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Paper No. 8
Date: April 17, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PALETTE LIFE SCIENCES, INC.,
Petitioner,

v.

INCEPT LLC.,
Patent Owner.

IPR2020-00003
Patent US 8,257,723 B2

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

FRANKLIN, *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 1–24 of U.S. Patent No. 8,257,723 B2 (Ex. 1001, "the '723 patent"). Paper 2 ("Petition" or "Pet."). Incept LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314. For the reasons provided below, we exercise our discretion under 35 U.S.C. § 314 to deny institution of an *inter partes* review.

A. Real Parties-in-Interest

Petitioner identifies Palette Life Sciences, Inc. and Pharmanest AB as real parties-in-interest. Pet. 1. Petitioner also identifies 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 as possible real parties-in-interest. *Id.*

Patent Owner identifies Incept LLC and Boston Scientific Corporation as real parties-in-interest. Paper 5, 1.

B. Related Proceedings

Petitioner has filed a second petition for *inter partes* review of the '723 patent as IPR2020-00002 ("the Wallace '723 Petition"). Pet. 2. Petitioner also filed petitions for *inter partes* review of related U.S. Patent No. 7,744,913 B2 in IPR2020-00004 and IPR2020-00005. Pet. 2.

Patent Owner states that it "is not presently aware of any proceedings other than those cited in the Petition." Paper 5, 1.

C. The '723 Patent

The '723 patent relates to a method of placing a degradable filler between the radiation target tissue (e.g., prostate) and other tissues (e.g., rectum) to increase the distance between the target tissue and the other tissues, so that the other tissues receive less radiation than the target tissue. *Id.* at 2:28–32. The degradable filler is installed once before radiation treatment and does not require subsequent manipulation, repositioning, or removal. *Id.* at 2:31–35. Fillers are biodegradable by either hydrolysis, proteolysis, the action of cells in the body, or by a combination of those mechanisms. *Id.* at 4:66–5:1. The Specification explains that "[b]iodegradation may be measured by palpitation or other observations to detect the change in volume of a filler after its introduction into a patient." *Id.* at 5:1–3. Biodegradation may occur over the course of weeks or months after introduction depending on the requirements for administering radiation therapy. *Id.* at 5:4–16.

The '723 patent describes a filler as "a substance that occupies a volume after its introduction into a body." *Id.* at 4:34–35. Filler materials include alginate, collagen, gelatin, fibrin, fibrinogen, albumin, polyethylene glycol, thixotropic polymers, and thermoreversible polymers. *Id.* at 4:35–46. Biocompatible materials are preferred, especially collagen or hyaluronic acid. *Id.* at 5:3–4. Fillers may also include osmotic agents and contain drugs. *Id.* at 5:17–29.

The filler may be injected through a needle into the patient's body. *Id.* at 10:51–53. After introduction into the body, the filler may increase in volume and form a gel *in situ* through a variety of processes, depending on the material. *See id.* at 5:30–56, 7:42–53. A filler solution may have low

viscosity when stored and higher viscosity after *in situ* self-assembly in the patient. *Id.* at 5:48–50.

The '723 patent also describes a study that shows a method of injecting collagen into Denonvillier's space, i.e., the region located between the rectum and the prostate, to displace the rectum away from the prostate during radiation therapy. *Id.* at 3:15–26; 15:1–16:32 (Example 2). The Specification explains that the combination of body temperature and pH causes the collagen fibrils to cooperate to form a fibrin gel. *Id.* at 5:43–48. "The collagen degraded in less than about sixty days and required no procedures after its initial introduction into the patients." *Id.* at 3:20–22. Patients receiving the collagen injections "appeared to have minimal rectal side effects associated from their radiotherapy." *Id.* at 3:30–32.

D. Illustrative Claim

Petitioner challenges claims 1–24 of the '723 patent. Claim 1, reproduced below, is the only independent claim and is illustrative of the claimed subject matter.

> 1. A method of delivering a therapeutic dose of radiation to a patient comprising introducing a biocompatible, biodegradable filler between an organ and a nearby tissue to increase a distance between the organ and the tissue, and treating the tissue with a therapeutic dose of radiation so that the presence of the filler causes the organ to receive less of the dose of radiation compared to the amount of the dose of radiation the organ would receive in the absence of the filler, wherein the filler is introduced as an injectable material and is a gel in the patient, and wherein the filler is removable by biodegradation in the patient.

Ex. 1001, 16:49–59.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–24 would have been unpatentable on the following grounds.

Claim(s) Challenged	35 U.S.C. §	Reference(s)
1, 14, 15, 23	102(b)	Burg[1]
1–7, 11, 14–18, 20, 22–24	103(a)	Burg
8–10, 12, 19, 21	103(a)	Burg, Carroll[2]
13	103(a)	Burg, Griffith-Cima[3]

Petitioner also relies on the Declaration of Adam Dicker, M.D., Ph.D. (Ex. 1003).

II. DISCRETIONARY DENIAL

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. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016). When determining whether to exercise our discretion

[1] Burg et al., US 6,206,930 B1, issued Mar. 27, 2001 ("Burg," Ex. 1041).
[2] Carroll, US 6,375,634 B1, issued Apr. 23, 2002 ("Carroll," Ex. 1013).
[3] Griffith-Cima et al., PCT Publication No. WO 94/25080, published Nov. 10, 1994 ("Griffith-Cima," Ex. 1011).

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 '723 Petition challenging the same claims. We instituted an *inter partes* review of claims 1–24 on the grounds presented in the Wallace '723 Petition. *See* IPR2020-00002, 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 '723 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 to challenging the claims. *Id.* Petitioner explains that the Wallace '723 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. According to Petitioner, separating the different approaches in the two different petitions "allows for increased efficiency." *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 Wallace '723 Petition, a second review in the instant Petition is still necessary.

Both the instant Petition and the Wallace '723 Petition rely on the same secondary references Carroll and Griffith-Cima in the same manner. In both Petitions, 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. 34–35 *with* Wallace Pet. 38–52. Additionally, both Petitions rely on Griffith-Cima to establish "the use of Pluronics™ to form a biocompatible hydrogel that may be crosslinked by temperature." *Compare* Pet. 35–36 *with* Wallace Pet. 37–38.

Therefore, having considered the parties' arguments and evidence in both IPR2020-00002 and the present proceeding, we find that the present Petition is not materially different from the Wallace '723 Petition, as the Petitions challenge the same claims based on similar teachings provided by a slightly different combinations of references. Moreover, Petitioner fails to persuasively show why we should exercise our discretion to institute multiple Petitions against the same claims of the same patent. Because we institute an *inter partes* review of all claims of the '723 patent on all grounds presented in the Wallace '723 Petition (*see* IPR2020-00002, Paper 8), we

exercise our discretion under 35 U.S.C. § 314(a) to deny instituting review of the same challenged claims based upon the instant Petition.

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 1–24 of the '723 patent.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), Petitioner's request for an *inter partes* review of claims 1–24 of the '723 patent is *denied*.

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