NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

MERCK SHARP & DOHME CORP.,
Appellant

v.

WYETH LLC,
Appellee

2018-2133, 2018-2134

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-00378, IPR2017-00380.

Decided: November 26, 2019

JEFFREY A. LAMKEN, MoloLamken LLP, Washington, DC, argued for appellant. Also represented by MICHAEL GREGORY PATTILLO, JR., BENJAMIN THOMAS SIROLLY; SARA MARGOLIS, New York, NY; ARLENE L. CHOW, Hogan Lovells US LLP, New York, NY; RYAN BOYD MCCRUM, Jones Day, Cleveland, OH; JENNIFER LORAINE SWIZE, Washington, DC.

JOHN P. SCHEIBELER, White & Case LLP, New York, NY, argued for appellee. Also represented by DIMITRIOS T.

DRIVAS, DANIEL LEDESMA, STEFAN MENTZER, AMIT THAKORE.

Before PROST, *Chief Judge,* DYK and WALLACH, *Circuit Judges.*

DYK, *Circuit Judge.*

Merck Sharp & Dohme Corp. ("Merck") appeals decisions of the Patent Trial and Appeal Board ("Board") declining to find claim 18 of U.S. Patent No. 8,562,999 ("the '999 patent") unpatentable as obvious. We vacate and remand for further proceedings.

BACKGROUND

The '999 patent, owned by Wyeth LLC ("Wyeth"), is directed to formulations for stabilizing polysaccharide-protein conjugate vaccines. These vaccines are derived from the capsular polysaccharides present on the surface of certain disease-causing bacteria. The human immune system can use these capsular polysaccharides to detect and identify different serotypes (i.e., strains) of a species of bacteria. Polysaccharide vaccines can be monovalent (comprising a single serotype), or multivalent (comprising multiple serotypes). For example, a 13-valent vaccine would contain polysaccharides from 13 different serotypes. Because these polysaccharides typically have low immunogenicity (i.e., ability to provoke an immune response), it is desirable to enhance the effectiveness of these vaccines by conjugating (i.e., bonding) the polysaccharides to a carrier protein with high immunogenicity. However, as the '999 patent explains, polysaccharide-protein conjugate vaccines aggregate (i.e., clump together) when exposed to silicone oil, a common lubricant used in vaccine storage containers. The invention described in the '999 patent is a formulation that inhibits silicone-induced aggregation by suspending the polysaccharide-protein conjugate in a mixture of (1) a pH-buffered saline solution and (2) an aluminum salt.

Claim 1, the sole independent claim of the '999 patent, recites a formulation comprising of: (1) a pH-buffered saline solution, (2) an aluminum salt, and (3) one or more polysaccharide-protein conjugates. Claim 18 recites a specific 13-valent pneumococcal polysaccharide conjugate with CRM_{197} as the sole carrier protein for use with the formulation recited in claim 1.

On December 1, 2016, Merck filed two petitions for *inter partes* review with the Board, challenging claims 1–6, 10, 11, 14, and 17–20 of the '999 patent. The Board instituted review of all challenged claims in two parallel proceedings, IPR2017-00378 ("the 378 IPR") and IPR2017-00380 ("the 380 IPR"). In each proceeding, the Board found all the challenged claims except one—claim 18—to be unpatentable as obvious. Claim 18 covers a 13-valent pneumococcal conjugate vaccine. In both proceedings, the Board rejected Merck's argument that the formulation recited by claim 18 was obvious in light of the prior art. Merck appeals the Board's decisions as to claim 18. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

"We review the Board's factual findings for substantial evidence and review its legal conclusions de novo." *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1280 (Fed. Cir. 2015). "The ultimate determination of obviousness under [35 U.S.C.] § 103 is a question of law based on underlying factual findings." *Id.*[1] "The presence or absence of a

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[1] Congress amended § 103 when it enacted the Leahy-Smith America Invents Act ("AIA"). Pub. L. No. 112-29, § 3(b)(1), 125 Stat. 284, 285–87 (2011). However, because the application that led to the '999 patent has never contained (1) a claim having an effective filing date on or after March 16, 2013, or (2) a reference under 35 U.S.C. §§ 120, 121, or 365(c) to any patent or application

motivation to combine references in an obviousness determination is a pure question of fact." *Intelligent Bio-Systems, Inc. v. Illumina Cambridge, Ltd.*, 821 F.3d 1359, 1366 (Fed. Cir. 2016) (quoting *Par Pharm., Inc. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014)). "The presence or absence of a reasonable expectation of success is also a question of fact." *Id.* (quoting *Par Pharm.*, 773 F.3d at 1196).

I

It is well established that "[t]he agency tribunal must make findings of relevant facts, and present its reasoning in sufficient detail that the court may conduct meaningful review of the agency action." *In re Lee*, 277 F.3d 1338, 1346 (Fed. Cir. 2002). "The [Board]'s own explanation must suffice for us to see that the agency has done its job and must be capable of being 'reasonably . . . discerned' from a relatively concise [Board] discussion." *In re NuVasive, Inc.*, 842 F.3d 1376, 1383 (Fed. Cir. 2016) (quoting *In re Huston*, 308 F.3d 1267, 1281 (Fed. Cir. 2002)).

On appeal, Merck argues that the Board's decisions here fail to provide a reasoned basis for upholding claim 18. For the reasons discussed below, we agree.

Claim 18 depends on claim 1, which recites:

> A formulation comprising (i) a pH buffered saline solution, wherein the buffer has a pKa of about 3.5 to about 7.5, (ii) an aluminum salt and (iii) one or more polysaccharide-protein conjugates, wherein the formulation is comprised in a siliconized container means and inhibits aggregation induced by the siliconized container means.

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that ever contained such a claim, the pre-AIA § 103 applies. *See id.* § 3(n)(1), 125 Stat. at 293.

'999 patent, col. 31, ll. 7–12.

Claim 18 recites:

> The formulation of claim 1, wherein the one or more polysaccharide-protein conjugate comprises [13 different *S. pneumoniae* serotype polysaccharides conjugated to a CRM_{197} polypeptide].

'999 patent, col. 32, ll. 24–45.[2]

In the 378 IPR, Merck challenged claim 1 as obvious in light of International PCT Application No. WO 03/009869 ("Chiron"); Edward J. Smith, *Siliconization of Parenteral Drug Packaging Components* (1988) ("Smith"); and International PCT Application No. WO 2004/071439 ("Elan"). In the 380 IPR, Merck challenged claim 1 as obvious in light of Chiron and Annex I of the European Medicines Agency's European Public Assessment Report for Prevenar ("Prevenar"). In both proceedings, the Board made detailed findings that claim 1 was obvious in light of the cited references.[3] The Board also found that a skilled artisan "would have found it obvious to prepare Chiron's formulation [according to claim 1 and also] comprising the seven

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[2] The 13 serotypes are 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F.

[3] The Board found that "Chiron teaches a formulation comprising the ingredients [pH-buffered saline solution, aluminum salt, and one or more polysaccharide-protein conjugate] recited in independent claim 1," J.A. 21, that "a person of ordinary skill in the art would have had reason to provide Chiron's formulation in a siliconized container means, and would have had a reasonable expectation of successfully doing so, as had been done with other . . . conjugate vaccines [identified by Chiron]," J.A. 29, and that "a person of ordinary skill in the art would have appreciated that Chiron's formulation inhibits aggregation induced by a siliconized container means," J.A. 32.

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