NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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**MERCK SHARP & DOHME CORP., MERCK SHARP & DOHME B.V., ORGANON USA, INC.,**
*Appellants*

**v.**

**MICROSPHERIX LLC,**
*Appellee*

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2019-2197, 2019-2200, 2019-2208

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Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2018-00393, IPR2018-00402, IPR2018-00602.

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Decided: June 9, 2020

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

LOURIE, *Circuit Judge*.

Merck appeals from three decisions of the United States Patent and Trademark Office's Patent Trial and Appeal Board ("the Board") in three *inter partes* reviews that Merck Sharp & Dohme Corp., Merck Sharp & Dohme B.V., and Organon USA, Inc. (collectively "Merck") failed to establish by a preponderance of the evidence that claims 1–5 and 9–25 of U.S. Patent 9,636,401 ("the '401 patent"), claims 1–19 of U.S. Patent 9,636,402 ("the '402 patent"), and claims 1–4, 9–12, and 14–20 of U.S. Patent 8,821,835 ("the '835 patent") are unpatentable. *Merck Sharp & Dohme Corp. v. Microspherix LLC*, IPR No. 2019-00402, (P.T.A.B. July 8, 2019) ("*401 Decision*"); *Merck Sharp & Dohme Corp. v. Microspherix LLC*, IPR No. 2019-00393, 2019 WL 2932663 (P.T.A.B. July 8, 2019) ("*402 Decision*"); *Merck Sharp & Dohme Corp. v. Microspherix LLC*, IPR No. 2018-00602, 2019 WL 2932664 (P.T.A.B. July 8, 2019) ("*835 Decision*"). Because the Board's decisions are supported by substantial evidence, *we affirm*.

## BACKGROUND

Microspherix LLC ("Microspherix") owns the '401, '402, and '835 patents, which are directed to implantable devices that deliver therapeutics and have a radiopaque marker for detecting the device's position after insertion. The claimed devices are small strands, open on both ends with a drug contained in the hollow interior. Claim 1 of the '401 patent is illustrative:

> 1. A flexible non-radioactive strand for implantation into a subject, comprising:

> a marker component configured to allow for the determination of the position of the strand 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; a biocompatible component; and
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> a therapeutic, prophylactic, and/or diagnostic agent, wherein the marker, biocompatible component and agent are disposed within the hollow interior;
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> wherein the length of the marker component is greater than the diameter of the hollow interior, and
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> wherein the substantially continuous wall includes at least one opening adapted to allow the agent to pass out of the hollow interior wherein the strand do not contain a radioisotope.

'401 patent col. 25 ll. 2–19.

Merck manufactures and markets Nexplanon®, an implantable contraceptive containing progestin and marked by a radiopaque medium. Microspherix sued Merck in the United States District Court for the District of New Jersey, alleging that Merck's product infringes the '401, '402, and '835 patents. Amended Complaint, *Microspherix LLC v. Merck Sharp & Dohme Corp.*, No. 2:17-cv-03984-CCC-MF (D.N.J. Oct. 18, 2017), ECF No. 27. Merck then filed the instant petitions for *inter partes* review.

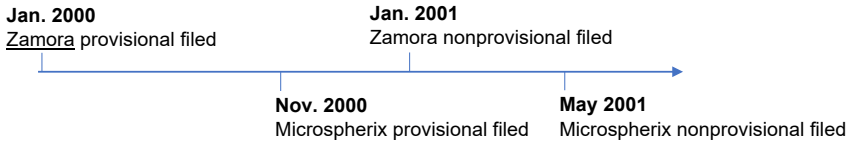
Merck relied on four U.S. patents as references in the proceedings: (1) U.S. Patent 5,150,718 ("de Nijs"), which discloses contraceptive implants; (2) U.S. Patent 4,012,497 ("Schopflin"), which teaches using barium sulfate as a

radiopaque marker; (3) U.S. Patent 6,575,888 ("Zamora"), which discloses bioabsorbable brachytherapy devices for treating cancers; and (4) U.S. Patent 5,626,862 ("Brem"), which discloses delivery of chemotherapy drugs using surgically implantable discs deposited near tumors. In three decisions, the Board upheld all claims of the three patents except for claims 1–5, 7, 8, 10–19 of the '402 patent.

There are two aspects of the Board's decisions that are relevant in this appeal. First, the Board rejected Merck's argument that a skilled artisan would have combined de Nijs and Schopflin. According to the Board, a skilled artisan would not have been motivated to combine the barium sulfate marker taught in Schopflin with the open-ended tube in de Nijs because barium sulfate was known to be toxic and could leach out.

Second, the Board rejected Merck's argument that the challenged claims would have been anticipated or obvious over Zamora alone or in combination with other references. Acceptance of Merck's Zamora-based arguments required acceptance of Merck's arguments regarding Zamora and the Microspherix's patents' priority dates. Zamora claims priority from U.S. Provisional App. 60/178,083 ("Zamora provisional"), which was filed in January 2000. The nonprovisional application issued as Zamora was filed in January 2001. All three Microspherix patents claim priority from U.S. Provisional App. 60/249,128 ("Microspherix provisional"), which was filed in November 2000. The earliest nonprovisional application in the Microspherix patents' priority chain was filed in May 2001.

A timeline may be instructive.



Based on this timeline, if the Microspherix patents cannot claim priority from the Microspherix provisional, Zamora would qualify as 35 U.S.C. § 102(e) (2006) prior art. Additionally, Zamora would still be prior art to Microspherix's patents if it was entitled to the date of the Zamora provisional. The Board found that neither is the case here.

Merck argued that the Microspherix patents were not entitled to the date of the Microspherix provisional application and that Zamora was entitled to the date of the Zamora provisional, but the Board rejected both arguments. The Board found that 37 of the 39 claims at issue in these appeals were supported by the Microspherix provisional. For the two unsupported claims, claims 2 and 3 of the '401 patent, the Board found on the merits that Zamora and Bren failed to disclose open-ended devices because Zamora teaches a device with closed ends, and Bren teaches a tube without specifying whether the ends are open or closed.

The Board also found that the Zamora provisional failed to provide written description support for Zamora's claim 1. Claim 1 of Zamora recites that a "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." Zamora col. 14 ll. 19–22. According to the Board, the Zamora provisional did not disclose coating a radiopaque material on the external surface of the tube, and therefore Zamora was not entitled to the date of its provisional.

Merck appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141(c).

## DISCUSSION

We review the Board's legal determinations *de novo*, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), and its fact findings for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the

evidence as sufficient to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

Obviousness is a question of law, supported by underlying fact questions. *In re Baxter Int'l, Inc.* 678 F.3d 1357, 1361 (Fed. Cir. 2012). In evaluating obviousness, we consider the scope and content of the prior art, differences between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, and any relevant secondary considerations. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17–18 (1966).

Merck argues that two of the Board's determinations lacked substantial evidence: (1) the Board's determination that the claims would not have been obvious over the combination of de Nijs and Schopflin and (2) the Board's determination that Zamora was not prior art to the challenged claims. We address each issue in turn.

First, Merck argues that the Board erred in holding that the challenged claims would not have been obvious in view of De Nijs and Schopflin. Specifically, Merck contests the Board's finding that a skilled artisan would not have been motivated to use barium sulfate with an open-ended implant because of toxicity concerns. According to Merck, the Board improperly required that the radiopaque marker used in the device be nontoxic because the claims do not require nontoxicity. Even if toxicity were relevant, Merck submits that the Board's findings lack substantial evidence and urges us to adopt and credit its view of the facts.

We disagree with Merck. The Board's finding that a skilled artisan would not have been motivated to combine Schopflin's barium sulfate, a known toxic radiopaque marker, with de Nijs's open-ended implant is supported by substantial evidence. Specifically, several references in the record teach that barium sulfate leaching was a known problem in the art. *See, e.g.*, U.S. Patent 4,866,132 col. 2 ll. 8–15 (explaining that inorganic barium salts "gradually leached out of the matrix causing discoloration of the

polymer and release of heavy metal toxins"); U.S. Patent App. 2003/0010929 ¶ [0010] ("Barium sul[f]ate is to be considered as critical for use in a long-term implant, because of the toxicity of barium ions, if it is not sufficiently encapsulated."). Although the claims do not require that the implant be nontoxic, the Board was permitted to consider the known problem of barium leaching in evaluating whether a person of skill in the art would have been motivated to combine barium sulfate with an open-ended implant. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1368 (Fed. Cir. 2016).

Merck also argues that the Board erred in its analysis of Zamora in relation to Microspherix's patents. For a subset of claims, Merck argues that Microspherix's patents are not entitled to the date of Microspherix provisional application because the provisional does not reasonably convey to a skilled artisan that the inventor had possession of an implantable unitary seed or strand that could be longer than 10 mm.[1] For claims 10–15 of the '402 patent, Merck argues that the provisional did not disclose a strand with a biocompatible component comprising a non-biodegradable polymer, and for claims 1–19 of the '402 patent, Merck argues that the provisional failed to disclose a polymeric coating on a non-radioactive strand. Merck also contends that the Zamora reference is entitled to the filing date of its provisional.

We disagree with Merck here as well. Microspherix's claims are entitled to the priority date of the Microspherix provisional if the provisional meets the requirements of

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[1] Merck's strand-length arguments concern claims 1, 3, 4, 9–12, 15–19 of the '835 patent, claims 1, 4, 5, 9–25 of the '401 patent, and claims 1–6, 9, 10, 13, 16, 17 of the '402 patent. Appellants' Br. 43.

35 U.S.C. § 112 ¶ 1. 35 U.S.C. § 119(e)(1) (2006).[2] Written description is adequate if "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 Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562–63 (Fed. Cir. 1991)).

Merck faults the Microspherix provisional for failing to disclose strands of greater than 10 mm, but while there are claims in the Microspherix patents that recite discrete strand lengths, Merck has not challenged those claims as unsupported by the provisional. Instead, Merck has challenged claims without a strand length limitation, and substantial evidence supports the Board's decision that the claims without explicit strand or seed length requirements are supported by the provisional. The provisional discloses seeds and strands of 2–10 mm with certain needles and 4–6 mm with other needles and the use of a plurality of spacers of between 0.5 mm and 50 mm in length. Microspherix provisional col. 5 ll. 3–17. This description adequately supports the claimed strand recited in Microspherix's patent claims.

As for Merck's argument about the provisional's failure to describe a biocompatible component comprising a non-biodegradable polymer, no claim at issue in this appeal recites this limitation, and claims 10–15 of the '402 patent, which do recite the limitation, were ruled invalid on other grounds. Even if Merck were correct that these claims are

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[2] The application that led to the Microspherix patents was filed before March 16, 2013, and the pre-Leahy–Smith America Invents Act, Pub L. No. 112-29, 125 Stat. 284 (2011), version of § 112 applies.

unsupported by the provisional, they have already been held invalid, and this court can provide no additional relief.

Finally, the polymeric coating argument for claims 6 and 9 of the '402 patent was not raised before the Board during the proceedings, and Merck is challenging a finding made only in the institution decision. We need not address Merck's argument because our review of Board proceedings does not include review of the merits of the institution decision. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2141 (2016). Having considered Merck's arguments regarding the Microspherix provisional, we conclude that the Board's decision is correct.

Next, we consider whether Zamora is entitled to the filing date of the Zamora provisional. "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 [the written description requirement]." *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1381 (Fed. Cir. 2015) (citing *In re Wertheim*, 646 F.2d 527, 537 (CCPA 1981)). On this record, we are not persuaded that Zamora is supported by its provisional. Zamora's claim 1 explicitly recites three options for radiopaque medium placement: on at least a portion of the external surface of the tube, within at least a portion of the structure of the tube, or within the radioactive material. Zamora col. 14 ll. 19–22. The first option—locating the radiopaque medium on the external surface of the tube—is absent from the provisional. While the Zamora provisional describes admixing the radiopaque material into the complex, Zamora provisional at 5, that disclosure falls short of teaching coating the external surface of the tube.

## CONCLUSION

We have considered the parties' remaining arguments but find them unpersuasive. Accordingly, the decisions of the Board are affirmed.

**AFFIRMED**