United States Court of Appeals for the Federal Circuit

MEDYTOX, INC.,
Appellant

v.

GALDERMA S.A., GALDERMA LABORATORIES INC., GALDERMA LABORATORIES, L.P., GALDERMA RESEARCH AND DEVELOPMENT, S.N.C., SHDS, INC., GALDERMA HOLDINGS S.A.,
Appellees

KATHERINE K. VIDAL, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2022-1165

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. PGR2019-00062.

Decided: June 27, 2023

VISHAL C. GUPTA, Steptoe & Johnson LLP, New York, NY, argued for appellant. Also represented by TYLER DOH, JOHN J. MOLENDA; CHRISTOPHER ALAN SUAREZ,

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Washington, DC.

JOSEPH A. MAHONEY, Mayer Brown, LLP, Charlotte, NC, argued for appellees. Also represented by AMANDA STREFF BONNER, ERICK J. PALMER, Chicago, IL.

ROBERT MCBRIDE, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by SARAH E. CRAVEN, THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED.

Before DYK, REYNA, and STARK, *Circuit Judges*.

REYNA, *Circuit Judge*.

Appellant Medytox, Inc. appeals a final written decision in a post-grant review proceeding of the Patent Trial and Appeal Board that denied Medytox's revised motion to amend to substitute claims 19–27 of U.S. Patent No. 10,143,728. On appeal, Medytox challenges the Board's findings on claim construction, written description, and enablement. Medytox also challenges the Board's Pilot Program concerning motion to amend practice and procedures under the Administrative Procedure Act. We affirm.

BACKGROUND

The patent-at-issue, U.S. Patent No. 10,143,728 (the "'728 patent") issued from an application filed on October 27, 2016, but claims priority from a provisional application filed on December 12, 2013. *See Galderma S.A. v. Medytox, Inc.*, PGR2019-00062, 2021 WL 3039217, at *2 (P.T.A.B. July 16, 2021) ("*Decision*"). The '728 patent is directed to the use of an animal-protein-free botulinum toxin composition that exhibits a longer lasting effect in the patient compared to an animal protein-containing botulinum toxin composition. '728 Patent, col. 2 ll. 57–62.

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According to the '728 patent, the animal-protein-free botulinum toxin composition can be used to treat both cosmetic and non-cosmetic conditions, from glabellar lines and lateral canthal lines to chronic migraines. '728 Patent, col. 11 l. 5–col. 12 l. 47.

Substitute claim 19 is representative of the substitute claims:

19. A method for treating glabellar lines ~~a condition~~ in a patient in need thereof, comprising:

locally administering a first treatment of ~~therapeutically effective amount of~~ a botulinum toxin composition comprising a serotype A botulinum toxin in an amount present in about 20 units of MT10109L, a first stabilizer comprising a polysorbate, and at least one additional stabilizer, and that does not comprise an animal-derived product or recombinant human albumin;

locally administering a second treatment of the botulinum toxin composition at a time interval after the first treatment;

wherein said time interval is the length of effect of the serotype A botulinum toxin composition as determined by physician's live assessment at maximum frown;

wherein said botulinum toxin composition has a greater length of effect compared to about 20 units of BOTOX®, when ~~whereby the botulinum toxin composition exhibits a longer lasting effect in the patient when compared to treatment of the same condition with a botulinum toxin composition that contains an animal-derived product or recombinant human albumin dosed at a comparable amount and~~ administered in the same manner for the treatment of glabellar lines ~~and to the same locations(s)~~ as that of the botulinum toxin composition; and

wherein said greater length of effect is determined by physician's live assessment at maximum frown and

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requires a responder rate at 16 weeks after the first treatment of 50% or greater. ~~that does not comprise an animal-derived product or recombinant human albumin, wherein the condition is selected from the group consisting of glabellar lines, marionette lines, brow furrows, lateral canthal lines, and any combination thereof.~~

J.A. 2683.[1]

The specification notes that two previous patent applications, which are incorporated by reference in their entireties into the '728 patent, disclose animal-protein-free botulinum toxin compositions. '728 Patent, col. 2 l. 63–col. 3 l. 14. The specification also describes the results of "experimental examples," i.e., two clinical trials, which compared animal-protein-free botulinum toxin composition with botulinum toxin stabilized with human serum albumin. '728 Patent, col. 13 l. 41–col. 31 l. 55. These examples were provided in "support of [the specification's] conclusion regarding longer lasting efficacy." *Decision*, at *3.

The first example is a Phase III clinical study comparing an animal-protein-free composition of MT10109L to BOTOX® in managing moderate to severe glabellar frown lines. '728 Patent, col. 13 l. 41–col. 22 l. 67. The results of example 1 demonstrated that "MT10109L treatment" led to "significant improvement" of frown line severity at week 4 and week 16. '728 Patent, col. 20 ll. 53–57.

The second example is a Phase II clinical study comparing MT10109 to BOTOX®. '728 Patent, col. 23 l. 1–col. 31 l. 55. The result of example 2 is that "lyophilized MT10109 dosed at 20 U" "displays an increased sustained

[1] Substitute claim 19 reflects Medytox's amendments to original claim 1 through underlined text (text added to) and strikethrough text (text deleted from). Appellant's Br. 17 n.6; *Decision*, at *4.

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effect compared to BOTOX®." '728 Patent, col. 31 ll. 48–52.

PROCEDURAL HISTORY

Appellee Galderma S.A., et. al., filed a petition requesting post-grant review of claims 1–10 of the '728 patent, which the Patent Trial and Appeal Board ("Board") granted on all challenged claims. *Decision*, at *1. Medytox filed a non-contingent motion to amend seeking to cancel claims 1–10 of the '728 patent and substitute claims 11–18.[2] J.A. 2635. Medytox requested that the Board issue a Preliminary Guidance in accordance with the pilot program concerning the motion to amend practice and procedures ("Pilot Program"). *Id.*[3] Galderma opposed the motion. *Decision,* at *1. Among other things, Galderma argued that the claims added new matter because the claims covered compounds with a 16-week responder rate between 50%

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[2] The Board's underlying decision refers to Appellant as "Medy-Tox" (J.A. 2), Galderma refers to Appellant as "MedyTox" (Appellee's Br. 1), but, for this opinion, we follow Appellant's spelling, that is, "Medytox" (Appellant's Br. 2).

[3] Patent owners can partake in the Pilot Program concerning motion to amend practice for motions filed in inter partes reviews, post-grant reviews, and covered business method patent reviews (i.e., AIA trials) before the Patent Trial and Appeal Board. 84 Fed. Reg. 9,497. After receiving the petitioner's opposition to its motion to amend, the Pilot Program allows a patent owner to receive a Preliminary Guidance from the Board regarding its motion or to file a revised motion to amend. *Id.* The Preliminary Guidance is an initial discussion about whether there is a reasonable likelihood that the motion to amend meets the statutory and regulatory requirements. *Id.*

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