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Paper 12
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PROLLENIUM US INC.,

Petitioner,

v.

ALLERGAN INDUSTRIE, SAS,

Patent Owner.

IPR2020-00084
Patent 9,089,519 B2

Before JOHN G. NEW, SHERIDAN K. SNEDDEN, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION
Instituting *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Petitioner Prollenium US Inc. filed a Petition (Paper 1, "Petition") requesting *inter partes* review of claims 1–8 of US Patent 9,089,519 B2 (Ex. 1001, "the '519 patent"). Patent Owner Allergan Industrie SAS (the "Patent Owner") timely filed a Preliminary Response. Paper 11 ("Prelim. Resp.").

Under 35 U.S.C. § 314, the Board "may not authorize an *inter partes* review to 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 one of the claims challenged in the petition." Upon consideration of the Petition and the Preliminary Response we determine that the evidence presented demonstrates a reasonable likelihood that Petitioner would prevail, on Petitioner's Grounds 4 and 5, in establishing the unpatentability of at least one claim of the '519 patent. We determine that Petitioner has not demonstrated a reasonable likelihood it would prevail as to Grounds 1–3. Although the panel finds that Petitioner is not likely to prevail on some Grounds, the Board here institutes on all grounds in the petition. *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition").

II. BACKGROUND

A. Related Matters

The parties identify the following consolidated civil action:

> *Allergan USA, Inc. and Allergan Industrie SAS v. Prollenium US Inc. and Prollenium Medical Technologies Inc.*, Civil Action No. 19-126-CFC (D. Del. filed Jan. 22, 2019).)

Paper 4, 1–2.

Petitioner has filed Petitions for *inter partes* review of related U.S. patents as follows: US Patent No. 8,450,475 B2 (the "'475 patent") in IPR2019-01505; US Patent No. 9,238,013 (the "'013 patent") in IPR2019-01508; US Patent No. 8,822,676 B2 (the "'676 patent") in IPR2019-01617; and US Patent No. 9,358,322 B2 (the "'322 patent") in IPR2019-01509. Pet. 68–69.

B. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–8 of the '519 patent are unpatentable based on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–4	102(a)(1)	PMA P050047/S005[1]
1–4	102(a)(1)	Weinkle[2]
1–4	102(a)(1)	U.S. 2010/0028438 A1[3]
1–8	103	Lebreton[4], Sadozai[5],

[1] Summary Review Memo Template, P050047/S005, Juvederm Ultra Xc And Juvederm Ultra Plus XC (January 6, 2010") ("P050047/S005") (Ex. 1060).

[2] S.H. Weinkle et al., *A Multi-Center, Double-Blind, Randomized Controlled Study of the Safety and Effectiveness of Juvederm® Injectable Gel with and without Lidocaine*, 8 J. COSMETIC DERMATOL. 205–10 (2009) ("Weinkle") (Ex. 1070).

[3] Lebreton (U.S. 2010/0028438 A1, February 4, 2010) (the "'438 application) (Ex. 1072).

[4] Lebreton (US 2006/0194758 A1, August 31, 2006) ("Lebreton") (Ex. 1029).

[5] Sadozai et al. (US 2005/0136122 Al, June 23, 2005) ("Sadozai") (Ex. 1030).

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–8	103	P050047[6], Kinney[7]

Petitioner also relies upon the Declaration of its declarant, Dr. Dale P. DeVore (the "DeVore Declaration") (Ex. 1002).

C. The '519 Patent

The '519 patent is generally directed to cohesive soft tissue fillers, for example, dermal and subdermal fillers, based on hyaluronic acids ("HA") and pharmaceutically acceptable salts thereof. Ex. 1001 Abstr. More specifically, the '519 patent teaches soft tissue filler compositions generally comprising: a hyaluronic acid component crosslinked with a crosslinking agent selected from the group consisting of 1,4-butanediol diglycidyl ether (BDDE), 1,4-bis(2,3-epoxypropoxy) butane, 1,4-bisglycidyloxybutane, 1,2-bis(2,3-epoxypropoxy) ethylene and 1-(2,3-epoxypropyl)-2,3-epoxycyclohexane, and 1,4-butanediol diglycidyl ether; and at least one anesthetic agent, generally lidocaine, combined with the crosslinked HA component. Ex. 1001 col. 2, ll. 54–62.

D. Illustrative Claim

Claim 1 is illustrative and recites:

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[6] Inamed Corporation, *Summary Of Safety And Effectiveness Data: JUVEDERM™: Premarket Approval Application (PMA) Number P050047* (June 2, 2006) ("P050047") (Ex. 1074).

[7] B.M. Kinney, *Injecting Puragen Plus into the Nasolabial Folds: Preliminary Observations of FDA Trial*, 26(6) AESTHETIC SURG. J. 741–48 (2006) ("Kinney") (Ex. 1012).

> 1. A first sterile dermal filler composition comprising hyaluronic acid crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and about 0.3% lidocaine by weight, wherein the first composition fills in facial lines and depressions substantially the same as a second sterile dermal filler comprising hyaluronic acid crosslinked with BDDE wherein the second composition does not include lidocaine but otherwise has the same composition as the first composition.

Ex. 1001 col. 19, ll. 16–23.

Independent claims 3 and 5 are similar, but recite, respectively, that the first sterile dermal filler composition "restores fat loss-related tissue volume loss substantially the same," or "is substantially as stable during storage under ambient conditions for at least 3 months," as the second dermal filler. *Id.* at col. 20, ll. 2–3, 12–13.

E. Prosecution History of the '519 Patent

In August and September 2008, Allergan filed a trio of provisional applications (US Appl. Ser. No. 61/085,956, August 04, 2008 (the "'956 application"); US Appl. Ser. No. 61/087,934, August 11, 2008 (the "'934 application"); and US Appl. Ser. No. 61/096,278, September 11, 2008 (the "'278 application") to which the '519 patent claims the priority benefit. Pet. 11.

The parent application of the '519 patent, US Appl. Ser. No. 14/242,747 (the "'747 application") was filed on April 1, 2014, as a continuation of US Appl. Ser. No. 13/419,079 ("the '079 application"), which is, in turn, a continuation of US Appl. Ser. No. 12/393,884 (the "'884 application"). Pet. 13. The Examiner issued a first action Notice of Allowance on October 10, 2014, citing arguments and evidence relied upon by the Patent Owner in the examination of the '884 application. *Id.* (citing Ex. 1049 6–7). Specifically, the then-applicant argued, citing a declaration submitted by the inventor, that a person of ordinary

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