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Paper 9
Entered: July 15, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OCULAR THERAPEUTIX,
Petitioner,

v.

MATI THERAPEUTICS, INC.,
Patent Owner.

Case IPR2019-00442
Patent 9,463,114 B2

Before ERICA A. FRANKLIN, J. JOHN LEE, and RYAN H. FLAX, *Administrative Patent Judges*.

LEE, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

INTRODUCTION

Ocular Therapeutix ("Petitioner") filed a Petition (Paper 8, "Pet.")[1] requesting an *inter partes* review of claims 1, 3, 5–8, 10, and 12–14 ("the challenged claims") of U.S. Patent No. 9,463,114 B2 (Ex. 1001, "the '114 Patent"). Mati Therapeutics, Inc. ("Patent Owner") timely filed a Preliminary Response (Paper 7, "Prelim. Resp.").

We have authority to institute an *inter partes* review only if the information presented in the Petition shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon consideration of the Petition and the Preliminary Response, we conclude the information presented fails to show a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of the challenged claims. Accordingly, the Petition is denied.

A. Related Cases

The parties identify a petition requesting *inter partes* review of U.S. Patent 9,849,082 (IPR2019-00448), which relates to the technology of the '114 Patent, but is not in the same patent family. Pet. 3; Paper 5, 2.

B. The '114 Patent

The '114 Patent relates to punctal plugs that are removably inserted into the punctal apertures of the eye to block the openings and prevent

[1] Petitioner filed the original Petition on December 14, 2018 (Paper 1), and subsequently filed a Corrected Petition on May 13, 2019 (Paper 8), to address a typographical error in the original Petition. All references to "Petition" herein refer to the Corrected Petition (Paper 8).

drainage of lacrimal fluid (tears). Ex. 1001, 1:13–18. In particular, the '114 Patent is directed to a method for administering an active agent in the eye of a subject by implanting a punctal plug to which the active agent is applied. *Id.*, Abstract. Figure 1 of the '114 Patent is reproduced below:

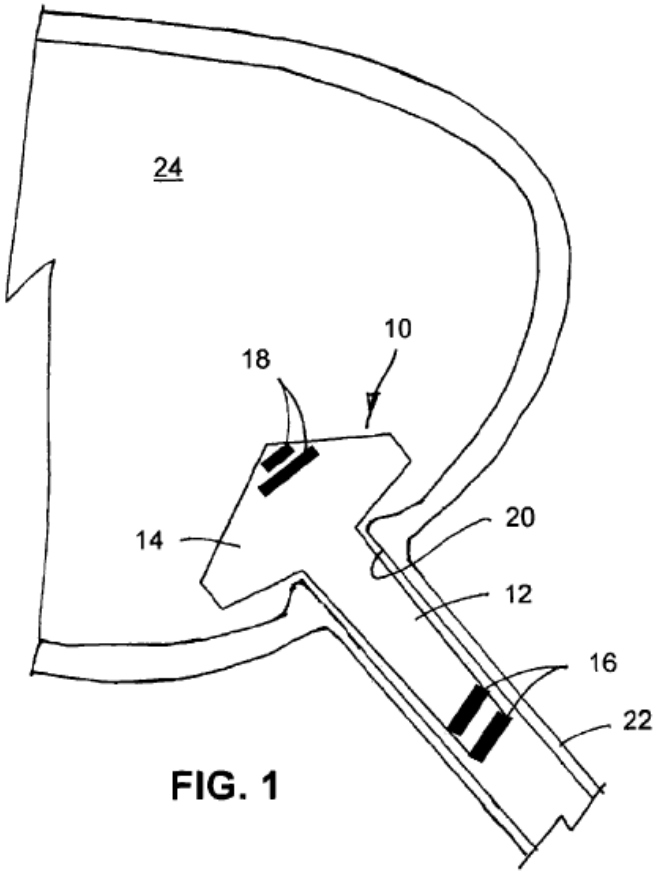

FIG. 1

Figure 1 illustrates punctal plug 10 with stem 12, which has been inserted into punctal aperture 20 of eye 24 to seal canaliculus 22 against the flow of tears onto the surface of eye 24. *Id.* at 1:65–67, 2:7–14. Figure 2 of the '114 Patent is reproduced below:

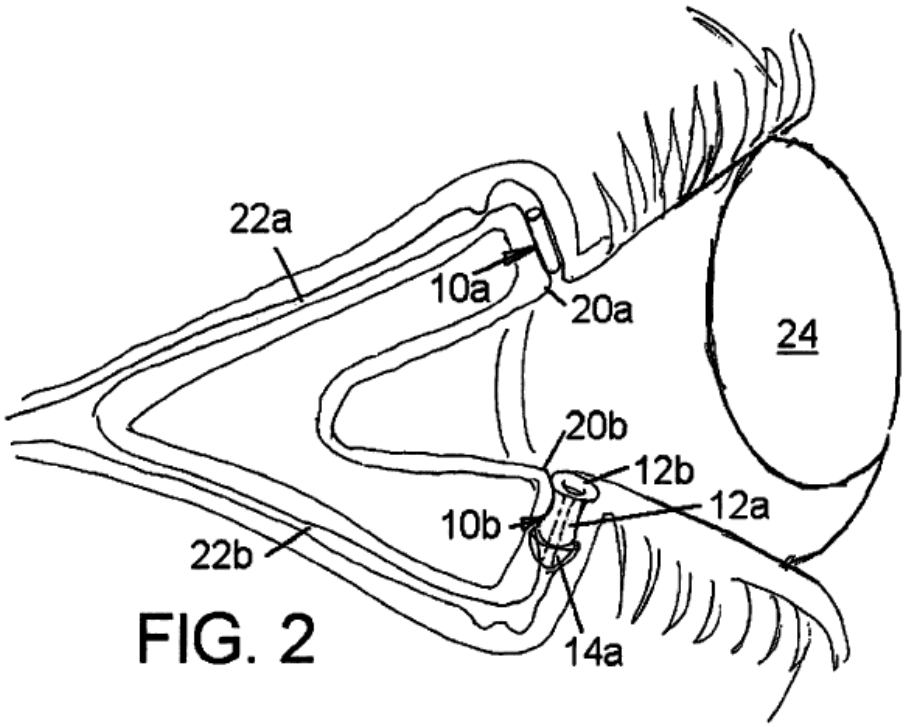

FIG. 2

Figure 2 depicts two versions of plug 10 as implants 10*a* and 10*b*. *Id.* at 2:1–2, 15–18. Implant 10*a* is a substantially-cylindrical solid collagen plug inserted into the upper punctum or tear duct 20*a*. *Id.* at 2:18–20. Implant 10*b*, which is inserted in lower punctum 20*b*, is hollow and includes a tapered stem 12*a* having flared open end 12*b*. *Id.* at 2:22–24. Plug 10 may be made entirely of a porous or absorbent material that is saturated with an active agent. *Id.* at 2:38–40. A "[p]olymer that is absorbent to the agent is preferable so that sufficient [active] agent is present and available for discharge into the surrounding tissues." *Id.* at 2:35–38. Appropriate active agents include a variety of medications for treating conditions, such as glaucoma, corneal infections, chronic diseases, allergic conjunctivitis and rhinitis, and dry eye. *See id.* at 2:51–64, 3:3–8.

C. Challenged Claims

Petitioner challenges claims 1, 3, 5–8, 10, and 12–14 of the '114 Patent. Claims 1, 8, and 14 are the independent claims. Claim 1 is illustrative and is reproduced below:

> 1. A method for administering an active agent to a subject using a punctal plug, the method comprising:
>
> inserting the punctal plug into a punctal aperture of the subject, wherein the composition of the punctal plug comprises:
>
> a) an active agent selected from the group consisting of topical prostaglandin; latanoprost; travoprost; bimatoprost; a medication for treatment of a corneal infection; ciprofloxacin; moxifloxacin; gatifloxacin; a systemic medication; a medication for treating hypertension; atenolol; nifedipine; hydrochlorothiazide; and a medication for treating allergic conjunctivitis, and
>
> b) a porous or absorbent material, and
>
> wherein the shape of the punctal plug consists of a constant diameter cylinder configured to be inserted into a canalicular puncta of the subject.

Ex. 1001, 3:31–47.

D. Asserted Grounds of Unpatentability and Asserted Prior Art

Petitioner challenges the patentability of claims 1, 3, 5–8, 10, and 12–14 of the '114 Patent on the following grounds (Pet. 27–28):

Reference(s)	Basis	Claims Challenged
Schmitt[2]	§ 102(b)	1, 3, 6–8, 10, 13
Schmitt and Higuchi[3]	§ 103(a)	1, 3, 6–8, 10, 13, 14
Schmitt and PDR[4]	§ 103(a)	1, 3, 6–8, 10, 13, 14
Schmitt and Cagle[5]	§ 103(a)	1, 3, 5–8, 10, 12–14[6]

In addition, Petitioner relies on the Declaration of Dr. Reza Dana (Ex. 1002) in support of the asserted grounds of unpatentability.

ANALYSIS

A. Claim Construction

As the original Petition was filed on December 14, 2018, we apply the claim construction standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). *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). Under the *Phillips* standard, claim terms must be given "the meaning that the term would have to a

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[2] U.S. Patent No. 5,469,867, issued Nov. 28, 1995 (Ex. 1004, "Schmitt").

[3] U.S. Patent No. 3,993,071, issued Nov. 23, 1976 (Ex. 1005, "Higuchi").

[4] PHYSICIAN'S DESK REFERENCE FOR OPHTHALMIC MEDICINES (Douglas J. Rhee et al. eds., 31st ed. 2003) (Ex. 1006, "PDR").

[5] U.S. Patent No. 6,509,327 B1, issued Jan. 21, 2003 (Ex. 1007, "Cagle").

[6] The Summary of Grounds in the Petition does not include claim 5 (Pet. 28), but the detailed discussion of the ground based on Schmitt and Cagle includes claim 5 (*id.* at 61, 65). Thus, we understand this asserted ground to include claim 5.

person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313.

Petitioner proposes a construction for the term "a medication for treatment of a corneal infection," as recited in claims 1 and 8, and a similar term recited in claims 6 and 13. Pet. 19–22. Patent Owner contends this term does not require express construction. Prelim. Resp. 13–14. We agree with Patent Owner and conclude that no claim terms require express construction for purposes of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

B. The Level of Ordinary Skill in the Art

Petitioner asserts that the "[t]he person of ordinary skill in the relevant art is an ophthalmologist with several years of experience in the design, development, or use of drug delivery devices and/or ocular inserts," relying on Dr. Dana's testimony in support. Pet. 18 (citing Ex. 1002 ¶ 28). Patent Owner disputes Petitioner's proposed level of skill, contending that a person of ordinary skill "is a medical doctor specializing in ophthalmology or a person having a doctorate degree in chemistry having at least 5 years of experience in designing and developing drug delivery ocular inserts." Prelim. Resp. 12–13.

Based on the current record, Patent Owner's contention is supported only by attorney argument. Petitioner's proposed formulation of the level of ordinary skill is supported by record evidence, i.e., Dr. Dana's testimony. Therefore, we accept and use Petitioner's proposed definition of the skilled artisan, taking into account the level of skill in the art reflected in the prior art of record. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Our conclusions in this Decision, however, do not turn on which

party's definition is used, and our determinations would be unchanged if we applied Patent Owner's definition.

C. Alleged Anticipation Under 35 U.S.C. § 102(b)

A claim is anticipated only if each and every element is disclosed and arranged as in the claim, either expressly or inherently, in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008); *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Petitioner contends that claims 1, 3, 6–8, 10, and 13 are unpatentable as anticipated by Schmitt. Pet. 29–42. As explained below, we conclude Petitioner has not demonstrated a reasonable likelihood of prevailing on this asserted ground of unpatentability.

1. Overview of Schmitt

Schmitt relates to medical devices and methods of treatment involving the occlusion of channels in living mammals using thermoplastic polymeric or composite channel occluders formed in situ. *Id.* at 1:6–11, 4:59–61. The thermoplastic polymeric material or composite "exhibits the special characteristic of being a flowable viscous liquid between the average temperature of the site and 50° C[] and a rheologically stable solid at or below the average temperature of the site is used." *Id.* at 4:66–5:2; *see also id.* at 13:65–67 ("[T]he polymers must be designed such that they are solid and non-flowable at body temperature and below."). The polymer is heated to create a flowable material or "preplug," which is loaded into an injecting device. *Id.* at 5:6–8. The flowable material (preplug) is injected into a mammalian channel, such as a canalicular canal, and the material cools and solidifies in place, forming a plug that blocks the channel. *Id.* at 5:16–19, 29–30; *see also id.* at 9:58–61 ("The polymer can be formed into a thin rod

or cylinder and inserted in a channel as it is undergoing a transition to a fluid form but is preferably injected into the channel.").

Figure 2 of Schmitt is reproduced below:

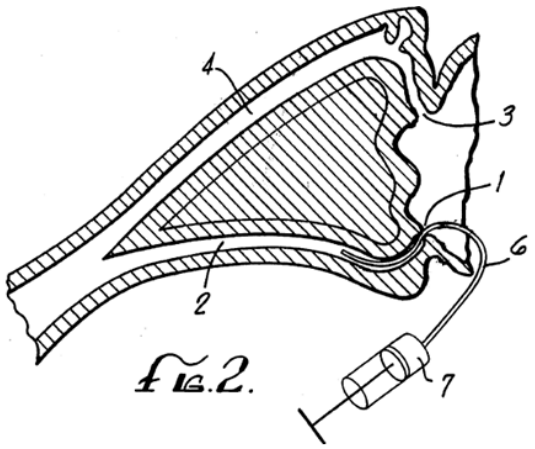

FIG. 2.

Figure 2 of Schmitt depicts injecting device nozzle 6 inserted through lower punctum 1 to inject flowable polymeric material 7 into canalicular canal 2. *Id.* at 6:54–56, 12:10–14. The injected polymeric material fills canalicular canal 2 and solidifies to form a plug that conforms to the size and shape of canalicular canal 2, acting as a blocking dam. *Id.* at 12:15–22.

Figure 3 of Schmitt is reproduced below:

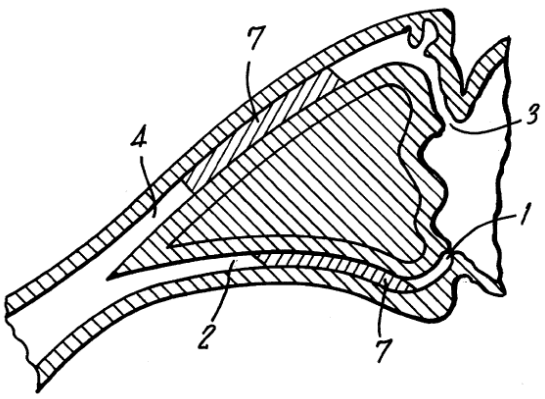

FIG. 3.

Figure 3 of Schmitt depicts plugs of polymeric material 7 that conform to, and block, canalicular channels 2 and 4. *Id.* at 6:58–60, 12:22–24. The

polymer material can be combined with biologically active substances, such as antibiotics, to produce a composite that leaches the biologically active substance from the plug in the channel. *Id.* at 8:34–36.

2. Independent Claims 1 and 8

Claims 1 and 8 recite, "wherein the shape of the punctal plug consists of a constant diameter cylinder configured to be inserted into a canalicular puncta of the subject." Based on the information presented in the Petition, we are not persuaded Petitioner has made an adequate showing that Schmitt discloses this "shape" limitation. Petitioner relies on two aspects of Schmitt as allegedly disclosing the "shape" limitation. *See* Pet. 34–37, 41.

First, Petitioner cites Schmitt's disclosure that "the polymer is 'formed into a thin rod or cylinder and inserted in a channel . . . .'" *Id.* at 34 (quoting Ex. 1004, 9:57–61). Petitioner further cites Schmitt's disclosure that the "'polymeric material may be included within the injecting device in a solid form,'" (*id.* (quoting Ex. 1004, 10:9–11)), and that the injection may be performed using, for example, hypodermic needles or pointed plastic tip applicators (*id.* (citing Ex. 1004, 8:62–64)). Based on Dr. Dana's testimony, Petitioner's contention is that Schmitt discloses including solid polymeric material in an injection device in the form of a rod or cylinder, and injecting it into a canalicular punctum such that the polymer is formed into a constant diameter cylinder by the injection device.[7] *See* Pet. 34, 36–37 (citing Ex. 1002 ¶¶ 78, 83).

[7] To the extent Petitioner also contends that Schmitt discloses injecting solid rods/cylinders already having a constant diameter directly into the canalicular puncta, we are not persuaded because Schmitt explicitly states that the rod/cylinder is inserted "as it is undergoing a transition to a fluid

Second, Petitioner contends Schmitt's disclosures about injecting the polymeric material "ensures that the punctal plug will have a cylindrical shape before and during insertion into the canaliculus," because the polymer would be pushed through a cylindrical tube of a constant diameter. *See* Pet. 34–37 (citing Ex. 1002 ¶¶ 79–83).

Thus, in summary, Petitioner contends Schmitt discloses the shape limitation because (a) it discloses using solid rods or cylinders of polymeric material for eventual injection into the canaliculus; and (b) whether using solid or flowable polymer, the material is injected through a cylindrical device (e.g., tube or needle) that would result in a constant diameter plug. *Id*. We are not persuaded, however, that these aspects of Schmitt disclose the "shape" limitation of claims 1 and 8.

As an initial matter, as Patent Owner notes (Prelim. Resp. 28), Schmitt explicitly distinguishes between a "plug" and a "preplug." A "plug" is expressly defined as "the polymer . . . in its solid form . . . *and in the shape and dimensions of the channel which it fills*." Ex. 1004, 8:43–46 (emphasis added). A "preplug," however, is defined as "the polymer . . . in its fluid form or state . . . and *takes the shape and dimensions of the container or injecting device which holds it*." *Id.* at 8:47–50 (emphasis added). Petitioner's contentions (and Dr. Dana's opinion) focus on the shape and dimensions of Schmitt's polymer before injection, and the shape and dimensions of the injecting device that allegedly causes the polymer to form a constant diameter cylinder—i.e., disclosures relating to a preplug (or,

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form." Ex. 1004, 9:58–61. Additionally, we note that Petitioner does not identify any evidence indicating that the disclosed rods/cylinders have a constant diameter before being used in the injection device.

perhaps, even pre-preplug material), not a plug. *See* Pet. 34–37; Ex. 1002 ¶¶ 79–84. Neither Petitioner nor the cited testimony from Dr. Dana address this distinction or explain why a person of ordinary skill would consider Schmitt's descriptions regarding a "preplug" as disclosing the "plug" recited in claims 1 and 8.

Moreover, we are not persuaded that Schmitt discloses that the polymer to be injected into the channel (i.e., the "preplug") necessarily "consists of a constant diameter cylinder configured to be inserted into a canalicular puncta of the subject" as recited in claim 1. Schmitt discloses that the polymer "can be formed into a thin rod or cylinder and inserted in a channel *as it is undergoing a transition to a fluid form*." Ex. 1004, 9:58–61 (emphasis added). This transition is accomplished, for example, by heating the entire injection device (and polymer within), passing the polymer through a heated catheter as it is injected, or heating the polymer with a laser beam as it is injected. *Id.* at 10:14–23. Thus, whether the polymer is in a solid or flowable form when inserted into the injection device, it is "configured to be inserted" into the canalicular puncta *in flowable form*. Schmitt discloses doing so because the polymer is intended to form a "plug" by taking on the "shape and dimensions of the channel which it fills" (*id.* at 8:43–46) such that "a perfect fit is achieved between the plug and the [channel] wall thus assuring that no passage of any biological fluids or substance will be allowed" (*id.* at 5:58–62). Patent Owner reasonably asserts, and the record indicates, that ordinary artisans would understand that such a plug would *not* be a constant diameter cylinder. *See* Prelim. Resp. 23–25 (citing Ex. 1012, 3:43–65).

We agree with Patent Owner (*id.* at 22–23, 26) that Schmitt's disclosure of a flowable polymer injected into a canalicular punctum to take on the shape and dimensions of the canaliculus does not disclose, expressly or inherently, a plug consisting of a constant diameter cylinder configured to be inserted into a canalicular puncta of the subject. Even to the extent the flowable polymer "preplug" could be said to take on a cylindrical shape temporarily as it is extruded into the canaliculus through a cylindrical tube or needle (*see* Pet. 34–37), Petitioner has not presented sufficient evidence to support a finding that this meets the limitation of a punctal "plug" that "consists of a constant diameter cylinder configured to be inserted into a canalicular puncta of the subject," as recited in claims 1 and 8.

For the above reasons and based on the evidence presented in the Petition, Petitioner has not demonstrated a reasonable likelihood of prevailing on its asserted ground of unpatentability that claims 1 and 8 are anticipated by Schmitt.

3. Dependent Claims 3, 6, 7, 10, and 13

Claims 3, 6, and 7 depend from claim 1, and claims 10 and 13 depend from claim 8; thus, each of these claims recites the same "shape" limitation by virtue of their associated independent claims. As a result, the deficiencies discussed above with respect to the independent claims also indicate Petitioner has not shown a reasonable likelihood of prevailing on its anticipation ground against these dependent claims.

D. Alleged Unpatentability Under § 103(a)

A claim is unpatentable under § 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, i.e., secondary considerations.[8] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Additionally, the obviousness inquiry typically requires an analysis of "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")); *see In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016) (citing *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006)).

Petitioner contends that claims 1, 3, 6–8, 10, 13, and 14 are unpatentable as obvious in view of Schmitt and Higuchi. Pet. 44–53. In addition, Petitioner contends that claims 1, 3, 6–8, 10, 13, and 14 are unpatentable as obvious in view of Schmitt and PDR. *Id.* at 53–61. Finally, Petitioner contends that claims 1, 3, 5–8, 10, and 12–14 are unpatentable as obvious in view of Schmitt and Cagle. *Id.* at 61–69.

In each of the asserted obviousness grounds, Petitioner relies solely on Schmitt as teaching the "shape" limitation—i.e., "wherein the shape of the

[8] Neither party presented any evidence or argument regarding secondary considerations of non-obviousness at this stage of the case. Thus, we do not consider any such considerations in our analysis for this Decision.

punctal plug consists of a constant diameter cylinder configured to be inserted into a canalicular puncta of the subject"—which is recited identically in each of independent claims 1, 8, and 14. *See* Pet. 47, 51–53, 55, 59–61, 63, 67, 69. Further, Petitioner cites and relies on the same arguments as it put forth for anticipation of claim 1 by Schmitt, and presents no additional analysis or evidence for its obviousness grounds with respect to Schmitt as it relates to the "shape" limitation. *See id*. For similar reasons as discussed above with respect to the anticipation ground, we conclude that Petitioner also has not shown sufficiently that Schmitt would have taught or suggested the "shape" limitation to an ordinary artisan. Thus, Petitioner has not demonstrated a reasonable likelihood of prevailing on its obviousness grounds with respect to independent claims 1, 8, and 14, as well as their challenged dependent claims.

E. Denial Under 35 U.S.C. 325(d)

Patent Owner contends that the Petition should be denied as an exercise of the Board's discretion under § 325(d) because substantially the same prior art was previously presented to the Office. Prelim. Resp. 18, 55–56. As explained above, we determine that Petitioner has not shown a reasonable likelihood of prevailing on any of its asserted grounds of unpatentability based on the merits of the substantive arguments and evidence presented in the Petition. Thus, we do not reach the question of whether to exercise our discretion under § 325(d).

CONCLUSION

For the foregoing reasons and on the present record, we determine that the information presented in the Petition does not demonstrate a reasonable

likelihood that Petitioner would prevail in establishing the unpatentability of claims 1, 3, 5–8, 10, and 12–14 of the ’114 Patent.

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* and no trial is instituted.

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