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Paper No. 8
Filed: June 26, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OCULAR THERAPEUTIX, INC.,
Petitioner,

v.

MATI THERAPEUTICS, INC.,
Patent Owner.

Case IPR2019-00448
Patent 9,849,082 B2

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

FLAX, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

Mati Therapeutics, Inc. ("Patent Owner") is the owner of U.S. Patent No. 9,849,082 B2 to Eugene de Juan, Jr. et al. (Ex. 1001, "the '082 patent"). Paper 5, 2. Ocular Therapeutix, Inc. ("Petitioner") filed a Petition requesting *inter partes* review of claims 1–23 of the '082 patent. Paper 3 ("Pet."). Patent Owner, in turn, filed a Preliminary Response. Paper 7 ("Prelim. Resp.").

Under 37 C.F.R. § 42.4(a), we have authority to determine whether to institute an *inter partes* review. We may institute an *inter partes* review if the information presented in the petition filed under 35 U.S.C. § 311, and any response filed under Section 313, shows that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314. After reviewing the parties' submissions, we conclude that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing at least one claim of the '082 patent is unpatentable. Therefore, we institute *inter partes* review of all aforementioned claims on all grounds raised in the petition, pursuant to 35 U.S.C. § 314. *See SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *see also* Guidance on the Impact of SAS on AIA Trial Proceedings (April 26, 2018) (available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial).

I. BACKGROUND

A. RELATED MATTERS

Petitioner has disclosed:

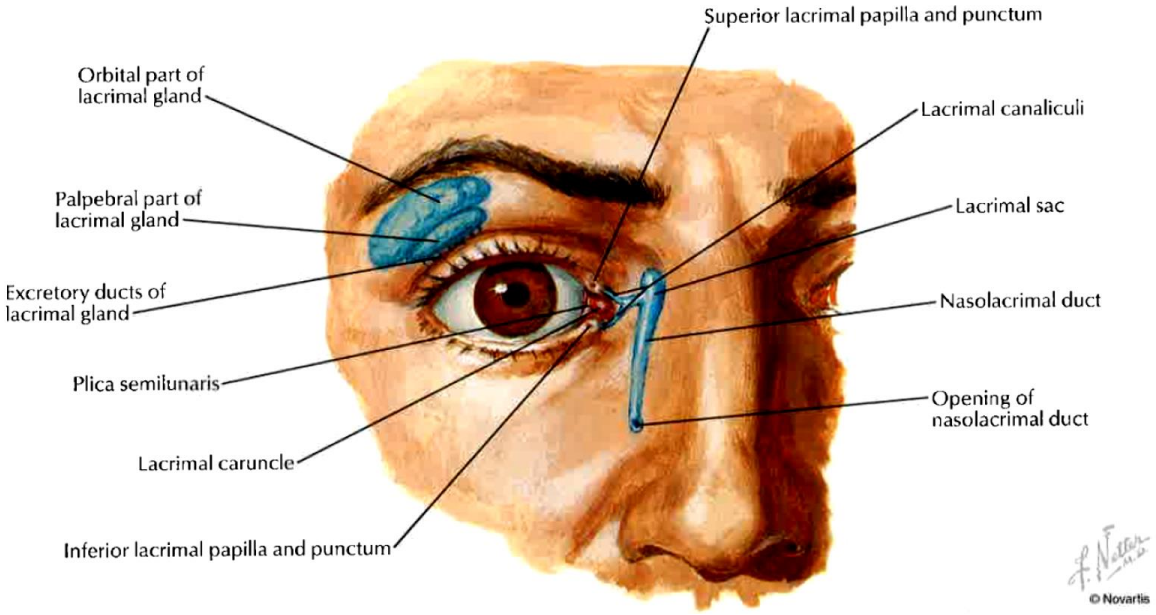
> Ocular is not aware of any pending litigation related to the '082 Patent nor of any requested reissue, reexamination, or review of the '082 Patent. Ocular is, however, aware of a co-pending IPR petition regarding U.S. Pat. No. 9,463,114 [IPR2019-00442], also filed by Ocular against the same Patentee, Mati. The '114 Patent is not related to the '082 Patent but is directed to similar technology.
>
> Ocular is aware of one pending continuation application, U.S. App. No. 15/852,619, that includes the '082 Patent among its priority claims. A non-final office action issued on August 28, 2018, rejecting the pending claims based on grounds similar to the one that the examiner raised against the '082 Patent.

Pet. 4. Patent Owner identifies the same *inter partes* review and '619 application as Petitioner. Paper 5, 2. Patent Owner also identifies U.S. Patent Application No. 16/168,554 as related to the '082 patent. *Id.*

B. THE CLAIMED INVENTION

The invention of the '082 patent relates to "[a]n implant for insertion through a punctum and into a canalicular lumen of a patient." Ex. 1001, Abstract. In the parties' submissions here, such devices are interchangeably called punctal, canalicular, nasolacrimal, ocular, and ophthamalic – plugs, inserts, and implants. *See, e.g.*, Pet. 1, 2, 6–7, 15, 17–18, 20–26, 36–51, 54–57, 62–64; Prelim. Resp. 2–14.

The relevant physiology is illustrated in a figure provided in the Preliminary Response, reproduced below:



Prelim. Resp. 3. Patent Owner's figure above shows (and labels) the physiology of the human eye, including a nasolacrimal duct connected to two openings, called puncta and respectively behind the upper and lower eyelids, via a lacrimal canaliculi duct that branches from the nasolacrimal duct toward the puncta. *See* Prelim. Resp. 3.

This physiology is also illustrated and described in the ’082 patent at Figure 1-1, as shown below:

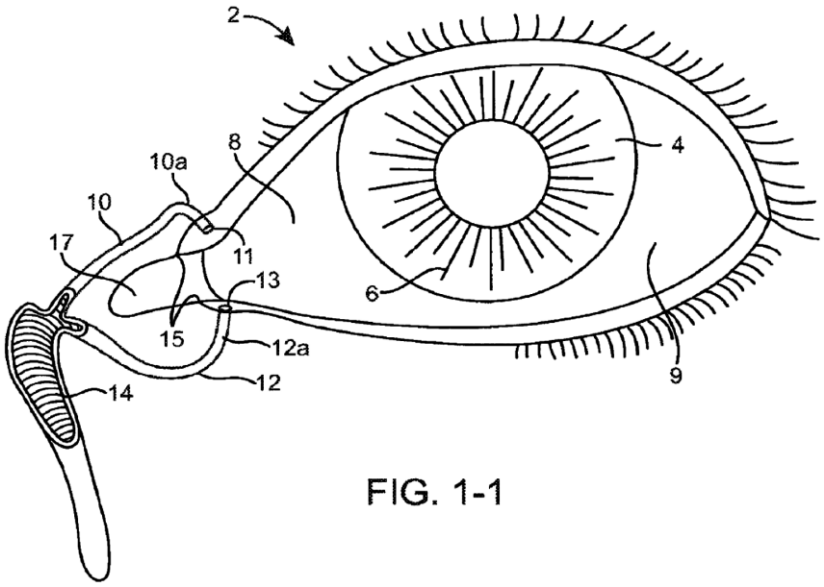


FIG. 1-1

“FIG[]. 1-1 [above] . . . show[s] anatomical tissue structures of an eye 2 suitable for treatment with implants,” where the upper and lower canaliculus are labeled 10 and 12, respectively, and each has a punctal opening labeled 11 and 13, respectively. Ex. 1001, 7:31–65.

An example of an implant for insertion through a punctum and into a canalicular lumen of a patient is illustrated in the ’082 patent at, for example, Figure 1G, reproduced below:

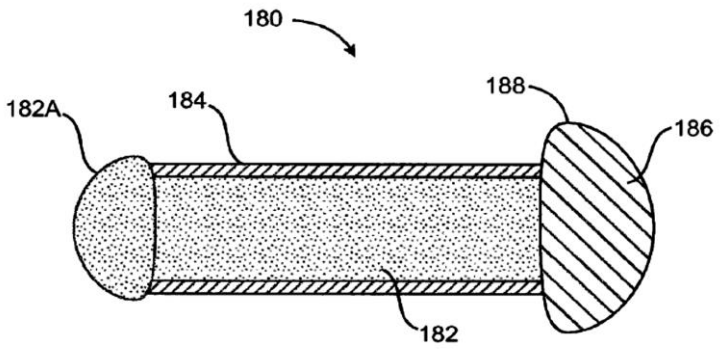


FIG. 1G

Figure 1G schematically illustrates, in cross-section, sustained release implant 180 having core 182 and sheath 184; this embodiment further includes exposed (core) convex surface area 182A to increase release of the therapeutic agent contained within the core, and retention structure 186 that blocks tear flow. *Id.* at 10:11–27.

The claims of the ’082 patent are generally directed to a generic, colored, cylindrical, hydrogel-composed version of such a device for treating certain conditions and/or incorporating certain therapeutic agents.

The '082 patent has 23 claims, of which claims 1, 11, and 18 are independent claims. Independent claim 1 is illustrative and reproduced below:

> 1. A drug delivery system for insertion into a lacrimal canaliculus of a patient, comprising:
>
> a therapeutic agent, a distinguishing color to show placement of the system in the lacrimal canaliculus of the patient and a body of material to hold the therapeutic agent wherein the body of material comprises hydrogel polymers and wherein the body of material is a cylindrical rod.

Id. at 30:20–27. Independent claim 11 is similar, but requires that the body of material "swells when placed in the lacrimal canaliculus." *Id.* at 30:51–67. Independent claim 18 is also similar, but requires that the "therapeutic agent [is] selected from an anti-glaucoma agent, a corticosteroid[,] an anti-microbial agent, and anti-allergy agent[,] or a non-steroidal anti-inflammatory agent." *Id.* at 31:8–17.

C. PETITIONER'S ASSERTED GROUNDS FOR UNPATENTABILITY

Petitioner asserts five (5) grounds for unpatentability, one under 35 U.S.C. § 102 for anticipation and the remaining four under 35 U.S.C. § 103 for obviousness. Pet. 13, 27–69. Petitioner's grounds are as follows:

> **Ground 1**: Claims 1–7, 9–16, 18–20, and 22–23 are anticipated by Pritchard[1] under 35 U.S.C. § 102;

[1] US 2005/0197614 A1 (published Sept. 8, 2005) (Ex. 1010, "Pritchard"); *see also* U.S. Provisional Application No. 60/557,368 (filed Mar. 29, 2004) (Ex. 1012, "Pritchard '368 Provisional") (cited for priority and incorporated by reference by Pritchard at paragraphs 1, 44, 46, 47, 59, 82, 101, 105, 116, 121).

> **Ground 2**: Claims 1–7, 9–16, 18–20, and 22–23 are obvious under 35 U.S.C. § 103 over Pritchard and Gillespie;[2]
>
> **Ground 3**: Claims 8, 17, and 21 are obvious under 35 U.S.C. § 103 over Pritchard, Gillespie, and Hellberg;[3]
>
> **Ground 4**: Claims 1–7, 9–16, 18–20, and 22–23 are obvious under 35 U.S.C. § 103 over Pritchard and Handbook;[4] and
>
> **Ground 5**: Claims 8, 17, and 21 are obvious under 35 U.S.C. § 103 over Pritchard, Handbook, and Hellberg.

Id.

In support of these grounds for unpatentability, Petitioner submitted, *inter alia*, a Declaration of Reza Dana, M.D.[5]

II. DISCUSSION

A. ORDINARY LEVEL OF SKILL IN THE ART

Petitioner contends "[t]he person of ordinary skill in the relevant art is an ophthalmologist with several years of experience in the design, development, and/or study of drug delivery devices and/or ophthalmic inserts." Pet. 26–27 (citing Dana Declaration, Ex. 1036 ¶¶ 23–27).

Patent Owner disputes Petitioner's definition of the skilled artisan because it "does not identify or provide a range of number of years that would meet the 'several years' criterion," and because an ophthalmologist would be unlikely to have experience in the design or development of

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[2] US 2002/0169409 A1 (published Nov. 14, 2002) (Ex. 1015, "Gillespie").
[3] US 6,646,001 B2 (issued Nov. 11, 2003) (Ex. 1017, "Hellberg").
[4] AMERICAN PHARMA ASSOCIATION, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS 146–53 (Arthur H. Kibbe, Ph.D. ed., 3d ed. 2000) (Ex. 1016, "Handbook").
[5] Declaration of Reza Dana, M.D. (Ex. 1036, "Dana Declaration").

relevant devices. Prelim. Resp. 21–22. Patent Owner, therefore, "propose[s] that a POSITA [person of ordinary skill in the art] 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." *Id.* at 22.

The two proposed definitions of the skilled artisan are very similar, except that Patent Owner's description more broadly encompasses a medical doctor specializing in ophthalmology *or* a person having a doctorate degree in chemistry, and more precisely requires the years of experience to be at least five, but without clearly specifying whether both identified persons would have such experience or only the latter.

At this stage of the proceeding, we note that Petitioner's definition of the level of ordinary skill in the art is supported by the Dana Declaration. Therefore, at this stage in the proceeding, 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) ("the prior art itself [may] reflect[] an appropriate level" as evidence of the ordinary level of skill in the art) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)). Our decision whether to institute, however, does not turn on which party's definition is used, and our determinations would be unchanged if we applied Patent Owner's definition. Further, we note that evidence may be presented as the case progresses to support Patent Owner's proposed definition, which may influence our determination of this issue.

B. CLAIM CONSTRUCTION

Based on the filing date of the Petition (Dec. 14, 2018), the Board interprets claim terms in an *inter partes* review ("IPR") using the same claim construction standard that is used to construe claims in a civil action in federal district court. *See* 83 Fed. Reg. 51,340 (Nov. 13, 2018) (to be codified at 37 C.F.R. pt. 42).

In construing claims, district courts give claims their ordinary and customary meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). Sources for claim interpretation include "the words of the claims themselves, the remainder of the specification, the prosecution history [i.e., the intrinsic evidence], and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). "[T]he claims themselves [may] provide substantial guidance as to the meaning of particular claim terms." *Id.* However, the claims "do not stand alone," but are part of "'a fully integrated written instrument,' consisting principally of a specification that concludes with the claims," and, therefore, the claims are "read in view of the specification." *Id.* at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978–79 (Fed. Cir. 1995)).

Petitioner proposes that the claim language "distinguishing color to show" and "sheath body" require interpretation. Pet. 10–12. Patent Owner argues they do not. Prelim. Resp. 22–24.

Regarding "distinguishing color to show," which is recited by every claim of the '082 patent, Petitioner contends, "[i]n the context of claim wording and the specification, a person of ordinary skill in the art would understand that 'distinguishing color to show' means ['a color that improves visibility.'" Pet. 11 (citing Dana Declaration, Ex. 1036 ¶ 51; Ex. 1001, 20:67–21:5).

In response, Patent Owner states:

> The [claimed] phrase, in full context, [is] "a distinguishing color to show placement of the system in the lacrimal canaliculus of the patient" as it appears in the claims, [and] is unambiguous and needs no construction. In other words, what makes a color of the system "distinguishing" is that it "show[s] placement of the system in the lacrimal canaliculus of the patent," as expressly recited by the claim.

Prelim Resp. 22. Patent Owner contends Petitioner's proposed interpretation of the language "renders an unambiguous term ambiguous," and thus argues that "[t]he claim language is clear and would be readily understood by the Board." *Id.*

At this stage of the proceedings, and for the purposes of this decision, we find it unnecessary to construe "distinguishing color to show," because this claim language is readily understandable on its face, within the context of the claims, to a person of ordinary skill in the art.

Regarding "sheath body," which is recited by claim 2 of the '082 patent, Petitioner contends "in the context of the specification of the '082 patent, a person of ordinary skill in the art would understand 'sheath body' to mean a 'material or structure that is impermeable to the therapeutic agent and that covers a portion of a drug core to prevent migration of the

therapeutic agent from the covered portion of the drug core.'" Pet. 12 (citing Dana Declaration, Ex. 1036 ¶¶ 68–70; Ex. 1001, 20:27–34).

Patent Owner, in response, states, "[i]n view of the claim language and the express teachings of the de Juan specification, a POSITA applying the plain and ordinary meaning of the term would fully ascertain proper claim scope. The claim language is clear and would be readily understood by the Board." Prelim. Resp. 24. Therefore, Patent Owner argues no construction is necessary. *Id.*

At this stage in the proceedings, and for the purposes of this decision, we find it unnecessary to construe "sheath body," because this claim language is readily understandable on its face, within the context of the claims, to the person of ordinary skill in the art.

C. Legal Standards for Anticipation and Obviousness

Regarding anticipation, our reviewing court has held:

> a patent is invalid [or unpatentable] as anticipated if "the [claimed] invention was described in" a patent or published application "before the invention by" the patentee. 35 U.S.C. § 102(e). In order to anticipate the claimed invention, a prior art reference must "disclose all elements of the claim within the four corners of the document," and it must "disclose those elements 'arranged as in the claim.'" *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). "However, a reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." *Kennametal*, 780 F.3d at 1381 (alteration in original) (quoting *In re Petering*, 301 F.2d 676, 681 (CCPA 1962)); *see also Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1344 (Fed. Cir. 2016) ("[A] reference may still anticipate

> if that reference teaches that the disclosed components or functionalities may be combined and one of skill in the art would be able to implement the combination." (citing *Kennametal*, 780 F.3d at 1383)).

Microsoft Corp. v. Biscotti, Inc., 878 F.3d 1052, 1068 (Fed. Cir. 2017); *see also Net MoneyIN*, 545 F.3d at 1371 (to anticipate "a reference [must] disclose[] within the four corners of the document . . . all of the limitations claimed [and] also all of the limitations arranged or combined in the same way as recited in the claim"). Put another way, an anticipating reference must clearly and unequivocally disclose the claimed subject matter or direct those skilled in the art to the claimed subject matter without any need for picking, choosing, and combining various disclosures of the reference not directly related to each other by its teachings. *In re Arkley*, 455 F.2d 586, 587–88 (CCPA 1972) ("picking and choosing may be entirely proper in the making of a 103, obviousness rejection, . . . but it has no place in the making of a 102, anticipation rejection."); *see also Purdue Pharma L.P. v. Epic Pharma, LLC*, 881 F.3d 1345, 1358–59 (Fed. Cir. 2016) (distinct, but directly related disclosures of a reference may be combined in an optional, anticipating embodiment, e.g., a controlled-release pharmaceutical formulation specifically disclosed as an embodiment with claimed components *directly relates* to a disclosed list of therapeutic compounds useable therewith).

Regarding obviousness, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* (383 U.S. at 17–18) that are applied in determining whether a claim

is reasonably likely to be unpatentable as obvious under 35 U.S.C. § 103(a) as follows: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) considering objective evidence indicating obviousness or non-obviousness. *KSR*, 550 U.S. at 406. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416. "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.* at 417.

With these standards in mind, we address the challenges below.

D. Grounds 1 and 2—Claims 1–7, 9–16, 18–20, and 22–23 as Anticipated by Pritchard or Obvious over Pritchard and Gillespie

The Parties' Positions

Petitioner contends, "Pritchard expressly discloses all of the limitations recited in Claims 1–7, 9–16, 18–20, and 22–23 of the '082 Patent." Pet. 28 (citing Dana Declaration, Ex. 1036 ¶¶ 46–48). Petitioner identifies Pritchard as directed to the same field as the invention of independent claims 1, 11, and 18, that is, canalicular inserts. *See, e.g.*, Pet. 27–35 (citing generally Ex. 1010); *see also id.* at 36–37, 57 (claim chart citing Ex. 1010 ¶¶ 2, 13, 14, 35, 37–39, 41, 43, 44, 57, 131–132). Further, Petitioner identifies Pritchard as teaching the claimed therapeutic agent (including anti-microbials, anti-glaucoma drugs, antihistamines, anti-

inflammatories, and non-steroidal anti-inflammatories), distinguishing color, and cylindrical-swellable-body of hydrogel. *Id.* at 36–49, 51, 54–60 (claim chart citing Ex. 1010 ¶¶ 1, 2, 8, 13, 14, 20, 22, 29, 30, 35–39, 41, 43, 44, 51–79, 86, 102, 104, 119, 131–132, 135, 137–140, 152, 156–161, Figures 2A, 2B, 7A, 7B, claims 11, 21, 37, 58, 70; and Ex. 1012, 3, 6, 9–12, 15, 36, 45, 49, 51). It is Petitioner's position that each element of independent claims 1, 11, and 18, and of dependent claims 2–7, 9, 10, 12–16, 19–20, and 22–23, is disclosed by Pritchard so that Pritchard anticipates these claims; Petitioner provides claim charts specifically identifying where and how Pritchard provides such a disclosure of the claimed drug delivery system for insertion into a lacrimal canaliculus of a patient, or, put otherwise, a drug-delivering canalicular plug. *See* Pet. 36–61.

Petitioner also submits and cites the Dana Declaration as evidence that Pritchard, read correctly, anticipates the aforementioned claims. *See* Pet. 28–61; *see also* Ex. 1036 ¶¶ 48–72. The Dana Declaration states, for example:

> a person of ordinary skill in the art would readily understand that *Pritchard* anticipates Claims 1-7, 9-16, 18-20, and 22-23 of the '082 Patent. *Pritchard* discloses all of the limitations in these claims as arranged in those claims. That is, *Pritchard* discloses hydrogel canalicular inserts that are cylindrical rods, that are colored, that swell, that comprise functional groups, and that deliver a therapeutic agent to treat various ophthalmic conditions, such as dry eye, glaucoma, and post-surgical discomfort.

Ex. 1036 ¶ 48.

To the extent the '082 patent's claims 1–7, 9–16, 18–20, and 22–23 are not anticipated by Pritchard, most specifically with regard to the claimed

"distinguishing color" limitation, Petitioner argues (as Ground 2) that the combination of Pritchard and Gillespie would have rendered these claims obvious. Pet. 61–64. Petitioner argues that the same teachings of Pritchard identified as anticipating are likewise applicable under an obviousness analysis, and further argues that Gillespie teaches that punctum plugs, as taught by Pritchard, can be colored to be more easily visualized because they are otherwise difficult to see. *Id.*; *see id.* at 63 (quoting Gillespie paragraph 11 that "[i[n [*sic*] one preferred embodiment, at least the outwardly exposed surface of the plug, or the entire plug body, is pigmented to contrast with surrounding tissue" (emphasis Petitioner's)).

In response to Petitioner's anticipation arguments, Patent Owner contends that, in contravention of the legal standard for anticipation set forth in *Net MoneyIN* requiring a reference to disclose the claimed subject matter arranged or combined in the same way as claimed, "*Pritchard* does not . . . disclose all the claim elements arranged or combined in the same way as recited in the claims" because "*Pritchard* provides ***15 separate embodiments*** and ***numerous sub-embodiments*** illustrating various controllably swellable materials for use in making the devices" and "Petitioner has cherry picked from disparate embodiments of *Pritchard* in an unavailing attempt to piece the claimed invention together." Prelim Resp. 29. Patent Owner identifies Pritchard's "15 separate embodiments" as:

> 1) "Gellan, Depolymerized Gellan, and Related Polysaccharides for Biomedical Uses" ([0045]-[0050]);
>
> 2) "Swellable Materials and Devices" ([0051]-[0055]);
>
> 3) "Anisotropically Swelling Materials and Devices" ([0056]-[0079]);

4) "Chelation-Resistant Materials and Devices" ([0080]-[0088]);

5) "Controllably Degradable Materials and Devices" ([0089]-[0099]);

6) "Triggerable Dissolution of Nasolacrimal Implants" ([0100]-[0108]);

7) "Fluidic Occlusive Elements and Materials" ([0109]-[0112]);

8) "Materials of Water-Soluble Polymers Which Gel Under Physiological Conditions" ([0113]-[0119]);

9) "Methods of Making Hydrophilic Extrusions, Fibers and Monofilaments Incorporating Carboxymethylcellulose" ([0120]-[0122]);

10) "Materials of Water-Insoluble Low-Substituted Hydroxy-propyl Cellulose" ([0123]-[0130]);

11) "Drug and Therapeutic Agent Delivery" ([0131]-[0140]);

12) "Removal of Hydrogel Occlusive Devices by Changes in Tonicity" ([0141]-[0150]);

13) "Additional Embodiments" ([0151]-[0156]);

14) "Swellable Temporary Punctum Plugs" ([0157]-[0158]); and

15) "In Vitro Testing of Gellan, Depolymerized to Varying Degrees" ([0159]-[0165]).

Prelim. Resp. 15–16. Patent Owner also contends that these 15 identified embodiments "further contain numerous sub-embodiments." *Id.* at 16.

Patent Owner also argues that "*Pritchard* does not contemplate improving the visibility of cylindrical rod-shaped subpunctal devices," thus providing another reason the reference does not anticipate. Prelim. Resp. 16–17. Patent Owner argues that the "light straw color" disclosed by Pritchard would not improve the device's visibility in the lacrimal canaliculus, providing a photograph of the human eye's anatomy to emphasize the point. *Id.* at 33–34. On the same issue, Patent Owner

contends Pritchard's disclosed color change from translucent to straw colored is not permanent. *Id.* at 35.

Turning to the obviousness Ground 2, Patent Owner argues Gillespie does not cure the above-noted, contended deficiencies in Pritchard. *Id.* at 36. Patent Owner further argues that the unpredictability of coloring an implant, such as the device claimed, including the potential stability and toxicity concerns or adverse effects evidenced by the art, supports the non-obviousness of the claimed invention. *Id.* at 37 (citing Handbook, Ex. 1016, 22–24 (noting "widely varying" stability and toxicity properties and that "[s]ome natural and synthetic organic colors are particularly unstable in light")).

Patent Owner also argues Gillespie "does not teach or suggest any devices that can be used for drug delivery into the canaliculus of a patient in need thereof," and that this means Gillespie's disclosed color additives would not be suitable for the drug-delivery implants of Pritchard. Prelim. Resp. 39. Similarly, because Pritchard focuses on controllably swellable materials for its implants and Gillespie teaches silastic rubber as an implant material (that is colored), Patent Owner argues there would not have been a reasonable expectation of success for the skilled artisan in making Petitioner's proposed prior art combination, which further supports non-obviousness. *Id.* at 41.

Finally, Patent Owner argues that, even if Pritchard and Gillespie were combined, the combination would still fail to teach the claimed drug-delivery system. Prelim. Resp. 43. Patent Owner contends "the combination at best provides a punctal plug with an outwardly exposed

surface, such as a rim, which is colored. It does not provide a drug delivery device with a cylindrical rod-shaped body for insertion into the lacrimal canaliculus that has a distinguishing color to show placement." *Id.* at 45.

Analysis

In some respects, the parties' arguments present us with a reasonably close question on anticipation because, as Patent Owner observes, the Pritchard reference does not disclose a single, stand-alone example of a lacrimal canalicular plug for insertion via a punctal opening having each element of the '082 patent's claims. *See, e.g.*, *Microsoft*, 878 F.3d. at 1071 (identifying that patent specifications can be written so that it is not a simple matter to understand the difference between what are intended to be separate embodiments and what are intended to be directly related elements of an invention, so as to present a reasonably close question). However, on balance, at this stage in the proceedings and for the reasons discussed below, we find Petitioner has carried its burden to show a reasonable likelihood of anticipation of at least one claim of the '082 patent.

We conclude, based on the evidence presented by Petitioner at this stage in the proceedings, that Pritchard discloses the subject matter of claims 1–7, 9–16, 18–20, and 22–23. In particular, Petitioner shows that Pritchard discloses a punctal plug and describes the remaining claim elements such that a person of ordinary skill in the art would immediately envisage selecting them, as if off a menu of directly related options, in the fashion claimed in the '082 patent. "[A]n anticipation analysis indisputably allows for some flexibility." *Microsoft*, 878 F.3d at 1069. Pritchard "anticipate[s] [here] even if it 'd[oes] not expressly spell out' all the limitations arranged

or combined as in the claim[s], [because] a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." *Id.* at 1068; *see also* Pet. 36–61 (claim charts identifying where and how Pritchard discloses the claimed subject matter); Ex. 1036 ¶¶ 48–72 (Dana Declaration discussing how and why Pritchard anticipates). The various disclosures of elements by Pritchard, at least respective of the '082 patent's claimed invention, appear to be "directly related disclosures," such that they "may be combined in an optimal anticipating embodiment." *See In re Arkley*, 455 F.2d at 587–88; *Purdue Pharma*, 881 F.3d at 1358–59.

At this stage, we are not persuaded that the disclosure of Pritchard includes the 15 separate and unrelated embodiments as argued by Patent Owner. Analyzing Patent Owner's contended list of independent Pritchard embodiments beginning with the first, what Patent Owner identifies as Pritchard's *embodiment 1*, i.e., paragraphs 45–50, is not a separately described embodiment, but the cited portion of the specification describes gellan as a polysaccharide material useful in the invention otherwise taught in Pritchard. *See* Prelim. Resp. 15; Ex. 1010 ¶¶ 45–50. Nothing in this portion of Pritchard hints that it should be considered a separate part of the disclosure not directly related to the rest. Similarly, Pritchard's paragraphs 51–55, which Patent Owner contends are its *embodiments 2 and 3*, describe why hydrogel and gellan materials swell (or swell anisotropically) and how they can be used in devices as taught throughout Pritchard, for example, cylindrical hydrogel or polysaccharide plugs that swell after implanting. *See* Prelim. Resp. 15; Ex. 1010 ¶¶ 51–79. Again, nothing in this portion of Pritchard's disclosure indicates that it should be considered separate and

independent from the rest of Pritchard's disclosure; to the contrary, it suggests that the swellability characteristics described would be useful generally. The portion of Pritchard that Patent Owner indicates is *embodiment 4* discusses how punctum plugs and other nasolacrimal occlusive devices can be made of chelation-resistant materials, including how the otherwise taught hydrogels and gellan can be made so. *See* Prelim. Resp. 15; Ex. 1010 ¶¶ 80–88. This disclosure is not segregating this subject matter from the other-disclosed subject matter in Pritchard.

The portion of Pritchard that Patent Owner identifies as *embodiment 11* relates to drug-delivery and teaches that essentially any embodiment of Pritchard could contain a therapeutic agent and is not describing a separate, independent, unrelated embodiment. *See* Prelim. Resp. 15; Ex. 1010 ¶¶ 131–140 ("The gels and other devices set forth herein could contain medicaments, therapeutic agents, antimicrobials (e.g., silver), bioactive minerals and glasses, radioactive therapeutic materials, cytotoxic agents (for tissue ablation), etc."). In fact, this portion of Pritchard expressly invokes the other portions of the disclosure that Patent Owner contends are independent, unrelated embodiments (i.e., hydrogel materials, gellan materials, swellable/anisotropically swellable devices). *See* Ex. 1010 ¶¶ 131–140. Further, this portion of Pritchard also expressly teaches incorporating drugs into a cylindrical, anisotropically swellable implant, that is a light straw color (as opposed to clear), which supports that such implant characteristics are related to one another, rather than being separate, independent embodiments. *Id.*

Based on our review of Pritchard, while it is possible that some embodiments disclosed therein could be considered separate and independent embodiments, the portions of Pritchard cited by Petitioner do not read this way. Instead, the cited portions of Pritchard appear to set forth a menu of directly related options that can be incorporated as elements of a punctal plug.

Turning to Patent Owner's next argument, that the coloration of plugs disclosed by Pritchard is an insufficient disclosure for the claimed "distinguishing color to show placement of the system in the lacrimal canaliculus of the patient," on the preliminary record before us, we disagree and find Petitioner's position is sufficiently supported by evidence. Petitioner has pointed to Pritchard's paragraphs 137–140 as disclosing this claimed subject matter as a changing of the device's color from colorless to a light straw color, which is retained. We find no persuasive evidence presented by Patent Owner at this point that such a color would not distinguish the device as placed in the lacrimal canaliculus from a patient's surrounding non-straw-colored tissue. Whether Pritchard discloses inducing this color change for the purpose of making the device more visible is immaterial; such intent is not a requirement of the claims. Rather, it is sufficient that the device is colored in a manner to allow an observer to identify it in its surroundings. Moreover, contrary to Patent Owner's contention, Pritchard discloses that the color change is retained by the device. *See* Ex. 1010 ¶ 140.

Even were there a determinative reason to disagree with Petitioner's anticipation case at this stage in the proceedings, which we do not find there

to be based on the preliminary evidence before us, Petitioner also asserts as Ground 2 that the same claims would have been obvious over Pritchard and Gillespie combined. On the evidence before us, even if we were to determine that Pritchard's separately disclosed elements could not at once be envisaged by the skilled artisan, we find the evidence supports a reasonable likelihood that it would have been obvious to combine Pritchard and Gillespie so as to achieve the subject matter of claims 1–7, 9–16, 18–20, and 22–23 of the '082 patent.

Indeed, Patent Owner does not reasonably dispute that Petitioner has shown where and how Pritchard teaches each element of the challenged claims, and also provides at least a suggestion for combining those elements in the manner claimed, in particular, independent claims 1, 11, and 18. *See, e.g.*, Pet. 27–28, 36–49, 51, 54–60 (claim chart citing Ex. 1010 ¶¶ 1, 2, 8, 13, 14, 20, 22, 29, 30, 35–39, 41, 43, 44, 51–79, 86, 102, 104, 119, 131–132, 135, 137–140, 152, 156–161, Figures 2A, 2B, 7A, 7B, claims 11, 21, 37, 58, 70; Ex. 1012, 3, 6, 9–12, 15, 36, 45, 49, 51). As further noted above, Patent Owner argues Pritchard's teaching of processing its implants to change their color from clear to straw-colored is not teaching imbuing the devices with a lasting, distinguishing color, as claimed. Patent Owner offers no evidence at this time to support this contention, however, and Pritchard and the Dana Declaration contradict this argument. *See* Prelim. Resp. 32–36; *see also* Ex. 1010 ¶¶ 137–140; Ex. 1036 ¶¶ 51–52.

"If a person of ordinary skill can implement a predictable variation [of a known work], § 103 likely bars its patentability." *KSR*, 550 U.S. at 417. From the evidence before us at this stage in the proceeding, we find it

reasonably likely that a person of ordinary skill could and would have predictably combined the elements taught by Pritchard to achieve the invention of claims 1–7, 9–16, 18–20, and 22–23. Here, the rationale for making a combination of the elements claimed in the '082 patent comes largely from Pritchard's disclosure itself, which discusses the advantages of an implant composed of a hydrogel, in a cylindrical shape, that swells once implanted, and that includes a therapeutic agent. *See supra* citations to Ex. 1010; *see, e.g.*, Ex. 1010 ¶ 61 ("Use of anisoptropic hydrogels as materials for punctal occlusion solves a problem with many devices"), ¶ 30 ("Subpunctal devices are simple in design, being cylindrical pieces of material . . ."), ¶ 132 ("The gel would entrap active therapeutic agents at the site where the gel is formed in a patient, or could slowly elute therapeutic agents into the patient, e.g., into the bloodstream or other tissues.").

Even assuming *arguendo* that Patent Owner's contention that a straw colored punctal plug, as taught by Pritchard, is not a sufficiently distinguishing color as claimed, Petitioner's Ground 2 combines Gillespie with Pritchard, and Gillespie is explicitly directed to coloring such punctal plugs with dye or pigment to make them contrast with surrounding tissue. *See, e.g.*, Ex. 1015, abstract, ¶¶ 1–7, 11, 13.

Regarding Patent Owner's arguments that there would have been unreasonable unpredictability foreclosing motivating the skilled artisan to combine Gillespie's plug coloring with Pritchard's devices, that Petitioner failed to show compatibility between Gillespie's and Pritchard's disclosed elements, or that there would have been no expectation of successful combination, Gillespie expressly states that its contrast-coloring invention

can be used with a "plug body . . . composed of any suitable material, including those presently used in the manufacture of such devices." *Id.* ¶ 6. Thus, Gillespie appears to teach or suggest that any punctal plug could be colored to distinguish it from surrounding tissue. On the evidence before us at this stage in the proceedings, Petitioner has sufficiently shown, and there is simply no reason to believe otherwise, that the devices and elements taught by Pritchard and Gillespie would have been compatible and predictably combined.

Regarding Patent Owner's argument that Gillespie's coloring would not be suitable for a drug-delivering implant as taught by Pritchard because Gillespie is silent on drug-incorporation, at this point we find Gillespie's teaching of general applicability of coloration to punctal plugs outweighs any potential drug-coloring interactions or adverse effects hinted at by the Handbook. *Compare* Ex. 1015 ¶ 6, *with* Ex. 1016, 22–24; *see also* Ex. 1036 ¶¶ 73–78 (discussing the applicability of Gillespie's coloring to Pritchard's devices).

To summarize, for the reasons above, we find that Petitioner has shown a reasonable likelihood of establishing unpatentability of claims 1–7, 9–16, 18–20, and 22–23 under Grounds 1 and 2.

E. Ground 3—Claims 8, 17, and 21 As Obvious Over Pritchard, Gillespie, and Hellberg

For Ground 3, directed to the '082 patent's claims 8, 17, and 21, Petitioner recognizes that these claims require that the claimed therapeutic agent is travoprost, which is a glaucoma drug, and that neither Pritchard nor Gillespie teach this drug. Pet. 64–65. Therefore, Petitioner argues that Hellberg, which discloses treating glaucoma with travoprost (e.g., topically),

would have been obvious to combine with Pritchard and Gillespie for such a teaching. *Id.* at 64–66 (citing Hellberg, Ex. 1017, 5:40–46, 7:56–62, claim 4; Ex. 1036 ¶ 80). Petitioner contends the skilled artisan would have been motivated to use Hellberg's travoprost as a glaucoma treating therapeutic agent and as a substitutable, equivalent alternative for Pritchard's disclosed therapeutic agents, e.g., latanaprost and bimatoprost. *Id.* at 65–66.

Patent Owner argues that Hellberg cannot cure the deficiencies (contentions noted above) found in Pritchard and Gillespie. Prelim. Resp. 46. Patent Owner also argues that there is no evidence that the skilled artisan would have selected "a single agent – travoprost – for delivery to treat glaucoma." *Id.* at 46–47.

On the evidence before us, we find that Petitioner has sufficiently shown that the skilled artisan would have reasonably substituted Hellberg's travoprost for the therapeutic agents disclosed by Pritchard.

At this stage in the proceedings, on this Ground 3, we find Petitioner has shown a reasonable likelihood that claims 8, 17, and 21 would have been obvious. As discussed above, we find no determinative deficiencies in the disclosures or combination of Pritchard and Gillespie on the present record. Moreover, we do not find that the claims necessarily require just a single therapeutic agent, as argued by Patent Owner. Claim 8 depends from claim 1, which uses the transitional term "comprising," and therefore could include other elements such as more than a single therapeutic agent. Claim 17 depends from claim 11, which uses the transitional term "consisting essentially of," which, because the basic and novel property(ies) of the invention is not identified, we interpret the same as "comprising," to the

same result as claim 8. *See, e.g.*, *PPG Indus. v. Guardian Indus. Corp*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). Claim 21 depends from claim 18, which like claim 1, is a "comprising" claim and is interpreted the same way.

F. GROUND 4—CLAIMS 1–7, 9–16, 18–20, AND 22–23 AS OBVIOUS OVER PRITCHARD AND HANDBOOK

Petitioner asserts Ground 4 as an alternative to Ground 2 and, instead of combining Pritchard with Gillespie, combines Pritchard with Handbook in contending claims 1–7, 9–16, 18–20, and 22–23 would have been obvious. Pet. 66–68. Petitioner's premise for Ground 4 is that Handbook includes a section disclosing coloring agents as used in medicinal products to make them distinctive to prevent counterfeiting and to make commercial products more uniform in appearance. *Id.* (citing Ex. 1016, 146–53). Petitioner argues the skilled artisan would have been motivated to color Pritchard's devices as taught by Handbook for these reasons. *Id.* at 67.

Patent Owner argues that Handbook is evidence that there are limits to using coloring agents in medicinal products and that it would have been unpredictable to color the devices of Pritchard. Prelim. Resp. 48. Patent Owner also argues Handbook's coloring agents are not suitable for Pritchard's devices, and that there would not have been a reasonable expectation of successfully combining Pritchard and Handbook because Handbook is silent on including such coloring agents in ocular, drug-delivery implants. *Id.* at 49–52.

On the record before us, Patent Owner is correct that Handbook is silent on using its coloring agents for devices of the type disclosed by Pritchard. Handbook is a general disclosure of the applicability of coloring agents to pharmaceutical products and lists some specific applications, such

as in coated tablets, uncoated tablets, hard and soft gelatin capsules, liquid oral preparations, oral and topical formulations, and cosmetics. *See* Ex. 1016, 146–53. Although Handbook assuages concerns over certain adverse effects by explaining that "continuous review, over many years, by such bodies as the FDA, has resulted in a list of permitted colors which are generally regarded as free of serious adverse toxicological effects," and that coloring agents "associated with adverse effects" relate to "a relatively small number of people," we are not persuaded on this record that such teachings or others of Handbook provide sufficient indication that Handbook's teachings relate to the use of its coloring agents to impart color to an implantable device. *Id*. at 148.

Further, Handbook's discussion of using a coloring agent to impart a distinctive or distinguishing color to a medicinal product is in the context manufacturing and marketing—to distinguish one product by its color from another. There is no suggestion in Handbook that such coloring agents are sufficient or suitable to provide a distinguishing color to show placement of an implant in an eye structure, as claimed. Insofar as Dr. Dana provides testimony that a person of skill in the art would have been motivated to combine the "color teachings of the Handbook to make the inserts of Pritchard easier to see" (Ex. 1036 ¶ 84), we note that discussion does not explain sufficiently how Handbook teaches or suggests the coloring agents are suitable for punctum plugs or any implant.

Thus, upon consideration of the proposed combination of Pritchard and Handbook as presented in the Petition (Pet. 66–68), and the supporting declaration testimony of Dr. Dana, at this stage we agree with Patent Owner

that Petitioner has not shown that a person of ordinary skill in the art would have been motivated, with a reasonable expectation of success, to combine the "color" teachings of the Handbook with the inserts of Pritchard. For these reasons, we find Petitioner has not shown a reasonable likelihood that claims 1–7, 9–16, 18–20, and 22–23 would have been obvious over Pritchard and Handbook.

GROUND 5—CLAIMS 8, 17, AND 21 WOULD HAVE BEEN OBVIOUS OVER PRITCHARD, HANDBOOK, AND HELLBERG

Petitioner asserts Ground 5 as an alternative to Ground 3 and, instead of combining Pritchard and Hellberg with Gillespie, combines Pritchard and Hellberg with Handbook so as to have rendered claims 8, 17, and 21 obvious. Pet. 68–69. Petitioner's premise for Ground 5 is essentially the same as those for Grounds 3 and 4—that it would have been obvious to use a colorant in Pritchard's devices as taught by Handbook, and that it would be obvious to use travoprost as the therapeutic agent as taught by Hellberg, as discussed above.

Patent Owner essentially invokes the same arguments over this Ground 5 as presented for Grounds 3 and 4, as discussed above.

At this point in the proceedings, we make the same findings here for Ground 5 as for Ground 4, as discussed above. For the same reasons, we find Petitioner has not shown a reasonable likelihood that claims 8, 17, and 21 would have been obvious over Pritchard, Handbook, and Hellberg.

III. CONCLUSION

On the record before us at this stage in the proceeding, Petitioner has demonstrated a reasonable likelihood of prevailing on Grounds 1–3 in showing that claims 1–23 of the '082 patent are either anticipated by Pritchard or would have been obvious over the cited prior art combinations

of Pritchard and Gillespie, and Pritchard, Gillespie, and Hellberg. Our decision at this stage derives from our preliminary review of the challenged claims, the asserted prior art, and the opinions set forth in the as yet unrebutted Dana Declaration.

In accordance with the Court's decision in *SAS Institute, Inc.*, 138 S. Ct. at 1359–60 and Office guidance,[6] we institute an *inter partes* review of all challenged claims of the '082 patent on all grounds alleged by Petitioner. Nevertheless, this decision does not reflect a final determination on the patentability of any claim. We further note that the burden remains on Petitioner to prove unpatentability of each challenged claim. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

ORDER

Accordingly, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review of claims 1–23 of the '082 patent, in accordance with each ground on which the challenge to each claim is based in the Petition, is hereby *instituted*; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '082 patent will commence

[6] Guidance on the Impact of SAS on AIA trial proceedings (Apr. 26, 2018), accessible at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial (last accessed Oct. 2, 2018) ("At this time, if the PTAB institutes a trial, the PTAB will institute on all challenges raised in the petition," and "for pending trials . . . , the panel may issue an order supplementing the institution decision to institute on all challenges raised in the petition.").

on the entry date of this Order, and notice is hereby given of the institution of a trial.

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