

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS  
CENTRAL DIVISION**

ABBOTT BIOTECHNOLOGY LTD.,

Plaintiff,

v.

CENTOCOR ORTHO BIOTECH INC.,

Defendant.

CIVIL ACTION NO.

**DEMAND FOR JURY TRIAL**

**COMPLAINT**

Plaintiff Abbott Biotechnology Limited (“Abbott” or “Plaintiff”) brings this complaint for a declaratory judgment and other relief for patent infringement against Defendant Centocor Ortho Biotech Inc. (“Centocor” or “Defendant”).

**NATURE OF ACTION**

1. This is an action seeking a declaratory judgment and other relief for patent infringement by and against the above-named Defendant.

**PARTIES**

2. Abbott is a corporation organized under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. Through intermediate organizations, it is owned by Abbott Laboratories, an Illinois corporation which conducts business in this District directly as well as through its subsidiary Abbott Bioresearch Center, Inc. (“ABC”), located in Worcester, Massachusetts (as more fully described below).

3. On information and belief, Defendant Centocor is a corporation organized under the laws of the Commonwealth of Pennsylvania, with a principal place of business at Ridgeview Drive, Horsham, Pennsylvania. Within the meaning of 28 U.S.C. § 1391(c), it resides in this District by reason of having continuous and systematic contacts with this District, including the

marketing and sales of health products in Massachusetts, such as the drug marketed and sold as “REMICADE,” which enjoyed U.S. sales of approximately \$2.8 billion in 2008.

### **JURISDICTION AND VENUE**

4. This is a declaratory judgment action pursuant to 28 U.S.C. §§ 2201-2202 for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271 et seq.

5. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338.

6. On information and belief, Defendant has been engaged in efforts to meet the regulatory requirements of the United States Food and Drug Administration (“FDA”) for marketing, distributing, offering for sale and/or selling SIMPONI™, an anti-TNF alpha therapy product that Defendant has sought FDA approval for with respect to the treatment of rheumatoid arthritis. See [www.simponi.com](http://www.simponi.com) (April 28, 2009).

7. On or about April 24, 2009, Defendant obtained FDA approval to market SIMPONI™ in the United States for use in combination with methotrexate as a treatment for rheumatoid arthritis and, on information and belief, Defendant either has begun efforts to produce substantial supplies of SIMPONI™ in anticipation of its imminent launch in the U.S. market, and/or will soon begin manufacturing, distributing, using, offering for sale, selling, and/or importing into the United States the SIMPONI™ therapy product, to be prescribed and used for the treatment, *inter alia*, of rheumatoid arthritis in combination with methotrexate.

8. On May 29, 2007, the United States Patent & Trademark Office (“USPTO”) duly and legally issued United States Patent No. 7,223,394 (the “394 Patent”), entitled “Human Antibodies that Bind Human TNF alpha,” to the listed inventors Jochen G. Salfeld of North Grafton, Massachusetts, and other co-inventors in Massachusetts (and other locations). Dr.

Salfeld and one or more of his co-inventors are current employees at the earlier-mentioned Abbott Bioresearch Center, Inc. (“ABC”), located at 100 Research Drive in Worcester, Massachusetts, where they carried out the research leading to the ’394 patent. The ’394 Patent has claims relating to methods for treating a subject suffering from rheumatoid arthritis by co-administering both a human antibody and methotrexate. The antibody in the claimed methods has particular affinity for and neutralizes human TNF alpha. Plaintiff Abbott is the assignee and owner of the ’394 Patent, a copy of which is attached as Exhibit A. Abbott’s product HUMIRA<sup>®</sup> is a fully human TNF alpha neutralizing antibody whose use together with methotrexate to treat rheumatoid arthritis is covered by the ’394 patent. Since its launch in 2002, HUMIRA<sup>®</sup> has benefitted hundreds of thousands of patients worldwide.

9. On information and belief, Defendant will be infringing Plaintiff’s ’394 Patent by virtue of the offer for sale and sale in the United States of its SIMPONI<sup>™</sup> product with the rheumatoid-arthritis indication discussed above, including by inducing infringement. By way of example, Centocor’s prescribing information for SIMPONI<sup>™</sup> states that “[f]or patients with rheumatoid arthritis (RA), SIMPONI should be given in combination with methotrexate.”

10. A real, immediate, substantial, and justiceable controversy has arisen and now exists between the parties under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c) and/or 1400(b), as *inter alia* the Defendant is subject to personal jurisdiction in this District.

### **COUNT FOR PATENT INFRINGEMENT**

12. Plaintiff incorporates by reference paragraphs 1-11 as if fully set forth herein.

13. As set forth above, an actual controversy now exists between the parties that Defendant’s SIMPONI<sup>™</sup> product, when co-administered with methotrexate to treat rheumatoid arthritis (per Centocor’s indication), will infringe Abbott’s ’394 Patent.

14. As set forth above, on information and belief, by making meaningful preparations to market, make, use, sell, offer for sale, and/or import SIMPONI™ into the United States, with the rheumatoid-arthritis indication discussed above, and having now recently obtained FDA approval, Defendant Centocor is engaged in activities that infringe and/or is making meaningful preparation toward activities that will imminently infringe the '394 Patent, including by inducing infringement under 35 U.S.C. § 271(b).

15. On information and belief, Defendant is aware of the '394 Patent and its imminent infringement is deliberate, willful, and in reckless disregard of Abbott's patent rights.

16. Abbott will be injured by the imminent infringing activities of Defendant.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff Abbott respectfully requests the following relief:

(a) a declaration that Defendant infringes the '394 Patent and a final judgment incorporating same;

(b) entry of preliminary and/or permanent equitable relief, including but not limited to a preliminary and/or permanent injunction that enjoins Defendant and any of its officers, agents, employees, assigns, representatives, privies, successors, and those acting in concert or participation with them from infringing and/or inducing infringement of the '394 Patent;

(c) an award of damages sufficient to compensate Abbott for infringement of the '394 Patent by Defendant, together with prejudgment and post-judgment interest;

(d) entry of an order compelling Defendant to compensate Abbott for any ongoing and/or future infringement of the '394 Patent, in an amount and under terms appropriate under the circumstances;

(e) a declaration or order finding that Defendant's infringement is willful and/or an order increasing damages under 35 U.S.C. § 284;

(f) a judgment holding that this is an exceptional case under 35 U.S.C. § 285 and awarding Abbott its reasonable attorneys fees, costs, and expenses;

(g) such other relief deemed just and proper.

**JURY DEMAND**

Under Rule 38 of the Federal Rules of Civil Procedure, Abbott hereby demands trial by jury of all issues so triable by a jury in this action.

DATED: May 1, 2009

Respectfully submitted,

/s/ Michael P. Angelini

Michael P. Angelini (BBO# 019340)

Douglas T. Radigan (BBO# 657938)

BOWDITCH & DEWEY LLP

311 Main Street

P.O. Box 15156

Worcester, MA 01615-0156

(508) 926-3400

[mangelini@bowditch.com](mailto:mangelini@bowditch.com)

[dradigan@bowditch.com](mailto:dradigan@bowditch.com)

Denise W. DeFranco (BBO# 558859)

FINNEGAN, HENDERSON, FARABOW,

GARRETT & DUNNER, L.L.P.

55 Cambridge Parkway

Cambridge, MA 02142-1215

(617) 452-1600

[denise.defranco@finnegan.com](mailto:denise.defranco@finnegan.com)

**Attorneys for Plaintiff**

**ABBOTT BIOTECHNOLOGY LTD.**