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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 **COMPLAINT FOR BREACH OF CONTRACT** **DEMAND FOR JURY TRIAL**

COMPLAINT

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

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

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

THE PARTIES

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

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

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

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

JURISDICTION AND VENUE

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

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

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

DIVISIONAL ASSIGNMENT

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

FACTS RELEVANT TO THE RELIEF CLAIMED

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

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

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

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

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

The Licensed Patents are defined as:

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

Licensed Product is defined as:

> 1.12. "Licensed Product" shall mean any antibody that binds specifically to 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.

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

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

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

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

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

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

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

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

FIRST CLAIM FOR RELIEF – BREACH OF CONTRACT

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

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

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

22. All conditions requiring Biogen's full performance under the License Agreement have occurred.

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

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

PRAYER FOR RELIEF

WHEREFORE, Genentech prays for judgment as follows:

1. For compensatory damages in an amount to be proven at trial, including, but not limited to, the royalties owed to Genentech for Biogen's Net Sales of all Licensed Product that was manufactured in or imported into the United States before December 18, 2018;

2. For prejudgment interest on the said sum at the per annum rate of two percent over the prime rate of interest on the day the payment was due, in accordance with Section 4.05 of the License;

3. For reasonable costs of the suit incurred herein, including reasonable attorneys' fees, to the extent recoverable under applicable law; and

4. For such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff Genentech hereby demands trial by jury on all issues so triable.

Dated: February 28, 2023

/s/ Paul B. Gaffney

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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