

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS )  
CORPORATION and )  
SUPERNUS PHARMACEUTICALS, INC., )  
 )  
Plaintiffs, )  
 )  
v. ) C.A. No. \_\_\_\_\_  
 )  
ANI PHARMACEUTICALS, INC., )  
 )  
Defendant. )

**COMPLAINT**

Plaintiffs United Therapeutics Corporation (“UTC”) and Supernus Pharmaceuticals, Inc. (“Supernus”) (collectively, “Plaintiffs”), by their undersigned attorneys, for their Complaint against ANI Pharmaceuticals, Inc. (“ANI”), allege 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. 7,417,070 (“the ’070 patent”) (attached as Exhibit A hereto), 7,544,713 (“the ’713 patent”) (attached as Exhibit B hereto), 8,252,839 (“the ’839 patent”) (attached as Exhibit C hereto), 8,349,892 (“the ’892 patent”) (attached as Exhibit D hereto), 8,410,169 (“the ’169 patent”) (attached as Exhibit E hereto), 8,747,897 (“the ’897 patent”) (attached as Exhibit F hereto), 9,050,311 (“the ’311 patent”) (attached as Exhibit G hereto), 9,278,901 (“the ’901 patent”) (attached as Exhibit H hereto), 9,393,203 (“the ’203 patent”) (attached as Exhibit I hereto), 9,422,223 (“the ’223 patent”) (attached as Exhibit J hereto), 9,593,066 (“the ’066 patent”) (attached as Exhibit K hereto), and 9,604,901 (“the ’4901 patent”) (attached as Exhibit L hereto).

2. This action arises out of ANI's submission of Abbreviated New Drug Application ("ANDA") No. 215667 ("ANI's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval, prior to the expiration of the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, and '4901 patents, to manufacture, market, and sell generic copies of UTC's ORENTRAM<sup>®</sup> (treprostinil) Extended-Release Tablets, which are approved by FDA for treatment of pulmonary arterial hypertension.

### **THE PARTIES**

3. UTC is a corporation organized and existing under the laws of the State of Delaware having a place of business at 1040 Spring Street, Silver Spring, Maryland 20910. UTC is a pharmaceutical and biotechnology company focused on the development and commercialization of products designed to address the needs of patients with chronic and life-threatening conditions.

4. Supernus is a corporation organized and existing under the laws of the State of Delaware having a place of business at 9715 Key West Avenue, Rockville, MD 20850. Supernus is a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) disorders.

5. Upon information and belief, ANI is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 210 Main Street West, Baudette, MN 56623.

### **JURISDICTION AND VENUE**

6. 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.

7. This Court has personal jurisdiction over ANI because, upon information and belief, ANI is incorporated and resides in Delaware.

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

### **BACKGROUND**

9. UTC holds an approved New Drug Application (No. 203496) for treprostinil extended-release tablets that UTC markets and sells under the registered trademark ORENITRAM®.

10. ORENITRAM® is a pharmaceutical product initially approved by FDA in December 2013, and is indicated for the treatment of pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare disease affecting the pulmonary vasculature and results in increased pressure in the pulmonary arteries, which increases strain on the heart, which, in turn, can lead to heart failure and death.

11. ORENITRAM® is an extended-release tablet available in four dosage strengths, 0.125 mg, 0.25 mg, 1 mg, and 2.5 mg. ORENITRAM® is designed to release treprostinil using an osmotic tablet technology.

12. The '070 patent, entitled "Compounds and methods for delivery of prostacyclin analogs," was duly and legally issued by the United States Patent and Trademark Office on August 26, 2008. The named inventors are Ken Phares and David Mottola.

13. UTC is the lawful owner of the '070 patent by assignment of all right, title and interest in and to the '070 patent, including the right to sue for infringement thereof.

14. The '713 patent, entitled "Compounds and methods for delivery of prostacyclin analogs," was duly and legally issued by the United States Patent and Trademark Office on June 9, 2009. The named inventors are Ken Phares and David Mottola.

15. UTC is the lawful owner of the '713 patent by assignment of all right, title and interest in and to the '713 patent, including the right to sue for infringement thereof.

16. The '839 patent, entitled "Compounds and methods for delivery of prostacyclin analogs," was duly and legally issued by the United States Patent and Trademark Office on August 28, 2012. The named inventors are Ken Phares and David Mottola.

17. UTC is the lawful owner of the '839 patent by assignment of all right, title and interest in and to the '839 patent, including the right to sue for infringement thereof.

18. The '892 patent, entitled "Solid formulations of prostacyclin analogs" was duly and legally issued by the United States Patent and Trademark Office on January 8, 2013. The named inventor is Kenneth R. Phares.

19. UTC is the lawful owner of the '892 patent by assignment of all right, title and interest in and to the '892 patent, including the right to sue for infringement thereof.

20. The '169 patent, entitled "Compounds and methods for delivery of prostacyclin analogs," was duly and legally issued by the United States Patent and Trademark Office on April 2, 2013. The named inventors are Ken Phares and David Mottola.

21. UTC is the lawful owner of the '169 patent by assignment of all right, title and interest in and to the '169 patent, including the right to sue for infringement thereof.

22. The '897 patent, entitled "Osmotic drug delivery system," was duly and legally issued by the United States Patent and Trademark Office on June 10, 2014. The named inventors are Argaw Kidane and Padmanabh P. Bhatt.

23. Supernus is the lawful owner of the '897 patent by assignment of all right, title and interest in and to the '897 patent, including the right to sue for infringement thereof. UTC is the exclusive licensee of the '897 patent, with the exclusive right to develop, make, have made, use, offer for sale, sell, have sold, and import products covered by the '897 patent.

24. The '311 patent, entitled "Compounds and methods for delivery of prostacyclin analogs," was duly and legally issued by the United States Patent and Trademark Office on June 9, 2015. The named inventors are Ken Phares, David Mottola, and Hitesh Batra.

25. UTC is the lawful owner of the '311 patent by assignment of all right, title and interest in and to the '311 patent, including the right to sue for infringement thereof.

26. The '901 patent, entitled "Compounds and methods for delivery of prostacyclin analogs," was duly and legally issued by the United States Patent and Trademark Office on March 8, 2016. The named inventors are Ken Phares, David Mottola, and Roger Jeffs.

27. 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 sue for infringement thereof.

28. The '203 patent, entitled "Osmotic drug delivery system," was duly and legally issued by the United States Patent and Trademark Office on July 19, 2016. The named inventors are Argaw Kidane and Padmanabh P. Bhatt.

29. Supernus is the lawful owner of the '203 patent assignment of all right, title and interest in and to the '203 patent, including the right to sue for infringement thereof. UTC is the exclusive licensee of the '203 patent, with the exclusive right to develop, make, have made, use, offer for sale, sell, have sold, and import products covered by the '203 patent.

30. The '223 patent, entitled "Compounds and methods for delivery of prostacyclin analogs," was duly and legally issued by the United States Patent and Trademark Office on August 23, 2016. The named inventors are Ken Phares, David Mottola, and Roger Jeffs.

31. UTC is the lawful owner of the '223 patent assignment of all right, title and interest in and to the '223 patent, including the right to sue for infringement thereof.

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