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Paper 66
Date: July 16, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GALDERMA S.A.; GALDERMA LABORATORIES, INC.; GALDERMA LABORATORIES LP; GALDERMA RESEARCH & DEVELOPMENT SNC; NESTLÉ SKIN HEALTH, INC.; NESTLÉ SKIN HEALTH S.A.; and NESTLÉ S.A.,
Petitioner,

v.

MEDY-TOX, INC.,
Patent Owner.

PGR2019-00062
Patent 10,143,728 B2

Before ZHENYU YANG, CHRISTOPHER G. PAULRAJ, and TIMOTHY G. MAJORS, *Administrative Patent Judges.*

PAULRAJ, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Cancelling Original Claims 1–10
Denying Patent Owner's Non-Contingent Revised Motion to Amend With Regard to Proposed Substitute Claims 19–27
35 U.S.C. § 328(a)

I. INTRODUCTION

This is our Final Written Decision pursuant to 35 U.S.C. § 328(a). For the reasons discussed below, we hereby deny Patent Owner's non-contingent revised Motion to Amend with regard to proposed substitute claims 19–27. Paper 30 ("revised MTA" or "Rev. Mot."). We do not address the patentability of original claims 1–10, each of which is cancelled by virtue of the non-contingent revised MTA.

A. Procedural Background and Summary

Galderma S.A., et al., ("Petitioner") filed a Petition requesting post-grant review of claims 1–10 of U.S. Patent No. 10,143,728 B2 (Ex. 1001, "the '728 patent"). Paper 2 ("Pet."). Medy-Tox, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 11.

We determined that the '728 patent was eligible for post-grant review and that Petitioner demonstrated that it is more likely than not that at least one of the challenged claims was unpatentable. Accordingly, we instituted trial as to claims 1–10 of the '728 patent. Paper 14 ("Institution Decision" or "Dec.").

Following institution, Patent Owner did not file a Response to the Petition to contest the unpatentability arguments presented in the Petition with regard to the original claims, and instead chose to file a non-contingent Motion to Amend. Paper 21. In its Motion to Amend, Patent Owner requested that we provide Preliminary Guidance concerning the Motion to Amend in accordance with the Board's pilot program concerning motion to amend practice and procedures. Mot. 3; *see also* Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497 (Mar. 15, 2019) (providing a patent

owner with the option to receive preliminary guidance from the Board on its motion to amend) ("Notice"). Petitioner filed an Opposition to the Motion to Amend. Paper 26.

In response to Patent Owner's request, we issued our Preliminary Guidance, indicating our initial, preliminary, non-binding views on whether Patent Owner had shown a reasonable likelihood that it had satisfied the statutory and regulatory requirements associated with filing a motion to amend in a post-grant review and whether Petitioner had established a reasonable likelihood that the substitute claims are unpatentable. Paper 28 ("Prelim. Guid.); *see* 35 U.S.C. § 326(d); 37 C.F.R. § 42.221; *see also* Notice, 84 Fed. Reg. at 9,497 ("The preliminary guidance . . . provides preliminary, non binding guidance from the Board to the parties about the [motion to amend].")

Patent Owner thereafter filed the non-contingent revised MMTA seeking to expressly cancel original claim 6 and replace the other original claims with proposed substitute claims 19–27. *See generally* Rev. Mot. Petitioner filed an Opposition to the revised MTA. Paper 40 ("Opp."). Patent Owner filed a Reply in support of its revised MTA, Paper 55 ("Reply"),[1] and Petitioner filed a Sur-Reply in opposition to the revised MTA, Paper 60.

After Patent Owner filed its revised MTA, the Chief Administrative Patent Judge extended the time to complete this proceeding by six months for good cause. Papers 32, 33, 34, 35. Prior to the oral hearing, we notified the parties of a potential *sua sponte* ground of unpatentability for substitute

[1] This corrected Reply replaced Patent Owner's originally filed Reply, Paper 52.

independent claim 19 as proposed in the revised MTA. Paper 54; *see Nike, Inc. v. Adidas AG*, 955 F.3d 45, 51 (Fed. Cir. 2020) (holding that the Board may *sua sponte* identify a patentability issue for a proposed substitute claim); *Hunting Titan, Inc. v. DynaEnergetics Europe GmbH*, IPR2018-00600, Paper 67 at 13 (PTAB July 6, 2020) (precedential) (explaining that the Board may, in rare circumstances, raise a ground of unpatentability not raised by the parties). We held the oral hearing on March 19, 2021, and the transcript of that hearing has been entered into the record. Paper 65 ("Tr.").

B. Real Parties-in-Interest

Petitioner initially identified Galderma S.A., Galderma Laboratories, Inc., Galderma Laboratories LP, Galderma Research & Development SNC, Nestlé Skin Health, Inc., Nestlé Skin Health S.A., and Nestlé S.A. as the real parties-in-interest for Petitioner. Pet. 4–5. Petitioner later updated its mandatory notices to indicate that Nestlé Skin Health S.A. was acquired by EQT Partners on October 2, 2019, and that Nestlé S.A. sold Galderma S.A., Galderma Laboratories, Inc., Galderma Laboratories L.P., Galderma Research & Development SNC, Nestlé Skin Health, Inc. (now SHDS, Inc.), and Nestlé Skin Health S.A. to an investment consortium of the following: (i) EQT Partners AB; (ii) PSP Investments; and (iii) Luxinva, a wholly owned subsidiary of Abu Dhabi Investment Authority. Paper 4. Petitioner contends that the consortium of investment partners are not real parties-in-interest because they did not have any role in directing, preparing, or filing the Petition, or any role in directing or controlling this proceeding. *Id.*

Patent Owner identifies Medy-Tox, Inc., Allergan Pharmaceuticals Ireland, Allergan Pharmaceuticals Holding (Ireland), and Allergan, Inc., as the real parties-in-interest for Patent Owner. Paper 5.

The parties do not dispute the identification of the real parties-in-interest.

C. Related Matters

Petitioner and Patent Owner report that the '728 patent is not the subject of any other judicial or administrative matter. Pet. 5; Paper 5, 2.

D. The '728 Patent

The '728 patent, titled "Long Lasting Effect of New Botulinum Toxin Formulation," discloses the use of an animal-protein-free botulinum toxin composition that exhibits a longer lasting effect compared to an animal-protein-containing botulinum toxin composition. Ex. 1001, codes (54), (57). The patent issued from an application (No. 15/336,119) filed October 27, 2016, but claims earliest priority to a provisional application (No. 61/915,476) filed December 12, 2013. *Id.* at codes (60), (63).

The specification explains that commercially available botulinum toxin A (BoNT/A) compositions, including BOTOX® (ona-BoNT/A), all contain animal proteins such as albumin and have a duration effect of approximately 3 months for treating conditions such as crow's feet lines or glabellar lines. *Id.* at 1:40–44. In contrast, the '728 patent claims methods of "locally administering a therapeutically effective amount of a botulinum toxin composition that does not comprise an animal-derived product or recombinant human albumin." *Id.* at 32:4–7.

As noted in the specification, animal-protein-free botulinum toxin compositions were previously disclosed in the inventors' prior patent applications, U.S. Application Publication No. 2010/0291136, now U.S. Patent No. 8,617,568 ("Jung I") (Exhibit 1006), and PCT/KR10–2012–0112248 ("Jung II") (Exhibit 1007), which are both incorporated by

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