

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MERCK SHARP & DOHME CORP.,  
Petitioner,

v.

WYETH LLC,  
Patent Owner.

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IPR2017-00378  
IPR2017-00380  
Patent 8,562,999 B2

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

FRANKLIN, *Administrative Patent Judge*.

ORDER<sup>1</sup>  
Conduct of Proceeding  
*37 C.F.R. § 42.5*

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<sup>1</sup> This Order addresses issues common to each captioned case. Thus, we enter the same Order in each case. The parties are not authorized to use this format for filings.

*Introduction*

On January 24, 2020, a conference call was held by Judges Prats, Franklin, and Snedden, with counsel for the parties in attendance. A Final Written Decision was entered for each of the captioned proceedings on June 8, 2018. IPR2017-00378, Paper 59 (PTAB June 8, 2018); IPR2017-00380, Paper 59 (PTAB June 8, 2018). On appeal, the Federal Circuit vacated and remanded those Decisions for further proceedings. *See Merck Sharp & Dohme Corp. v. Wyeth LLC.*, Nos. 2018-2133 and 2018-2134, 2019 WL 6320454, at \*1–4. The Court entered the Mandate on January 2, 2020. Case: 18-2133 (Document 71). The purpose of the conference call was to discuss the parties’ proposals for a procedure on remand, as discussed in the Patent Trial and Appeal Board Standard Operating Procedure 9 (“SOP 9”), App’x 2, “Guidance for Parties Regarding Remand Procedures.”

*Remand Background*

In the Final Written Decision for IPR2017-00378, the Board determined that Petitioner established by a preponderance of the evidence that claims 1–6, 10, 11, 14, 17, 19, and 20 of U.S. Patent No. 8,562,999 B2 (Ex. 1001, “the ’999 patent”) are unpatentable under 35 U.S.C. § 103 as obvious over Chiron, Smith, and Elan, and that claim 17 of the ’999 patent is also unpatentable over Chiron, Smith, Elan, and Peña. IPR2017-00378, Paper 59 at 48–49. However, the Board determined that Petitioner had not established that claim 18 of the ’999 patent is unpatentable as obvious over either combination of references. *Id.* at 40, 45, 48.

Similarly, in the Final Written Decision for IPR2017-00380, the Board determined that Petitioner established by a preponderance of the evidence that claims 1–6, 10, 11, 14, 17, 19, and 20 of the ’999 patent are

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unpatentable under 35 U.S.C. § 103 as obvious over Prevenar and Chiron. IPR2017-00380, Paper 59 at 41. However, the Board determined that Petitioner had not established that claim 18 is unpatentable as obvious over the combination of Prevenar and Chiron, or the combination of Prevenar, Chiron, and Peña. *Id.* at 33–34, 37.

Petitioner appealed to the Federal Circuit each Final Written Decision, only with respect to the Board’s determination that Petitioner had not shown by a preponderance of the evidence that claim 18 was obvious over any of the asserted combinations of prior art. *See Merck Sharp & Dohme*, 2019 WL 6320454, at \*1–2.

The Federal Circuit found 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 into a CRM197 conjugate or whether the potential loss of immunogenicity would have dissuaded someone skilled in the art from making such combination.” *Id.* at \*4. The Court vacated the Board’s obviousness findings with respect to claim 18, and remanded the Decisions “for further consideration of the parties’ arguments and evidence as to (1) motivation to combine and (2) reasonable expectation of success and, if the Board find sufficient motivation to combine and reasonable expectation of success, other issues such as secondary considerations.” *Id.*

#### *The Parties’ Positions*

Prior to the conference call, the parties met and conferred regarding a proposed remand procedure. During the conference call, the parties confirmed that they do not seek to file new evidence. Petitioner requested additional briefing to streamline for us the relevant arguments and evidence

directed to claim 18 in each proceeding. Patent Owner's position is that additional briefing is not warranted.

*Discussion*

The Federal Circuit Decision includes an explicit instruction for us to reconsider our obviousness determinations with respect to claim 18 of the '999 patent in each proceeding. *See Merck Sharp & Dohme*, 2019 WL 6320454, at \*4. In particular, the Court instructs us to further consider the parties' arguments and evidence as to motivation to combine and reasonable expectation of success and, if appropriate, other issues such as secondary considerations. *Id.* In other words, we are instructed to consider further the parties' arguments already of record regarding those issues.

With its request, Petitioner does not allege that it has not previously had an adequate opportunity to brief those issues raised by the Court. Nor do we find such is the case. Rather, Petitioner seeks additional briefing to draw our attention to what has been argued. However, doing so in the form of additional briefing runs the risk of a party adding or incorporating arguments and/or evidence to the record with respect to what has previously been presented regarding the challenges to claim 18. To avoid that risk, while still allowing the parties to highlight arguments and evidence of record previously asserted regarding the challenge to claim 18 in each proceeding, we authorize the parties to file a concise table listing the pages of the papers and exhibits that they previously presented addressing that challenge. The table shall not include headings as to subject matter. Any listing of an exhibit must identify the paper and page of that paper referring to the exhibit.

This listing is not an opportunity for the parties to incorporate by reference additional evidence or arguments to their previous submissions regarding claim 18 in either proceeding. Thus, the parties are cautioned not to attempt to do so here.

### ORDER

Accordingly, it is

ORDERED that in each of the above-captioned proceedings, each party is authorized to file a table listing the location, i.e., paper number and page, of its arguments and evidence previously submitted and directed to claim 18;

FURTHER ORDERED that such table listing shall include only the paper numbers and pages of those arguments, and if relevant, the exhibit numbers and pages referenced within those arguments;

FURTHER ORDERED that the table shall not include headings as to subject matter or any discussion or argument;

FURTHER ORDERED that each party shall file the authorized table, wherein the filing is no more than 5 pages, on or before Friday, February 21, 2020; and

FURTHER ORDERED that no additional filings are authorized in these proceedings.

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