate as the marker in De Nijs's open-ended devices.

Accordingly, we determine that Petitioner has not shown by a preponderance of the evidence that a person of ordinary skill in the art would have had a reason to combine Schopflin and De Nijs to arrive at an implantable device containing barium sulfate as the marker.

C. Reasonable Expectation of Success

Petitioner asserts that a person of ordinary skill in the art would have had a reasonable expectation that the teachings of De Nijs and Schopflin is could be successfully combined because they both disclose implants that heavily overlap. Pet. 46 (citing Ex. 1002 ¶ 116 ("Given the substantial overlap, a POSA would have an expectation that these references could be successfully combined" to create a radiopaque device.). Petitioner proposes that a POSA would have retained the polymer of De Nijs and added the barium sulfate marker of Schopflin to arrive at the claimed implants. Pet. 52, 57.

Patent Owner argues that "[m]erely showing references "overlap" [as suggested by Petitioner (Pet. 46)] does not show it would have been obvious to combine the references." PO Resp. 56 (citing *Securus Techs., Inc. v. Glob. Tel*Link Corp.*, 701 F. App'x 971, 977 (Fed. Cir. 2017); *Leo Pharma. Prods. Ltd. v. Rea,* 726 F.3d 1346, 1356 (Fed. Cir. 2013); *In re*

Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063, 1070 (Fed. Cir. 2012)).

The parties dispute, thus, centers on whether Petitioner has established by a preponderance of the evidence that a person of ordinary skill in the art would have had a reasonable expectation of success in adding the barium sulfate marker component disclosed in Schopflin into the open ended drug carrying matrix disclosed in De Nijs.

Patent Owner asserts that a person of ordinary skill in the art "would have concerns about leakage [of barium sulfate] out of the unsealed ends in an undesired amount, potentially resulting in adverse effects." PO Response 60 (citing Ex. 2142, 81:7–16, 83:2–5). Patent Owner asserts that adding barium sulfate to De Nijs's open-ended implant would lead a person of ordinary skill in the art to understand that barium sulfate release (leakage) would follow the same pattern of release as that of the drug incorporated into De Nijs's core. PO Resp. 60–61 (citing 2147 ¶ 276). Patent Owner argues that the De Nijs implant with open ends releases the drug in a burst through the open end and one would expect any other material in the implant to similarly be released. *See* PO Resp. 16 ("the ***open ends*** release a drug burst much more rapidly than the membrane [covered section], suggesting anything in the core could be rapidly released (and result in high local concentrations of the released material" (citing Ex. 2147 ¶ 82)).

Patent Owner argues that around 2000 a person of ordinary skill in the art would have had concerns about leakage of material from an implant, especially material that is toxic. PO Resp. 60 (citing Ex. 2002 1:54–58 Petitioner's expert, Dr. Langer, generally agrees. Ex. 2142, 81:14–16. Patent Owner's expert, Dr. Kiser also agrees that barium sulfate has low

solubility, but low solubility does not mean no solubility. *See* Ex. 1054, 133:5–7 ("But by toxicity it's a huge worry that any barium sulfate could -- because it does have a nonzero solubility; it's not completely insoluble."); Ex. 1055, 457:18–21 ("I would agree that barium salt -- barium sulfate is -- is quite insoluble. I don't -- but that doesn't mean that it has zero solubility."). Moreover, there is additional evidence to support the position that it was known in 2000 that barium salt is toxic. Ex. 2130, 2:13–15 ("The [barium] salt gradually leached out of the matrix causing discoloration of the polymer and release of heavy metal toxins"); Ex. 2143, 1:30–33 ("There are several disadvantages with the current methods [such as compounding materials like barium sulfate into an object for the purpose] of rendering objects radio-opaque. In particular, medical devices treated with the current methods have low bio compatibility and may be toxic to tissues.")). Patent Owner contends that a person of ordinary skill in the art would not have added barium marker with a drug and mixed it with a material core because there would be an expectation that the core not only release the drug but would also release the barium marker at the same time. PO Resp. 53 (citing Ex. 2147 ¶ 262).

Petitioner contends that both experts agree that barium sulfate is an ionic compound. Pet. Reply. 16 (citing Ex. 2142, 78:13-22; 151:4-23; 174:22-175:8; Ex. 1054, 131:16-22; Ex. 1055, 457:15-21). Petitioner's expert, Dr. Langer, testified that barium sulfate would bind tightly to the EVA. Pet. Reply 16; Tr. 34:18–19 (referring to Ex. 2142 at 78 13–22 ("Q. And in your view, the barium sulfate wouldn't migrate through that EVA out any open ends of a De Nijs-like implant? A. It's hard for me to see how one of ordinary skill would think that. I mean, you know, in contrast, to say, a

progesterone, which might. I mean, you know -- but in other words, this is an ionic compound, so I wouldn't expect it to migrate now. I wouldn't expect one of ordinary skill to think it would migraine [sic]."), 151:12–13 ("I wouldn't expect it [i.e. barium sulfate] to come out if it's De Nijs [matrix]."), 174:22–175: ("one of ordinary skill in the art would have the expectation that because of its low solubility -- you know, now it's embedded in ethylene-vinyl acetate – that's one of the parameters that I mentioned, would be key to -- you know, like if it was high solubility, then it might come out faster. With low solubility, I'd expect it to come out very slowly, if at all.")).

We find that there is insufficient evidentiary support for Petitioner's position that around 2000 it was known that barium sulfate binds tightly to EVA. *See* Pet. Reply 16 (citing Ex. 2142, 78: 151:12–13 ("I wouldn't expect it [i.e. barium sulfate] to come out if it's De Nijs [matrix]."") Dr. Langer does not explain how the barium sulfate binds tightly to the EVA, or why based on barium sulfate's low solubility a person of ordinary skill in the art would not expect barium sulfate to be released when combined with EVA. Dr. Langer's opinion is that "there's no such thing as a toxic substance, just toxic amounts of substances." Ex. 2142, 173:6–8. Dr. Langer, however, does not provide any evidence that barium sulfate in the concentration contemplated by Schopflin would be a non-toxic amount if any or all of it leaches out of the implant. One's expertise, even when draped with a skilled-artisan veil, does not entitle a naked opinion to much weight. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) ("Lack of factual support for expert opinion going

to factual determinations" is sufficient to "render the testimony of little probative value in a validity determination.").

Because barium sulfate was known to be toxic and leaching of the material from devices was a concern to an ordinary artisan at the time the invention was made, we are not persuaded that Petitioner has shown a person of ordinary skill in the art to have a reasonable expectation of successfully combining De Nijs and Schopflin. *See* Ex. 2131, ¶¶ 10 (barium is toxic if "not sufficiently encapsulated"), 27 (warning barium sulfate, "which has a toxic effect" must be coated to prevent "being released in the body of a patient."); Ex. 2147 ¶¶ 157, 219, 276; *see* PO Resp. 61. We credit the testimony of Patent Owner's expert, Dr. Kiser, who testified that

> toxicity [of barium sulfate] it's a huge worry that any barium sulfate could -- because it does have a nonzero solubility; it's not completely insoluble. And any barium sulfate leaching out of that implant for the types of durations that we're looking at here could be -- could be a real cause of -- of concern for, you know, anyone designing an implant.

Ex. 1054, at 133:5–12.

When balancing Patent Owner's unrebutted evidence showing that leaching of barium sulfate was a known concern with other medical implants (*see* PO Sur Reply 15 (citing Ex. 2142, 81:7–16, 83:2–5; Ex 2130, 2:15–15; Ex 2143, 1:30–33; Ex. 2147, ¶¶ 49, 275)) against Petitioner's unsupported position that barium sulfate binds EVA tightly, we find that the weight of the evidence does not support Petitioner's assertion that a person of ordinary skill in the art would have had a reasonable expectation of success in combining De Nijs and Schopflin to achieve the claimed invention.

We conclude that Petitioner does not demonstrate, by a preponderance of the evidence, that independent claim 1 is obvious over De Nijs and Schopflin. Petitioner's analysis with respect to independent claims 17 and 20 as well as dependent claims 2–4, 10, 14, and 16 suffers from the same defects as those set out for claim 1. Accordingly, we conclude that Petitioner does not demonstrate, by a preponderance of the evidence, that claims 1–4, 10, 14, 16, 17, and 20 of the '835 patent are obvious over De Nijs and Schopflin.

G. Ground 4. Obviousness over De Nijs, Schopflin, and Brem

Petitioner asserts that the combination of De Nijs and Schopflin teaches all the limitations of claims 1–4, 9–12, 14, 16, 17, and 20. Pet. 58. Petitioner relies on Brem for teaching diffusion of a therapeutic compound through the micropore lattice of the EVA polymer. *Id.* (citing Ex. 1002 ¶¶ 147–157). Petitioner asserts that one of ordinary skill in the art would have been motivated to combine the teachings of Brem in order to achieve greater control of the release rate of the drug from EVA implants taught by De Nijs. *Id.* at 60 (citing Ex. 1002 ¶ 150).

Patent Owner makes the same arguments as addressed above in Ground 3. PO Resp. 62–65. For the same reasons discussed above (II.F.3.B (Ground 3)), we have determined that Petitioner has not shown by a preponderance of the evidence claims 14 and 20 are unpatentable as obvious over De Nijs and Schopflin. Because Brem does not cure the deficiencies of De Nijs and Schopflin, we determine Petitioner has not shown by a preponderance of the evidence that claims 1–4, 9–12, 14, 16, 17, and 20 are unpatentable as obvious over De Nijs, Schopflin, and Brem, either.

III. CONCLUSION

We conclude that Petitioner has not demonstrated that claims 1–4, 9–12, and 14–20 of the '835 patent are unpatentable.

IV. PETITIONER'S MOTION TO EXCLUDE

The party moving to exclude evidence bears the burden of proving that it is entitled to the relief requested—namely, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence ("FRE"). *See* 37 C.F.R. §§ 42.20(c), 42.62(a).

Petitioner moves to exclude a number of exhibits for various reasons. First, Petitioner asserts certain exhibits and testimony should be excluded as irrelevant because they have not been discussed in any substantive paper. Paper 36, 2–4. But, as Patent Owner notes, Dr. Kiser cited the objected-to exhibits in his declarations to show his understanding of the state of the art. Paper 38, 3. Moreover, we agree with Patent Owner that the uncited portions of Dr. Kiser's declarations include paragraphs of technical and legal background that provide context for his opinions. *Id.* at 5. We agree with Patent Owner that Dr. Kiser's understanding of the state of the art and the exhibits supporting that understanding are relevant to the understanding of persons of ordinary skill in the art. *Id.* at 3–5. Accordingly, we deny Petitioner's motion to exclude such testimony and exhibits.

Petitioner also moves to exclude exhibits related to the prosecution history of Merck's unrelated, later-filed patent as irrelevant and prejudicial. Paper 36, 4–5. Petitioner asserts the exhibits should be excluded because Patent Owner's estoppel argument is meritless. *Id.* We are not persuaded. Petitioner's assertion goes to the weight of Patent Owner's estoppel

argument, and not to the admissibility of the challenged exhibits. Although we ultimately rejected Patent Owner's estoppel argument, the exhibits are relevant to the issues in this proceeding. Accordingly, we deny Petitioner's motion to exclude Exhibits 2002, 2003, 2020, 2062–2064, and 2070.

Petitioner also moves to exclude Dr. Kiser's testimony as irrelevant and prejudicial and not related to his area of expertise. Paper 36, 6–8. Specifically, Petitioner asserts that it was improper for Dr. Kiser to discuss the prosecution history of the '037 patent, the alleged bias of Dr. Langer, the post-priority activities of Merck in marketing Implanon and Nexplanon products, the Zamora priority issue, and Patent Owner's Amended Complaint. *Id.* We are not persuaded that any of the objected-to testimony is irrelevant or prejudicial to Petitioner. Regardless, we do not rely on the majority of the objected-to paragraphs of Dr. Kiser's testimony in making our decision here. To the extent we rely on Dr. Kiser's testimony regarding the Zamora priority issue (i.e., Ex. 2147 ¶¶ 88–97), we rely on these exhibits with respect to factual issues relating to understanding the art and not legal issues.

Finally, Petitioner moves to exclude various exhibits as irrelevant evidence that post-dates the filing date of the '835 patent and as hearsay. Paper 36, 8–13. Of the objected-to exhibits (Exs. 2005, 2010–2012, 2057, 2065, 2074, 2093, 2106, 2117, 2131, 2143, and 2145), we have only relied on Exhibits 2131 and 2143. Petitioner's motion with respect to the other exhibits is, therefore, dismissed as moot.

Regarding Exhibits 2131 and 2143, both exhibits relate to the safety of barium sulfate. Exhibit 2131 is a U.S. Patent Application Publication No. 2003/0010929 A1, which was filed January 8, 2001, from a foreign

application that was filed January 31, 2000. Ex. 2131, [22], [30]. Exhibit 2143 is U.S. Patent No. 6,599,448 B1, which was filed May 10, 2000. Ex. 2143, [22]. Thus, Exhibits 2131 and 2143 are prior art to the '835 patent, whose earliest effective filing date is November 2000. Petitioner objects to both Exhibits 2131 and 2143 as hearsay, arguing Patent Owner is offering the exhibits for their truth that barium is toxic. Paper 36, 12. Patent Owner argues it is properly offering the exhibits to support Dr. Kiser's opinions about the understanding of an ordinary artisan, and not for the truth of the matter asserted. Paper 38, 13. Specifically, Patent Owner argues it offers Exhibit 2131 to show a person of ordinary skill in the art's understanding of the dangers associated with leaching barium sulfate, and Exhibit 2143 to show their understanding of the potential adverse effects of barium sulfate. *Id.* We agree with Patent Owner that the exhibits are not being offered for their truth, but as a reflection of what a person of ordinary skill in the art understood at the time of the invention. Thus, we deny Petitioner's motion to exclude as to those exhibits.

V. ORDER

In consideration of the foregoing, it is hereby

ORDERED that on the record before us, Petitioner has not shown by a preponderance of the evidence that claims 1–4, 9–12, and 14–20 of the '835 patent are unpatentable.

FURTHER ORDERED that Petitioner's Motion to Exclude is *denied* with regard to Exhibits 2002, 2003, 2009, 2013–25, 2029, 2030, 2032, 2033, 2035, 2036, 2038–50, 2052, 2054, 2057, 2059–65, 2068–70, 2075, 2084–92, 2094, 2097, 2109–13, 2131, 2143, 2148, as well as designated portions of

Exhibit 2147, and are *dismissed* as *moot* with regard to Exhibits 2005, 2010–2012, 2057, 2065, 2074, 2093, 2106, 2117, and 2145;

FURTHER ORDERED that this is a Final Written Decision. Parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. §90.2.

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