United States Court of Appeals for the Federal Circuit

PFIZER INC.,
Appellant

v.

SANOFI PASTEUR INC., SK CHEMICALS CO., LTD.,
Appellees

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

2019-1871, 2019-1873, 2019-1875, 2019-1876, 2019-2224

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-02131, IPR2017-02132, IPR2017-02136, IPR2017-02138, IPR2018-00187.

Decided: March 5, 2024

JOHN P. SCHEIBELER, White & Case LLP, New York, NY, argued for appellant. Also represented by DIMITRIOS T. DRIVAS, AMIT THAKORE; ELIZABETH K. CHANG, CATALIN

SEBASTIAN ZONTE, Los Angeles, CA; HENRY HUANG, Palo Alto, CA.

SIEGMUND Y. GUTMAN, Proskauer Rose LLP, Los Angeles, CA, argued for appellees. Also represented by JOHN E. ROBERTS, Boston, MA.

MARY L. KELLY, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by PETER J. AYERS, DANIEL KAZHDAN, FARHEENA YASMEEN RASHEED; SCOTT R. MCINTOSH, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC.

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

LOURIE, *Circuit Judge*.

Pfizer Inc. appeals from five final written decisions of the U.S. Patent and Trademark Office Patent Trial and Appeal Board ("the Board") concluding that claims 1–45 of U.S. Patent 9,492,559 ("the '559 patent") are unpatentable. *Merck Sharp & Dohme Corp. v. Pfizer Inc.*, No. IPR2017-02131, 2019 WL 1222935 (P.T.A.B. Mar. 13, 2019) (holding claims 1–10, 16–19, and 38–45 unpatentable) ("*'131 Decision*"), J.A. 1–81; *Merck Sharp & Dohme Corp. v. Pfizer Inc.*, No. IPR2017-02132, 2019 WL 1220899 (P.T.A.B. Mar. 13, 2019) (same) ("*'132 Decision*"), J.A. 82–160; *Merck Sharp & Dohme Corp. v. Pfizer Inc.*, No. IPR2017-02136, 2019 WL 1222965 (P.T.A.B. Mar. 13, 2019) (holding claims 11–15 and 20–37 unpatentable) ("*'136 Decision*"), J.A. 161–216; *Merck Sharp & Dohme Corp. v. Pfizer Inc.*, No. IPR2017-02138, 2019 WL 1220900 (P.T.A.B. Mar. 13, 2019) (same) ("*'138 Decision*"), J.A. 217–71; *Sanofi Pasteur Inc. v. Pfizer Inc.*, No. IPR2018-00187, 2019 WL 2352182 (P.T.A.B. June 3, 2019) (holding claims 1–45 unpatentable) ("*Sanofi*

Decision"), J.A. 272–360.[1] The Board also denied Pfizer's contingent motions to amend the claims filed in three of the five IPRs, concluding that proposed claims 46–52, which Pfizer proposed to substitute for claims 1–4, 9, 41, and 42, respectively, were not independently patentable. *Sanofi Decision* at *27–37; *'131 Decision* at *24–33; *'132 Decision* at *23–32.

For the following reasons, we affirm the Board's conclusions that claims 1–45 are unpatentable. We further affirm the Board's denials of Pfizer's motions to amend by adding proposed claims 46, 47, and 50–52. But we vacate those denials as to proposed claims 48 and 49, and remand to the Board for further consideration of those claims.

BACKGROUND

Pfizer owns the '559 patent, which is directed to immunogenic compositions comprising conjugated *Streptococcus pneumoniae* capsular saccharide antigens (*i.e.*, glycoconjugates) for use in pneumococcal vaccines. *See* '559 Patent at Abstract, J.A. 845. As the '559 patent explains, *S. pneumoniae* "is a Gram-positive encapsulated coccus, surrounded by a polysaccharide capsule." *Id.* at col. 1, ll. 50–52, J.A. 863. There are over 91 different pneumococcus serotypes, some of which cause diseases such as pneumonia, febrile bacteremia, and meningitis. *See id.* at col. 1, ll. 52–58, J.A. 863. Claim 1 is the only independent claim. It reads as follows:

> 1. An immunogenic composition comprising a *Streptococcus pneumoniae* serotype 22F glycoconjugate, wherein the glycoconjugate has a molecular weight of between 1000 kDa and 12,500 kDa and

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[1] The final written decisions consolidated in this appeal share similar analyses of the issues relevant to the parties' disputes. Unless otherwise indicated, we cite the *Sanofi Decision* as representative.

> comprises an isolated capsular polysaccharide from *S. pneumoniae* serotype 22F and a carrier protein, and wherein a ratio (w/w) of the polysaccharide to the carrier protein is between 0.4 and 2.

Id. at col. 141, ll. 28–34, J.A. 933. As relevant here, dependent claims 3 and 4 recite that the composition further includes various additional glycoconjugates. Those claims read as follows:

> 3. The immunogenic composition of claim 1, wherein the composition further comprises a *S. pneumoniae* serotype 15B glycoconjugate and a *S. pneumoniae* serotype 33F glycoconjugate.
>
> 4. The immunogenic composition of claim 3, 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.

Id. at col. 141, ll. 38–46, J.A. 933.

Across five IPR petitions, Merck Sharp & Dohme Corp. ("Merck") and Sanofi Pasteur Inc. and SK Chemicals Co., Ltd. (collectively, "Sanofi") separately challenged all claims of the '559 patent, arguing that they would have been obvious over, *inter alia*, PCT Patent Application Publication 2007/071711 ("GSK-711") and U.S. Patent Application Publication 2011/0195086 ("Merck-086").[2] GSK-711 is

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[2] Sanofi asserted that the claims would have been obvious over GSK-711 and Merck-086, while Merck asserted that the claims would have been obvious over International Patent Application Publication 2011/100151 ("Merck 2011") and International Patent Application Publication 2009/000825 ("GSK 2008"). Merck-086 is the U.S. counterpart to Merck 2011, while GSK-711 and GSK 2008

directed to *S. pneumoniae* vaccines comprising "capsular saccharide antigens (preferably conjugated), wherein the saccharides are derived from at least ten serotypes of *S. pneumoniae*," which may include an "*S. pneumoniae* saccharide conjugate of 22F." GSK-711 at p. 6, ll. 4, 24–26, J.A. 4578. Merck-086 is directed to "multivalent immunogenic composition[s] having 15 distinct polysaccharide-protein conjugates" in which an *S. pneumoniae* serotype, including 22F, is conjugated to a carrier protein. Merck-086 at Abstract, J.A. 4667.

The Board instituted review based on each petition and issued final written decisions which, taken together, found all claims unpatentable. *See, e.g.*, *Sanofi Decision* at *39. The Board also rejected Pfizer's contingent motions to amend, finding that Merck and Sanofi had each demonstrated that the proposed substitute claims were unpatentable. *Id.* at *27; *'131 Decision* at *24; *'132 Decision* at *23.

Pfizer timely appealed. After a stay pending the Supreme Court's decision in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021), we remanded for the limited purpose of allowing Pfizer the opportunity to request Director Review of the Board's decisions. *See, e.g.*, Appeal 2019-1871, ECF No. 82. The Director denied those requests on February 4, 2022, *see id.*, ECF No. 85, so the Board's final written decisions are now ripe for our review. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141(c).

DISCUSSION

Pfizer raises four challenges on appeal. First, it argues that the Board erred in determining that GSK-711 and

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are related international applications with substantively identical disclosures. For clarity, we will refer only to the Sanofi-asserted references, GSK-711 and Merck-086, in this opinion.

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