

1 Lloyd R. Day, Jr., State Bar No. 90875
DayL@howrey.com
2 Robert M. Galvin, State Bar No. 171508
GalvinR@howrey.com
3 Jackie N. Nakamura, State Bar No. 148531
NakamuraJ@howrey.com
4 HOWREY LLP
1950 University Avenue, 4th Floor
5 East Palo Alto, CA 94303
Telephone: (650) 798-3500
6 Facsimile: (650) 798-3600

7 Attorneys for Plaintiffs
GLAXO GROUP LIMITED and
8 GLAXOSMITHKLINE LLC

9 UNITED STATES DISTRICT COURT
10 FOR THE NORTHERN DISTRICT OF CALIFORNIA
11 SAN FRANCISCO DIVISION

12 GLAXO GROUP LIMITED and
GLAXOSMITHKLINE LLC,

13 Plaintiffs,

14 vs.

15 GENENTECH, INC., and CITY OF HOPE,

16 Defendants.

Case No.:

**COMPLAINT FOR DECLARATORY
JUDGMENT OF INVALIDITY,
UNENFORCEABILITY, AND
NONINFRINGEMENT**

FILED
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FEB 17 2010

RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
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18 Plaintiffs Glaxo Group Limited and GlaxoSmithKline LLC (collectively, "GSK"), for their
19 Complaint against Genentech, Inc. and City of Hope (collectively, "Defendants"), allege as follows:

20 **NATURE OF THE CASE**

21 1. GSK seeks a declaration that U.S. Patent 6,331,415 titled "Methods of Producing
22 Immunoglobulins, Vectors and Transformed Host Cells for Use Therein" (the "Cabilly II patent"
23 attached as Exhibit A), including the *Ex Parte* Reexamination Certificate issued pursuant to
24 Reexamination Nos. 90/007,542 and 90/007,859 (attached as Exhibit B), is invalid, unenforceable,
25 and not infringed by the manufacture, use, sale, offer to sell, or importation of GSK's ofatumumab
26 (Arzerra™) antibody product.

27 2. GSK recently began marketing and selling Arzerra™ in the United States for the
28 treatment of patients whose chronic lymphocytic leukemia ("CLL") is refractory to previous

1 therapies (fludarabine and alemtuzumab). GSK brings this action to lift the cloud created by the
2 imminent threat of Defendants' enforcement of the Cabilly II patent against GSK. Without
3 declaratory relief, the threat of enforcement of the Cabilly II patent poses a substantial risk of injury
4 to GSK as well as the patients, nurses, and doctors now using Arzerra™ for treatment. The
5 continued existence and enforcement of this invalid and unenforceable patent impedes not only the
6 development and sale of Arzerra™, but also the development and sale of other life-saving
7 recombinant antibody products.

8 3. Defendants have asserted that the Cabilly II patent broadly covers the use of certain
9 well-known, conventional recombinant methods to produce any antibody product in any type of host
10 cell. Defendants have filed infringement claims under the Cabilly II patent against companies who
11 have made and sold antibody products that were produced using recombinant methods similar to the
12 recombinant methods used by GSK to make Arzerra™. Defendant Genentech, Inc. has specifically
13 identified GSK's Arzerra™ antibody product as a potential competitor to one of Genentech's own
14 products, and has stated that it expects to be involved in future litigation relating to the enforcement
15 of the Cabilly II patent. During GSK's dealings with Genentech, Genentech has repeatedly taken the
16 position that GSK requires a license under the Cabilly II patent to make and sell a variety of different
17 antibody products, including products produced by the same or similar process as Arzerra™. As
18 recently as the Fall of 2008, after GSK acquired rights to Arzerra™, counsel for Genentech inquired
19 what GSK would do about the Cabilly II patent. Given Defendants' past acts and statements and
20 GSK's sale of Arzerra™ in the United States, a real, immediate, and substantial dispute exists
21 between the parties concerning the Cabilly II patent for which GSK now seeks declaratory relief.

22 THE PARTIES

23 4. Plaintiff Glaxo Group Limited d/b/a GlaxoSmithKline is an English corporation
24 having a principal place of business at Glaxo Wellcome House, Berkley Avenue, Greenford,
25 Middlesex, UB6 0NN, United Kingdom.

26 5. Plaintiff GlaxoSmithKline LLC is a Delaware limited liability company having a
27 principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania, 19102.

28

1 ***Patent Interference***

2 14. At the time the Cabilly I patent issued, the Cabilly Applicants had a continuation
3 application (the “Cabilly II application”) pending in the PTO. The Cabilly Applicants copied claims
4 from U.S. Patent 4,816,397 (the “Boss patent”) in order to provoke the PTO Board of Patent Appeals
5 and Interferences to initiate an interference proceeding to determine whether the Boss patentees or
6 the Cabilly Applicants were entitled to priority for the inventions claimed in the Boss patent.

7 15. In February 1991, the PTO Board declared a patent interference between the pending
8 Cabilly II application and the Boss patent on the ground that both the Boss patentees and the Cabilly
9 Applicants claimed the same purported invention. After seven years of adversarial proceedings in
10 the PTO, in August 1998, the PTO Board found that the Boss patentees were entitled to priority over
11 the Cabilly Applicants. *See Cabilly v. Boss*, 55 U.S.P.Q.2d 1238 (B.P.A.I. 1998). The PTO Board
12 concluded that the Cabilly Applicants had failed to establish conception or reduction to practice of
13 the claimed inventions prior to March 25, 1983 – the filing date of the Boss patent. According to the
14 PTO Board, “there is no evidence that immunoglobulins, multiple chain proteins, had been produced
15 by recombinant DNA techniques from a single host cell prior to March 25, 1983.” Moreover, “the
16 evidence indicates that Cabilly et al. had but a **hope or wish to produce active antibodies in**
17 **bacteria**; and, there is no supporting evidence to establish the development of the means to
18 accomplish that result or evidence of a disclosure to a third party of complete conception.”
19 (emphasis added). The Final Decision therefore indicated that the Cabilly Applicants were “not
20 entitled to a patent.”

21 16. In October 1998, Genentech filed an action in this District under 35 U.S.C. § 146
22 against the owner of the Boss patent, Celltech Therapeutics Ltd. (“Celltech”), to appeal the decision
23 of the PTO Board awarding priority to the Boss patent. *Genentech, Inc. v. Celltech Therapeutics*
24 *Ltd.*, Case No. C98-3926 (N.D. Cal.). In March 2001, the parties to that action filed a notice of
25 settlement and joint request for entry of settlement instruments. As part of their settlement
26 agreement, the parties asked the district court to find that, contrary to the PTO Board’s prior
27 decision, Genentech’s Cabilly Applicants were entitled to priority. On information and belief, as
28 part of the Genentech-Celltech agreement, Celltech obtained certain rights relating to the Cabilly II

1 patent as well as certain payments from Genentech in exchange for its agreement to stipulate that the
2 Cabilly Applicants were entitled to priority for the inventions claimed in the Boss patent. The
3 precise terms of the settlement agreement are confidential and, despite reasonable inquiry, unknown
4 to GSK.

5 17. Notably, the Boss patent would have expired by 2006. By obtaining Celltech's
6 stipulation to priority of invention for the claimed subject matter of the Boss patent, GSK is
7 informed and believes that Genentech sought to extend the life of patent protection for the inventions
8 claimed in the Boss patent beyond the expiration date of the Boss patent.

9 18. Pursuant to the Genentech-Celltech agreement, the district court issued an order
10 directing the PTO to vacate its determination that the Boss applicants were entitled to priority, to
11 revoke the Boss patent, and to issue a patent to the Cabilly Applicants claiming the same subject
12 matter as the Boss patent. The Cabilly II patent issued on December 18, 2001, and on its face is
13 assigned to Genentech, and, by certificate of correction, is also assigned to City of Hope.

14 19. If the PTO Board's decision in favor of the Boss patent had not been reversed as a
15 result of the private Genentech-Celltech agreement, the Boss patent would have expired in 2006, and
16 the public would thereafter have been free to use the inventions claimed in the Cabilly II patent.
17 Instead, because Genentech and Celltech agreed to request that the court reverse that result,
18 Defendants received the Cabilly II patent, which will not expire until 2018. Consequently, due to
19 the private Genentech-Celltech agreement, Defendants have ostensibly extended their power to
20 exclude others from making, using, or selling the inventions claimed in the Boss and Cabilly II
21 patent until 2018 – more than 35 years after their original 1983 patent application, and more than 12
22 years after the expiration of the Boss patent. The combined period of patent exclusivity secured by
23 Defendants for the Cabilly I and Cabilly II patents, which share the same patent specification, is 29
24 years.

25 20. In 2008 alone, according to Genentech's 2009 Form 10-K filing, Defendants received
26 \$298 million in royalties on the Cabilly II patent. In short, two years after the original expiration
27 date of the Boss patent, Genentech is receiving nearly \$300 million in annual royalties on the
28 inventions claimed in the Boss patent.

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