NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

PFIZER INC.,
Appellant

v.

SANOFI VACCINES US INC., SK BIOSCIENCE CO., LTD.,
Appellees

2024-2199, 2024-2201, 2024-2202

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-02131, IPR2017-02132, IPR2018-00187.

Decided: July 31, 2026

JOHN PAUL SCHEIBELER, White & Case LLP, New York, NY, argued for appellant. Also represented by DIMITRIOS T. DRIVAS, AMIT THAKORE; CATALIN SEBASTIAN ZONTE, Los Angeles, CA.

SIEGMUND Y. GUTMAN, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, PC, Los Angeles, CA, argued for appellees. Also represented by ERIN JANELLE SHORT; PETER CUOMO, Boston, MA.

Before LOURIE, PROST, and STARK, *Circuit Judges*.

LOURIE, *Circuit Judge*.

This case comes back to us after we previously remanded it for the Patent Trial and Appeal Board ("the Board") to consider, in its *inter partes* review ("IPR") proceeding, the patentability of proposed substitute claims 48 and 49 of Pfizer Inc.'s ("Pfizer's") U.S. Patent 9,492,559 ("the '559 patent"). On remand, the Board determined in a final written decision that those proposed substitute claims would have been obvious over certain prior art publications and therefore denied Pfizer's motion to amend its claims. *Sanofi Pasteur Inc. v. Pfizer Inc.*, Nos. IPR2018-00187, IPR2017-02131, IPR2017-02132, 2024 WL 2927019 (P.T.A.B. June 10, 2024) ("*Decision*"), J.A. 71–105.[1] For the following reasons, we *affirm*.

BACKGROUND

The '559 patent is directed to compositions for use in pneumococcal vaccines; specifically, "immunogenic compositions comprising conjugated *Streptococcus pneumoniae* [("*S. pneumoniae*")] capsular saccharide antigens (glycoconjugates)." '559 patent, Abstract. *S. pneumoniae* (also known as pneumococcus) is "[t]he etiological agent of pneumococcal disease," and "is a Gram-positive encapsulated coccus, surrounded by a polysaccharide capsule." *Id.* col. 1 ll. 49–52. The polysaccharide capsule can be made of vari-

[1] The Board issued three substantively identical decisions for three IPRs: IPR2017-02131 (J.A. 1–35), IPR2017-02132 (J.A. 36–70), and IPR2018-00187 (J.A. 71–105). We cite the IPR2018-00187 decision, and filings relevant to that proceeding, throughout this opinion, but our determinations are applicable to all three IPRs.

ous compositions, which results in at least ninety-one different serotypes, or variations, of *S. pneumoniae*, some of which can cause diseases such as pneumonia, febrile bacterium, and meningitis. *Id.* col. 1 ll. 27–30, 52–53.

The claims of the '559 patent recite various serotypes of *S. pneumoniae*, with each separate serotype designated by a numeric or alphanumeric identifier. For example, claim 1 recites serotype 22F, dependent claim 3 further recites serotypes 15B and 33F, and dependent claim 4 further recites serotypes 12F, 10A, 11A, and 8. *Id.* col. 141 ll. 27–33, col. 141 ll. 38–46.

Sanofi Vaccines US Inc.[2] and SK Bioscience Co., Ltd.[3] (collectively, "Sanofi") petitioned for IPR, challenging all claims of the '559 patent. J.A. 14477–571. The Board instituted IPR proceedings, and Pfizer moved to substitute proposed claims 46, 48, and 49 for claims 1, 3, and 4. Those proposed substitute claims recite:

> 46. An immunogenic composition comprising:
>
> a *Streptococcus pneumoniae* serotype 22F glycoconjugate, wherein the 22F glycoconjugate has a molecular weight of between 1000 kDa and 12,500 kDa and comprises an isolated capsular polysaccharide from *S. pneumoniae* serotype 22F and a CRM_{197} carrier protein, and wherein a ratio (w/w) of the polysaccharide to the carrier protein is between 0.4 and 2;

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[2] During the course of litigation, Sanofi changed its full name from "Sanofi Pasteur Inc." to "Sanofi Vaccines US Inc." *See* ECF Docket No. 48.

[3] During the course of litigation, the appeal and related interests transferred from SK Chemicals Co., Ltd. to its subsidiary, SK Bioscience Co., Ltd. *See* ECF Docket No. 30.

glycoconjugates from *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F all individually conjugated to CRM_{197};

an aluminum salt adjuvant; and

wherein the composition exhibits more than a 2-log increase above baseline in serum IgG levels in New Zealand White Rabbits across all serotypes in the composition following administration of two equal doses of the composition in the form of an initial dose and a booster dose.

48. The immunogenic composition of claim ~~1~~ 46, wherein the composition further comprises a *S. pneumoniae* serotype 15B glycoconjugate and a *S. pneumoniae* serotype 33F glycoconjugate, wherein said serotypes 15B and 33F are all individually conjugated to CRM_{197}.

49. The immunogenic composition of claim ~~3~~ 48, wherein the composition further comprises a *S. pneumoniae* serotype 12F glycoconjugate, a *S. pneumoniae* serotype 10A glycoconjugate, a *S. pneumoniae* serotype 11A glycoconjugate and a *S. pneumoniae* serotype 8 glycoconjugate, wherein said serotypes 12F, 10A, 11A and 8 are all individually conjugated to CRM_{197}.

J.A. 11072–73 (proposed additions underlined and proposed deletions struck through). In relevant part, the proposed substitute claims included additional serotypes and the limitation that "the composition exhibits *more than a 2-log increase above baseline in serum IgG levels* in New Zealand White Rabbits *across all serotypes* in the composition following administration of two equal doses of the composition." *Id.* at 11072 (emphasis added). The claimed "2-log increase" corresponds to a more than 100-fold increase above baseline serum IgG levels.

The Board denied Pfizer's motion to amend, determining that the proposed claims would have been obvious over a combination of U.S. Patent Application Publication 2012/0237542 ("Hausdorff"), U.S. Patent Application Publication 2011/0195086 ("Merck-086"), and PCT Patent Application Publication 2007/071711 ("GSK-711"). *See* J.A. 22286–303.

Pfizer appealed to this court, and we affirmed as to proposed claim 46 and remanded as to proposed claims 48 and 49. *Pfizer Inc. v. Sanofi Pasteur Inc.*, 94 F.4th 1341, 1351–53 (Fed. Cir. 2024). We determined that substantial evidence supported the Board's conclusion that proposed substitute claim 46 would have been obvious, but that the Board's decision was "silent as to why proposed substitute claims 48 and 49 would have been obvious over the references," offering no analysis and only "a conclusory statement" for those claims. *Id.* Specifically, we concluded that the Board's determination as to the 2-log increase for the serotypes recited in proposed substitute claims 48 and 49 was not supported by substantial evidence, and it therefore abused its discretion in denying Pfizer's motion to amend. *Id.* at 1353. We therefore remanded "for the Board to further consider Pfizer's motion[]." *Id.*

On remand, the Board concluded that proposed substitute claims 48 and 49 would also have been obvious, and in doing so concluded that a skilled artisan would have had a reasonable expectation of success in achieving a 2-log increase above serum IgG levels for the serotypes recited in those claims. *Decision*, 2024 WL 2927019, at *8, *10–14. The Board therefore denied Pfizer's motion to amend. *Id.* at *14.

Pfizer timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

"We review the Board's decision to deny a motion to amend under the APA and must set aside the Board's action if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Pfizer*, 94 F.4th at 1350 (quoting 5 U.S.C. § 706(2)(A)). "Obviousness is a question of law that we review *de novo*, but the Board's underlying findings of fact are reviewed for substantial evidence." *Liqwd, Inc. v. L'Oreal USA, Inc.*, 941 F.3d 1133, 1136 (Fed. Cir. 2019). "Whether or not a person of ordinary skill would have had the requisite motivation to combine references, and whether or not she would have had a reasonable expectation of success in doing so, are questions of fact we review for substantial evidence." *Pfizer*, 94 F.4th at 1347. Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. of N.Y. v. Nat'l Lab. Rels. Bd.*, 305 U.S. 197, 229 (1938).

Pfizer argues that the Board's determination that proposed substitute claims 48 and 49 would have been obvious lacks substantial evidence, and the Board therefore abused its discretion in denying Pfizer's motion to amend. *See* Open. Br. 30–32. Specifically, Pfizer argues that there was no substantial evidence supporting the Board's conclusion that a skilled artisan would have had a reasonable expectation of success in achieving "more than a 2-log increase above baseline in serum IgG levels in New Zealand White Rabbits across" serotypes 15B and 33F in claim 48 and serotypes 12F, 10A, 11A and 8 in claim 49. We disagree.

For that limitation, the Board pointed to Hausdorff's Table 3, which showed a more than 2-log increase above baseline serum IgG levels for thirteen of the fourteen serotypes required by proposed substitute claim 46. *Decision*, 2024 WL 2927019, at *11 (citing J.A. 4034). To the Board, this indicated that "there would have been a reasonable expectation of success in the inclusion of serotypes 22F, 33F,

8, 10A, 11A, 12F, and 15B in Hausdorff's pneumococcal vaccine while retaining the 2-log increased immune response of the thirteen serotypes *and also retaining a 2-log increase in the immune response to the added serotypes*." *Id.* (emphasis added). Indeed, Sanofi's expert testified that "[t]here was a clear motivation to further increase the IgG levels above the baseline for all serotypes as serum IgG levels are one of the indicators of immunogenicity of vaccine." J.A. 20182.

The Board additionally pointed to expert testimony from another Sanofi expert in a related IPR proceeding, also concerning the '559 patent. *Decision*, 2024 WL 2927019, at *11. The expert acknowledged that "[w]ith conjugates on CRM_{197} it has been possible to induce good immunity to new serotypes without negatively affecting the components already in the vaccine." J.A. 5272 (emphasis omitted) (quoting J.A. 5246).

The Board's conclusion that a skilled artisan would have had a reasonable expectation of success in achieving the 2-log increase for all serotypes in proposed substitute claims 48 and 49 is therefore supported by substantial evidence consisting of: (1) Hausdorff's Table 3 showing a 2-log increase for *all* serotypes included in a vaccine, (2) expert testimony that a skilled artisan would want to increase baseline IgG levels to improve immunogenicity, and (3) expert testimony that adding additional serotypes is possible without negatively affecting other components in the vaccine (that is, without negatively affecting the immunogenicity of other components).

While it is true that the prior art references contain no immunogenicity data for serotypes 15B, 33F, 12F, 10A, 11A, and 8, these are all known serotypes, and "a finding of obviousness does not require a guarantee of success." *Pfizer*, 94 F.4th at 1352. Indeed, "an expectation of success need only be *reasonable*, not absolute." *Id.* (emphasis in

original). As explained above, substantial evidence supports the Board's conclusion that there was a *reasonable* expectation of success in achieving a 2-log increase above baseline serum IgG levels for the additional serotypes listed in proposed substitute claims 48 and 49.

In sum, proposed substitute claims 48 and 49 are composition claims that recite known serotypes. They include a limitation that all those known serotypes exhibit a 2-log increase above baseline serum IgG levels. Although the prior art references do not show every serotype recited in claims 48 and 49 achieving the 2-log increase, the Board relied on substantial evidence showing that a skilled artisan would have had a reasonable expectation of success in achieving the 2-log increase for all the claimed serotypes. The Board therefore did not abuse its discretion in denying Pfizer's motion to amend.

CONCLUSION

We have considered Pfizer's remaining arguments but find them unpersuasive. For the foregoing reasons, we *affirm*.

AFFIRMED