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GENENTECH, INC.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SAN DIEGO DIVISION

GENENTECH, INC., a Delaware corporation,

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana corporation,

Defendant.

Case No. 3:18-cv-01518-JLS-JLB

AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT

DEMAND FOR JURY TRIAL

Plaintiff Genentech, Inc. ("Genentech") alleges as follows:

THE PARTIES

1. Genentech is a corporation organized under the laws of the State of Delaware, with its principal place of business at 1 DNA Way, South San Francisco, California 94080. The company is dedicated to discovering, developing, and commercializing medicines to treat patients with debilitating and life-threatening diseases.

2. Defendant Eli Lilly and Company ("Lilly") is an Indiana corporation with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

THE NATURE OF THIS ACTION

3. This is an action arising under the patent laws of the United States, codified at 35 U.S.C. §§ 1, *et seq.*, over which this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) for infringement of U.S. Patent No 10,011,654 (the "'654 patent"). This action arises out of the manufacture, use, importation, offer for sale, and/or sale by Lilly of Taltz® (containing ixekizumab as its active ingredient), a prescription medicine approved by the U.S. Food and Drug Administration to treat psoriatic arthritis and moderate to severe plaque psoriasis in adults.

JURISDICTION AND VENUE

4. Genentech incorporates each of the preceding paragraphs 1-3 as if fully set forth herein.

5. The '654 patent issued at 12:00 a.m. Eastern time on July 3, 2018, and the Complaint was filed immediately thereafter.

6. Lilly is subject to personal jurisdiction in this district, and venue is proper in this district.

7. Lilly is subject to personal jurisdiction in this district because it regularly and continuously conducts business, including business directly related to

Taltz, within the state of California and in this district. Lilly has purposefully directed infringing activities in this district, including promoting and marketing the use of, offering for sale, and selling Taltz in this district, thereby directly infringing the '654 patent and inducing infringement by physicians and patients using Taltz in this district. As detailed in Paragraph 15 below, Lilly sponsors ongoing clinical trials for ixekizumab, including in this district. (Exhibit 1, attached hereto.) Six ongoing ixekizumab clinical trials have study locations in the Southern District of California, with a seventh trial anticipated to begin in this district next month. (*Id.*)

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) at least because Lilly has a regular and established place of business in this district and has committed acts of infringement here. Lilly's website lists San Diego, California, as one of "[o]ur U.S. locations." (*See* "Our U.S. Locations" section, at https://www.lilly.com/our-us-locations (last visited October 8, 2018).) Lilly has purposefully directed infringing activities in this district, including promoting and marketing the use of, offering for sale, and selling Taltz in this district, thereby directly infringing the '654 patent and inducing infringement by physicians and patients to use Taltz in this district. Lilly employs sales representatives and advertises in this district for the purpose of promoting and marketing the use of Taltz to physicians and patients in this district.

9. In June 2017, Lilly announced completion of a $90 million expansion of the Lilly Biotechnology Center, located at 10290 Campus Point Drive, San Diego, California 92121. (*See* "Invested in Biomedical Innovation" section, at https://www.lilly.com/invested-in-san-diego (last visited October 8, 2018).) The Lilly Biotechnology Center was "officially established in 2009." (Declaration of Wolfgang Glaesner, Ph.D., filed Sept. 25, 2018 (ECF No. 24-2), ¶ 6.) The initial discovery and engineering of the antibody that led to Taltz was conducted in San Diego by Applied Molecular Evolution ("AME"), a company acquired by Lilly in 2004. (*Id.* ¶ 11.) Lilly scientists in Indianapolis "worked closely with the

AME group on the Taltz project for discovery, engineering, and biological testing." (*Id.*) FDA approval of Taltz was "the culmination of years of work, including discovery efforts by Lilly scientists in Indianapolis and San Diego." ("In the Lab in San Diego," at https://www.lilly.com/in-the-lab-in-san-diego (last visited October 8, 2018).)

10. A 2009 Lilly press release states that ixekizumab (Taltz) "w[as] designed and engineered by scientists now based at the Lilly Biotechnology Center [in] San Diego." (Exhibit 2, attached hereto.)

11. One or more Lilly employees working at the Lilly Biotechnology Center in San Diego, California, were involved in the research and development of Taltz. A 2016 publication by Lilly scientists, titled "Generation and Characterization of Ixekizumab, a Humanized Monoclonal Antibody That Neutralizes Interleukin-17A," names among its authors Barrett W. Allan, Ying Tang, Barbra Barmettler, and James Nelson. (Exhibit 3, attached hereto.) The article indicates that the location for each of these authors is the AME department at the Lilly Biotechnology Center in San Diego. To this day, these four individuals continue to work at the Lilly Biotechnology Center in San Diego.

12. Barrett W. Allan is one of the inventors of Taltz and performed his research and development work at the Lilly Biotechnology Center in San Diego. Barrett W. Allan is listed as the first named inventor on two issued United States patents, U.S. Patent Nos. 7,838,638 (the "'638 patent") and 8,110,191 (the "'191 patent"), both titled "Anti-IL-17 Antibodies." Ying Tang, who co-wrote the article cited in Paragraph 10 and is also based in San Diego, is also named as an inventor on the '191 patent. On or about May 17, 2016, Lilly applied for patent term extensions for both of these patents, based on the FDA's approval of Taltz. (*See* Exhibits 4 and 5, attached hereto.) According to Lilly's patent term extension applications, both of these patents "claim[] the approved product TALTZ." (*See*

Patent Term Extension Applications for the '638 and '191 patents, available on Public Pair, https://portal.uspto.gov/pair/PublicPair.) Further, according to the Declarations and Powers of Attorney filed with the '638 and '191 patents, Mr. Allan resides in Encinitas, California, and Ms. Tang resides in San Diego, California. (Exhibits 6 and 7, attached hereto.)

13. According to Lilly's Senior Vice President of Biotechnology and Immunology Research, Thomas F. Bumiol, in a 2017 Lilly press release: "Being in the ***San Diego area*** for the last 13 years has been a game changer for us, specifically in the arena of discovering medicines for hard-to-treat autoimmune conditions. . . .With compounds such as Taltz® (ixekizumab) for psoriasis, we've not only provided patients with a new treatment option, but we've also moved the needle for advancing science." (*See* Exhibit 8, attached hereto (emphasis added).)

14. Similarly, in a 2017 interview, in response to the question, "As you look back over the last 13 years since Lilly's presence was established in ***San Diego***, what are you most proud of?"; Dr. Bumiol responded, "While we've had a number of innovative biologic candidates come through our labs which continue to be evaluated clinically, we are very proud of Taltz® (ixekizumab), which was approved in the U.S. in 2016 for the treatment of psoriasis." (Exhibit 9, attached hereto (emphasis added).)

15. Further, of the 20 Lilly-sponsored Phase III clinical trials for ixekizumab, six trials were conducted with study sites in the Southern District of California and are ongoing. In addition, a Phase IV trial is anticipated to begin in this district in November 2018. (Exhibit 10, attached hereto.) Each of the six ongoing Phase III studies enrolled several hundred individual patients from cities throughout this district, including from La Jolla, La Mesa, El Cajon, Escondido, Oceanside, and San Diego. Clinical testing at these sites began as early as August 2009 and is anticipated to continue through at least March 2021. These studies are directed to evaluating various diseases, such as psoriatic arthritis, axial

spondyloarthritis, plaque psoriasis, spondyloarthritis, and rheumatoid arthritis. (*Id.*)

16. Thus, jurisdiction and venue are proper in this district.

THE ASSERTED PATENT

17. Genentech incorporates each of the preceding paragraphs 1-16 as if fully set forth herein.

18. The '654 patent issued on July 3, 2018, and is titled "Antibodies Directed to IL-17A/IL-17F Heterodimers." The claims of the '654 patent are directed to humanized monoclonal antibodies that bind to the IL-17A/F heterodimer.

19. Genentech is the owner of all right, title, and interest in the '654 patent.

TALTZ

20. Genentech incorporates each of the preceding paragraphs 1-19 as if fully set forth herein.

21. Taltz is a prescription injection product approved in the United States to treat psoriatic arthritis and moderate to severe plaque psoriasis in adults. (*See* www.taltz.com.)

22. The active ingredient in Taltz is ixekizumab, a humanized IgG4 monoclonal antibody. (Exhibit 2 at 1; *see also* Taltz® Medication Guide, at http://uspl.lilly.com/taltz/taltz.html#mg (last visited October 8, 2018).)

23. Ixekizumab binds to IL-17A/F. (Exhibit 2 at 5.) According to the European Medicines Agency, "Ixekizumab is a monoclonal antibody that binds with high affinity and specificity to both forms of interleukin 17A (IL-17A and IL-17A/F)." (Exhibit 11, attached hereto.)

24. The FDA announced the approval of Taltz in 2016. Lilly thereupon began to commercially make, use, offer for sale, sell, or import Taltz in the United States, including in California and in this district, and continues to do so.

COUNT I—INFRINGEMENT OF THE '654 PATENT UNDER 35 U.S.C. § 271

25. Genentech incorporates each of the preceding paragraphs 1-24 as if fully set forth herein.

26. The commercial manufacture, use, offer for sale, or sale of Taltz in the United States or importation of Taltz into the United States constitutes an act of infringement of at least claims 1, 4, 5, and 7 of the '654 patent.

27. Independent claim 1 of the '654 patent recites: "An isolated humanized monoclonal antibody that binds to an IL-17A/IL-l7F heterodimer comprising the polypeptide of SEQ ID NO: 3 and the polypeptide of SEQ ID NO: 4 with or without their associated signal peptides."

28. Taltz comprises ixekizumab, an isolated humanized monoclonal antibody purified from cell culture components, in a pharmaceutical formulation.

29. Ixekizumab binds to an IL-17A/IL-l7F heterodimer comprising the polypeptide of SEQ ID NO: 3 and the polypeptide of SEQ ID NO: 4 with or without their associated signal peptides. The polypeptides of Sequence ID Nos. 3 and 4 are IL-17A and IL-17F, which form a heterodimer.

30. Thus, Taltz meets each limitation of claim 1.

31. Claim 4 depends from claim 1 and recites: "The isolated antibody of claim 1, wherein the antibody is an IgG isotype."

32. Ixekizumab, the isolated antibody in Taltz, is an IgG isotype.

33. Thus, Taltz meets each limitation of claim 4.

34. Claim 5 depends from claim 4 and recites: "The isolated antibody of claim 4, wherein the antibody is an IgGl, IgG2 or IgG4 isotype."

35. Ixekizumab, the isolated antibody in Taltz, is an IgG4 isotype.

36. Thus, Taltz meets each limitation of claim 5.

37. Claim 7 depends from claim 1 and recites: "A pharmaceutical composition comprising the isolated antibody of claim 1."

38. Taltz is a pharmaceutical composition comprising the isolated ixekizumab antibody.

39. Thus, Taltz meets each limitation of claim 7.

40. Lilly is committing these acts of infringement without license or authorization.

41. Lilly's infringement of the '654 patent is injuring and harming Genentech.

42. On June 27, 2018, Genentech notified Lilly that the '654 patent would issue on July 3, 2018, and offered Lilly a license at a royalty rate to be determined by arbitration. Lilly rejected the offer.

43. After the '654 patent issued on July 3, 2018, Lilly continued manufacturing, using, offering for sale, marketing, promoting, and/or selling Taltz. Lilly knows of the '654 patent, Genentech's infringement allegations, and the evidence of infringement represented by its own admissions. Thus, any manufacture, use, import, offer for sale, and/or sale of Taltz after July 3, 2018, is willful.

PRAYER FOR RELIEF

WHEREFORE, Genentech requests the following relief:

1. Judgment that Lilly's Taltz infringes one or more claims of the '654 patent;

2. Judgment awarding Genentech damages resulting from such infringement;

3. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

4. In lieu of a permanent injunction, a running or ongoing royalty adequate to compensate Genentech for ongoing infringement, and/or all further and other equitable relief as this Court may deem just and proper;

5. A determination that Lilly's infringement has been willful and that the damages against it be increased up to treble on this basis or for any other basis within the Court's discretion;

6. An award of Genentech's costs and expenses in this action; and

7. Such further and other relief as this Court may deem just and proper.

Dated: October 17, 2018

MORRISON & FOERSTER LLP

By: *s/ Michael A. Jacobs*
MICHAEL A. JACOBS

Attorneys for Plaintiff
GENENTECH, INC.

Email: MJacobs@mofo.com

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, Plaintiff demands a jury trial as to all matters triable of right by a jury.

Dated: October 17, 2018

MORRISON & FOERSTER LLP

By: *s/ Michael A. Jacobs*
MICHAEL A. JACOBS

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GENENTECH, INC.

Email: MJacobs@mofo.com

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on October 17, 2018 a true and correct copy of the foregoing was transmitted electronically to the Electronic Filing System of the United States District Court for the Southern District of California which, under Local Civil Rule 5.4(b)-(d), is believed to have sent notice of such filing, constituting service of the filed document, on all Filing Users, all of whom are believed to have consented to electronic service.

Executed on October 17, 2018, at San Francisco, California.

s/ Michael A. Jacobs
MICHAEL A. JACOBS
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