

1 HARVEY SISKIND LLP  
D. PETER HARVEY (State Bar No. 55712)  
2 pharvey@harveysiskind.com  
3 RAFFI V. ZEROUNIAN (State Bar No. 236388)  
rzerounian@harveysiskind.com  
4 Four Embarcadero Center, 39th Floor  
San Francisco, California 94111  
5 Telephone: 415-354-0100  
Facsimile: 415-391-7124  
6

7 FITZPATRICK, CELLA, HARPER & SCINTO  
WILLIAM E. SOLANDER (admitted *pro hac vice*)  
8 wsolander@fchs.com  
DOMINICK A. CONDE (admitted *pro hac vice*)  
9 dconde@fchs.com  
PETER D. SHAPIRO (admitted *pro hac vice*)  
10 pshapiro@fchs.com  
JOSHUA A. DAVIS (admitted *pro hac vice*)  
11 jdavis@fchs.com  
12 1290 Avenue of the Americas  
New York, New York 10104  
13 Telephone: 212-218-2100  
Facsimile: 212-218-2200  
14

15 Attorneys for Plaintiff  
SANOFI-AVENTIS DEUTSCHLAND GMBH  
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17 **UNITED STATES DISTRICT COURT**  
18 **NORTHERN DISTRICT OF CALIFORNIA**  
19 **SAN FRANCISCO DIVISION**

20 SANOFI-AVENTIS DEUTSCHLAND  
21 GMBH,  
22 Plaintiff,  
23 v.  
24 GENENTECH, INC. and BIOGEN IDEC  
25 INC.,  
26 Defendants.  
27

**Case No.: C 08-04909 SI (BZ)**  
**Case No.: C 09-04919 SI**

**SANOFI-AVENTIS DEUTSCHLAND  
GMBH'S AMENDED COMPLAINT**

**JURY TRIAL DEMANDED**

1 NOW COMES Plaintiff Sanofi-Aventis Deutschland GmbH (“Sanofi”), and for its Amended  
2 Complaint against Defendants Genentech, Inc. (“Genentech”) and Biogen Idec Inc. (“Biogen”), states  
3 as follows:

4 **PARTIES**

5 1. Sanofi is a corporation organized and existing under the laws of Germany, with offices  
6 located at Brüningstrasse 50, D-65929 Frankfurt am Main, Germany.

7 2. Genentech is a corporation organized and existing under the laws of the State of  
8 Delaware, with offices located at 1 DNA Way, South San Francisco, California.

9 3. Biogen is a corporation organized and existing under the laws of the State of  
10 Delaware, with offices located at 14 Cambridge Center, Cambridge, Massachusetts. On information  
11 and belief, Biogen was formed by the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation  
12 in 2003.

13 **JURISDICTION AND VENUE**

14 4. Sanofi’s counterclaims allege infringement of two United States Patents under  
15 35 U.S.C. § 271, including at least § 271(a), § 271(b) and § 271(g).

16 5. This Court has subject matter jurisdiction over these counterclaims pursuant to 28  
17 U.S.C. §§ 1331 and 1338(a).

18 6. This Court has personal jurisdiction over Genentech and Biogen. Genentech and  
19 Biogen have purposefully availed themselves of the benefits and protections of the laws of the State  
20 of California, and this judicial district, by bringing this action. Genentech has offices in this judicial  
21 district, and Biogen has offices in this State. Genentech and Biogen have also purposefully and  
22 voluntarily placed their infringing products into the stream of commerce with the expectation that  
23 these products will be purchased by consumers in this judicial district. These products have been and  
24 continue to be purchased by consumers in this judicial district.

25 7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400.  
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**FACTS**

1  
2           8.       Sanofi is a part of a leading international pharmaceutical group that strives to meet a  
3 wide array of healthcare needs through innovative products. Sanofi's extensive research and  
4 development efforts are focused on health care challenges in cardiology, oncology and internal  
5 medicine, as well as metabolic diseases, central nervous system disorders and vaccines.

6           9.       Sanofi is the owner of all right, title and interest in and to U.S. Patent No. 5,849,522  
7 ("the '522 Patent"), entitled "Enhancer for Eukaryotic Expression Systems," which issued on  
8 December 15, 1998. Sanofi is the owner of all right, title and interest in and to U.S. Patent No.  
9 6,218,140 ("the '140 Patent"), entitled "Enhancer for Eukaryotic Expression Systems," which issued  
10 on April 17, 2001. The '522 Patent and the '140 Patent both pertain to, among other things, nucleic  
11 acid enhancers for cellular expression systems useful for producing drugs and antibodies for human  
12 therapy. A true and correct copy of the '522 Patent is attached hereto as Exhibit 1 and a true and  
13 correct copy of the '140 Patent is attached hereto as Exhibit 2.

14           10.      On August 6, 1992, representatives of Genentech and Behringwerke AG, Postfach 11  
15 40, 3550 Marburg, Federal Republic of Germany, entered into a license agreement with an effective  
16 date of January 1, 1991 ("the 1991 License Agreement"). Under the 1991 License Agreement,  
17 Behringwerke AG granted to Genentech a nonexclusive license to, *inter alia*, the '522 Patent and the  
18 '140 Patent. Subsequently, Sanofi became the owner of all right, title and interest in and to the '522  
19 Patent and the '140 Patent. In a letter dated August 27, 2008, Genentech purported to provide the  
20 defunct Behringwerke AG and sanofi-aventis S.A., but not Sanofi, with notice of termination of the  
21 License Agreement, the termination intended to be effective on October 27, 2008.

22           11.      On information and belief, Genentech is a healthcare company with locations in the  
23 United States that uses human genetic information to manufacture and commercialize  
24 biotherapeutics.

25           12.      On information and belief, Genentech manufactures and/or commercializes multiple  
26 biotherapeutics for medical conditions in the areas of oncology, immunology and disorders of tissue  
27 growth and repair, including Avastin® (bevacizumab) and Rituxan® (rituximab). On information  
28

1 and belief, Genentech has manufactured, used, offered for sale and/or sold these products in the  
2 United States, including within this judicial district.

3 13. On information and belief, Biogen is a healthcare company with locations in the  
4 United States that uses human genetic information to manufacture and commercialize  
5 biotherapeutics.

6 14. On information and belief, Biogen manufactures and/or commercializes multiple  
7 biotherapeutics for medical conditions in the areas of oncology, immunology and neurology,  
8 including Rituxan® (rituximab). On information and belief, Biogen has manufactured, used, offered  
9 for sale and/or sold these products in the United States, including within this judicial district.

10 **A. Rituxan® (rituximab)**

11 15. On information and belief, Rituxan® (rituximab) is manufactured and promoted by  
12 Biogen and Genentech jointly.

13 16. The U.S. Food and Drug Administration issued Department of Health and Human  
14 Services Biologics License No. 1235 to IDEC Pharmaceuticals Corporation (Biogen's predecessor-  
15 in-interest) on November 26, 1997. Under that license, Biogen is authorized to manufacture and ship  
16 for sale the product Rituximab Formulated Bulk (For Further Manufacturing Use). Pursuant to that  
17 authorization, Biogen is approved to manufacture Rituximab Formulated Bulk at a facility in San  
18 Diego, California for use in the manufacture of Rituxan® (rituximab) by Genentech under a shared  
19 manufacturing arrangement. On information and belief, Biogen and its predecessor-in-interest  
20 manufactured Rituximab Formulated Bulk at a facility in San Diego, California between 1997 and  
21 2007. On information and belief, Genentech has operated a facility in San Diego, California for the  
22 manufacture of Rituximab Formulated Bulk since 2007. On information and belief, Rituximab  
23 Formulated Bulk has been manufactured continuously in California since at least 1997.

24 17. The U.S. Food and Drug Administration issued Department of Health and Human  
25 Services Biologics License No. 1048 to Genentech on November 26, 1997. Under that authorization,  
26 Genentech is approved to manufacture Rituxan® (rituximab) utilizing Formulated Bulk Rituximab  
27 (For Further Manufacturing Use) manufactured by IDEC Pharmaceuticals Corp. (Biologics License  
28

1 No. 1235) or its successor under a shared manufacturing arrangement. Specifically, under that  
2 license, final containers of Rituximab are filled, labeled, packaged and distributed under the  
3 tradename Rituxan® (rituximab) by Genentech at its facility in South San Francisco, California. On  
4 information and belief, Genentech has filled, labeled, packaged and distributed Rituxan® (rituximab)  
5 from its facility in South San Francisco, California continuously since at least 1997.

6 18. On information and belief, the method of manufacture and production of Rituxan®  
7 (rituximab) has not changed since IDEC and Genentech received their licenses in 1997. However,  
8 prior to 2009, neither Genentech nor Biogen indicated that the method of commercial manufacture  
9 and production of Rituxan® (rituximab) was publicly available. Prior to 2009, neither Genentech nor  
10 Biogen publicized the sequences of the nucleic acid enhancers for the cellular expression system used  
11 for the commercial manufacture of Rituxan® (rituximab) by indicating that those enhancers were part  
12 of the construct used in the expression of Rituxan® (rituximab).

13 19. On information and belief, the sequences of the nucleic acid enhancers for the cellular  
14 expression system for Rituxan® (rituximab), how those sequences have been made, and how they  
15 were inserted into host cells are not confidential or part of a secret process. During an April 9, 2009  
16 case management conference before the Honorable Ron Clark of the U.S. District Court for the  
17 Eastern District of Texas in *Sanofi-Aventis Deutschland GmbH v. Genentech, Inc. and Biogen Idec*  
18 *Inc.*, Civil Action No. 9:08-CV-203, Donald R. Ware (counsel for Biogen) stated:

19 The information as to what the sequence is and how that sequence was made and how  
20 it was inserted into host cells is not a matter of confidentiality or secret process. It was  
disclosed in 1994 in a scientific publication by Biogen Idec's predecessor, Idec.

21 Mr. Ware further stated at the case management conference, referring to the enhancer sequence, that  
22 "[t]here's actually a map in that paper in 1994 that shows exactly where it is."

23 20. The sequences of the nucleic acid enhancers for the cellular expression system for  
24 Rituxan® (rituximab), how those sequences have been made, and how they were inserted into host  
25 cells were not actually all available in a single 1994 scientific publication. In addition, there is no  
26 map in a 1994 scientific publication that shows exactly where the enhancer sequence is located. On  
27 information and belief, no information publicly available before Genentech and Biogen filed this  
28

1 action identified a specific method of production as being the method of commercial manufacture of  
2 Rituxan® (rituximab).

3 21. On information and belief, the sequences of the nucleic acid enhancers for the cellular  
4 expression system for Rituxan® (rituximab), how those sequences have been made, and how they  
5 were inserted into host cells can be obtained from the combination of public documents and  
6 information provided by Mr. Ware in relation to *Sanofi-Aventis Deutschland GmbH v. Genentech,*  
7 *Inc. and Biogen Idec Inc.*, Civil Action No. 9:08-CV-203. In a letter dated April 17, 2009, Mr. Ware  
8 stated:

9 The publicly available documents I referenced at last week's Status Conference before  
10 Judge Clark and in my letter to you yesterday are:

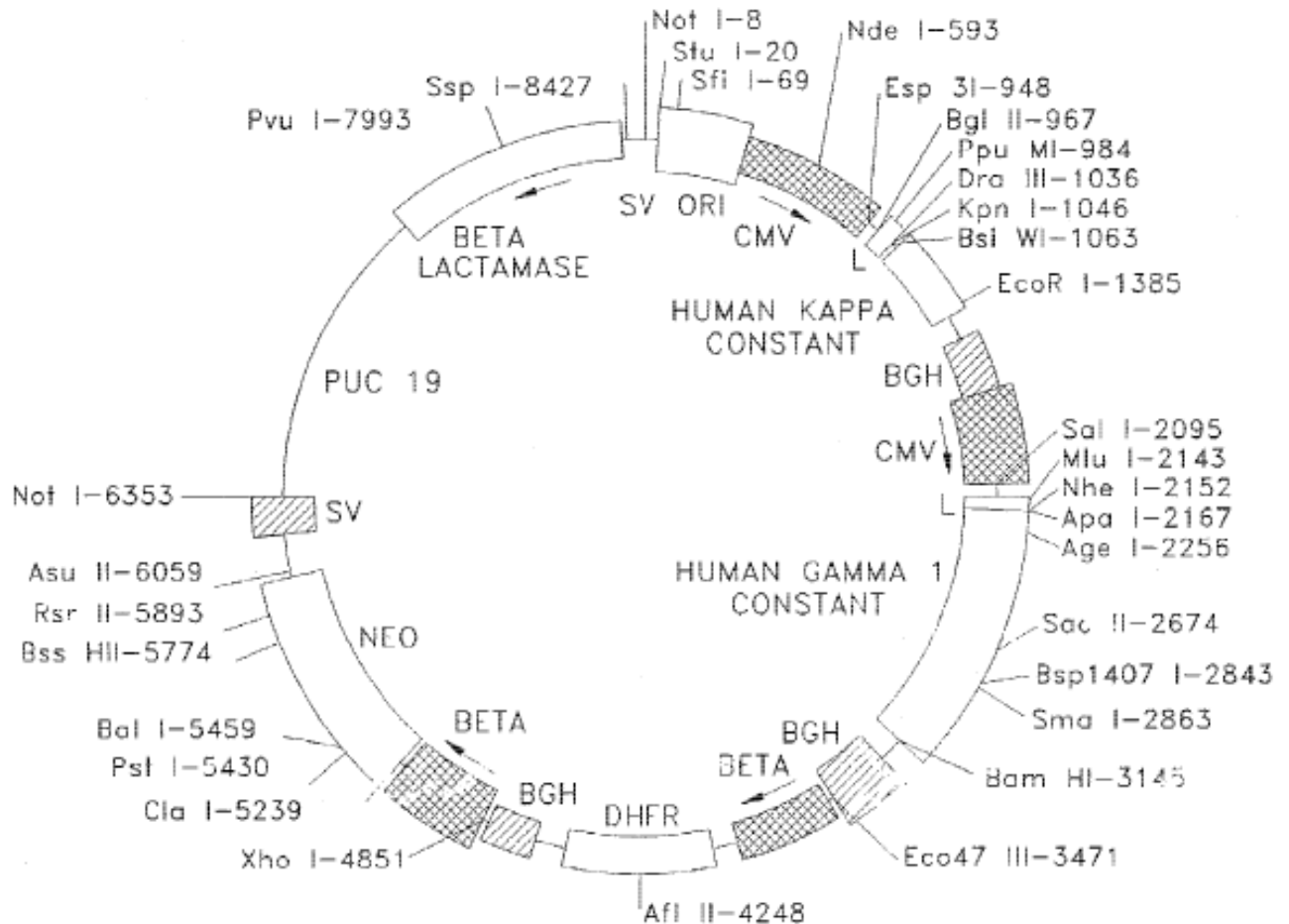
- 11 • M. Reff, et al., Depletion of B cells in vivo by a chimeric mouse human  
monoclonal antibody to CD20, *Blood*, 83, 435-445 (1994).
- 12 • Anderson et al., U.S. Patent No. 5,736,137.

13 A true and correct copy of the Reff *et al.* article is attached hereto as Exhibit 3. A true and correct  
14 copy of the Anderson *et al.* patent is attached hereto as Exhibit 4. Neither the Reff *et al.* article nor  
15 the Anderson *et al.* patent uses the term "RITUXAN." Neither the Reff *et al.* article nor the  
16 Anderson *et al.* patent uses the term "rituximab."

17 22. On information and belief, Rituxan® (rituximab) is expressed from mammalian host  
18 cells. On information and belief, Rituxan® (rituximab) is expressed from Chinese hamster ovary  
19 ("CHO") host cells. Both the Reff *et al.* article and the Anderson *et al.* patent describe the expression  
20 of an antibody construct from CHO host cells.

21 23. On information and belief, the mammalian host cells from which Rituxan®  
22 (rituximab) is expressed (the mammalian host cells from which Rituxan® (rituximab) is expressed  
23 hereafter referred to as "Rituxan Host Cells") have been transformed with a recombinant DNA  
24 plasmid. On information and belief, the recombinant DNA plasmid used to transform the Rituxan  
25 Host Cells is a tandem chimeric antibody expression vector comprising cDNA encoding murine light  
26 and heavy chain variable regions derived from a monoclonal antibody to CD20, where the  
27 recombinant DNA plasmid is known as "anti-CD20 in TCAE 8". On information and belief, the  
28

1 tandem chimeric antibody expression vector is known as "TCAE 8". On information and belief, the  
 2 following is an accurate diagrammatic representation of the TCAE 8 tandem chimeric antibody  
 3 expression vector:



20 *FIG. 1*

22 Both the Reff *et al.* article and the Anderson *et al.* patent describe the use of a tandem chimeric  
 23 antibody expression vector to transform mammalian host cells for the expression of the desired  
 24 antibody. The diagrammatic representation of the TCAE 8 tandem chimeric antibody expression  
 25 vector shown above is Figure 1 from the Anderson *et al.* patent. Figure 3 from the Reff *et al.* article  
 26 also shows a schematic representation of the TCAE 8 expression vector. On information and belief,  
 27 the complete DNA sequence of the TCAE 8 tandem chimeric antibody expression vector is shown in  
 28

1 Figures 2A through 2F of the Anderson et al. patent. On information and belief, the complete DNA  
2 sequence of the recombinant DNA plasmid used to transform the Rituxan Host Cells, known as “anti-  
3 CD20 in TCAE 8,” is shown in Figures 3A through 3F of the Anderson et al. patent.

4 24. On information and belief, the recombinant DNA plasmid used to transform the  
5 Rituxan Host Cells includes two DNA molecules isolated from the immediate early (“IE”)  
6 promoter/regulatory region of human cytomegalovirus (“HCMV”). In the diagrammatic  
7 representation of the TCAE 8 tandem chimeric antibody expression vector shown in the paragraph 23  
8 above, those DNA molecules isolated from the IE promoter/regulatory region of HCMV are  
9 identified as “CMV.” Figure 1 from the Anderson *et al.* patent identifies DNA molecules isolated  
10 from the IE promoter/regulatory region of HCMV as “CMV.” Figures 2A, 2B, 3A, and 3B from the  
11 Anderson *et al.* patent identify DNA molecules isolated from the IE promoter/regulatory region of  
12 HCMV as “CMV PROMOTER-ENHANCER”. Figure 3 from the Reff *et al.* article identifies DNA  
13 molecules isolated from the IE promoter/regulatory region of HCMV as “CMV.”

14 25. On information and belief, the recombinant DNA plasmid used to transform the  
15 Rituxan Host Cells includes a heterologous gene positioned downstream from each of the DNA  
16 molecules isolated from the IE promoter/regulatory region of HCMV. In the diagrammatic  
17 representation of the TCAE 8 tandem chimeric antibody expression vector shown in the paragraph 23  
18 above, portions of heterologous genes are identified as “HUMAN KAPPA CONSTANT” and  
19 “HUMAN GAMMA 1 CONSTANT.” Figure 1 from the Anderson *et al.* patent identifies portions of  
20 heterologous genes as “HUMAN KAPPA CONSTANT” and “HUMAN GAMMA 1 CONSTANT.”  
21 Figures 3A and 3B from the Anderson *et al.* patent identify additional portions of heterologous genes  
22 as “LIGHT CHAIN VARIABLE REGION” and “HEAVY CHAIN VARIABLE REGION,”  
23 respectively. Figure 3 from the Reff *et al.* article identifies portions of heterologous genes as  
24 “HUMAN KAPPA CONSTANT” and “HUMAN GAMMA 1 CONSTANT.”

25 26. On information and belief, the heterologous genes positioned downstream from each  
26 of the DNA molecules isolated from the IE promoter/regulatory region of HCMV in the recombinant  
27 DNA plasmid used to transform the Rituxan Host Cells are operatively linked to the DNA molecules  
28



1 isolated from the IE promoter/regulatory region of HCMV. On information and belief, the portions  
2 of heterologous genes identified as “HUMAN KAPPA CONSTANT” and “HUMAN GAMMA 1  
3 CONSTANT” in Figures 1, 2A, 2B, 3A, and 3B from the Anderson *et al.* patent are operatively  
4 linked to the DNA molecules isolated from the IE promoter/regulatory region of HCMV and  
5 identified as “CMV.” On information and belief, the portions of heterologous genes identified as  
6 “HUMAN KAPPA CONSTANT” and “HUMAN GAMMA 1 CONSTANT” in Figure 3 from the  
7 Reff *et al.* article are operatively linked to the DNA molecules isolated from the IE  
8 promoter/regulatory region of HCMV and identified as “CMV.”

9       27. On information and belief, one of the DNA molecules isolated from the IE  
10 promoter/regulatory region of HCMV in the recombinant DNA plasmid used to transform the  
11 Rituxan Host Cells has 567 base pairs. On information and belief, the 567 base pair DNA molecule  
12 isolated from the IE promoter/regulatory region of HCMV in the recombinant DNA plasmid used to  
13 transform the Rituxan Host Cells is identified in the Anderson *et al.* patent as a “CMV  
14 promoter/enhancer” and is shown in Figure 3A of the Anderson *et al.* patent as extending from  
15 position 361 to position 927. On information and belief, that “CMV promoter/enhancer” is in front  
16 of the DNA encoding for the immunoglobulin light chain of Rituxan® (rituximab).

17       28. On information and belief, one of the DNA molecules isolated from the IE  
18 promoter/regulatory region of HCMV in the recombinant DNA plasmid used to transform the  
19 Rituxan Host Cells has 334 base pairs. On information and belief, the 334 base pair DNA molecule  
20 isolated from the IE promoter/regulatory region of HCMV in the recombinant DNA plasmid used to  
21 transform the Rituxan Host Cells is identified in the Anderson *et al.* patent as a “CMV promoter-  
22 enhancer” and is shown in Figure 3B of the Anderson *et al.* patent as extending from position 2018 to  
23 position 2351. On information and belief, that “CMV promoter/enhancer” is in front of the DNA  
24 encoding for the immunoglobulin heavy chain of Rituxan® (rituximab). According to the Anderson  
25 *et al.* patent,

26       The CMV promoter/enhancer in front of the immunoglobulin heavy chain is a  
27 truncated version of the promoter/enhancer in front of the light chain from the Nhe I  
28 site at -350 [of the HCMV genome] to the Sst I site [of the HCMV genome] at -16  
(see 41 *Cell* 521, 1985).

1 On information and belief, each of the “CMV promoter/enhancers” is less than 3,000 base pairs  
2 upstream of the DNA encoding for an immunoglobulin chain.

3  
4 29. On information and belief, both of the “CMV promoter/enhancers” from the “anti-  
5 CD20 in TCAE 8” recombinant DNA plasmid are incorporated into the genome of the Rituxan Host  
6 Cells. On information and belief, the “CMV promoter/enhancers” enhance the transcription of DNA  
7 in the Rituxan Host Cells. Specifically, on information and belief, the “CMV promoter/enhancers”  
8 enhance the transcription of DNA coding for portions of Rituxan® (rituximab) in the Rituxan Host  
9 Cells, leading to increased expression of Rituxan® (rituximab) from the Rituxan Host Cells.

10 30. On information and belief, the “CMV promoter/enhancers” that enhance the  
11 transcription of DNA in the Rituxan Host Cells were derived from samples of HCMV DNA  
12 originally received from the laboratory of Dr. Bernhard Fleckenstein, the first named inventor on the  
13 '522 and '140 patents.

14 31. Genentech and Biogen are commercialization partners with respect to the product  
15 known as Rituxan® (rituximab) in the United States, which is known as MabThera® (rituximab) in  
16 certain other countries. Genentech and Biogen co-promote Rituxan® (rituximab) in the United  
17 States. On information and belief, Genentech licenses Rituxan® (rituximab) and MabThera®  
18 (rituximab) to F. Hoffman-LaRoche Ltd. for sale worldwide, excluding the United States and Japan.  
19 On information and belief, Genentech licenses Rituxan®/MabThera® (rituximab) to Zenyaku Kogyo  
20 Co., Ltd. and Chugai Pharmaceutical Co. Ltd. for sale in Japan. On information and belief, Rituxan®  
21 (rituximab) and MabThera® (rituximab) are manufactured only in the United States.

22 **B. Avastin® (bevacizumab)**

23 32. On information and belief, Avastin® (bevacizumab) is manufactured by Genentech in  
24 South San Francisco, California.

25 33. The U.S. Food and Drug Administration issued a license related to Bevacizumab  
26 under existing Department of Health and Human Services Biologics License No. 1048 to Genentech  
27 on February 26, 2004. Under that license, Genentech is authorized to manufacture and introduce or  
28 deliver for introduction into interstate commerce the product Bevacizumab. Pursuant to that

1 authorization, Genentech is approved to manufacture Bevacizumab at a facility in South San  
2 Francisco, California. On information and belief, Bevacizumab has been manufactured continuously  
3 in California since at least 2004.

4 34. On information and belief, the method of manufacture and production of Avastin®  
5 (bevacizumab) has not changed since Genentech received its license in 2004. However, Genentech  
6 has never indicated that the method of commercial manufacture and production of Avastin®  
7 (bevacizumab) has been publicly available.

8 35. On information and belief, Avastin® (bevacizumab) is expressed from mammalian  
9 host cells. On information and belief, Avastin® (bevacizumab) is expressed from Chinese hamster  
10 ovary (“CHO”) host cells. The package insert for Avastin® (bevacizumab) indicates, “Avastin is  
11 produced by a Chinese Hamster Ovary mammalian cell expression system.”

12 36. On information and belief, the mammalian host cells from which Avastin®  
13 (bevacizumab) is expressed (the mammalian host cells from which Avastin® (bevacizumab) is  
14 expressed hereafter referred to as “Avastin Host Cells”) have been transformed with a recombinant  
15 DNA plasmid.

16 37. On information and belief, the recombinant DNA plasmid used to transform the  
17 Avastin Host Cells includes at least one DNA molecule isolated from the immediate early (“IE”)   
18 promoter/regulatory region of human cytomegalovirus (“HCMV”).

19 38. On information and belief, the recombinant DNA plasmid used to transform the  
20 Avastin Host Cells includes a heterologous gene positioned downstream from the DNA molecule  
21 isolated from the IE promoter/regulatory region of HCMV.

22 39. On information and belief, the heterologous gene positioned downstream from the  
23 DNA molecule isolated from the IE promoter/regulatory region of HCMV in the recombinant DNA  
24 plasmid used to transform the Avastin Host Cells is operatively linked to the DNA molecule isolated  
25 from the IE promoter/regulatory region of HCMV.

26 40. On information and belief, the DNA molecule isolated from the IE  
27 promoter/regulatory region of HCMV is incorporated into the genome of the Avastin Host Cells. On  
28

1 information and belief, the DNA molecule isolated from the IE promoter/regulatory region of HCMV  
2 enhances the transcription of DNA coding for portions of Avastin® (bevacizumab) in the Avastin  
3 Host Cells, leading to increased expression of Avastin® (bevacizumab) from the Avastin Host Cells.

4 41. On information and belief, the DNA molecule isolated from the IE  
5 promoter/regulatory region of HCMV that enhances the transcription of DNA in the Avastin Host  
6 Cells was derived from samples of HCMV DNA originally received from the laboratory of Dr.  
7 Bernhard Fleckenstein, the first named inventor on the '522 and '140 patents.

8 **PATENT INFRINGEMENT**

9 **COUNT I**

10 42. Sanofi incorporates herein the allegations of paragraphs 1 through 41 above, as if set  
11 forth herein in full.

12 43. On information and belief, Genentech and Biogen are infringing and will continue to  
13 infringe the '522 Patent by making, using, selling and/or offering for sale in the United States,  
14 including within this judicial district, certain biotherapeutics made in the United States in mammalian  
15 cell suspension cultures utilizing the invention claimed in one or more claims of the '522 Patent,  
16 including Avastin® (bevacizumab) and Rituxan® (rituximab).

17 44. As a result of the infringement by Genentech and Biogen, Sanofi is being and will  
18 continue to be irreparably harmed.

19 45. Genentech and Biogen were well aware of the '522 Patent prior to the commission of  
20 the infringing acts alleged herein, and their infringement is and will continue to be reckless, egregious  
21 and willful.

22 46. Sanofi has no adequate remedy at law.

23 47. On information and belief, Genentech and Biogen will continue their infringing  
24 activities, and continue to damage Sanofi, unless enjoined by this Court. Sanofi's damages from the  
25 aforesaid actions of Genentech and Biogen are not yet determined.

26 48. Genentech and Biogen's reckless, egregious and willful infringement of the '522  
27 Patent makes this an exceptional case under 35 U.S.C. § 285.

28

**COUNT II**

1  
2 49. Sanofi incorporates herein the allegations of paragraphs 1 through 41 above, as if set  
3 forth herein in full.

4 50. On information and belief, Genentech and Biogen are infringing and will continue to  
5 infringe the '140 Patent by making, using, selling and/or offering for sale in the United States,  
6 including within this judicial district, certain biotherapeutics made in the United States in mammalian  
7 cell suspension cultures utilizing the invention claimed in one or more claims of the '140 Patent,  
8 including Avastin® (bevacizumab) and Rituxan® (rituximab).

9 51. As a result of the infringement by Genentech and Biogen, Sanofi is being and will  
10 continue to be irreparably harmed.

11 52. Genentech and Biogen were well aware of the '140 Patent prior to the commission of  
12 the infringing acts alleged herein, and their infringement is and will continue to be reckless, egregious  
13 and willful.

14 53. Sanofi has no adequate remedy at law.

15 54. On information and belief, Genentech and Biogen will continue their infringing  
16 activities, and continue to damage Sanofi, unless enjoined by this Court. Sanofi's damages from the  
17 aforesaid actions of Genentech and Biogen are not yet determined.

18 55. Genentech and Biogen's reckless, egregious and willful infringement of the '140  
19 Patent makes this an exceptional case under 35 U.S.C. § 285.

20 **DECLARATORY JUDGMENT**

21 **COUNT III**

22 56. Sanofi incorporates herein the allegations of paragraphs 1 through 41 above, as if set  
23 forth herein in full.

24 57. On information and belief, Genentech and Biogen are infringing and will continue to  
25 infringe the '522 Patent by making, using, selling and/or offering for sale in the United States,  
26 including within this judicial district, certain biotherapeutics which were made in the United States in  
27  
28

1 mammalian cell suspension cultures utilizing the invention claimed in one or more claims of the '522  
2 Patent including Avastin® (bevacizumab) and Rituxan® (rituximab).

3 58. Genentech and Biogen's activities related to the making, using, selling and/or offering  
4 for sale certain biotherapeutics, including Avastin® (bevacizumab) and Rituxan® (rituximab) are an  
5 infringement of the '522 Patent under 35 U.S.C. § 271.

6 59. There is an ongoing and justiciable case and controversy based on Genentech and  
7 Biogen's infringement of the '522 Patent. Sanofi is entitled to a declaratory judgment that Genentech  
8 and Biogen infringe or will infringe one or more claims of the '522 Patent.

9 **COUNT IV**

10 60. Sanofi incorporates herein the allegations of paragraphs 1 through 41 above, as if set  
11 forth herein in full.

12 61. On information and belief, Genentech and Biogen are infringing and continue to  
13 infringe the '140 Patent by making, using, selling and/or offering for sale in the United States,  
14 including within this judicial district, certain biotherapeutics which were made in the United States in  
15 mammalian cell suspension cultures utilizing the invention claimed in one or more claims of the '140  
16 Patent, including Avastin® (bevacizumab) and Rituxan® (rituximab).

17 62. Genentech and Biogen's activities related to the making of certain biotherapeutics,  
18 including Avastin® (bevacizumab) and Rituxan® (rituximab), are an infringement of the '140 Patent  
19 under 35 U.S.C. § 271.

20 63. There is an ongoing and justiciable case and controversy based on Genentech and  
21 Biogen's infringement of the '140 Patent. Sanofi is entitled to a declaratory judgment that Genentech  
22 and Biogen infringe or will infringe one or more claims of the '140 Patent.

23 **WHEREFORE**, Sanofi prays for judgment that:

24 A. Determines and declares that Genentech and Biogen have infringed claims of the '522  
25 Patent;

1 B. Genentech and Biogen, their officers, agents, servants and employees, and those  
2 persons in active concert and participation with any of them, be preliminarily and permanently  
3 enjoined from further infringement of the '522 Patent;

4 C. Determines and declares that Genentech and Biogen have infringed claims of the '140  
5 Patent;

6 D. Genentech and Biogen, their officers, agents, servants and employees, and those  
7 persons in active concert and participation with any of them, be preliminarily and permanently  
8 enjoined from further infringement of the '140 Patent;

9 E. Sanofi be awarded damages sufficient to compensate it for the infringement, but in no  
10 event less than a reasonable royalty for such infringement, and that such damages be increased to  
11 three times the amount found or assessed pursuant to 35 U.S.C. § 284, together with prejudgment  
12 interest;

13 F. This case be declared exceptional pursuant to 35 U.S.C. § 285 and that Sanofi-Aventis  
14 be awarded its attorney's fees, costs and expenses in this action; and

15 G. Sanofi-Aventis be awarded such other and further relief as the Court may deem just.

16 **DEMAND FOR JURY TRIAL**

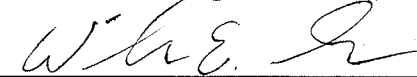
17 Sanofi hereby demands a jury trial on all issues.

18 Dated: April 1, 2010

Respectfully submitted,

19 HARVEY SISKIND LLP  
20 D. PETER HARVEY  
21 RAFFI V. ZEROUNIAN

22 FITZPATRICK, CELLA, HARPER & SCINTO  
23 WILLIAM E. SOLANDER (*pro hac vice*)  
24 DOMINICK A. CONDE (*pro hac vice*)  
25 PETER D. SHAPIRO (*pro hac vice*)  
26 JOSHUA A. DAVIS (*pro hac vice*)

27 By:   
28 William E. Solander

Attorneys for Plaintiff  
SANOFI-AVENTIS DEUTSCHLAND GMBH