IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
LIQUIDIA TECHNOLOGIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiff United Therapeutics Corporation ("UTC"), by its undersigned attorneys, for its Complaint against Liquidia Technologies, Inc. ("Liquidia"), alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.*, involving United States Patent Nos. 9,593,066 (the '066 patent") (attached as Exhibit A hereto) and 9,604,901 (the '901 patent") (attached as Exhibit B hereto) (collectively, the "Patents-in-Suit").

2. This action arises out of Liquidia's submission of New Drug Application No. 213005 under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("Liquidia's 505(b)(2) Application") to the United States Food and Drug Administration ("FDA") seeking approval, prior to the expiration of the '066 patent and the '901 patent, to manufacture, market, and sell a generic copy of UTC's TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml that is approved by FDA for treatment of pulmonary arterial hypertension ("Liquidia's Proposed Generic Product").

THE PARTIES

3. UTC is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 1040 Spring Street, Silver Spring, Maryland 20910. UTC is a biotech company focused on the development and commercialization of products designed to address the needs of patients with chronic and life-threatening conditions. UTC continues to research and develop treatments for cardiovascular and pulmonary diseases, pediatric cancers, and other orphan diseases.

4. Upon information and belief, Liquidia is a corporation organized and existing under the laws of the State of Delaware, with a registered office at 51 Little Falls Drive, Wilmington, Delaware 19808, and a principal place of business at 419 Davis Drive, Suite 100, Morrisville, North Carolina 27560.

5. Upon information and belief, to manufacture Liquidia's Proposed Generic Product, Liquidia purchases the treprostinil sodium active pharmaceutical ingredient ("API") from third-party manufacturer Yonsung Fine Chemicals Co., LTD ("Yonsung"), operating out of South Korea. Upon information and belief, Liquidia will import treprostinil sodium API from Yonsung into the United States.

6. Upon information and belief, Liquidia's Proposed Generic Product delivers treprostinil through a dry powder inhaler ("DPI") that is manufactured by Plastiape SpA ("Plastiape"). Upon information and belief, Plastiape has a principal place of business at Via Primo Maggio, 8 Osnago, 23875 Italy. Upon information and belief, Plastiape is a wholly-owned subsidiary of Berry Global Group, Inc. Upon information and belief, Berry Global Group, Inc. has a principal place of business at 101 Oakley Street, Evansville, Indiana 47710.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this Court under 28 U.S.C. § 1400(b).

9. Upon information and belief, this Court has personal jurisdiction over Liquidia because it is a corporation organized and existing under the laws of the State of Delaware with a registered agent in the State of Delaware. Further, upon information and belief, Liquidia has publicly stated its intent to engage in commercializing Liquidia's Proposed Generic Product throughout the United States without any limitation. Upon information and belief, Liquidia will manufacture, market, distribute, and/or sell Liquidia's Proposed Generic Product throughout the United States, including in Delaware, and will derive substantial revenue therefrom. Upon information and belief, upon approval of Liquidia's 505(b)(2) Application, Liquidia will place Liquidia's Proposed Generic Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such products will ultimately be purchased and used by consumers in Delaware.

BACKGROUND

10. UTC holds New Drug Application No. 022387, which has been approved for TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml, which UTC markets and sells under the registered trademark TYVASO®.

11. TYVASO® is a pharmaceutical product initially approved by FDA in the United States in July 2009 and is indicated for the treatment of pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare disease affecting the pulmonary vasculature and results

in high pressure in the pulmonary arteries, which increases strain on the right ventricle of the heart, thereby leading to heart failure and death.

12. TYVASO® is an inhalable product approved for sale in a 0.6 mg/mL concentration.

13. The '066 patent, entitled "Process to prepare treprostinil, the active ingredient in Remodulin®," was duly and legally issued by the United States Patent and Trademark Office on March 14, 2017, and is scheduled to expire on December 15, 2028. The named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh.

14. UTC is the lawful owner of the '066 patent by assignment of all right, title and interest in and to the '066 patent, including the right to bring infringement suits thereon.

15. The '901 patent, entitled "Process to prepare treprostinil, the active ingredient in Remodulin®," was duly and legally issued by the United States Patent and Trademark Office on March 28, 2017, and is scheduled to expire on December 15, 2028. The named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh.

16. UTC is the lawful owner of the '901 patent by assignment of all right, title and interest in and to the '901 patent, including the right to bring infringement suits thereon.

17. TYVASO® and its FDA approved manufacture and uses are covered by one or more claims of the '066 patent and the '901 patent, which have been listed in connection with TYVASO® in the FDA's *Approved Drug Products with Therapeutic Equivalents* publication (also known as the "Orange Book").

ACTS GIVING RISE TO THIS ACTION

18. Liquidia notified UTC by letter dated April 24, 2020, which was delivered to UTC on or about April 27, 2020 ("Liquidia's Notice Letter"), that it had submitted NDA No. 213005 to

the FDA seeking approval to engage in the commercial manufacture, use and/or sale of Liquidia's Proposed Generic Product prior to the expiration of the'066 patent and the '901 patent.

19. Liquidia's Notice Letter included a statement pursuant to 21 U.S.C. § 355(b)(3)(D)(ii) and 21 C.F.R.§ 314.52(c)(6) purporting to recite Liquidia's "factual and legal basis" for its opinion that the '066 patent and the '901 patent are invalid, unenforceable, and/or are not, and will not, be infringed by the commercial manufacture, use or sale of Liquidia's Proposed Generic Product. That statement did not include anything beyond conclusory statements as to why the claims of the '066 patent and the '901 patent were allegedly invalid. The statement also did not include anything beyond conclusory statements regarding alleged non-infringement.

20. Upon information and belief, Liquidia submitted Liquidia's 505(b)(2) Application to FDA seeking approval to commercially manufacture, market, use, and sell generic copies of UTC's TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/mL prior to the expiration of the '066 patent and the '901 patent.

21. UTC is commencing this action before the expiration of forty-five days from the date it received Liquidia's Notice Letter.

22. Upon information and belief, Liquidia's Proposed Generic Product contains the same active compound, treprostinil, as UTC's approved TYVASO® product.

23. Upon information and belief, Liquidia's 505(b)(2) Application seeks approval from the FDA to market Liquidia's Proposed Generic Product for the same indication as UTC's approved TYVASO® product.

24. Upon information and belief, Liquidia's 505(b)(2) Application refers to and relies upon UTC's NDA No. 022387 for TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.