

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

ABBOTT GMBH & CO., KG,)	
ABBOTT BIORESEARCH CENTER, INC.,)	
AND ABBOTT BIOTECHNOLOGY LTD.,)	
)	Civil Action No. 4:09-cv-11340-FDS
Plaintiffs,)	
)	
v.)	
)	
CENTOCOR ORTHO BIOTECH, INC. AND)	
CENTOCOR BIOLOGICS, LLC.,)	
)	
Defendants.)	
)	

FIRST AMENDED COMPLAINT AND JURY DEMAND

Plaintiffs Abbott GmbH & Co., KG (“Abbott GmbH”), Abbott Bioresearch Center, Inc. (“ABC”) and Abbott Biotechnology Ltd. (“ABL”) (collectively, “Abbott”) complain against Defendants Centocor Ortho Biotech, Inc. and Centocor Biologics, LLC. (collectively “Centocor”), as follows:

INTRODUCTION

1. This action arises under the Patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and relates to U.S. Patent No. 6,914,128 (the “128 Patent”) and U.S. Patent No. 7,504,485 (the “485 Patent”).

PARTIES

2. Abbott GmbH is a limited partnership organized under the laws of Germany with its principal place of business at Max-Planck-Ring 2, Wiesbaden, Germany 65205.

3. ABC is a corporation organized under the laws of Delaware with its principal place of business at 100 Research Drive, Worcester, Massachusetts 01605. ABC, through its activities in this District, was extensively involved in the development of the antibodies which

led to the inventions embodied in the '128 Patent and the '485 Patent. Also within this District, ABC continues to develop and refine products embodying the technologies disclosed and claimed in the '128 Patent and the '485 Patent.

4. ABL is a corporation organized under the laws of Bermuda with its principal place of business at 2 Church Street, Hamilton HM11, Bermuda.

5. On information and belief, Centocor Ortho Biotech, Inc., a subsidiary of Johnson & Johnson, is a corporation organized under the laws of the Commonwealth of Pennsylvania, and has a principal place of business at 800/850 Ridgeway Drive, Horsham, Pennsylvania 19044.

6. On information and belief, Centocor Biologics LLC, a subsidiary of Centocor Ortho Biotech, Inc., is a corporation organized under the laws of the Commonwealth of Pennsylvania, and has a principal place of business at 4777 Le Bourget Drive, St. Louis, Missouri 63134.

JURISDICTION AND VENUE

7. This Court has jurisdiction over Abbott's claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

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

FACTUAL ALLEGATIONS

9. Abbott GmbH is the assignee of the '128 Patent, entitled "Human Antibodies that Bind Human IL-12 and Methods for Producing." The '128 Patent was duly and legally issued on July 5, 2005. A copy of the '128 Patent is attached as Exhibit A.

10. Abbott GmbH is the assignee of the '485 Patent, entitled "Human Antibodies That Bind Human IL-12." The '485 Patent was duly and legally issued on March 17, 2009. A copy of the '485 Patent is attached as Exhibit B.

11. ABL is the exclusive licensee of the '128 and '485 Patents as a result of a license agreement executed between ABL and Abbott GmbH dated December 9, 2009.

12. The '128 Patent and '485 Patent each describe and claim antibodies that neutralize IL-12. In healthy individuals, interleukin-12 ("IL-12") is naturally produced by the human body to help regulate the immune system and is involved in the inflammation response to infection or damage to the body.

13. In some individuals, however, IL-12 is overproduced. The overproduction of IL-12 causes an overactive immune system response and can lead to a number of disorders, such as psoriasis. Psoriasis is an autoimmune disease in which skin cells multiply faster than the normal rate. In the most common form of psoriasis, the excess skin cells pile up on the skin's surface, forming red, scaly plaques that can be painful and disfiguring. According to the National Institutes of Health, as many as 7.5 million Americans are afflicted by psoriasis.

14. These "anti-IL-12 antibodies" invented by Abbott are administered to psoriasis sufferers, where the antibodies bind to a portion of IL-12 and neutralize it, preventing the IL-12 from causing damage to otherwise healthy cells in the body. This treatment reduces inflammation and helps alleviate the symptoms of the autoimmune disorder. The antibodies that are the subject of the '128 and '485 Patents are believed to be useful in the treatment of other diseases in addition to psoriasis.

15. Abbott was the first company to develop these pioneering anti-IL-12 antibodies, and filed the parent application for both the '128 Patent and '485 Patent on March 25, 1999. Abbott's anti-IL-12 antibody, known as ABT-874, is presently in late-stage clinical trials for the treatment of psoriasis and has shown promising results.

16. As the United States Patent and Trademark Office's Board of Patent Appeals and Interferences ("BPAI") has explicitly recognized, Centocor developed its competing anti-IL-12 antibody, known as ustekinumab, after Abbott developed the antibodies that are the subject of the '128 Patent. In an attempt to prevent Abbott from exercising its right to patent the novel anti-IL-12 antibodies invented at ABC, Centocor provoked an interference proceeding, claiming that it had invented ustekinumab prior to Abbott's invention of the '128 Patent claimed antibodies. On August 6, 2009, the BPAI rejected Centocor's claims and recognized that Abbott had not only conceived of the claimed anti-IL-12 antibodies, but had successfully reduced the claimed antibodies to practice before Centocor completed its development of ustekinumab.

17. As a part of the interference proceeding, Centocor also sought a ruling that the claims of the '128 Patent were unpatentable for obviousness under 35 U.S.C. § 103. The BPAI ruled against Centocor and recognized on August 6, 2009 that the claimed anti-IL-12 antibodies were not "obvious" and thus that Abbott's anti-IL-12 antibodies are patentable under 35 U.S.C. § 103.

18. Centocor now seeks to benefit from Abbott's patented technology through the manufacture, use, and sale of its later-developed anti-IL-12 antibody, ustekinumab, marketed under the tradename Stelara. Stelara was first approved in January 2009 by the European Commission for the treatment of plaque psoriasis, permitting sales and marketing of the drug in all 27 countries in the European Union. On September 25, 2009, the Federal Drug Administration approved Stelara for treatment of plaque psoriasis in the United States. On information and belief, Centocor's acts of infringement have occurred, and continue to occur in this District and throughout the United States.

19. Centocor was given notice of its infringement of the '128 and '485 Patents. Despite that notice, Centocor has been and continues to infringe, induce infringement of, and/or contribute to the infringement of the '128 and '485 patents by, *inter alia*, making, using, offering for sale, and/or selling Stelara .

20. On information and belief, Centocor has willfully infringed the '128 and '485 patents by continuing its acts of infringement after being on notice of these patents.

**FIRST CLAIM FOR RELIEF
(Patent Infringement)**

21. Plaintiffs repeat and reallege paragraphs 1-19 above as if set forth fully herein.

22. Defendant Centocor has infringed and continues to infringe, literally and/or under the doctrine of equivalents, the '128 Patent by making, using, offering for sale and/or selling in the United States, Stelara, an IL-12 antibody that embodies the claimed invention of the '128 Patent in violation of 35 U.S.C. § 271.

23. As a result of Centocor's infringement, Abbott has suffered, and will continue to suffer, substantial damages. Abbott will also suffer severe and irreparable harm unless Centocor's infringement is enjoined by this Court.

**SECOND CLAIM FOR RELIEF
(Patent Infringement)**

24. Plaintiffs repeat and reallege paragraphs 1-22 above as if set forth fully herein.

25. Defendant Centocor has infringed and continues to infringe the '485 Patent by making, using, offering for sale and/or selling in the United States, Stelara, an IL-12 antibody that embodies the claimed invention of the '485 Patent in violation of 35 U.S.C. § 271.

26. As a result of Centocor's infringement, Abbott has suffered, and will continue to suffer, substantial damages. Abbott will also suffer severe and irreparable harm unless Centocor's infringement is enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

- a) Adjudge that Abbott is the owner of the '128 Patent and all rights of recovery under it;
- b) Adjudge that the '128 Patent is not invalid and is enforceable;
- c) Adjudge that Centocor has infringed and continues to infringe the claims of the '128 Patent;
- d) Adjudge that Centocor's infringement of the '128 patent was willful;
- e) Permanently enjoin Centocor from further infringement of the '128 Patent;
- f) Adjudge that Abbott is the owner of the '485 Patent and all rights of recovery under it;
- g) Adjudge that the '485 Patent is not invalid and is enforceable;
- h) Adjudge that Centocor has infringed and continues to infringe the claims of the '485 Patent;
- i) Adjudge that Centocor's infringement of the '485 patent was willful;
- j) Permanently enjoin Centocor from further infringement of the '485 Patent;
- k) Award Abbott compensatory damages together with pre- and post-judgment interest and costs;
- l) Award Abbott treble damages pursuant to 35 U.S.C. § 284;
- m) Award Abbott costs and attorney fees; and
- n) Award Abbott such other relief as the Court deems just and proper.

PLAINTIFFS DEMAND A TRIAL BY JURY ON ALL ISSUES SO TRIABLE.

DATE: July 8, 2010

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CERTIFICATE OF SERVICE

I certify that, on July 8, 2010, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Violetta G. Watson_____