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15 Attorneys for Plaintiff  
16 MEDIMMUNE, INC.

17 UNITED STATES DISTRICT COURT  
18 CENTRAL DISTRICT OF CALIFORNIA

19 MEDIMMUNE, INC.

20 Plaintiff,

21 vs.

22 GENENTECH, INC., CITY OF HOPE, and  
23 CELLTECH R&D LTD.

24 Defendants.

) Case No. 03-2567 MRP (CTX)

) PLAINTIFF MEDIMMUNE, INC.'S FIRST  
) AMENDED COMPLAINT FOR:

- ) 1. Declaratory Judgment;  
) 2. Patent Invalidity;  
) 3. Patent Unenforceability;  
) 4. Non-Infringement;  
) 5. Section 1 of the Sherman Act;  
) 6. Section 2 of the Sherman Act;  
) 7. The Cartwright Act; and  
) 8. Section 17200 of the Cal. Bus. & Profs.  
) Code.

) DEMAND FOR JURY TRIAL

GNE-GSK 00061405

Sanofi/Regeneron Ex. 1047, pg 1115

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1 **JURISDICTION AND VENUE**

2 1. Plaintiff MedImmune, Inc. ("MedImmune") seeks declaratory relief  
3 pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter  
4 jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337 and 1338(a). This Court has jurisdiction over  
5 the state law claims asserted hereunder pursuant to 28 U.S.C. § 1367. This Court has personal  
6 jurisdiction over defendant Genentech, Inc. ("Genentech") based on its principal place of  
7 business in California. This Court has personal jurisdiction over defendant City of Hope  
8 ("COH") based on its organization under the laws of the state of California and because its  
9 principal place of operation is in California. This Court has personal jurisdiction over defendant  
10 Celltech R&D Ltd. ("Celltech") based on its activities in this jurisdiction, including, but not  
11 limited to, Celltech's filing of a suit against Genentech under 35 U.S.C. § 146 in the Northern  
12 District of California captioned *Celltech R&D Ltd. v. Genentech, Inc.*, Civ. Act 01-3560JCS  
13 (N.D. Cal. 2001).

14 2. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), (c), (d),  
15 and 15 U.S.C. §§ 15, 22.

16 **THE PARTIES**

17 3. Plaintiff MedImmune, by and through its undersigned attorneys, brings  
18 this action under antitrust, patent, and unfair competition laws against defendants Genentech,  
19 COH and Celltech (collectively, "Defendants") seeking to challenge an illegal and  
20 anticompetitive agreement between Genentech and Celltech to secure the issuance of an invalid  
21 and unenforceable patent. MedImmune seeks declaratory relief that the patent is invalid,  
22 unenforceable and/or not infringed by MedImmune's Synagis® product and that MedImmune  
23 owes no payments under license agreements with Genentech.

24 4. MedImmune is a Delaware corporation with its principal place of business  
25 in Gaithersburg, Maryland. MedImmune uses biotechnology to develop and produce antibody  
26 therapies.

27 5. MedImmune's most successful product, Synagis®, is used for the  
28 prevention of serious lower respiratory tract disease caused by respiratory syncytial virus

1 ("RSV") in pediatric patients at high risk of RSV disease. RSV infection can be fatal in certain  
2 high-risk pediatric patients.

3 6. Defendant Genentech is a Delaware corporation with its principal place of  
4 business in South San Francisco, California.

5 7. Defendant COH is a California non-for-profit organization with its  
6 principal place of operation in Duarte, California. COH is an assignee of the patent at issue in  
7 this case.

8 8. Upon information and belief, Celltech is a British company with its  
9 principal place of business in Slough, England. Through an intermediary, the Medical Research  
10 Counsel, Celltech sub-licensed MedImmune to use the technology patented in U.S. Patent No.  
11 4,816,397 (the "Boss Patent").

12 **SUMMARY OF THIS ACTION**

13 9. MedImmune has filed this action to challenge an illegal and  
14 anticompetitive agreement (the "Agreement") between Genentech and Celltech, two large  
15 biotechnology companies, which has the effect of creating a 29-year patent monopoly over what  
16 Genentech now claims is the "fundamental technology" required for the artificial synthesis of  
17 antibody molecules. MedImmune likewise seeks a declaration that the patent improperly created  
18 by this Agreement is invalid, unenforceable and/or not infringed by MedImmune's sale of its  
19 antibody product, Synagis®, and that MedImmune owes no payments under license agreements  
20 with Genentech.

21 10. Genentech and Celltech have conceded the existence of the Agreement but  
22 to date have refused to make it public. Their refusal to disclose the Agreement is purportedly  
23 based on confidentiality grounds, notwithstanding the fact that the alleged "invention" at issue is  
24 already twenty years old and is described in issued patents. Nonetheless, the parties' own press  
25 releases and public filings about the terms of the Agreement have demonstrated its collusive  
26 nature and the fact that it benefits only Celltech and Genentech, while harming competition.

27 11. The Agreement between Celltech and Genentech was reached in the  
28 context of a dispute that began in the United States Patent and Trademark Office ("PTO")

1 between Genentech and Celltech regarding priority of invention. Simply put, Genentech asserted  
2 that its assignors had invented the same subject matter claimed by the Boss Patent before  
3 Celltech's assignors. Thus, Genentech asserted that the Boss Patent held by Celltech (which had  
4 been in effect since 1989) should never have issued and that, instead, a new patent should be  
5 granted to Genentech covering this same technology. At the time the Agreement was entered  
6 into, the PTO had already rejected Genentech's assertion that it, and not Celltech, was entitled to  
7 a patent after conducting an administrative proceeding, known as an interference, that lasted  
8 seven years. Additionally, a federal court that considered Genentech's appeal had already  
9 rejected Genentech's attempts to obtain summary judgment in its favor.

10           12. Notwithstanding Celltech's legal victories over Genentech in this  
11 controversy, some time prior to March 16, 2001 Celltech and Genentech entered into the  
12 Agreement, pursuant to which (a) Genentech was declared the winner of the legal dispute  
13 between them and awarded priority of invention; (b) the PTO would immediately be asked to  
14 revoke Celltech's Boss Patent; and (c) the PTO would be asked to issue simultaneously a new  
15 patent to Genentech substantially identical to the Boss Patent (the "New Cabilly Patent"), but  
16 with a fresh 17-year life.

17           13. By entering the Agreement, Celltech obtained more benefits than it ever  
18 could have achieved simply by prevailing in the lawsuit with Genentech. Significantly, a  
19 Celltech Annual Report revealed that Genentech agreed to provide Celltech with a "preferential"  
20 license to the New Cabilly Patent. Moreover, although Celltech agreed to an immediate  
21 revocation of its Boss Patent, upon information and belief, it suffered no monetary harm from  
22 doing so. According to a Celltech press release, Genentech agreed to make Celltech whole for  
23 any royalties Celltech would have received had its Boss Patent remained in existence until 2006,  
24 when it was to expire. Thus, as part of the Agreement, Genentech agreed to pay Celltech, the  
25 nominal "loser" in the legal dispute, the royalties that Celltech would have received had Celltech  
26 won. Additionally, Celltech benefits to the extent that Genentech uses the New Cabilly Patent to  
27 harm competitors of Celltech.

1           14.    The Agreement thus provided Genentech with monopoly power based on  
2 a brand new patent with a full 17-year life that would enable Genentech to deny competitors  
3 access to what it asserts to be fundamental technology necessary for the production of  
4 monoclonal antibodies.

5           15.    The Agreement has profoundly and fundamentally altered the competitive  
6 landscape in the biotechnology industry. Before the Agreement, Celltech had granted its  
7 competitors broad access to this technology by liberally licensing its Boss Patent. Upon  
8 information and belief, in reliance upon the permissive licensing policy of Celltech and the  
9 expectation that the patent would expire in 2006, numerous biotechnology companies, including  
10 MedImmune, launched research programs to develop monoclonal antibody products that  
11 potentially could provide great health benefits to society.

12           16.    Many of these health and life-enhancing products are now in clinical trials  
13 to obtain FDA approval and are being prepared for commercialization. Genentech's New Cabilly  
14 Patent is an obstacle that can prevent these new antibody products from coming to market.

15           17.    Genentech is thus in a position to demand a much higher royalty for use of  
16 this technology until 2018 (when the New Cabilly Patent will expire). Thus, the Agreement  
17 allows Genentech to exclude competitors from the market until 2018 or reap monopoly profits  
18 from any licenses which it may choose to grant. Celltech also benefits from this state of affairs  
19 because it has "preferential access" to the New Cabilly Patent and to the extent that the New  
20 Cabilly Patent may be used to exclude firms that compete with Celltech.

21           18.    With its New Cabilly Patent in hand, Genentech immediately exercised its  
22 illegally obtained monopoly by advising MedImmune that the New Cabilly Patent covers  
23 MedImmune's Synagis® product. As a consequence of this assertion, MedImmune began to  
24 make and continues to make significant payments to Genentech under an agreement entered into  
25 by MedImmune and Genentech on or about June 5, 1997 (the "1997 License Agreement"). This  
26 1997 License Agreement provided rights to various intellectual property, including the patent  
27 application that later matured into the New Cabilly Patent. After issuance of the New Cabilly  
28 Patent, MedImmune was forced to obtain additional license agreements from Genentech on or

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