United States Court of Appeals for the Federal Circuit

ALMIRALL, LLC,
Appellant

v.

AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,
Appellees

ANDREW HIRSHFELD, PERFORMING THE FUNCTIONS AND DUTIES OF THE UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2020-2331

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2019-00207, IPR2019-01095.

Decided: March 14, 2022

JAMES TRAINOR, Fenwick & West LLP, New York, NY, argued for appellant. Also represented by ADAM GAHTAN, RICHARD SHEA; ELIZABETH B. HAGAN, Seattle, WA.

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DENNIES VARUGHESE, Sterne Kessler Goldstein & Fox, PLLC, Washington, DC, argued for appellees. Also represented by KRISTINA CAGGIANO KELLY, ADAM LAROCK.

ROBERT J. MCMANUS, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for intervenor. Also represented by BENJAMIN T. HICKMAN, THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED.

Before LOURIE, CHEN, and CUNNINGHAM, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Almirall, LLC ("Almirall") appeals from the final written decision of the U.S. Patent and Trademark Office Patent Trial and Appeal Board (the "Board") holding that claims 1–8 of U.S. Patent 9,517,219 (the "'219 patent") would have been obvious over the cited prior art at the time the alleged invention was made.[1] *See Amneal Pharms. LLC v. Almirall, LLC*, No. IPR2019-00207, 2020 WL 2833274 (P.T.A.B. May 29, 2020) ("*Decision*"). For the reasons provided below, we affirm.

BACKGROUND

Almirall owns the '219 patent, which relates to methods of treating acne or rosacea with dapsone formulations that include an acrylamide/sodium acryloyldimethyl taurate copolymer ("A/SA") thickening agent and the solvent diethylene glycol monoethyl ether ("DGME"). Dapsone can be used for treating various dermatological conditions.

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[1] Because the challenged claims of the '219 patent have an effective filing date before March 16, 2013, we apply the version of 35 U.S.C. § 103 in effect before the adoption of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011).

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'219 patent, col. 1 ll. 19–23. DGME allows compositions to be prepared with increased solubilized concentrations of dapsone. *Id.* at col. 2 ll. 48–50. A polymeric viscosity builder such as an A/SA agent can minimize the intensity of yellowing of the composition. *Id.* at col. 2, ll. 54–61. It can also influence dapsone crystallization by reducing the particle size and minimizing a gritty feel upon application. *See id.*

Adapalene is a compound used for treating dermatological conditions, sometimes in combination with dapsone. *See Decision* at *18. The '219 patent includes 62 generalized composition embodiments, '219 patent, col. 6 l. 58–col. 12 l. 40, and eight specific example formulations, *id.* at col. 12 l. 42–col. 15 l. 33. Several of the examples are described as including adapalene.

Independent claims 1 and 6 read as follows:

> 1. A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea a topical pharmaceutical composition comprising:
>
> about 7.5% w/w dapsone;
>
> about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
>
> **about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer**; and
>
> water;
>
> **wherein the topical pharmaceutical composition does not comprise adapalene**.

Id. at col. 15 l. 40–col. 16 l. 13 (emphases added).

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> 6. A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea a topical pharmaceutical composition comprising:
>
> about 7.5% w/w dapsone;
>
> about 30% w/w diethylene glycol monoethyl ether;
>
> **about 4% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer**; and
>
> water;
>
> **wherein the topical pharmaceutical composition does not comprise adapalene**.

Id. at col. 16 ll. 23–36 (emphases added).

Amneal filed a petition for *inter partes* review of claims 1–8 of the '219 patent. J.A. 120. Amneal argued that claims 1–8 would have been obvious over Int'l Patent Pub. WO 2009/061298 ("Garrett") and Int'l Patent Pub. WO 2010/072958 ("Nadau-Fourcade"). J.A. 117–18. Amneal also argued that claims 1–8 would have been obvious over Garrett and a publication titled "Characterization and Stability of Emulsion Gels Based on Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer" ("Bonacucina").[2] *Id.*

Garrett describes topical dapsone treatments for treating dermatological conditions including acne and rosacea. Garrett states that the dapsone may exist in "a microparticulate form, a dissolved form, or both." J.A. 1475. Garrett

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[2] Giulia Bonacucina, *et al., Characterization and Stability of Emulsion Gels Based on Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer*, 10(2) AAPS PHARMSCITECH 368–75 (2009).

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does not disclose any formulations that include adapalene. For example, Garrett identifies a commercial product, Aczone®, that lacks adapalene. J.A. 1482.

Garrett's formulations include thickening agents. J.A. 1486. Garrett describes suitable thickening agents as including polymer thickeners such as hydrophilic gelling agents used in the cosmetic and pharmaceutical industries. J.A. 1485. Garrett explains that a gelling agent preferably comprises between about 0.2% to about 4% by weight of the composition. *Id.* Garrett identifies Carbopol® as a preferred thickening agent. *Id.* Carbopol® is one of numerous cross-linked acrylic acid polymers that are given the name "carbomer." *Id.* Garrett's preferred compositional weight percent range for Carbopol® is between about 0.5% to about 2%.

Garrett discloses a preferred embodiment that "includes about 0.5% to 4.0% carbomer . . .; about 53.8% to 84.2% water; about 10% to 30% ethoxydiglycol [i.e., DGME]; about 0.2% methylparaben; about 5% to 10% dapsone in a microparticulate and dissolved state; and about 0.1% to 2% sodium hydroxide solution." *Decision* at *5 (citing J.A. 1476). But Garrett also contemplates adjustments for optimization. "The relative percentages for each of the reagents used . . . may vary depending upon the desired strength of the target formulation, gel viscosity, and the desired ratio of microparticulate to dissolved dapsone. Unless otherwise designated, all reagents listed . . . are commonly known by one of ordinary skill in the art and are commercially available from pharmaceutical or cosmetic excipient suppliers." *Id.* at *6 (citing J.A. 1490, 1495).

Nadau-Fourcade describes topical pharmaceutical compositions with a water-sensitive active pharmaceutical ingredient in dissolved form. J.A. 1529. The compositions are for dermatologic use for conditions including acne and rosacea. J.A. 1578. Nadau-Fourcade's compositions may include a hydrophilic gelling agent. J.A. 1574. Nadau-

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