QUINN EMANUEL URQUHART
& SULLIVAN, LLP
Adam B. Wolfson (SBN 262125)
adamwolfson@quinnemanuel.com
865 S. Figueroa St., 10th Floor
Los Angeles, California 90017
Telephone: (213) 443-3000
Facsimile: (213) 443-3100

Raymond N. Nimrod (*pro hac vice pending*)
raynimrod@quinnemanuel.com
Matthew A. Traupman (*pro hac vice pending*)
matthewtraupman@quinnemanuel.com
51 Madison Ave.
New York, NY 10010
Telephone: (212) 849-7000
Facsimile: (212) 849-7100

Attorneys for Plaintiff
MERCK SHARP & DOHME CORP.

[LIST OF COUNSEL CONTINUED ON NEXT PAGE]

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MERCK SHARP & DOHME CORP.,

Plaintiff,

vs.

GENENTECH, INC. and CITY OF HOPE,

Defendants.

CASE NO.: 2:16-CV-4992

COMPLAINT FOR DECLARATORY JUDGMENT OF INVALIDITY AND NONINFRINGEMENT

JURY TRIAL DEMANDED

SIMPSON THACHER &
BARTLETT LLP
Jeffrey E. Ostrow (SBN 213118)
jostrow@stblaw.com
2475 Hanover St.
Palo Alto, CA 94304
Telephone: (650) 251-5000
Facsimile: (650) 251-5002

Katherine A. Helm (*pro hac vice pending*)
khelm@stblaw.com
425 Lexington Ave.
New York, NY 10017
Telephone: (212) 455-2000
Facsimile: (212) 455-2502

Attorneys for Plaintiff
MERCK SHARP & DOHME CORP.

Plaintiff Merck Sharp & Dohme Corp. ("Plaintiff" or "Merck"), for its Complaint against Genentech, Inc. ("Genentech") and City of Hope (collectively, "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. Plaintiff Merck seeks a declaration that U.S. Patent No. 7,923,221 entitled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen" (the "Cabilly III patent," attached as Exhibit A) is invalid, unenforceable and/or not infringed by the manufacture, use, sale, offer of sale, or importation of Merck's KEYTRUDA® (pembrolizumab) and/or bezlotoxumab products. The Cabilly III patent was filed as a continuation application on April 13, 1995, claiming priority to an earlier-filed application that issued on December 18, 2001, as U.S. Patent No. 6,331,415 (the "Cabilly II Patent").

2. The Cabilly II patent was filed as a continuation application of an application that was filed on April 8, 1983 and issued as U.S. Patent No. 4,816,567 (the "Cabilly I patent"), which expired on March 28, 2006. The Cabilly I, II and III patents will collectively be referred to as the "Cabilly patents." The Cabilly I and II patents are not at issue in this case.

3. Plaintiff has received approval from the U.S. Food and Drug Administration ("FDA") to market and sell KEYTRUDA® (pembrolizumab) in the United States. The current approved indications are for the treatment of patients with unresectable or metastatic melanoma and for the treatment of patients with metastatic, PD-L1 positive, non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy.

4. Plaintiff is currently seeking approval from the FDA to market and sell bezlotoxumab in the United States for the prevention of *Clostridium difficile* infection recurrence, an intestinal tract infection that is an increasingly frequent cause of morbidity and mortality among older adult hospitalized patients. Plaintiff

has expended substantial resources in preparing to launch and commercialize bezlotoxumab. The FDA granted Priority Review for bezlotoxumab, with a Prescription Drug User Fee Act action date of July 23, 2016.

5. Plaintiff brings this action to lift the cloud created by the imminent threat of a lawsuit by Defendants against Plaintiff for infringement of the Cabilly III patent. Without declaratory relief, the threat of suit poses a substantial risk of injury to Plaintiff as well as the patients, physicians and nurses using KEYTRUDA® (pembrolizumab) and/or planning to use bezlotoxumab. The continued existence and threat of suit of this invalid patent harms Plaintiff's manufacture, marketing, sale and use of KEYTRUDA® (pembrolizumab) and bezlotoxumab.

6. Defendants have asserted that the Cabilly patents broadly cover the use of certain well-known, conventional recombinant methods to produce any antibody product in any type of host cell. Defendants have filed infringement claims under the Cabilly III patent against numerous companies who have made and sold antibody products that were produced using recombinant methods similar to the recombinant methods used by Plaintiff to make KEYTRUDA® (pembrolizumab) and bezlotoxumab.

7. Defendants have also previously initiated patent license negotiations with Plaintiff concerning the Cabilly patents with respect to KEYTRUDA® (pembrolizumab), bezlotoxumab and other Merck antibody products in development. Given Defendants' acts and statements, Plaintiff's manufacture and sale of KEYTRUDA® (pembrolizumab) and Plaintiff's manufacture and expected future sale of bezlotoxumab in the United States, a real, immediate, and substantial dispute exists between the parties concerning the Cabilly III patent for which Plaintiff now seeks declaratory relief.

THE PARTIES

8. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 2000 Galloping Hill Road

Kenilworth, NJ 07033. Merck is a wholly owned subsidiary of Merck & Co., Inc., a New Jersey corporation which has its principal place of business at 2000 Galloping Hill Road Kenilworth, NJ 07033.

9. On information and belief, Defendant Genentech, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1 DNA Way, South San Francisco, California 94080. On information and belief, Genentech is in the business of, among other things, developing, manufacturing, marketing and selling pharmaceutical products in the United States, including in the Central District of California, and conducts business throughout the United States.

10. On information and belief, Defendant City of Hope is a not-for-profit organization organized and existing under the laws of California, having its principal place of business in this District at 1500 East Duarte Road, Duarte, California 91010.

11. On information and belief, Genentech and City of Hope are co-assignees of the Cabilly III patent.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201-2202), Title 28 of the United States Code, for the purposes of determining an actual and justiciable controversy between the parties, and under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over Genentech based on its principal place of business in California. This Court has personal jurisdiction over City of Hope based on its organization under the laws of the State of California and because its principal place of operation is in this judicial district in California.

14. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b)because both Defendants reside in this District and a substantial part of the events or omissions giving rise to the claims occurred in this District.

PLAINTIFF'S KEYTRUDA® (PEMBROLIZUMAB) PRODUCT

15. KEYTRUDA® (pembrolizumab) is a recombinantly-engineered monoclonal antibody that targets the programmed death receptor-1 ("PD-1"). KEYTRUDA® (pembrolizumab) is FDA-approved for the treatment of patients with unresectable or metastatic melanoma, and for the treatment of patients with metastatic or PD-L1 positive, non-small cell lung cancer ("NSCLC"), as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy.

16. KEYTRUDA® was the first anti-PD-1 therapy approved in the United States and received the FDA's Breakthrough Therapy Designation for advanced melanoma. It is also the first anti-PD-1 therapy approved for both squamous and non-squamous metastatic NSCLC.

17. Following FDA approval, Plaintiff has begun marketing and selling KEYTRUDA® in the United States, physicians have begun prescribing KEYTRUDA®, and patients have begun taking KEYTRUDA® to treat the above-mentioned types of cancer. Plaintiff has expended substantial revenues researching, developing, launching and commercializing KEYTRUDA®.

PLAINTIFF'S BEZLOTOXUMAB PRODUCT

18. Bezlotoxumab is a recombinantly-engineered monoclonal antibody that targets and neutralizes *Clostridium difficile* toxin B, a toxin that can damage the intestinal tract and cause inflammation, leading to the symptoms of *C. difficile* enteritis. In January 2016, the FDA granted Priority Review for Merck's Biologics License Application ("BLA") for bezlotoxumab for prevention of *C. difficile* infection recurrence. If approved, bezlotoxumab will be the first therapy for the prevention of recurrent disease caused by *C. difficile*.

19. On June 9, 2016, the FDA's Antimicrobial Drugs Advisory Committee met to discuss bezlotoxumab and recommend approval of Merck's BLA. The Prescription Drug User Fee Act ("PDUFA") action date for the FDA's review of bezlotoxumab is July 23, 2016.

HISTORY AND BACKGROUND OF THE CABILLY III PATENT

20. On April 8, 1983, Shmuel Cabilly, Herbert Heyneker, William Holmes, Arthur Riggs, and Ronald Wetzel (collectively, the "Cabilly Applicants") filed a patent application in the United States Patent and Trademark Office ("PTO") that issued on March 28, 1989 as the Cabilly I patent. The Cabilly Applicants assigned their rights to Genentech and the City of Hope. The Cabilly I patent expired over a decade ago; on March 28, 2006.

21. At the time the Cabilly I patent issued, the Cabilly Applicants had a continuation patent application pending in the PTO, which ultimately issued as the Cabilly II patent. The Cabilly II Patent has an extended prosecution history, including a patent interference and subsequent action under 35 U.S.C. § 146 and two reexaminations. Because the PTO ruled that the claims of the Cabilly III patent are not patentably distinct from the claims of the Cabilly II patent and, absent a terminal disclaimer would be invalid for obviousness-type double patenting, several aspects of the Cabilly II prosecution history are highlighted herein.

22. Notably, during prosecution of the application that led to the Cabilly II patent, the Cabilly Applicants copied claims from U.S. Patent 4,816,397 (the "Boss patent") to provoke the PTO Board of Patent Appeals and Interferences (the "PTO Board") to initiate an interference proceeding to determine whether the Boss patentees or the Cabilly Applicants were entitled to priority for the invention claimed in the Boss patent.

23. In February 1991, the PTO Board declared a patent interference between the pending Cabilly II application and the Boss patent on the ground that both the Boss patentees and the Cabilly Applicants claimed the same purported

invention. The PTO Board designated the Boss patentees as the senior party in the interference, which means that the Boss patentees were entitled to the presumption of being the prior inventor.

24. In August 1998, after seven years of adversarial proceedings, the PTO Board ruled that the Boss patentees won priority of invention over the Cabilly Applicants. *See Cabilly v. Boss,* 55 U.S.P.Q.2d 1238 (B.P.A.I. 1998). The PTO Board concluded that the Cabilly Applicants had failed to establish conception or reduction to practice of the claimed inventions prior to the March 25, 1983 filing date of the Boss patent. According to the PTO Board, "there is no evidence that immunoglobulins, multiple chains proteins, had been produced by recombinant DNA techniques from a single host cell prior to March 25, 1983." *Id.* at *22. Moreover, "the evidence indicates that Cabilly et al. had **but a hope or wish** to produce active antibodies in bacteria; and, there is no supporting evidence to establish the development of the means to accomplish that result or evidence of a disclosure to a third party of complete conception." *Id.* (emphasis added). The Final Decision therefore concluded that the Cabilly Applicants were "not entitled to a patent." *Id.* at *23.

25. In October 1998, Genentech filed an action under 35 U.S.C. § 146 against the owner of the Boss patent, Celltech Therapeutics Ltd. ("Celltech") to appeal the PTO Board's decision awarding priority to Boss. *Genentech, Inc. v. Celltech Ltd.,* No. 98-cv-3926-MMC (N.D. Cal. 1998). In March 2001, the parties filed a notice of settlement. As part of that settlement, the parties asked the district court to find that, contrary to the PTO Board's prior decision, the Cabilly Applicants were entitled to priority.

26. On information and belief, as part of the Genentech-Celltech agreement, Celltech obtained certain rights relating to the Cabilly II patent as well as certain payments from Genentech in exchange for its agreement to stipulate that the Cabilly Applicants were entitled to priority for the inventions claimed in the Boss

patent. According to Celltech's 2001 Annual Report, "the royalty stream arising from the sale of antibody products covered by the Boss patent is important to Celltech, consequently . . . [t]he settlement with Genentech involves the payment of compensation to Celltech in terms of income from sales of products which would otherwise have been covered under the Boss patent. Importantly, Celltech has also secured preferential access for its development programmes to the Cabilly patent, which covers the production of a broad range of antibody or antibody fragment products, for its 17 year life."

27. Ten days after the Genentech-Celltech agreement was filed, the district court issued a "Judgment" and order directing the PTO to vacate its determination that the Boss applicants were entitled to priority, to revoke the Boss patent, and to issue a patent to the Cabilly Applicants claiming the same subject matter as the Boss patent. The Cabilly II patent issued on December 18, 2001, and is co-assigned Genentech and City of Hope. The Cabilly II patent expires on December 18, 2018—more than 35 years after the Cabilly Applicants' original 1983 patent application, and more than 12 years after the Boss Patent would have expired.

28. The Cabilly III continuation patent application was pending in the PTO when the Cabilly II patent issued. The Cabilly III patent ultimately issued on April 12, 2011 and is also assigned to Genentech and City of Hope. Much like its parent, the Cabilly III Patent has also been through an extended prosecution as well as a patent interference and appeal thereof. Because, as noted *supra*, the PTO rejected the Cabilly III patent claims as being invalid over the Cabilly II patent claims, the Cabilly III patent is subject to a terminal disclaimer over the Cabilly II patent, and hence also expires on December 18, 2018.

29. In January 2007, the PTO Board declared a patent interference between the then-pending Cabilly III application (U.S. Application No. 08/422,187), which claimed priority to the April 8, 1983 Cabilly I patent filing date, and a then-pending Boss application (U.S. Application No. 08/450,727), which claimed priority to the

March 25, 1983 Boss patent filing date. Accordingly, the PTO Board once again designated Boss as the senior party in the interference and entitled them to the presumption of being the prior inventor.

30. In December 2008, the PTO Board ruled that the Boss application won priority of invention over the Cabilly III application. *See Cabilly v. Boss,* (B.P.A.I., unpublished decision, Dec. 8, 2008). In its decision, the PTO Board declined to consider all of the potential invalidity grounds for the Cabilly III application, stating, *e.g.,* "we believe obviousness-type double patenting is best considered in the first instance by the examiner upon resumption of ex parte prosecution." *Id.* at 25.

31. On appeal, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") affirmed the PTO's ruling regarding priority. *See Boss v. Cabilly*, 355 Fed. Appx. 416 (Fed. Cir. 2009) (Appeal No. 2009-1264).

32. On July 12, 2010, Defendants filed a request to reopen prosecution of the Cabilly III patent application and concurrently submitted 409 prior art references to the PTO.

33. On December 21, 2010, without any further substantive prosecution, the Examiner issued an Examiner's Amendment, recorded the terminal disclaimer that had been filed over the Cabilly II patent in response to the PTO's ruling that the Cabilly III patent application includes substantially the same invention as the Cabilly II patent, and allowed the Cabilly III patent application, which went on to issue as the Cabilly III patent with the same expiration date as the Cabilly II patent.

34. The same day that the Cabilly III patent application was allowed by the PTO, Defendants alerted this Court of this fact by filing the PTO Notice of Allowance for the Cabilly III patent in a then-pending litigation involving GSK and its antibody product, Arzerra®. *See Glaxo Group Ltd. v. Genentech, Inc.*, Case No. 2:10-cv-02764 (C.D. Cal.) (Notice of Notice of Allowance and Fee(s) Due Issued by the United States Patent and Trademark Office, dated January 28, 2011), Dkt No. 84.

35. Defendants have asserted the Cabilly III patent in every Cabilly-related litigation since that date.

36. If the PTO Board's first interference decision in favor of the Boss patent had not been reversed as a result of the private Genentech-Celltech agreement, the Boss patent would have expired in 2006, and the public would thereafter have been free to use the inventions claimed in the Cabilly patents, as is the case everywhere in the world, except the United States. Instead, because Genentech and Celltech agreed to request that the Court reverse that result, Defendants received the Cabilly II and Cabilly III patents, which would not be in force but for the private Genentech-Celltech agreement. Consequently, Defendants have ostensibly extended their power to exclude others from making, using, or selling the inventions claimed in the Boss Cabilly patents until 2018—more than 35 years after the initial Cabilly I application, and more than 12 years after the prior Boss patent would have expired. The combined period of patent exclusivity secured by the Defendants for the Cabilly patents, which all share the same specification, is 29 years.

PLAINTIFF'S DISPUTE WITH GENENTECH REGARDING THE CABILLY III PATENT

37. Genentech has aggressively enforced the Cabilly patents across the biopharmaceutical industry through multiple litigations and licensing demands.

38. Through its statements and actions, Genentech has made clear to the biopharmaceutical industry generally, and to Plaintiff in particular, that it contends the claims of the Cabilly patents preclude others from commercially manufacturing recombinant antibodies without Genentech's permission.

39. For example, in 2002, after the Cabilly II patent issued, Sean Johnston, then Genentech's Vice President of Intellectual Property and now Genentech's Senior Vice President and General Counsel said:

> "The recently issued patent **broadly covers** the co-expression of immunoglobulin heavy and light chain genes in a single host cell .... We do not believe that the claims are limited by type of antibody (murine, humanized [90% human sequence], or human) or by host cell type."

See Exhibit B ("Genentech Awarded Critical Antibody Patent," *Nature Biotechnology,* vol. 20, p. 108 (Feb. 2002)) at 1 (emphasis added).

40. Genentech has also made public statements about pursuing an aggressive litigation policy to protect its products against competition and to protect against alleged infringement of the Cabilly patents. In its 2009 Form 10-K filing with the Securities and Exchange Commission, Genentech states:

> "Intellectual property protection of our products is crucial to our business. Loss of effective intellectual property protection could result in lost sales to competing products and loss of royalty payments (for example, royalty income associated with the **Cabilly patent)** from licenses. We are often involved in disputes over contracts and intellectual property, and **we work to resolve these disputes in** confidential negotiations or **litigation**. **We expect legal challenges in this area to continue.** We plan to continue to build upon and defend our intellectual property position."

See Exhibit C (Genentech's Form 10-K filed with the U.S. Securities and Exchange Commission for the fiscal year ended December 31, 2008) at 39 (emphasis added).

41. Genentech also states: "We have in the past been, are currently, **and may in the future be involved in material litigation** and other legal proceedings

related to our proprietary rights, **such as the Cabilly patent litigation and reexamination** ...." *See id.* at 18 (emphasis added).

42. This aggressive litigation policy is evidenced by the numerous prior lawsuits involving the Cabilly III patent. On information and belief, Genentech contends that the process and certain starting materials used to produce KEYTRUDA® (pembrolizumab) and/or bezlotoxumab infringe one or more claims of the Cabilly III patent. KEYTRUDA® (pembrolizumab) and bezlotoxumab are made by recombinant DNA techniques, and as discussed below, Genentech has asserted the Cabilly patents against several other antibodies made by recombinant DNA techniques.

43. Genentech has alleged infringement of the Cabilly III patent by other manufacturers of recombinant antibodies, including Human Genome Sciences, Inc. ("HGS"), GlaxoSmithKline LLC ("GSK"), Lonza Biologics, Inc. ("Lonza"), Bristol-Myers Squibb Company ("BMS"), Eli Lilly and Company ("Eli Lilly"), Sanofi-Aventis U.S. LLC ("Sanofi") and Regeneron Pharmaceuticals, Inc. ("Regeneron"), and Genzyme Corporation ("Genzyme"). *Human Genome Sciences Inc. v. Genentech, Inc. et al.*, No. 11-cv-6594-MRP-JEM (C.D. Cal. 2011); *Genentech, Inc. et al. v. Glaxo Group Ltd. et al.*, No. 11-cv-3065-MRP-JEM (C.D. Cal. 2011); *Bristol-Myers Squibb Co. v. Genentech, Inc. et al.*, No. 13-cv-5400-MRP-JEM (C.D. Cal. 2013); *Eli Lilly & Co. et al. v. Genentech, Inc. et al.*, No. 13-cv-7248-MRP-JEM (C.D. Cal 2013); *Sanofi-Aventis US LLC, et al. v. Genentech, Inc. et al.* No. 15-cv-5685-GW-AGR (C.D. Cal. 2015); *Genzyme Corp. v. Genentech, Inc. et al.*, No. 15-cv-9991-GW-AGR (C.D. Cal. 2015). In fact, Genentech and City of Hope filed a patent infringement action against HGS, GSK, and Lonza for infringement of the Cabilly III patent on the very day that the PTO issued the Cabilly III patent. *Genentech, Inc. et al. v. Glaxo Group Ltd. et al.*, No. 11-cv-3065-MRP-JEM (C.D. Cal. 2011), Dkt. 1 (filed April 12, 2011).

44. In addition, Genentech has never disputed that an actual case or controversy exists whenever a company has sought a declaratory judgment of invalidity or non-infringement of the Cabilly III patent. On information and belief, Genentech contends that the recombinant methods used by Merck to produce KEYTRUDA® (pembrolizumab) and bezlotoxumab are similar in relevant aspects to the recombinant methods used by HGS, GSK, BMS, Eli Lilly, Sanofi/Regeneron, and Genzyme to produce their antibody products including, among others: Benlysta®, Arzerra®, Yervoy®, Erbitux®, Praluent®, and Lemtrada®.

45. Genentech has also asserted the Cabilly II patent in litigation against other manufacturers of recombinant antibodies, including MedImmune, Inc. ("MedImmune"), Centocor Ortho Biotech, Inc. ("Centocor"), HGS, GSK, BMS, and Eli Lilly. *MedImmune, Inc. v. Genentech ,Inc. et al.*, No. 03-cv-02567-MRP-CT (C.D. Cal. 2003); *Centocor Inc. v. Genentech, Inc. et al.*, No. 08-cv-3573-MRP-JEM (C.D. Cal. 2008); *Human Genome Sciences Inc. v. Genentech, Inc. et al.*, No. 11-cv-6519-MRP-JEM (C.D. Cal. 2011); *Glaxo Group Ltd. et al. v. Genentech, Inc. et al.*, No. 10-cv-02764-MRP-FMO (C.D. Cal. 2010); *Bristol-Myers Squibb Co. v. Genentech, Inc. et al.*, No. 13-cv-5400-MRP-JEM (C.D. Cal. 2013); *Eli Lilly & Co. et al. v. Genentech, Inc. et al.*, No. 13-cv-7248-MRP-JEM (C.D. Cal 2013). On information and belief, Genentech contends that the recombinant methods used by Merck to produce KEYTRUDA® (pembrolizumab) and bezlotoxumab are similar in relevant aspects to the recombinant methods used by MedImmune, Centocor, HGS, GSK, BMS and Eli Lilly to produce their various antibody products, including: Synagis®, ReoPro®, Remicade®, Stelara®, Benlysta®, Arzerra®, Yervoy® and Erbitux®.

46. Genentech has also pursued an aggressive licensing campaign. Following reexamination of the Cabilly II patent in the PTO, Genentech touted the licensing of the Cabilly II patent by "many biotechnology and pharmaceutical companies…for their commercial products," explaining that the patent broadly

relates to "methods used to make antibodies and antibody fragments by recombinant DNA technology, as well as recombinant cells and DNA that are used in those methods." *See* Exhibit D ("Genentech Receives Final Notification Upholding Cabilly Patent in Reexamination Proceeding," Genentech Press Release (Feb. 24, 2009)) at 1-2.

47. On information and belief, Genentech has received a significant amount of revenue from licensing the Cabilly patents. For example, according to Genentech, between 1991 and 2013, Genentech entered into a total of 70 licenses granting rights to the Cabilly II patent. *See Sanofi-Aventis U.S. LLC and Regeneron Pharmaceuticals, Inc. v. Genentech, Inc. et al.*, IPR2015-01624, Paper No. 14 (Patent Owners' Preliminary Response under 37 C.F.R. § 42.107) (Nov. 9, 2015) at 6-7.

48. In addition to the statements and conduct directed at others, Defendants have made statements and engaged in conduct directed to Plaintiff that create a real and immediate dispute between the parties regarding the Cabilly III patent. Specifically, Plaintiff and Defendants have been involved in patent license discussions with respect to KEYTRUDA® and bezlotoxumab.

49. In sum, Genentech's statements that it will enforce its intellectual property, and specifically the Cabilly III patent, to defend its hefty patent royalty stream, the numerous examples of similar infringement suits it has filed, and past license negotiations between Plaintiff and Genentech with respect to KEYTRUDA®, bezlotoxumab and other investigational antibody products establish that a real and immediate dispute exists between parties with adverse legal interests concerning the Cabilly III patent and Merck's sale of KEYTRUDA® (pembrolizumab) and future sale of bezlotoxumab. Plaintiff therefore has a reasonable apprehension of suit by Genentech regarding the Cabilly III patent.

FIRST CAUSE OF ACTION

PATENT INVALIDITY

50. Plaintiff re-alleges and incorporates by reference the allegations of the preceding paragraphs of this Complaint as if fully set forth herein.

51. An actual and substantial controversy has arisen and now exists between the parties concerning the validity of the Cabilly III patent.

52. Claims 1-47 of the Cabilly III patent is invalid because the purported inventions therein fail to meet the conditions for patentability specified in 35 U.S.C. §§ 101 *et seq*., including but not limited to 35 U.S.C. §§ 102, 103, and 112, and nonstatutory common law doctrines.

53. By way of example and without limiting the grounds of invalidity that will be asserted in this action, each claim of the Cabilly III patent is invalid at least because each claim is invalid under the judicially-created doctrine of obviousness-type double patenting in view of the claims of the Cabilly I patent alone or in combination with other prior art references and/or the knowledge of a person of ordinary skill in the art.

54. By way of further example and without limiting the grounds of invalidity that will be asserted in this action, each claim of the Cabilly III patent is invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112. The claims of the Cabilly III patent are directed generally to methods for producing any type of immunoglobulin molecule in any type of host cell using any number of vectors and assembly techniques; however, the Cabilly III patent fails to convey to a person of skill in the art that the inventors were in possession of the full scope of the claimed subject matter. The Cabilly III patent fails to provide sufficient written description for a representative number of species to demonstrate that the inventors were in possession of the full scope of the claimed subject matter.

55. By way of further example and without limiting the grounds of invalidity that will be asserted in this action, each claim of the Cabilly III patent is

invalid for failure to satisfy the enablement requirement of 35 U.S.C. § 112. As noted *supra*, the claims of the Cabilly III are directed generally to methods for producing any type of immunoglobulin molecule in any type of host cell using any number of vectors and assembly techniques. The Cabilly III patent provides only a single experimental example that uses a single type of vector in a single type host cell using a single type of assembly technique to purportedly make a single type of immunoglobulin molecule. The Cabilly III patent fails to provide sufficient teachings that would enable a person of ordinary skill in the art to make and use the full scope of the claims without undue experimentation.

56. Merck expressly reserves the right to assert additional grounds of invalidity after having the ability to conduct discovery.

57. Plaintiff seeks a declaratory judgment that the Cabilly III patent is invalid.

SECOND CAUSE OF ACTION

NON-INFRINGEMENT

58. Plaintiff re-alleges and incorporates by reference the allegations of the preceding paragraphs of this Complaint as if fully set forth herein.

59. An actual and substantial controversy has arisen and now exists between the parties concerning whether Plaintiff's manufacture, use, sale, offer for sale, or importation of Merck's KEYTRUDA® (pembrolizumab) and/or bezlotoxumab products infringes any valid and enforceable claim of the Cabilly III patent, either directly or indirectly, literally, under the doctrine of equivalents, or otherwise.

60. By way of example and without limiting the grounds of non-infringement that will be asserted, Merck's KEYTRUDA® (pembrolizumab) and bezlotoxumab products do not infringe because they do not contain a "variable region comprising non human mammalian variable region sequences."

61. Merck expressly reserves the right to assert additional grounds of non-infringement after having the ability to conduct discovery and the Court has construed the claims.

62. Plaintiff seeks a declaratory judgment that making, using, offering to sell, selling, and importing KEYTRUDA® (pembrolizumab) and/or bezlotoxumab does not and will not infringe any valid and enforceable claim of the Cabilly III patent.

THIRD CAUSE OF ACTION

UNENFORCEABILITY DUE TO PROSECUTION LACHES

63. Plaintiff re-alleges and incorporates by reference the allegations of the preceding paragraphs of this Complaint as if fully set forth herein.

64. An actual controversy has arisen and now exists between the parties concerning the enforceability of the Cabilly III patent.

65. The Cabilly III patent is unenforceable under the doctrine of prosecution laches. The Cabilly III patent issued on April 12, 2011 from an application filed on April 13, 1995 and which claims priority to an application filed on April 8, 1983. Thus, the claims of the Cabilly III patent issued over 28 years after the original priority application was filed.

66. The Cabilly III patent's 28 year prosecution is the result of Defendants purposeful delay in prosecuting of the claims of the Cabilly III patent. For example, Defendants unreasonably delayed in waiting over twelve years to even file the application that led to the Cabilly III patent and, once filed, Defendants failed to reasonably advance prosecution of the application that led to the Cabilly III patent, including, *inter alia*, by allowing the application to go abandoned for over two years despite having already receiving a Notice of Allowance and presenting new claims in July 2010, over fifteen years after the application was filed and over ten years after the PTO first issued a Notice of Allowance.

67. Defendants' unreasonable delay in prosecuting the claims of the Cabilly III patent has caused actual harm to Plaintiff and the public. For example, during the period of Defendants' delay Merck and others invested significant amounts of money in developing antibody products, including, for example, KEYTRUDA® (pembrolizumab).

68. Plaintiff seeks a declaratory judgment that the Cabilly III patent is unenforceable under the doctrine of prosecution laches.

JURY TRIAL DEMANDED

69. Pursuant to Federal Rule of Civil Procedure 38(b) and Local Rule 38-1 of this Court, Plaintiff demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that judgment be entered in favor of Plaintiff and against Defendants Genentech and City of Hope:

(a) Declaring the Cabilly III patent invalid;

(b) Declaring that the manufacture, use, sale, offer of sale, or importation of Plaintiff's KEYTRUDA® (pembrolizumab) and/or bezlotoxumab products does not infringe any valid and enforceable claim of the Cabilly III patent;

(c) Declaring the Cabilly III patent unenforceable;

(d) Enjoining Genentech and City of Hope from enforcing the Cabilly III patent;

(e) A finding that this case is exceptional under 35 U.S.C. § 285;

(f) Awarding Plaintiff their costs and attorney's fees; and

(g) Awarding Plaintiff such other relief as the Court deems just and proper.

DATED: July 7, 2016

Respectfully submitted,

QUINN EMANUEL URQUHART & SULLIVAN, LLP

By /s/ *Adam B. Wolfson*

Adam B. Wolfson (SBN 262125)
adamwolfson@quinnemanuel.com
QUINN EMANUEL URQUHART & SULLIVAN, LLP
865 S. Figueroa St., 10th Floor
Los Angeles, California 90017
Telephone: (213) 443-3000
Facsimile: (213) 443-3100

Raymond N. Nimrod (*pro hac vice pending*)
raynimrod@quinnemanuel.com
Matthew A. Traupman (*Pro hac pending*)
matthewtraupman@quinnemanuel.com
51 Madison Avenue, 22nd Floor
New York, NY 10010
Telephone: (212) 849-7000
Facsimile: (212) 849-7100

SIMPSON THACHER & BARTLETT LLP
Jeffrey E. Ostrow (SBN 213118)
jostrow@stblaw.com
2475 Hanover St.
Palo Alto, CA 94304
Telephone: (650) 251-5000
Facsimile: (650) 251-5002

Katherine A. Helm (*pro hac vice pending*)
khelm@stblaw.com
425 Lexington Ave.
New York, NY 10017
Telephone: (212) 455-2000
Facsimile: (212) 455-2502

Attorneys for Plaintiff Merck Sharp & Dohme Corp.