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SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF SAN MATEO

23-CIV-00924

GENENTECH, INC., a corporation Plaintiff, v. MILLENNIUM PHARMACEUTICALS, INC., a corporation Defendant.	Case No. _____ **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 Millennium Pharmaceuticals, Inc. ("Millennium"), 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 Millennium 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 Millennium used the Cabilly method to manufacture the active ingredient in Entyvio, an FDA-approved treatment for Crohn's disease and ulcerative colitis, for many years it paid Genentech substantial quarterly royalties on Net Sales of that product. But in February 2019 Millennium stopped making payments on all "Net Sales." It took the position that it owed no royalties on Entyvio 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 Entyvio that Millennium 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 Millennium 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 Millennium is a Delaware 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 like Millennium.

JURISDICTION AND VENUE

7. This action arises under the common law of the State of California.

8. Because it has had continuous and ongoing business contacts with residents in California and in this County, and purposefully availed itself to the privilege of conducting activities in California and this County, Millennium 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 County, and furthermore specifies that it shall be governed by, and interpreted in accordance with, the laws of the State of California. Through February 2019, Millennium regularly paid quarterly royalties to Genentech, and the unpaid royalties for which this suit seeks recovery include amounts Millennium owes on sales of Licensed Product in California.

9. Venue is proper in the County of San Mateo because a substantial part of the acts or omissions giving rise to the claim occurred here. Venue is further proper because the intellectual property that is subject of the License Agreement is owned by a party located in San Mateo County, and the injuries sustained as a result of Millennium's breach of contract occurred, in part, in San Mateo County.

FACTS RELEVANT TO THE RELIEF CLAIMED

10. Entyvio is a prescription medicine whose active ingredient is vedolizumab, a humanized monoclonal antibody that binds to the protein known as MAdCAM-1.

11. In May 2014, after several years of clinical testing, the Food and Drug Administration approved Entyvio for treatment of adults with moderate to severe ulcerative colitis and Crohn's disease. Sales of Entyvio commenced shortly thereafter.

12. Anticipating FDA approval, Millennium negotiated a License with Genentech so that Millennium could make, import, sell and/or offer to sell Entyvio 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.

13. Genentech and Millennium executed the License on May 12, 2004. The License defined Millennium as the "Licensee," and granted it 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 (and have sold), 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:

> 1.10. "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, supplemental protection certificates, 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:

> 1.11. "Licensed Product" shall mean any product that binds specifically to MadCAM-1, 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 Millennium, and promising not to sue it for infringing Cabilly, Millennium agreed in § 3.03 of the License to pay Genentech a mid-single-figure royalty of "the aggregate annual Net Sales of Licensed Products that is less than or equal to U.S. $500,000,000," and a slightly higher royalty on "the portion of aggregate annual Net Sales of all Licensed Product that is greater than U.S. $500,000,000." 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 and not intended for further chemical or genetic manipulation or transformation."

14. The License required Millennium to pay royalties quarterly, with payments due within sixty days from the end of each quarter. Starting in 2014, Millennium began paying quarterly royalties on sales of Entyvio.

15. Entyvio is manufactured at the Millennium's manufacturing plant in Brooklyn Park, Minnesota and, on information and belief, at other facilities located inside and/or outside the United States.

16. Millennium made its last royalty payment to Genentech on February 28, 2019, for "Net Sales" of Entyvio that occurred in the fourth quarter of 2018. This payment did not include royalties on "Net Sales" of Entyvio that occurred after December 18, 2018 when the Cabilly patent expired, even though the vedolizumab 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. Millennium's failure to pay a royalty on these "Net Sales" breached the License.

17. 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 vedolizumab in the Entyvio that Millennium 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, Millennium has not paid Genentech any royalties on these "Net Sales."

FIRST CAUSE OF ACTION – BREACH OF CONTRACT

Against Defendant Millennium

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

19. Millennium entered into a binding and enforceable contract with Genentech to license the Cabilly patents. Under protection of the License, Millennium manufactured and sold its product Entyvio.

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

21. All conditions requiring Millennium's full performance under the License Agreement have occurred.

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

23. As a direct and proximate result of Millennium's breach of the License, 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, but in no event less than eighty million dollars ($80,000,000).

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 Millennium's Net Sales of all Licensed Product that was manufactured in or imported into the United States before December 18, 2018, but in no event less than eighty million dollars ($80,000,000);

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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