

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME CORP.,
Petitioner,

v.

WYETH LLC,
Patent Owner.

IPR2017-00378
Patent 8,562,999 B2

Before FRANCISCO C. PRATS, ERICA A. FRANKLIN, and
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.¹

FRANKLIN, *Administrative Patent Judge*.

JUDGMENT

Final Decision on Remand

Determining Claims 1–6, 10, 11, 14, 17, 19, and 20 Unpatentable
35 U.S.C. §§ 144, 318

¹ As explained in the Panel Change Order, Administrative Patent Judge Francisco C. Prats replaces Administrative Patent Judge Jacqueline T. Harlow, who is no longer with the Patent Trial and Appeal Board. *See* Paper 63.

I. INTRODUCTION

We address this case on remand after a decision by the U.S. Court of Appeals for the Federal Circuit in *Merck Sharp & Dohme Corp. v. Wyeth LLC.*, 792 F. App'x 813 (Fed. Cir. 2019) (“Merck”).

As background, Merck Sharp & Dohme Corp. (“Petitioner”) filed a Petition (Paper 1; “Pet.”) to institute an *inter partes* review of claims 1–6, 10, 11, 14, and 17–20 of U.S. Patent 8,562,999 B2 (Ex. 1001; “the ’999 patent”). Wyeth LLC (“Patent Owner”) filed a Patent Owner’s Preliminary Response (Paper 6; “Prelim. Resp.”).

On June 13, 2017, we instituted an *inter partes* review of all challenged claims. Paper 9 (“Dec. Inst.”). On September 13, 2017, Patent Owner filed a Patent Owner Response to the Petition. Paper 16 (“PO Resp.”). On December 13, 2017, Petitioner filed a Reply to the Patent Owner Response. Paper 28 (“Reply”).

Petitioner and Patent Owner each filed a Motion to Exclude Evidence. Papers 34 and 38. Each party filed an Opposition to the other party’s motion. Papers 42 and 45. Each party also filed a Reply to the other party’s Opposition. Papers 49 and 55.² Patent Owner filed Motions for Observation on Cross-Examination Testimony. Papers 39 and 40. Petitioner filed a Response to each of Patent Owner’s Motions for Observation. Paper 43 and 46.

² We authorized Patent Owner to file a Revised Reply to Petitioner’s Opposition to Patent Owner’s Motion to Exclude Evidence that complied with the page limit set forth in 37 C.F.R. § 42.24(c)(2). See Paper 54.

On February 27, 2018, the parties presented arguments at an oral hearing. The hearing transcript has been entered in the record. Paper 56 (“Tr.”). We issued a Final Written Decision, in accordance with 37 C.F.R. § 42.73, on June 8, 2018. Paper 59 (“FWD”). In the Final Written Decision, we determined that Petitioner had shown by a preponderance of the evidence that claims 1–6, 10, 11, 14, 17, 19, and 20 are unpatentable. *See* 35 U.S.C. § 316(e). Additionally, we determined that Petitioner had not shown by a preponderance of the evidence that claim 18 is unpatentable. In the Final Written Decision, we also addressed the parties’ Motions to Exclude Evidence, as set forth below in Section III. FWD 45–48.

Neither party requested a rehearing of any matter decided in the Final Written Decision. Petitioner, however, appealed the Final Written Decision to the United States Court of Appeals for the Federal Circuit, challenging only our determination that Petitioner had not shown by a preponderance of the evidence that claim 18 is unpatentable.

On November 26, 2019, the Federal Circuit issued a decision in *Merck* vacating and remanding the Final Written Decision for further proceedings. *Merck*, 792 F. App’x at 814. The Court entered the Mandate on January 2, 2020. Mandate, *Merck Sharp & Dohme Corp. v. Wyeth LLC*, No. 18-2133 (Fed. Cir. Jan. 2, 2020), ECF No. 71. The Court found that our findings were insufficient to support a determination that Petitioner failed to demonstrate a motivation or a reasonable expectation of success for modifying the prior art to yield the subject matter of dependent claim 18. *Merck*, 792 F. App’x at 817. In particular, the Federal Circuit explained that the Board “did not address the evidence as to whether someone skilled in the art would have been motivated to combine the 13 serotypes [disclosed in the

prior art and recited by claim 18] into a CRM₁₉₇ conjugate or whether the potential loss of immunogenicity would have dissuaded someone skilled in the art from making such a combination.” *Id.* at 818.

On January 24, 2020, we held a conference call with the parties to discuss their proposals for a procedure on remand, in view of the Board’s Standard Operating Procedure 9 (“SOP 9”), App’x 2, “Guidance for Parties Regarding Remand Procedures.” *See* Paper 66 (Conduct of the Proceeding Order). As a result, we authorized each party to file a table highlighting arguments and evidence of record previously asserted in this proceeding regarding the challenge to claim 18. Paper 66, 4. We explained that submission of the table was not an opportunity to incorporate by reference any additional evidence or arguments to their previous submissions regarding claim 18. *Id.* at 5. Thereafter, such briefing was completed. *See* Paper 69 (Patent Owner’s Citation Table), Paper 70 (Petitioner’s Citation Table).

Although the Federal Circuit vacated the Final Written Decision only with respect to “the Board’s obviousness findings with respect to claim 18,” this Decision on Remand includes: our previous, unappealed analysis on the patentability of challenged claims 1–6, 10, 11, 14, 17, 19, and 20;³ our previous determination on the parties’ Motions to Exclude Evidence, with

³ Patent Owner’s appeal was limited to claim 18 and did not challenge the findings or conclusions regarding claims 1–6, 10, 11, 14, 17, 19, and 20. Our original analysis of claims 1–6, 10, 11, 14, 17, 19, and 20 is included in this Decision on Remand only for completeness and we have not revisited those claims here.

revised remarks relating to Exhibit 1037;⁴ and our further discussion regarding the challenges to claim 18. In other words, in this Decision on Remand, we revisit only the challenges to claim 18 and the Motion to Exclude Exhibit with respect to 1037.

A. Related Proceedings

We issued Final Written Decisions in two additional *inter partes* reviews challenging claims of the '999 patent in IPR2017-00380 and IPR2017-00390. Petitioner has appealed our Final Written Decision in IPR2017-00380 and the Federal Circuit has vacated and remanded that decision for the same reasons involved here. *Merck*, 792 F. App'x at 813–819. The Decision on Remand in that case is issued concurrently with the Decision on Remand in the instant case.

B. The '999 patent

In some aspects, the '999 patent relates to formulations comprising an immunogen in the form of a polysaccharide-protein conjugate, a pH buffered saline solution, and an aluminum salt. Ex. 1001, 2:62–64, 12:9–15. The Specification defines the term “polysaccharide” as including “any antigenic saccharide element (or antigenic unit) commonly used in the immunologic and bacterial vaccine arts, including, but not limited to, a ‘saccharide’, an ‘oligosaccharide’, a ‘polysaccharide’, a ‘liposaccharide’, a ‘lipo-oligosaccharide (LOS)’, a ‘lipopolysaccharide (LPS)’, a ‘glycosylate’, a

⁴ Petitioner submits Exhibit 1037 and identifies it as “Ireland EPA Memorandum regarding ‘Application for IPC licence from AHP Manufacturing B.V. Trading as Wyeth Medica Ireland for the Wyeth BioPharma Campus at Grange Castle Reg. No. 652’ (June 11, 2003).” Pet. viii.; Ex. 1037 (“Ireland EPA Memo”).

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