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FILED  
CLERK, U.S. DISTRICT COURT  
JUL 2 2009  
CENTRAL DISTRICT OF CALIFORNIA  
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14 Attorney for Plaintiff  
15 CENTOCOR ORTHO BIOTECH INC.

**UNITED STATES DISTRICT COURT**

**CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION**

16  
17  
18  
19 CENTOCOR ORTHO BIOTECH ) Case No. CV 08-03573 MRP (CTx)  
20 INC. )  
21 Plaintiff, ) **SECOND AMENDED COMPLAINT**  
22 ) **FOR DECLARATORY JUDGMENT**  
23 v. )  
24 GENENTECH, INC. and CITY )  
25 OF HOPE, )  
26 Defendants. )

Woodcock Washburn LLP  
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**SECOND AMENDED COMPLAINT FOR DECLARATORY JUDGMENT**

Sanofi/Regeneron Ex. 1049, pg 1160

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

3  
4 **NATURE OF THE CASE**

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

8  
9 **THE PARTIES**

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

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

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

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

22  
23 **JURISDICTION AND VENUE**

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

28  
- 1 -

**SECOND AMENDED COMPLAINT FOR DECLARATORY JUDGMENT**

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Sanofi/Regeneron Ex. 1049, pg 1161

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

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

7  
8 **THE CABILLY PATENTS**

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

15 10. On the same day that the Cabilly I patent issued, U.S. Patent  
16 4,816,397 (the "Boss patent") issued to Michael Boss, John Kenten, John Emtage  
17 and Clive Wood (the "Boss Applicants"). On information and belief, the Boss  
18 Applicants assigned their rights to Celltech Therapeutics Limited ("Celltech").  
19 Celltech is a British company with its principal place of business in Slough,  
20 England.

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

28

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

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

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

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

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

23 17. One of the papers submitted by the Cabilly Applicants prior to  
24 declaration of the interference was an Information Disclosure Statement that  
25 identified, among other references, Valle et al., *Nature*, 300:71-74 (1982). In its  
26 Information Disclosure Statement, the Cabilly II Applicants characterized this  
27 reference as being cited as part of a group of references identified “in the interests  
28



1 of good order” because it was cited during prosecution of the Cabilly I application.  
2 The Cabilly Applicants also expressly represented that the Valle (1982) work “is  
3 readily distinguishable from the instant claims in that the oocytes are not  
4 transformed with DNA, but instead are used to transiently express mRNA  
5 preparations.” (Sept. 18, 1991 IDS at page 2). This Information Disclosure  
6 Statement was signed by a representative of Genentech. This representation,  
7 however, contradicted a representation Genentech had made about the Valle  
8 (1982) reference when it was opposing Celltech’s European Boss patent.

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

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

23 clearly teaches the production of an immunologically  
24 functional heterologous immunoglobulin molecule in  
25 eukaryotic cells transfected by separate DNA molecules  
26 encoding its heavy and light chains, respectively. In  
27 view of the broad implications evidenced by the Abstract,  
28

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