IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,	)	
Plaintiff,	)	
v.	)	C.A. No. 20-755-RGA
LIQUIDIA TECHNOLOGIES, INC.,	)	
Defendant.	)	

DEFENDANT'S ANSWER TO COMPLAINT AND COUNTERCLAIMS

Defendant Liquidia Technologies, Inc. ("Liquidia" or "Defendant") hereby files its answer, defenses, and counterclaims ("Answer") to the Complaint filed by Plaintiff United Therapeutics Corporation ("UTC" or "Plaintiff"). Each of the paragraphs below corresponds to the same numbered paragraphs in the Complaint. In responding to the Complaint, Liquidia has kept Plaintiff's headings for ease of reference, but in so doing, Liquidia is not admitting to the accuracy of any statements made or agreeing with any characterizations made in such headings. Liquidia denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Liquidia further denies that Plaintiff is entitled to the relief requested in the Complaint, or to any other relief.

NATURE OF THE ACTION

1. Liquidia admits that the Complaint purports to assert a patent infringement action. Liquidia admits that U.S. Patent No. 9,593,066 (the "'066 patent") and U.S. Patent No. 9,604,901 (the "'901 patent") (collectively the "patents-in-suit") each bear the title "Process to Prepare Treprostinil, the Active Ingredient in Remodulin®". Liquidia admits that Exhibits A and B attached to the Complaint appear to be copies of the '066 and '901 patents. Liquidia is without

knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 1, and therefore denies them.

2. Liquidia admits that it submitted New Drug Application No. 213005 under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("Liquidia's NDA") to the United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use and/or sale of LIQ861 (treprostinil) inhalation powder (the "Liquidia Product" or "LIQ861 Product"). Liquidia denies the remaining allegations in paragraph 2.

THE PARTIES

3. Liquidia is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3, and therefore denies them.

4. Liquidia admits the allegations in paragraph 4.

5. Liquidia admits that it purchases treprostinil from Yonsung Fine Chemicals Co., LTD. Liquidia denies the remaining allegations in paragraph 5.

6. Liquidia admits that the Liquidia Product delivers treprostinil through a dry powder inhaler ("DPI") that is manufactured by Plastiape SpA ("Plastiape"). Liquidia denies the remaining allegations in paragraph 6.

JURISDICTION AND VENUE

7. Liquidia admits that this Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and 1338(a), provided that standing and other requirements are met. Liquidia denies that the Plaintiff's claims in its complaint have any merit or that Plaintiff is entitled to any relief. Liquidia denies the remaining allegations in paragraph 7.

8. Liquidia admits that venue is proper for purposes of this case.

9. Liquidia admits that this Court has personal jurisdiction over Liquidia for purposes of this case. Liquidia denies the remaining allegations in paragraph 9.

BACKGROUND

10. Liquidia admits that UTC is identified as the holder of New Drug Application No. 022387, which has been approved for TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml. Liquidia is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 10, and therefore denies them.

11. Liquidia admits that TYVASO® was approved by the FDA in the United States on July 20, 2009, and, according to the TYVASO® prescribing information, is indicated "for the treatment of pulmonary arterial hypertension (WHO Group I) in patients with NYHA Class III symptoms, to increase walk distance." Liquidia denies the remaining allegations in paragraph 11.

12. Liquidia admits that TYVASO®, according to its prescribing information, is a sterile solution for oral inhalation: 2.9 mL ampule containing 1.74 mg treprostinil (0.6 mg per mL).

13. Liquidia admits that the '066 patent is entitled "Process to prepare treprostinil, the active ingredient in Remodulin®," was issued by the United States Patent and Trademark Office on March 14, 2017, and names as inventors Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh. Liquidia denies the remaining allegations in paragraph 13.

14. Liquidia is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 14, and therefore denies them.

15. Liquidia admits that the '901patent is entitled "Process to prepare treprostinil, the active ingredient in Remodulin®," was issued by the United States Patent and Trademark Office on March 28, 2017, and names as inventors Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh. Liquidia denies the remaining allegations in paragraph 15.

16. Liquidia is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 16, and therefore denies them.

17. Liquidia admits that the '066 and '901 patents are listed in the Orange Book (FDA's

Approved Drug Products with Therapeutic Equivalence Evaluations publication) in connection with TYVASO®. Liquidia denies the remaining allegations in paragraph 17.

[ALLEGED] ACTS GIVING RISE TO THIS ACTION

18. Liquidia admits that it notified UTC by letter dated April 24, 2020 ("Liquidia's Notice Letter") that it had submitted Liquidia's NDA to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of the Liquidia Product. Liquidia is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 18, and therefore denies them.

19. Liquidia admits that its Notice Letter included a detailed statement of the present factual and legal basis that the claims of the '066 and/or '901 patents are invalid, unenforceable and/or are not, and will not, be infringed by the Liquidia Product. Liquidia denies the remaining allegations in paragraph 19.

20. Liquidia admits that it submitted its NDA to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of the Liquidia Product. Liquidia denies the remaining allegations of paragraph 20.

21. Liquidia admits that UTC filed its Complaint on June 4, 2020.

22. Liquidia admits that the Liquidia Product contains treprostinil. Liquidia denies the remaining allegations in paragraph 22.

23. Liquidia admits that its NDA seeks approval from the FDA to market Liquidia's Product for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability in patients with NYHA Functional Class II-III symptoms. Liquidia denies the remaining allegations in paragraph 23.

24. Liquidia admits that it filed its NDA, which is in compliance with all relevant statutory sections. Liquidia denies the remaining allegations in paragraph 24.

25. Liquidia admits that it submitted its NDA to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of the Liquidia Product. Liquidia denies the remaining allegations in paragraph 25.

26. Liquidia admits that its NDA contains Paragraph IV Certifications that the '066 patent and '901 patent are not infringed by Liquidia's Proposed Product and/or are invalid and/or unenforceable.

27. Liquidia admits that its Notice Letter refers to 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R. § 314.52(c)(6).

28. Liquidia admits that its Notice Letter contained an Offer of Confidential Access Pursuant to 21 U.S.C. § 355(c)(3)(D)(i)(III) ("OCA"). Liquidia further admits that Liquidia negotiated the terms of confidential access in good faith in order to permit UTC access to information contained within Liquidia's NDA. Liquidia denies the remaining allegations in paragraph 28.

29. Liquidia admits that 21 U.S.C. § 355(c)(3)(D)(i)(III) states an "offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

30. Liquidia admits that it attempted to negotiate the terms of its OCA with UTC. Liquidia's OCA contained provisions that would apply to protective orders. For example, Liquidia's OCA contained reasonable access restrictions on attorneys representing UTC and in-house counsel and the staff of such counsel that were present in the protective order entered into by UTC in *United Therapeutics Corp. v. Watson Labs., Inc.*, No. 3:15-cv-05723-PGS-LHG, Dkt. No. 36 at 6-7 (D.N.J. Jan. 13, 2016), which is a prior litigation concerning TYVASO®. Liquidia

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