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**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA**

GENENTECH, INC.,

Plaintiff,

v.

BIOGEN MA, INC.,

Defendant.

) Case No. 3:23-cv-909

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) **COMPLAINT FOR BREACH OF  
CONTRACT**

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) **DEMAND FOR JURY TRIAL**

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**COMPLAINT**

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2 1. This breach of contract action seeks royalties owed under a patent license. In 2004,  
3 Defendant Biogen MA, Inc. (“Biogen”), pursuant to a written agreement with Plaintiff Genentech, Inc.,  
4 obtained non-exclusive rights to a patent family known as Cabilly. Claiming, among other things, an  
5 inventive method of manufacturing antibodies, Cabilly was one of the most widely licensed patents in  
6 the biotechnology industry. The license agreement at issue in this case (“License”) required Biogen to  
7 pay Genentech a small percentage royalty on “Net Sales” of “Licensed Products,” defined as antibodies  
8 whose manufacture, importation, and/or sale, but for the license agreement, would infringe Cabilly.

9 2. Because Biogen used the Cabilly method to manufacture the active ingredient in Tysabri,  
10 an FDA-approved treatment for multiple sclerosis and Crohn’s disease, for many years it paid  
11 Genentech substantial quarterly royalties on Net Sales of that product. But in March 2019, Biogen  
12 stopped making payments on all “Net Sales.” It took the position that it owed no royalties on Tysabri  
13 sold after Cabilly expired on December 18, 2018, even if the antibodies that comprised its active  
14 ingredient were manufactured before that date using a patented method.

15 3. It is undisputed that the stockpile of Tysabri that Biogen had on hand in the United States  
16 prior to Cabilly’s expiration is “Licensed Product” as the parties defined that term. The size of that  
17 stockpile is unknown to Genentech at this time, but based on industry experience Genentech believes  
18 that Biogen owes tens of millions of dollars in unpaid royalties on sales of that product.

**THE PARTIES**

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20 4. Plaintiff Genentech is a Delaware corporation with its principal place of business in  
21 South San Francisco, California.

22 5. Defendant Biogen MA is a Massachusetts corporation with its principal place of business  
23 in Cambridge, Massachusetts.

24 6. Genentech is the co-owner, with City of Hope, a Los Angeles-based nonprofit  
25 organization, of U.S. Patent Nos. 6,331,415 and 7,923,221, along with various foreign counterparts.  
26 These patents are known as “Cabilly” after Shmuel Cabilly, a City of Hope scientist in the 1980s who  
27 with several other City of Hope and Genentech scientists conducted the research giving rise to the  
28

1 claimed inventions. By way of agreement with City of Hope, Genentech had exclusive rights to license  
2 Cabilly to third parties such as Biogen.

3 **JURISDICTION AND VENUE**

4 7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332  
5 because there is complete diversity of citizenship and the amount in controversy exceeds \$75,000.

6 8. Because it has had continuous and ongoing business contacts with residents in California  
7 and in this District, and purposefully availed itself of the privilege of conducting activities in California  
8 and this District, Biogen is subject to personal jurisdiction in this Court pursuant to California Code of  
9 Civil Procedure § 410.10. The License under which this dispute arises was made, performed, and  
10 breached within California and this District, and furthermore specifies that it shall be governed by, and  
11 interpreted in accordance with, the laws of the State of California. Through March 2019, Biogen  
12 regularly paid quarterly royalties to Genentech, and the unpaid royalties for which this suit seeks  
13 recovery include amounts Biogen owes on sales of Licensed Product in California.

14 9. Venue in this District is proper under 28 U.S.C. § 1391 because a substantial part of the  
15 events or omissions giving rise to the claim occurred here, because the intellectual property that is  
16 subject of the License Agreement is owned by a party located here, and/or because Biogen is subject to  
17 the Court’s personal jurisdiction with respect to the claim.

18 **DIVISIONAL ASSIGNMENT**

19 10. Pursuant to the Court’s Assignment Plan (General Order No. 44), this case should be  
20 assigned to the San Francisco Division or Oakland Division of the Court because a substantial part of  
21 the events or omissions giving rise to the claim occurred in San Mateo County and because the  
22 intellectual property that is subject of the License Agreement is owned by a party located San Mateo  
23 County.

24 **FACTS RELEVANT TO THE RELIEF CLAIMED**

25 11. Tysabri is a prescription medicine used for the treatment of multiple sclerosis and  
26 Crohn’s disease. Its active ingredient is natalizumab, a humanized monoclonal antibody that binds to the  
27 protein known as Alpha4 integrin. Biogen developed Tysabri in collaboration with Elan  
28 Pharmaceuticals, Inc. (“Elan”).

1           12.     In November 2004, after several years of clinical testing, the Food and Drug  
2 Administration approved Tysabri for treating relapsing forms of multiple sclerosis. Sales of Tysabri  
3 commenced shortly thereafter.

4           13.     Anticipating FDA approval, about four months earlier Biogen and Elan negotiated a  
5 License with Genentech so that they could make, import, sell and/or offer to sell Tysabri free from  
6 claims that the product infringed Cabilly. Genentech and City of Hope, Cabilly’s owners, had decided  
7 years earlier that they would make their patented methods, products, and processes available for a  
8 modest royalty to the nascent biotechnology field that was increasingly focused on developing  
9 antibodies for treating a variety of diseases including for example cancers, rheumatoid arthritis, and  
10 psoriasis. Among the prior licensees was Idec Pharmaceuticals, a San Diego biotechnology company  
11 that merged with Biogen in 2003.

12           14.     Genentech, Biogen, and Elan executed the License on July 30, 2004. The License  
13 defined Biogen and Elan collectively as the “Licensee,” and granted them the following rights:

14                   2.01. License. Genentech hereby grants to Licensee and Licensee hereby accepts  
15 a non-exclusive license under Licensed Patents during the Term to make (and  
16 have made), use, sell, offer for sale, and import Licensed Product in the Territory  
17 in the Field of Use. Licensee shall have a limited right to grant sublicenses as  
18 provided in Section 2.02.

19           The Licensed Patents are defined as:

20                   1.11. “Licensed Patents” shall mean (i) U.S. Patent No. 6,331,415, issued  
21 December 18, 2001, (ii) any patent(s) issuing from divisionals, continuations, or  
22 continuations-in-part of any patent application from which U.S. Patent No. 6,331,  
23 415 claims priority, and (iii) patents that are reissues, reexaminations, extensions,  
24 or foreign counterparts of any of the foregoing (i) or (ii), provided, however, that  
25 Licensed Patents shall not include Chimera Patents.

26           Licensed Product is defined as:

27                   1.12. “Licensed Product” shall mean any antibody that binds specifically to  
28 Alpha4, the making (or having made), using, selling, offering for sale or  
importing of which, but for the license granted under this Agreement, would  
infringe a Valid Claim of a patent included in Licensed Patents.

1 In consideration for Genentech granting rights to Biogen and Elan, and promising not to sue them for  
2 infringing Cabilly, Biogen and Elan agreed in § 3.3 of the License to pay Genentech a mid-single-figure  
3 royalty of all “Net Sales of Licensed Products sold in the United States,” and a lower royalty on “Net  
4 Sales of all Licensed Product sold” throughout the rest of the world. The parties defined “Net Sales” as  
5 follows:

6 1.13. “Net Sales” shall mean the gross invoice or contract price to Third Party  
7 customers for Finished Product. Finished Product used or consumed by Licensee  
8 or its Affiliates or Designees as part of the delivery of services to customers for  
9 which Licensee derives compensation shall be considered Net Sales at the gross  
10 invoice or contract price of like Finished Product which are sold to customers. If  
11 Licensed Product is sold in combination with one or more active ingredients, Net  
12 Sales shall be calculated by multiplying Net Sales of the combination product by  
13 the fraction  $A/(A+B)$  where A is the sales price of the Finished Product in the  
14 combination when sold separately and B is the total sales price of all other active  
15 ingredients in the combination when sold separately. If the Finished Product and  
16 the other active ingredients are not sold separately, the percentage of the total cost  
17 of the combination product attributed to Cost of Product shall be multiplied times  
18 the sales price of the combination product to arrive at Net Sales. For all Licensed  
19 Product used or consumed by others than Licensee, Licensee shall be entitled to  
20 deduct 5% from Net Sales in lieu of all other deductions such as taxes, shipping  
21 charges, allowances and the like prior to calculating royalties due.

22 “Finished Product” is defined in Section 1.09 as “any and all Licensed Product in the form for use by an  
23 End User Customer and not intended for further chemical or genetic manipulation or transformation.”

24 15. The License required Biogen and Elan to pay royalties quarterly, with payments due  
25 within sixty days from the end of each quarter. Starting in 2005, Biogen and Elan began paying  
26 quarterly royalties on sales of Tysabri.

27 16. In 2013, following a dispute between them, Elan sold Biogen full rights to Tysabri for an  
28 immediate payment of \$3.25 billion and promised payments tied to future sales. Since that transaction,  
29 Biogen has been Genentech’s sole counterparty on the License. Biogen manufactures Tysabri at the  
30 company’s manufacturing plant in Research Triangle Park in North Carolina and, on information and  
31 belief, at a facility in Denmark.

32 17. Biogen made its last royalty payment to Genentech on March 1, 2019, for “Net Sales” of  
33 Tysabri that occurred in the fourth quarter of 2018. This payment did not include royalties on “Net  
34 Sales” of Tysabri that occurred after December 18, 2018 when the Cabilly patent expired, even though

1 the natalizumab in those vials was manufactured in or imported into the United States prior to that date  
2 and therefore was “Licensed Product” under the agreement’s plain terms. Biogen’s failure to pay a  
3 royalty on these “Net Sales” breached the License.

4 18. Because the process for manufacturing antibodies is complex and the consequences of a  
5 stockout potentially catastrophic, it is customary for biopharmaceutical firms that make and sell  
6 therapeutic antibodies to stockpile at least several calendar quarters worth of product, and often more  
7 than that. Therefore, on information and belief, most or all of the natalizumab in the Tysabri that  
8 Biogen sold in 2019 and beyond was made in or imported into the United States prior to the expiration  
9 of Cabilly, and therefore is “Licensed Product.” Notwithstanding this, and in breach of the License  
10 Agreement, Biogen has not paid Genentech any royalties on these “Net Sales.”

11 **FIRST CLAIM FOR RELIEF – BREACH OF CONTRACT**

12 19. Genentech incorporates each of the foregoing Paragraphs as though fully set forth herein.

13 20. Biogen entered into a binding and enforceable contract with Genentech to license the  
14 Cabilly patents. Though Elan Pharmaceuticals was initially also a party to the agreement, Biogen  
15 assumed the role of Genentech’s sole counterparty to the License in 2013 and, under the protection of  
16 the License, Biogen continued manufacturing and selling Tysabri and making royalty payments to  
17 Genentech in accordance with the License until March 2019.

18 21. Genentech materially performed all of its obligations under the License.

19 22. All conditions requiring Biogen’s full performance under the License Agreement have  
20 occurred.

21 23. Nevertheless, as set forth above, Biogen materially breached its contractual obligations  
22 by refusing to remit royalties owed to Genentech for “Net Sales” of “Licensed Product” that Biogen  
23 manufactured in or imported into the United States prior to Cabilly’s expiration.

24 24. As a direct and proximate result of Biogen’s breach of the License Agreement,  
25 Genentech has suffered damages including lost royalties owed, attorneys’ fees, and costs in connection  
26 with this matter, in an amount to be determined by this Court.

27 **PRAYER FOR RELIEF**

28 WHEREFORE, Genentech prays for judgment as follows:



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**FILER'S ATTESTATION**

I, Jeffrey E. Faucette, am the ECF user whose identification and password are being used to file this document. In compliance with Local Rule 5-1(i)(3), I hereby attest that all signatories hereto concur in this filing.

/s/ Jeffrey E. Faucette

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