MICHAEL A. JACOBS (CA SBN 111664)
MJacobs@mofo.com
ESTHER KIM CHANG (CA SBN 258024)
EChang@mofo.com
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105-2482
Telephone: 415.268.7000
Facsimile: 415.268.7522

DAVID A. MANSPEIZER (NY SBN 4867602)
DManspeizer@mofo.com
MORRISON & FOERSTER LLP
250 West 55th Street
New York, New York 10019-9601
Telephone: 212.468.8000
Facsimile: 212.468.7900

ERIC M. ACKER (CA SBN 135805)
EAcker@mofo.com
MORRISON & FOERSTER LLP
12531 High Bluff Drive Suite 100
San Diego, California 92130-2040
Telephone: 858.720.5100
Facsimile: 858.720.5125

Attorneys for Plaintiff
GENENTECH, INC.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GENENTECH, INC., a Delaware corporation,

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana corporation,

Defendants.

Case No. '18CV1518 MMAJLB

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 this complaint is being 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. On information and belief, 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.

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 July 2, 2018).)

9. In June 2017, Lilly announced completion of a $90 million expansion of its 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 July 2, 2018).)

10. One or more Lilly employees working at the Lilly Biotechnology Center in San Diego, California, were involved in the research or 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 1, attached hereto.) The article indicates that the location for each of these authors is the Applied Molecular Evolution department at the Lilly Biotechnology Center in San Diego.

11. Barrett W. Allan is one of the inventors of Taltz and performed his research and development work at the Lilly Biotechnology Center. 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." 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 2 and 3, 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. (Exhibits 4 and 5, attached hereto.)

THE ASSERTED PATENT

12. Genentech incorporates each of the preceding paragraphs 1-11 as if fully set forth herein.

13. 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.

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

TALTZ

15. Genentech incorporates each of the preceding paragraphs 1-14 as if fully set forth herein.

16. 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.)

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

18. Ixekizumab binds to IL-17A/F. (Exhibit 1 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 6, attached hereto.)

19. 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

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

21. 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.

22. 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."

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

24. 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.

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

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

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

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

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

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

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

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

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

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

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

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

37. 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. Lilly knows of the '654 patent, Genentech's infringement allegations, and the evidence of infringement represented by its own admissions. Thus, any subsequent manufacture, use, import, offer for sale, and/or sale of Taltz 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: July 2, 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: July 2, 2018

MORRISON & FOERSTER LLP

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

Attorneys for Plaintiff
GENENTECH, INC.

Email: MJacobs@mofo.com