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medac Gesellschaft für klinische Spezialpräparate mbH*

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MEDAC PHARMA, INC. and MEDAC)
GESELLSCHAFT FÜR KLINISCHE)
SPEZIALPRÄPARATE MBH,)
)
Plaintiffs,)
)
v.)
)
ANTARES PHARMA, INC., LEO)
PHARMA A/S and LEO PHARMA INC.,)
)
Defendants.)

C.A. NO.: _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs medac Pharma, Inc. and medac Gesellschaft für klinische Spezialpräparate mbH, by and through their undersigned counsel, file this Complaint against Antares Pharma, Inc., LEO Pharma A/S and LEO Pharma Inc. (collectively, “Defendants”) and allege as follows:

The Parties

1. Plaintiff medac Pharma, Inc. (“medac Pharma”) is a corporation organized under the laws of the State of Delaware, having its principal place of business at 29 North Wacker Drive Suite 704, Chicago, Illinois 60606.

2. Plaintiff medac Gesellschaft für klinische Spezialpräparate mbH (“medac”) is a corporation organized under the laws of Germany, having its principal place of business at Theaterstrasse 6, 22880 Wedel, Germany.

3. medac Pharma is a wholly-owned subsidiary of medac.

4. Upon information and belief, defendant Antares Pharma, Inc. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 100 Princeton South, Suite 300, Ewing, New Jersey 08628.

5. Upon information and belief, defendant LEO Pharma A/S is a corporation organized under the laws of Denmark, having its principal place of business at Industriparken 55, DK-2750 Ballerup, Denmark.

6. Upon information and belief, defendant LEO Pharma Inc. is an affiliate of LEO Pharma A/S and is a corporation organized under the laws of the State of Delaware, having its principal place of business at 1 Sylvan Way, Parsippany, New Jersey 07054.

7. Upon information and belief, the acts of LEO Pharma Inc. are performed at the direction and/or authorization of, and/or with the cooperation and/or assistance of LEO Pharma A/S, and are performed at least in part for the benefit of LEO Pharma A/S.

Jurisdiction And Venue

8. This is an action arising under the patent laws of the United States, 35 U.S.C. §§ 1
et seq.

9. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Antares Pharma, Inc. Upon information and belief, Antares Pharma, Inc. maintains its principal place of business in the State of New Jersey. Furthermore, upon information and belief, Antares Pharma, Inc. has engaged and currently engages in continuous and systematic contacts with the State of New Jersey. Upon information and belief, Antares Pharma, Inc. has marketed, placed and continues to place medical products in the stream of commerce via established distribution channels, with the knowledge and/or understanding that such products are marketed and/or sold within this District.

11. This Court has personal jurisdiction over LEO Pharma Inc. Upon information and belief, LEO Pharma Inc. maintains its principal place of business in the State of New Jersey. Furthermore, upon information and belief, LEO Pharma Inc. has engaged and currently engages in continuous and systematic contacts with the State of New Jersey. Upon information and belief, LEO Pharma, Inc. has marketed, placed and continues to place medical products in the stream of commerce via established distribution channels, with the knowledge and/or understanding that such products are marketed and/or sold within this District.

12. This Court has personal jurisdiction over LEO Pharma A/S. Upon information and belief, LEO Pharma A/S engages in continuous and systematic contacts with the State of New Jersey through its affiliate, LEO Pharma Inc.

13. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

The Patent-In-Suit

14. medac is a global pharmaceutical company with products and services directed to treatment, therapy and diagnosis of diseases in the fields of oncology, urology, autoimmune

diseases and fibrinolysis. medac Pharma is a wholly owned subsidiary of medac with products and services directed to the commercialization of treatments for autoimmune diseases (including the treatment of rheumatoid arthritis and psoriasis) and cancer. medac protects these products and services through, *inter alia*, its intellectual property portfolio, including patents. medac has expended significant resources to develop and acquire this intellectual property. medac Pharma has expended significant resources to prepare to commercialize products related to this intellectual property, should those products be approved for sale in the United States.

15. medac and medac Pharma are innovators and leaders in the field of subcutaneous methotrexate administration, in particular for its use in the treatment of inflammatory autoimmune diseases, including rheumatoid arthritis and psoriasis.

16. medac Pharma recently secured acceptance by the United States Food and Drug Administration (“FDA”) of a new drug application (“NDA”) for a methotrexate-containing autopen. This autopen contains a subcutaneous injectable form of methotrexate in a concentration of more than 30 mg/mL that has the potential to improve bioavailability and to overcome tolerability issues associated with methotrexate taken orally and is able to deliver higher amounts of methotrexate at reduced drug volumes through subcutaneous injection, addressing the stigmas associated with injectable medications, including methotrexate.

17. medac is the lawful owner of all right, title and interest in U.S. Patent 8,664,231 (“the ‘231 patent”), entitled “Concentrated Methotrexate Solutions.” medac Pharma is an exclusive licensee of the ‘231 patent and has the right to use, supply, distribute, sell, offer for sale, and import into the United States products for the use in methods claimed in the ‘231 patent.

18. The '231 patent claims, among other things, a method for the treatment of inflammatory autoimmune diseases in a patient in need thereof, comprising subcutaneously administering to said patient a medicament comprising methotrexate in a pharmaceutically acceptable solvent at a concentration of more than 30 mg/mL.

19. The United States Patent and Trademark Office duly and legally issued the '231 patent on March 4, 2014. A true and correct copy of the '231 patent is attached to this Complaint as Exhibit A.

Factual Background

20. Upon information and belief, Antares Pharma, Inc. received FDA approval to market OTREXUP[™] (methotrexate) injection for subcutaneous use in the treatment of forms of rheumatoid arthritis and psoriasis in adults and polyarticular idiopathic arthritis in children on October 11, 2013, and announced the availability of OTREXUP[™] (methotrexate) injection at distribution centers throughout the United States in a Press Release, dated January 15, 2014, which is attached to this Complaint as Exhibit B. It is available in four dosage strengths: 10 mg/0.4 mL methotrexate, 15 mg/0.4 mL methotrexate, 20 mg/0.4 mL methotrexate, and 25 mg/0.4 mL methotrexate. The latter three strengths are concentrations of more than 30 mg/mL methotrexate, as recited in claims of the '231 patent.

21. Upon information and belief, Antares Pharma, Inc. manufactures, sells and offers to sell OTREXUP[™] (methotrexate) injection for subcutaneous use to treat the approved forms of rheumatoid arthritis and psoriasis in adults and polyarticular idiopathic arthritis in children. *See* Exhibit B.

22. Upon information and belief, Antares Pharma, Inc. is selling and offering to sell and intends to continue selling and offering to sell its OTREXUP[™] (methotrexate) injection for

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