David C. Kistler
BLANK ROME LLP
301 Carnegie Center, 3rd Floor
Princeton, New Jersey 08540
(609) 750-2643-4444 (telephone)
(609) 897-7291 (facsimile)

Of Counsel:
Christopher J. Harnett
James F. Haley, Jr.
Hassen A. Sayeed
Jacqueline M. James
Steven K. Mossey
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, New York 10036
(212) 596-9000 (telephone)
(212) 596-9090 (facsimile)

Attorneys for Plaintiffs medac Pharma, Inc. and 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,	)	**C.A. NO.: _____**
Plaintiffs,	)	
v.	)	JURY TRIAL DEMANDED
ANTARES PHARMA, INC., LEO PHARMA A/S and LEO PHARMA INC.,	)	
Defendants.	)	

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

treating the approved forms of psoriasis in adults through an exclusive promotion and marketing agreement with LEO Pharma A/S. *See* November 14, 2013, Antares Pharma, Inc. Press Release attached to this Complaint as Exhibit C.

23. Upon information and belief, LEO Pharma Inc., an affiliate of LEO Pharma A/S, carries out LEO Pharma A/S's promotion and marketing responsibilities for the OTREXUP™ (methotrexate) injection in the United States.

COUNT I
(INFRINGEMENT OF U.S. PATENT 8,664,231 BY DEFENDANTS)

24. medac and medac Pharma reallege and incorporate by reference paragraphs 1 through 23, inclusive, as if fully set forth in this paragraph.

25. Upon information and belief, OTREXUP™ (methotrexate) injection is an autoinjector for subcutaneous injection that administers a single 0.4 mL dose of methotrexate solution in one of 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 of which dosage strengths have a concentration of more than 30 mg/mL.

26. Upon information and belief, the FDA approved OTREXUP™ (methotrexate) injection for treatment of forms of rheumatoid arthritis and psoriasis in adults and polyarticular idiopathic arthritis in children.

27. Upon information and belief, rheumatoid arthritis, polyarticular idiopathic arthritis and psoriasis, and the forms of those diseases for which the OTREXUP™ (methotrexate) injection is approved, are autoimmune diseases.

28. Upon information and belief, Antares Pharma, Inc. represents that the OTREXUP™ (methotrexate) injection will expand treatment options for rheumatoid arthritis, polyarticular idiopathic arthritis and psoriasis patients in the United States.

29. Upon information and belief, Antares Pharma, Inc. indicated the availability of OTREXUP™ (methotrexate) injection as of January 15, 2014 at distribution centers throughout the United States for the treatment of the approved forms of rheumatoid arthritis, polyarticular idiopathic arthritis and psoriasis. *See* Exhibit B.

30. Upon information and belief, one or more of the following entities are involved with the promotion and marketing of OTREXUP™ (methotrexate) injection for the treatment of the approved forms of psoriasis in the United States: LEO Pharma A/S and LEO Pharma Inc. *See* Exhibit C and Antares Pharma, Inc.'s Cowen & Company 34th Annual Health Care Conference Presentation "Overview of Recent Events," attached to this Complaint as Exhibit D.

31. Upon information and belief, Defendants knew or should have known of the 12/374,528 application that issued as the '231 patent as of at least December 14, 2012, the date of the filing of the OTREXUP™ (methotrexate) injection NDA because, among other reasons, a corporate entity that conducts intellectual property diligence on its planned products would have been aware of the 12/374,528 application, the prosecution status of which was publicly available via Patent Application Information Retrieval at the PTO website (http://portal.uspto.gov/external/portal/pair) from the time that the PCT application, designating the United States, was published in January 2008 and the U.S. application was published in January 2010; from the time the claims, as issued in the '231 patent, were filed on March 21, 2012; and from the time those claims were allowed on January 7, 2014. Defendants also knew or should have known of the 12/374,528 application as of at least January 27, 2014, the date of a Press Release issued by medac Pharma announcing the allowance of a patent application directed to a method for the treatment of inflammatory autoimmune diseases by subcutaneously administering methotrexate at a concentration of more than 30 mg/mL. A copy of that Press Release is attached to this

Complaint as Exhibit E. The filing of this Complaint also constitutes actual notice of the '231 patent to Defendants under 35 U.S.C. § 287.

32. Upon information and belief, Defendants directly infringe, contributorily infringe and/or actively induce the infringement by others under 35 U.S.C. § 271, either literally or under the doctrine of equivalents, at least claim 1 of the '231 patent, by activities including but not limited to making, using, selling, importing and/or offering to sell FDA-approved OTREXUP™ (methotrexate) injection in the United States for the treatment of the approved forms of rheumatoid arthritis, polyarticular idiopathic arthritis and psoriasis, together with instructing, directing and/or advising others how to carry out such infringement using such OTREXUP™ (methotrexate) injection.

33. Upon information and belief, Defendants sell, and offer for sale, FDA-approved OTREXUP™ (methotrexate) injection with a package insert that includes instructions for a method of treating the approved forms of rheumatoid arthritis, polyarticular idiopathic arthritis and psoriasis using such OTREXUP™ (methotrexate) injection by subcutaneous injection.

34. Upon information and belief, Defendants actively induce the infringement of at least claim 1 of the '231 patent, either literally or under the doctrine of equivalents, by offering for sale and/or selling FDA-approved OTREXUP™ (methotrexate) injection in the United States, together with a package insert setting forth instructions for a method of treating the approved forms of rheumatoid arthritis, polyarticular idiopathic arthritis and psoriasis using such OTREXUP™ (methotrexate) injection by subcutaneous injection.

35. Upon information and belief, when physicians or others use FDA-approved OTREXUP™ (methotrexate) injection according to the method of treating the approved forms of rheumatoid arthritis, polyarticular idiopathic arthritis and psoriasis set forth on the package insert

provided by Defendants, those acts constitute direct infringement of at least claim 1 of the '231 patent, either literally or under the doctrine of equivalents.

36. Upon information and belief, Defendants contributorily infringe, either literally or under the doctrine of equivalents, at least claim 1 of the '231 patent by offering for sale and/or selling FDA-approved OTREXUP™ (methotrexate) injection in the United States, while knowing that such OTREXUP™ (methotrexate) injection is especially made or especially adapted for use in the infringement of the '231 patent, and is not a staple article suitable for substantial non-infringing use.

37. As a result of Defendants' acts of infringement, medac and medac Pharma have been and will continue to be irreparably harmed and have and will continue to suffer damages in an amount to be proved at trial.

Prayer For Relief

WHEREFORE, medac and medac Pharma request the Court to enter judgment in its favor and grant the following relief:

(a) A judgment that Defendants directly infringe, contribute to and/or actively induce the infringement of the '231 patent by making, using, selling, importing and/or offering to sell FDA-approved OTREXUP™ (methotrexate) injection in the United States;

(b) A judgment and order permanently restraining and enjoining Defendants and their directors, officers, agents, servants, employees, attorneys, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all persons in active concert or privity with them, and their successors and assigns, from infringing the '231 patent by making, using, selling, importing or offering for sale FDA-approved OTREXUP™ (methotrexate) injection in the United States;

(c) A judgment and order requiring the Defendants to pay all available and legally permissible damages to compensate medac and medac Pharma for Defendants' infringing acts, but in no event less than a reasonable royalty in accordance with 35 U.S.C. § 284;

(d) A finding that the complained-of conduct by the Defendants has been willful, warranting an award of treble damages under 35 U.S.C. § 284;

(e) A finding that this case is exceptional under 35 U.S.C. § 285, warranting an award to medac and medac Pharma of their costs, including attorney fees and other expenses incurred in connection with this action;

(f) A judgment and order requiring Defendants to pay medac and medac Pharma pre-judgment interest and post-judgment interest on all damages awarded; and

(g) Such further relief as this Court deems just and appropriate.

Demand For Jury Trial

Pursuant to Fed. R. Civ. P. 38, medac and medac Pharma demand a trial by jury of all issues so triable.

Respectfully submitted,

Dated: March 7, 2014

By: *s/ David C. Kistler*

David C. Kistler
BLANK ROME LLP
301 Carnegie Center, 3rd Floor
Princeton, NJ 08540
(609) 750-2643 (telephone)
(609) 897-7291 (facsimile)
kistler@blankrome.com

Of Counsel:
Christopher J. Harnett
James F. Haley, Jr.
Hassen A. Sayeed
Jacqueline M. James
Steven K. Mossey
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, New York 10036
(212) 596-9000 (telephone)
(212) 596-9090 (facsimile)
james.haley@ropesgray.com
christopher.harnett@ropesgray.com
hassen.sayeed@ropesgray.com
jacqueline.james@ropesgray.com
steven.mossey@ropesgray.com

Attorneys for Plaintiffs medac Pharma, Inc. and medac Gesellschaft für klinische Spezialpräparate mbH

LOCAL CIVIL RULE 11.2 CERTIFICATION

Plaintiffs medac and medac Pharma hereby certify that, to their knowledge, the matter in controversy in this action is not the subject of any other pending lawsuit, arbitration, or administrative proceeding.

Respectfully submitted,

Dated: March 7, 2014

By: *s/ David C. Kistler*

David C. Kistler
BLANK ROME LLP
301 Carnegie Center, 3rd Floor
Princeton, NJ 08540
(609) 750-2643 (telephone)
(609) 897-7291 (facsimile)
kistler@blankrome.com

Of Counsel:
Christopher J. Harnett
James F. Haley, Jr.
Hassen A. Sayeed
Jacqueline M. James
Steven K. Mossey
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, New York 10036
(212) 596-9000 (telephone)
(212) 596-9090 (facsimile)
james.haley@ropesgray.com
christopher.harnett@ropesgray.com
hassen.sayeed@ropesgray.com
jacqueline.james@ropesgray.com
steven.mossey@ropesgray.com

Attorneys for Plaintiffs medac Pharma, Inc. and medac Gesellschaft für klinische Spezialpräparate mbH