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14 Attorneys for Plaintiff
GENENTECH, INC.

16 UNITED STATES DISTRICT COURT
17 SOUTHERN DISTRICT OF CALIFORNIA

19 GENENTECH, INC., a Delaware
20 corporation,

21 Plaintiff,

22 v.

23 ELI LILLY AND COMPANY, an Indiana
24 corporation,

25 Defendants.

Case No. '18CV1518 MMAJLB

**COMPLAINT FOR PATENT
INFRINGEMENT**

DEMAND FOR JURY TRIAL

28

1 Plaintiff Genentech, Inc. (“Genentech”) alleges as follows:

2 **THE PARTIES**

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

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

11 **THE NATURE OF THIS ACTION**

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

20 **JURISDICTION AND VENUE**

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

23 5. The ’654 patent issued at 12:00 a.m. Eastern time on July 3, 2018, and
24 this complaint is being filed immediately thereafter.

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

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

1 Taltz, within the state of California and in this district. On information and belief,
2 Lilly has purposefully directed infringing activities in this district, including
3 promoting and marketing the use of, offering for sale, and selling Taltz in this
4 district.

5 8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) at
6 least because Lilly has a regular and established place of business in this district
7 and has committed acts of infringement here. Lilly's website lists San Diego,
8 California, as one of "[o]ur U.S. locations." (See "Our U.S. Locations" section, at
9 <https://www.lilly.com/our-us-locations> (last visited July 2, 2018).)

10 9. In June 2017, Lilly announced completion of a \$90 million expansion
11 of its Biotechnology Center located at 10290 Campus Point Drive, San Diego,
12 California 92121. (See "Invested in Biomedical Innovation" section, at
13 <https://www.lilly.com/invested-in-san-diego> (last visited July 2, 2018).)

14 10. One or more Lilly employees working at the Lilly Biotechnology
15 Center in San Diego, California, were involved in the research or development of
16 Taltz. A 2016 publication by Lilly scientists, titled "Generation and
17 Characterization of Ixekizumab, a Humanized Monoclonal Antibody That
18 Neutralizes Interleukin-17A," names among its authors Barrett W. Allan, Ying
19 Tang, Barbra Barmettler, and James Nelson. (Exhibit 1, attached hereto.) The
20 article indicates that the location for each of these authors is the Applied Molecular
21 Evolution department at the Lilly Biotechnology Center in San Diego.

22 11. Barrett W. Allan is one of the inventors of Taltz and performed his
23 research and development work at the Lilly Biotechnology Center.
24 Barrett W. Allan is listed as the first named inventor on two issued United States
25 patents, U.S. Patent Nos. 7,838,638 (the "638 patent") and 8,110,191 (the
26 "191 patent"), both titled "Anti-IL-17 Antibodies." On or about May 17, 2016,
27 Lilly applied for patent term extensions for both of these patents, based on the
28 FDA's approval of Taltz. (See Exhibits 2 and 3, attached hereto.) According to

1 Lilly’s patent term extension applications, both of these patents “claim[] the
2 approved product TALTZ.” (See Patent Term Extension Applications for the
3 ’638 and ’191 patents, available on Public Pair,
4 <https://portal.uspto.gov/pair/PublicPair>.) Further, according to the Declarations and
5 Powers of Attorney filed with the ’638 and ’191 patents, Mr. Allan resides in
6 Encinitas, California. (Exhibits 4 and 5, attached hereto.)

7 **THE ASSERTED PATENT**

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

10 13. The ’654 patent issued on July 3, 2018, and is titled “Antibodies
11 Directed to IL-17A/IL-17F Heterodimers.” The claims of the ’654 patent are
12 directed to humanized monoclonal antibodies that bind to the
13 IL-17A/F heterodimer.

14 14. Genentech is the owner of all right, title, and interest in the
15 ’654 patent.

16 **TALTZ**

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

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

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

25 18. Ixekizumab binds to IL-17A/F. (Exhibit 1 at 5.) According to the
26 European Medicines Agency, “Ixekizumab is a monoclonal antibody that binds
27 with high affinity and specificity to both forms of interleukin 17A (IL-17A and
28 IL-17A/F).” (Exhibit 6, attached hereto.)

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

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

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

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

11 22. Independent claim 1 of the '654 patent recites: “An isolated
12 humanized monoclonal antibody that binds to an IL-17A/IL-17F heterodimer
13 comprising the polypeptide of SEQ ID NO: 3 and the polypeptide of SEQ ID NO: 4
14 with or without their associated signal peptides.”

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

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

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

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

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

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

26 29. Claim 5 depends from claim 4 and recites: “The isolated antibody of
27 claim 4, wherein the antibody is an IgG1, IgG2 or IgG4 isotype.”

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

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

2 32. Claim 7 depends from claim 1 and recites: “A pharmaceutical
3 composition comprising the isolated antibody of claim 1.”

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

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

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

9 36. Lilly’s infringement of the ’654 patent is injuring and harming
10 Genentech.

11 37. On June 27, 2018, Genentech notified Lilly that the ’654 patent would
12 issue on July 3, 2018, and offered Lilly a license at a royalty rate to be determined
13 by arbitration. Lilly rejected the offer. Lilly knows of the ’654 patent, Genentech’s
14 infringement allegations, and the evidence of infringement represented by its own
15 admissions. Thus, any subsequent manufacture, use, import, offer for sale, and/or
16 sale of Taltz is willful.

17 **PRAYER FOR RELIEF**

18 WHEREFORE, Genentech requests the following relief:

19 1. Judgment that Lilly’s Taltz infringes one or more claims of the
20 ’654 patent;

21 2. Judgment awarding Genentech damages resulting from such
22 infringement;

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

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

28

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

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

5 7. Such further and other relief as this Court may deem just and proper.
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8 Dated: July 2, 2018

MORRISON & FOERSTER LLP

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

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GENENTECH, INC.

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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

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