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Paper No. 8
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PALETTE LIFE SCIENCES, Inc.,
Petitioner,

v.

INCEPT LLC,
Patent Owner.

Case IPR2020-00005
Patent US 7,744,913 B2

Before ERICA A. FRANKLIN, ULRIKE W. JENKS, and TINA E. HULSE, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge.*

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

I. INTRODUCTION

Palette Life Sciences Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–25 ("the challenged claim") of Patent No. US 7,744,913 B2 (Ex. 1001, "the '913 patent"). Paper 2 ("Pet."). Incept LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp.").

An *inter partes* review may not be instituted unless "the information presented in the petition . . . and any response . . . shows that 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). Further, a decision to institute may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018).

We have authority, acting on the designation of the Director, to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). For the reasons that follow, we exercise our delegated discretion under 35 U.S.C. § 314(a) and deny institution of *inter partes* review. *See* 35 U.S.C. § 314(a); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016).

A. Real Parties in Interest

Petitioner identifies Palette Life Sciences, Inc. and Pharmanest AB as the real parties-in-interest. Pet. 1. Petitioner additionally identifies the following as possible real parties-in-interest: Galderma S.A., Galderma Laboratories, Inc., Galderma Laboratories LP, Galderma Research & Development SNC, Nestlé Skin Health, Inc., Nestlé Skin Health S.A., Nestlé

S.A., EQT Partners AB, Public Sector Pension Investment Board (PSP Investments), Luxinva, and Abu Dhabi Investment Authority. *Id.*

Patent Owner identifies the real parties-in-interest as Incept LLC and Boston Scientific Corporation. Paper 5, 2.

B. Related Proceedings

Petitioner challenges claims 1–25 of the '913 patent in another concurrently filed petition, IPR2020-00004 ("the Wallace '913 Petition"). In addition, Petitioner requested *inter partes* review, IPR2020-00002 and IPR2020-00003, of a related patent, Patent No. US 8,257,723 B2 ("the '723 patent," Ex. 1002). The '723 patent is a continuation of the '913 patent. In IPR2020-00004, Petitioner relies on Wallace[1] or Ball[2] as the primary reference.

C. The '913 Patent (Ex. 1001)

The '913 patent is titled "fillers and methods for displacing tissues to improve radiological outcomes." Ex. 1001, [54]. The '913 patent issued from Application No. 10/602,256 ("the '256 application"), filed June 24, 2003, which ultimately claims the benefit of U.S. Provisional Application No. 60/391,027, filed June 24, 2002, U.S. Provisional Application No. 60/427,662, filed Nov. 19, 2002, and U.S. Provisional Application No. 60/444,143, filed Jan. 31, 2003. *Id.* at [60].

The '913 patent describes methods for improving radiological outcomes by introducing a filler between two tissues in order to increase the

[1] Wallace et al, US 6,624,245 B2, issued Sept. 23, 2003 (Ex. 1010).
[2] Ball et al., *Silicone implant to prevent visceral damage during adjuvant radiotherapy for retroperitoneal sarcoma*, 63 BRITISH J. RADIOLOGY 346–48 (1990) (Ex. 1012).

distance between the two tissues. *Id.* at [57]. Figure 1 of the '913 patent, reproduced below, shows the male prostate and surrounding anatomy.

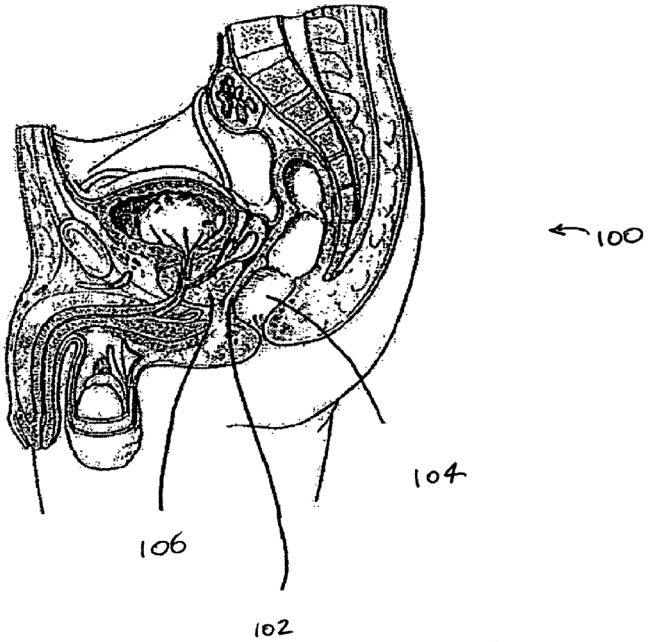

FIG.1

Figure 1, shows the patient 100 having Denonvillier's space 102 between rectum 104 and prostate 106. *Id.* at 15:28–29; 2:15–16. Real time ultrasound guidance is used to ensure that the delivery, a needle, is positioned in the Denonvillier's space located anterior to the rectal wall and posterior to the prostate. *Id.* at 15:14–27.

The '913 patent describes fillers as "a substance that occupies a volume after its introduction into a body. Examples of fillers include but are not limited to polymers, gels, sols, hydrogels, sponges, bulking agents, and balloons." *Id.* at 4:34–37. The '913 patent also describes that "[a]n expandable device may be used for filler, e.g., a balloon or sponge." *Id.* at 2:9–11, *see also id.* at 10:17–21 ("a filler that comprises a device having a reversible volume, for example, a balloon. A balloon may be introduced,

inflated, and then deflated after a dose of radiation has been administered, or recovered after the radiation treatment has been completed."). Fillers may additionally contain osmotic agents or drugs. *Id.* at 5:17–29.

D. Illustrative Claim

Claims 1 and 17 are independent claims. Claim 1 of the '913 patent is reproduced below:

> 1. A method of delivering a therapeutic dose of radiation to a patient comprising introducing a biocompatible, biodegradable filler device between a first tissue location and a second tissue location to increase a distance between the first tissue location and the second tissue location, and treating the second tissue location with the therapeutic dose of radiation so that the presence of the filler device causes the first tissue location to receive less of the dose of radioactivity compared to the amount of the dose of radioactivity the first tissue location would receive in the absence of the filler device, wherein the filler device is introduced an injectable material and is a gel in the patient that is removed by biodegradation of the filler device in the patient wherein the first tissue location is associated with the rectum and the second tissue location is associated with the prostate gland.

Ex. 1001, 16:42–57.

E. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–25 of the '913 patent on the following grounds:

Claim(s)	Basis[3]	Reference(s)
1–9, 12, 14−19, 23	§ 103(a)	Burg,[4] Fishman[5]
10, 11, 13, 20−22, 24	§ 103(a)	Burg, Fishman, Carrol[6]
25	§ 103(a)	Burg, Fishman, Griffith-Cima[7]

Petitioner also relies on the Declaration of Dr. Adam Dicker (Ex. 1003) to support its assertions.

II. DISCUSSION

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) (explaining that section "314(a) invests the Director with discretion on the question whether to institute review") (emphasis omitted); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."); *see also* 37 C.F.R. § 42.4(a) ("The Board institutes the trial on behalf of the Director."). "[T]he PTO is permitted, but never compelled, to institute an IPR proceeding." *Harmonic Inc.*, 815 F.3d at 1367. When determining

[3] We apply pre-AIA 35 U.S.C. § 103 because the effective filing date of the '913 patent precedes the March 16, 2013, effective date for changes to 35 U.S.C. § 103. *See* MPEP § 2159 (Rev. 08.2017).
[4] Burg et al., US 6,206,930 B1, issued Mar. 27, 2001 (Ex. 1041).
[5] Fishman, US 6,066,856, issued May 23, 2000 (Ex. 1055).
[6] Carroll, US 6,375,634 B1, issued Apr. 23, 2002 (Ex. 1013).
[7] Griffith-Cima et al., WO 94/25080, published Nov. 10, 1994 (Ex. 1011).

whether to exercise our discretion under § 314(a), we consider, among other factors, whether a petitioner has filed multiple other petitions challenging the same patent.

As explained above, in addition to the instant Petition, Petitioner has concurrently filed the Wallace '913 Petition challenging the same claims. We instituted an *inter partes* review of claims 1–25 on the grounds presented in the Wallace '913 Petition. *See* IPR2020-00004, Paper 8. Here, however, we find it is appropriate that we exercise our discretion to deny institution of this Petition under 314(a).

Although "there may be circumstances in which more than one petition may be necessary," "one petition should be sufficient to challenge the claims of a patent in most situations." Patent Trial and Appeal Board Consolidated Trial Practice Guide, November 2019, 59, *available at* https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf (citing 37 C.F.R. § 42.100(b) (2019)) ("November 2019 TPG"). According to the November 2019 TPG, "[t]wo or more petitions filed against the same patent at or about the same time (e.g., before the first preliminary response by the patent owner) may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns." *Id.* (citing 35 U.S.C. § 316(b)).

The November 2019 TPG states

> To aid the Board in determining whether more than one petition is necessary, if a petitioner files two or more petitions challenging the same patent, then the petitioner should, in its petitions or in a separate paper filed with the petitions, identify: (1) a ranking of the petitions in the order in which it wishes the Board to consider the merits, if the Board uses its discretion to institute any of the petitions, and (2) a succinct explanation of

> the differences between the petitions, why the issues addressed by the differences are material, and why the Board should exercise its discretion to institute additional petitions if it identifies one petition that satisfies petitioner's burden under 35 U.S.C. § 314(a). The Board encourages the petitioner to use a table to aid in identifying the similarities and differences between petitions.

Id. at 59–60 (footnote omitted).

In accordance with the November 2019 TPG, Petitioner filed a separate paper ranking the petitions, stating that we should consider the Wallace '913 Petition first, and the instant Petition second. Paper 3, 1. Petitioner asserts we should institute review for both Petitions because each Petition provides a different approach. The Wallace '913 Petition challenges "are based on the introduction of only a gel filler" while in the instant Petition the challenges "are based on the introduction of two biodegradable fillers." *Id.* at 2. Petitioner argues that the different approaches in the two different petitions "allow[] for increased efficiency" by separating the arguments. *Id.* at 4. We are not persuaded.

The November 2019 TPG provides that Petitioner should provide "a succinct explanation of the differences between the petitions, why the issues addressed by the differences are material, and why the Board should exercise its discretion to institute additional petitions if it identifies one petition that satisfies petitioner's burden under 35 U.S.C. 314(a)." November 2019 TPG at 60. Petitioner asserts that

> the challenges based on Burg are based on the use of the transition phrase 'comprising' in the independent claim, which does not preclude embodiments that use multiple fillers–*i.e.*, it does not preclude embodiments where a filler, in the form of a

> balloon or envelope, contains a second filler, in the form of a liquid or gel.

Paper 3, 3.

We are not persuaded. Simply saying that the petitions present alternative arguments directed to the same claims is not a sufficiently meaningful explanation to establish that the differences between the Petitions are material and justify exercising our discretion to institute additional petitions. The November 2019 TPG nowhere indicates that mere alternative arguments that are different from each other constitute sufficient justification for filing multiple petitions. Petitioner does not explain why, if review is instituted in the Wallace '913 Petition, a second review in the instant Petition is still necessary.

We acknowledge that the instant Petition also relies on a different secondary reference, Fishman, than what is asserted in the Wallace '913 Petition, i.e., Ein-Gal.[8] In each Petition, the respective secondary reference is relied on for teaching "that the tissue [for displacement] may be rectum or prostate gland" when applying radiation therapy. *Compare* Pet. 31, 40 *with* Wallace '913 Pet. 33, 42. Petitioner, however, does not identify, and we do not discern, any material differences relating to Fishman that substantively distinguish the arguments here from those made in connection with the Ein-Gal in the Wallace '913 Petition. *See generally* Paper 3, 1.

In addition, both this Petition and the Wallace '913 Petition rely on the same secondary references Griffith-Cima and Carroll. In both Petitions, Griffith-Cima is relied on to establish "the use of Pluronics™ to form a

[8] Ein-Gal, US 6,210,314 B1, issued Apr. 3, 2001 (Ex. 1049).

biocompatible hydrogel that may be crosslinked by temperature." *Compare* Pet. 44 *with* Wallace '913 Pet. 45. Carroll is relied on in both Petitions to teach the use of polysaccharides as a polymer for forming hydrogel compositions as well as the inclusion markers in the hydrogel for the purpose of visualization. *Compare* Pet. 42 *with* Wallace '913 Pet. 59–60.

In sum, having considered the parties' arguments and evidence in both IPR2020-00004 and the present proceeding, we find that the present Petition is not materially different from the Wallace '913 Petition, merely adding grounds that make the same arguments based on similar teachings provided by a slightly different combination of references. Because we institute an *inter partes* review of all claims of the '913 patent on all grounds presented in the Wallace '913 Petition (*see* IPR2020-00004, Paper 8), we exercise our discretion under 35 U.S.C. § 314(a) to deny instituting review of the Petition here.

III. CONCLUSION

For the foregoing reasons, based on the circumstances of this case, we exercise our discretion under 35 U.S.C. § 314(a) and deny the Petition requesting institution of an *inter partes* review of claims 1–25 of the '913 patent.

IV. ORDER

Accordingly, it is

ORDERED that Petitioner's request for an *inter partes* review of claims 1–25 of the '913 patent is denied and no *inter partes* review is instituted.

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