IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Case No. 1:22-cv-00061-TSK **JURY TRIAL DEMANDED** **OUTSIDE COUNSELS' EYES ONLY**

PLAINTIFF REGENERON PHARMACEUTICALS, INC.'S RESPONSE TO MYLAN'S STATEMENT OF UNCONTROVERTED FACTS

Local Rule of Civil Procedure 7.02 provides that "[m]otions for summary judgment shall include or be accompanied by a short and plain statement of uncontroverted facts." Mylan's twenty-five-page submission ("Mylan's Statement") (ECF 430-2), is neither "short and plain," nor are the alleged "facts" set forth therein "uncontroverted." Further, many of the allegations in Mylan's Statement are neither cited nor even seemingly relied upon in its Motion for Summary Judgment (ECF 429) or Memorandum in Support (ECF 430-1).

Nevertheless, Regeneron has endeavored to respond here to Mylan's Statement as concisely as possible and to the extent it can understand Mylan's allegations. In those circumstances where Regeneron disputes a Mylan allegation regarding a lack of evidence or absence of opinion, Regeneron has not attempted to identify here every relevant piece of evidence or expert statement among the many thousands of pages of documents, experts' reports, transcripts, and discovery responses generated or served in this litigation. Rather, Regeneron has attempted to respond to the particular assertions made by Mylan and make clear the nature of the

dispute. The paragraph numbering set forth below corresponds to the paragraph numbering of Mylan's statement.

I. U.S. Patent No. 11,104,715

1. Regeneron does not dispute that, prior to the filing of its stipulation regarding summary judgment and case narrowing (ECF 433), Regeneron was asserting claims 2-3, 6, 12-14, and 16 of U.S. Patent No. 11,104,715 ("the '715 patent").

2. Regeneron does not dispute that claims 2-3, 6, and 12-14 of the '715 patent depend, directly or indirectly, from claim 1 of the '715 patent.

3. Regeneron does not dispute that claim 1 of the '715 patent recites the following:

> 1. A method of producing aflibercept harvested from a host cell cultured in a chemically defined medium (CDM), comprising:
> (a) providing a host cell genetically engineered to express aflibercept;
> (b) culturing said host cell in said CDM under conditions suitable in which said host cell expresses said aflibercept wherein the cumulative concentration of nickel in said CDM is less than or equal to 0.4 μM or about 0.4 μM and one or more of the following:
> i. the cumulative concentration of iron in said CDM is less than or equal to 55.0 μM;
> ii. the cumulative concentration of copper in said CDM is less than or equal to 0.8 μM;
> iii. the cumulative concentration of zinc in said CDM is less than or equal to 56.0 μM;
> iv. the cumulative concentration of cysteine in said CDM is less than or equal to 10.0 mM, and
> v. said CDM includes anti-oxidants where the cumulative concentration of an antioxidant is about 0.001 mM to about 10.0 mM for any single anti-oxidant; and
> (c) harvesting aflibercept produced by said host cell.

4. Regeneron does not dispute that claim 16 of the '715 patent recites the following:

> **16**. A method of producing aflibercept harvested from a host cell cultured in a chemically defined medium (CDM), comprising:
>
> (a) culturing said host cell in said CDM under conditions suitable in which said host cell expresses said aflibercept wherein the cumulative concentration of nickel in said CDM is less than or equal to 0.4 μM or about 0.4 μM and one or more of the following:
>
> i. the cumulative concentration of iron in said CDM is less than or equal to 55.0 μM;
>
> ii. the cumulative concentration of copper in said CDM is less than or equal to 0.8 μM;
>
> iii. the cumulative concentration of zinc in said CDM is less than or equal to 56.0 μM;
>
> iv. the cumulative concentration of cysteine in said CDM is less than or equal to 10.0 mM; and
>
> v. said CDM includes anti-oxidants where the cumulative concentration of an antioxidant is about 0.001 mM to about 10.0 mM for any single anti-oxidant; and
>
> (b) harvesting aflibercept produced by said host cell.

5. Regeneron does not dispute that Mylan has excerpted portions of Dr. Swartzwelder's Opening Report, although Regeneron notes that the excerpts are incomplete and/or contain modifications to the report, which speaks for itself.

6. Regeneron does not dispute that Mylan has excerpted a portion of Dr. Swartzwelder's Opening Report, although Regeneron notes that the excerpt is incomplete and/or contain modifications to the report, which speaks for itself.

7. Regeneron does not dispute that Mylan has excerpted portions of Dr. Swartzwelder's Opening Report, although Regeneron notes that the excerpts are incomplete and/or contain modifications to the report, which speaks for itself.

8. Regeneron does not dispute that Mylan has excerpted a portion of Dr. Swartzwelder's Opening Report, although Regeneron notes that the excerpt is incomplete and/or contain modifications to the report, which speaks for itself.

9. Regeneron does not dispute that Mylan has excerpted a portion of Dr. Swartzwelder's Opening Report, although Regeneron notes that the excerpt is incomplete and/or contain modifications to the report, which speaks for itself.

10. Regeneron does not dispute that Mylan has excerpted a portion of Dr. Swartzwelder's Opening Report, although Regeneron notes that the excerpt is incomplete and/or contain modifications to the report, which speaks for itself.

11. Regeneron does not dispute that Mylan has excerpted a portion of Dr. Swartzwelder's Opening Report, although Regeneron notes that the excerpt is incomplete and/or contain modifications to the report, which speaks for itself.

12. Regeneron does not dispute that it is not presently contending that Mylan infringes claims 2-3, 6, 12-14, or 16 of the '715 patent pursuant to the claim constructions adopted by the Court.

13. Regeneron does not dispute that Mylan has excerpted a portion of Dr. Swartzwelder's deposition transcript, although Regeneron notes that the excerpt is incomplete and/or contain modifications to the transcript, which speaks for itself.

14. Regeneron does not dispute that it is not presently contending that Mylan infringes claims 2-3, 6, 12-14, or 16 of the '715 patent pursuant to the claim constructions adopted by the Court.

II. U.S. Patent No. 11,084,865

15. Regeneron does not dispute that the '865 patent's "invention includes liquid pharmaceutical formulations having increased stability." Mylan Ex. 13 ('865 patent) at 1:49-50.

16. Regeneron does not dispute that it is presently asserting claims 4, 7, 9, 11, and 14-18 of the '865 patent.

17. Regeneron does not dispute that claim 18 of the '865 patent recites: "18. The vial of claim 5, wherein said formulation does not contain phosphate."

18. Regeneron does not dispute that Mylan has excerpted a portion of Dr. Trout's Opening Expert Report, although Regeneron notes that Dr. Trout offered additional opinions with respect to claim 18, Mylan Ex. 15 (Trout Reply) at ¶¶ 37-44.

19. Regeneron does not dispute that Mylan has excerpted a portion of Dr. Trout's Opening Expert Report.

20. Regeneron does not dispute that Mylan has excerpted a portion of Dr. Trout's Opening Expert Report and Mylan's BLA document MYL-AFL-BLA0002664.

21. [redacted]

22. [redacted]

23. Regeneron does not dispute that it did not test YESAFILI™ to measure phosphate levels.

III. U.S. Patent Nos. 11,253,572 and 10,888,601

24. It is undisputed that the '572 and '601 patents each issued from a series of provisional and nonprovisional patent applications. It is further undisputed that the first provisional application to which the '572 and '601 patents claim priority was filed on January 13, 2011. Mylan Ex. 17 ('601 patent) at 1:7-20; Mylan Ex. 18 ('572 patent) at 1:7-28; Mylan Ex. 4 (Csaky Resp.) at ¶ 21.

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