

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.

REGENERON PHARMACEUTICALS, INC.
Patent Owner

Case IPR2021-00881¹
Patent 9,254,338 B2

DECLARATION OF DORIS WEBER

Mylan v. Regeneron IPR2021-00881 U.S. Pat. 9,254,338 Exhibit 2286
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¹ IPR2022-00258 and IPR2022-00298 have been joined with this proceeding.

I, Doris Weber, declare as follows:

1. I am a Senior Litigation Support Specialist with Patent Owner Regeneron Pharmaceuticals, Inc. I have personal knowledge of the facts in this declaration.

2. Exhibit 2059 is a true and correct copy of the Regeneron Sample Analysis Report: PK06005-9-SA-01V1, which was signed by Study Director Ellen M. Koehler-Stec on July 28, 2010.

3. Exhibit 2060 is a true and correct copy of Table 14.2.3/2a (“Summary of Proportion of Vision Loss from Baseline to Week 96, Last Observation Carried Forward”) of the VIEW1 Clinical Study Report (Protocol VGFT-OD-0605).

4. Exhibit 2073 is a true and correct copy of the “Zaltrap non-comparability issue: Regeneron Sanofi Analytical Investigation Workshop” presentation of March 14, 2014.

5. Exhibit 2128 is a true and correct copy of a compilation of Regeneron’s VGFT-OD-0605 (VIEW 1 Trial) Protocol Signature Pages, accompanying protocols dated June 3, 2009, January 16, 2008, October 19, 2007, June 16, 2007, and May 24, 2007, all of which were executed by Matthew Benz.

6. Exhibit 2133 is a true and correct copy of Regeneron’s Earnings Call Transcript of February 13, 2012, as obtained from Bloomberg Transcript.

7. Exhibit 2134 is a true and correct copy of Regeneron's Earnings Call Transcript of April 26, 2012, as obtained from Bloomberg Transcript.

8. Exhibit 2135 is a true and correct copy of Regeneron's Earnings Call Transcript of July 25, 2012, as obtained from Bloomberg Transcript.

9. Exhibit 2136 is a true and correct copy of Regeneron's Eylea Marketing Material dated February 2013.

10. Exhibit 2137, uploaded in two parts, is a true and correct copy of Regeneron's Eylea Marketing Material dated November 2013.

11. Exhibit 2138 is a true and correct copy of Regeneron's "Physician ATU: Wave 2" presentation of February 2013.

12. Exhibit 2139 is a true and correct copy of Regeneron's "For the Treatment of Wet Age-Related Macular Degeneration" presentation from 2012, including presenter's notes.

13. Exhibit 2140 is a true and correct copy of Regeneron's "Physician ATU: Wave 5" presentation of November 2013.

14. Exhibit 2163 is a true and correct copy of Regeneron's "Physician ATU: Wave 4" presentation of August 6, 2013.

15. Exhibit 2169, uploaded in six parts, is a true and correct copy of Regeneron's "Eylea Sample Disbursement 2013 to 2021," where pages 1 through

16891 present data from October 2013 to November 2020, and pages 16892 through 25515 present data from October 27, 2020 to December 17, 2021.

16. Exhibit 2170 is a true and correct copy of Regeneron's "US Eylea P&L LTD" as of December 2021, which is a profit and loss statement for US Eylea sales from 2011 to 2021.

17. Exhibit 2176 is a true and correct copy of Regeneron's "Q4 2020 Performance Update Wet AMD, DME, MEfRVO & DR w/out DME" presentation of January 29, 2021.

18. Exhibit 2197 is a true and correct copy of Regeneron's "Physician ATU – Benchmark Wave" presentation of September 15, 2011.

19. Exhibit 2200 is a true and correct copy of Regeneron's "U.S. Eylea Historical Brand P&L" presentation of May 2021.

20. Exhibit 2205 is a true and correct copy of Regeneron's "DME Market Assessment" presentation of August 2014.

21. Exhibit 2208 is a true and correct copy of Regeneron's "Eylea MD ATU – Wave 2 Final Questionnaire" dated December 19, 2012.

22. Exhibit 2218 is a true and correct copy of Regeneron's "Eylea (afibercept) Injection: Components of Reimbursement" presentation of September 2015, including presenter's notes.

23. Exhibit 2229 is a true and correct copy of Regeneron's WAC Pricing File, which was exported on May 19, 2021.

24. Exhibit 2272 is a true and correct copy of Regeneron's "Eylea Q2 2021 Performance" presentation of August 2, 2021.

25. Exhibit 2273 is a true and correct copy of the "Anti-VEGF Category Sales Shares" report dated February 2022, which was received from Vestrum Health, LLC.

26. Exhibit 2274 is a true and correct copy of Regeneron's "Eylea Wet AMD Line of Therapy Insights" presentation of April 6, 2020.

27. Exhibit 2275 is a true and correct copy of Regeneron's "Vestrum Anti-VEGF Market Share Adjustment Overview" presentation of May 10, 2019.

28. Exhibit 2276 is a true and correct copy of Regeneron's "Eylea Q2 2020 Performance (Vestrum Projection Data)" presentation of August 4, 2020.

29. Exhibit 2277 is a true and correct copy of Regeneron's "Marketing Planning Process" presentation of September 2011.

30. Exhibit 2278 is a true and correct copy of Regeneron's "Wave 1 2021 Performance Update Wet AMD, DME, MEfRVO, and DR w/out DME" presentation of September 2021.

31. Exhibit 2279 is a true and correct copy of Regeneron's "ATU Sales Share Data: All Indications," copyrighted 2021.

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