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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION

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CENTOCOR ORTHO BIOTECH INC.	) Case No. CV 08-03573 MRP (CTx)
	)
Plaintiff,	) **SECOND AMENDED COMPLAINT**
	) **FOR DECLARATORY JUDGMENT**
v.	)
	)
GENENTECH, INC. and CITY OF HOPE,	)
	)
Defendants.	)

Plaintiff Centocor Ortho Biotech Inc. ("Centocor"), for its second amended complaint, alleges as follows:

NATURE OF THE CASE

1.   In this action, Centocor seeks a declaration that U.S. Patent 6,331,415 (the "Cabilly II patent") is invalid, unenforceable and/or not infringed by Centocor's abciximab and ustekinumab antibody products.

THE PARTIES

2.   Centocor is a corporation organized under the laws of the Commonwealth of Pennsylvania with a principal place of business in Horsham, Pennsylvania. Centocor's full name, Centocor Ortho Biotech Inc., is the new name of the surviving corporation of a merger effective December 29, 2008 between Centocor, Inc. and Ortho Biotech, Inc.

3.   On information and belief, Genentech, Inc. ("Genentech") is a Delaware corporation with its principal place of business in South San Francisco, California.

4.   On information and belief, City of Hope is a California not-for-profit organization with its principal place of operation in Duarte, California.

5.   On information and belief, Genentech and City of Hope are co-assignees of the Cabilly II patent.

JURISDICTION AND VENUE

6.   This action arises under the Declaratory Judgment Act, Title 28 of the United States Code, Chapter 151, for the purpose of determining an actual and justiciable controversy between the parties hereto. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7.   This Court has personal jurisdiction over Genentech based on its principal place of business in California. This Court has personal jurisdiction over City of Hope based on its organization under the laws of the state of California and because its principal place of operation is in California.

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

THE CABILLY PATENTS

9.   On April 8, 1983, Shmuel Cabilly, Herbert Heyneker, William Holmes, Arthur Riggs and Ronald Wetzel (the "Cabilly Applicants") filed a patent application in the United States Patent and Trademark Office ("PTO") that issued on March 28, 1989, as U.S. Patent No. 4,816,567 (the "Cabilly I patent"). On information and belief, the Cabilly Applicants assigned their rights to Genentech and/or City of Hope.

10.   On the same day that the Cabilly I patent issued, U.S. Patent 4,816,397 (the "Boss patent") issued to Michael Boss, John Kenten, John Emtage and Clive Wood (the "Boss Applicants"). On information and belief, the Boss Applicants assigned their rights to Celltech Therapeutics Limited ("Celltech"). Celltech is a British company with its principal place of business in Slough, England.

11.   At the time that the Boss and Cabilly I patents issued, the Cabilly Applicants had a continuation application pending in the PTO (the "Cabilly II application"). The Cabilly Applicants copied claims from the Boss patent in order to provoke the PTO Board of Patent Appeals & Interferences to initiate an interference proceeding to determine priority – *i.e.,* to determine whether it was the Cabilly Applicants or the Boss Applicants who had made the purported invention first.

12.   In February 1991, the PTO Board declared a patent interference between the pending Cabilly II application and the Boss patent on the basis that both claimed the same purported invention.

13.   After years of adversarial proceedings in the PTO, in August 1998, the PTO Board found that the Boss patent was entitled to priority over the Cabilly II application. The Final Decision indicated that the Cabilly Applicants were "not entitled to a patent . . . ."

14.   In October 1998, Genentech filed a civil action to appeal the decision of the PTO Board awarding priority to the Boss patent (*Genentech, Inc. v. Celltech Ltd.*, Case no. C98-3926 (N.D. Cal.)). In March 2001, the parties to that action filed a notice of settlement and joint request for entry of settlement instruments. As part of their settlement, the parties asked the district court to find that Genentech won the priority contest. The district court then issued an order directing the PTO to vacate its determination that the Boss Applicants were entitled to priority, to revoke the Boss patent, and to issue a patent on the Cabilly II application.

15.   The Cabilly I patent expired in 2006. Were it not revoked, the Boss patent also would have expired in 2006.

16.   After the district court issued its order to the PTO, the PTO referred the Cabilly II application to an examiner for further action, including consideration of materials previously submitted to the PTO that had not clearly been considered by the examiner.

17.   One of the papers submitted by the Cabilly Applicants prior to declaration of the interference was an Information Disclosure Statement that identified, among other references, Valle et al., *Nature*, 300:71-74 (1982). In its Information Disclosure Statement, the Cabilly II Applicants characterized this reference as being cited as part of a group of references identified "in the interests

of good order" because it was cited during prosecution of the Cabilly I application. The Cabilly Applicants also expressly represented that the Valle (1982) work "is readily distinguishable from the instant claims in that the oocytes are not transformed with DNA, but instead are used to transiently express mRNA preparations." (Sept. 18, 1991 IDS at page 2). This Information Disclosure Statement was signed by a representative of Genentech. This representation, however, contradicted a representation Genentech had made about the Valle (1982) reference when it was opposing Celltech's European Boss patent.

18. During the time that Genentech and Celltech were involved in the interference proceeding, Genentech submitted an opposition to Celltech's European patent (EP-B-0120694), the European patent corresponding to the Boss patent. The claims in the Celltech European Boss patent and the claims in the Cabilly II application were both directed, *inter alia*, to processes for producing a heterologous Ig molecule in a single host cell comprising transforming the host cell with separate DNA sequences encoding polypeptide chains comprising at least the variable domains of the heavy and light chains and then expressing those chains separately in the transformed host cell.

19. As part of the grounds for opposition in the European proceeding, Genentech identified the Valle (1982) publication as a reference that anticipated the Boss European patent. Contrary to the characterization of this reference during the Cabilly II application prosecution, Genentech specifically represented to the European Patent Office that Valle (1982):

> clearly teaches the production of an immunologically functional heterologous immunoglobulin molecule in eukaryotic cells transfected by separate DNA molecules encoding its heavy and light chains, respectively. In view of the broad implications evidenced by the Abstract,

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