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NORTHERN DISTRICT OF CALIFORNIA
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ORIGINAL

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

ELI LILLY AND COMPANY, an Indiana corporation, and IMCLONE SYSTEMS LLC, a Delaware limited liability company,

Plaintiffs,

v.

GENENTECH, INC., a Delaware corporation, and CITY OF HOPE, a California not-for-profit company,

Defendants.

Case No. CV13- 0919 YGR

COMPLAINT FOR DECLARATORY JUDGMENT OF INVALIDITY, UNENFORCEABILITY, AND NONINFRINGEMENT

DEMAND FOR JURY TRIAL

Plaintiffs Eli Lilly and Company and ImClone Systems LLC (collectively, "Lilly"), for their Complaint against Genentech, Inc. ("Genentech") and City of Hope (collectively, "Defendants"), allege as follows:

NATURE OF THE CASE

1. Lilly seeks a declaration that U.S. Patent No. 6,331,415 titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein" (the "Cabilly II patent" attached as Exhibit A), including the *Ex Parte* Reexamination Certificate issued pursuant to merged Reexamination Nos. 90/007,542 and 90/007,859 (attached as Exhibit B), and U.S. Patent No. 7,923,221 titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen" (the "Cabilly III patent" attached as Exhibit C) are invalid, unenforceable, and not infringed by the manufacture, use, sale, offer to sell, or importation of Lilly's Erbitux® (cetuximab) product. (The Cabilly II patent and Cabilly III patent are collectively referred to as the "Cabilly Patents").

2. ImClone Systems Incorporated ("ImClone") first received approval for Erbitux in the United States in 2004 for the treatment of certain types of colorectal cancers. Beginning in 2006, ImClone received approval for Erbitux for the treatment of certain types of head and neck cancers as well. Lilly has a commercial agreement with Bristol-Myers Squibb Company and E.R. Squibb & Sons, LLC (collectively "BMS") relating to Erbitux. Lilly co-develops Erbitux in the U.S. and Canada with BMS. Lilly is responsible for the manufacture and supply of all requirements of Erbitux in bulk-form active pharmaceutical ingredient ("API") for clinical and commercial use in the U.S. and Canada. BMS purchases all of its requirements of API for commercial use from Lilly and exclusively sells Erbitux in the U.S. and Canada. Eli Lilly and Company acquired ImClone in 2008 and ImClone currently operates as a wholly-owned subsidiary of Eli Lilly and Company.

3. Lilly brings this action to lift the cloud created by the imminent threat of Defendants' enforcement of the Cabilly Patents against Lilly. Without declaratory relief, the threat of enforcement of the Cabilly Patents poses a substantial risk of injury to Lilly as well as the patients, nurses, and physicians now using Erbitux for treatment. The continued existence and enforcement of these invalid and unenforceable patents impedes not only the development and sale of Erbitux, but also the development and sale of other life-saving recombinant antibody products.

4. Defendants have asserted that the Cabilly II patent broadly covers the use of certain well-known, conventional recombinant methods to produce any antibody product in any type of host cell. For example, according to Sean Johnson, Genentech's then Vice President of Intellectual Property, "[t]he recently issued [Cabilly II] patent *broadly* covers the co-expression of immunoglobulin heavy and light chain genes in a single host. We do not believe the claims are limited by the type of antibody… or by [the] host cell type." *See* Debra Robertson, "Genentech awarded critical antibody patent," *Nature Biotechnology* 20, 108 (2002) (attached as Exhibit D). Defendants have filed infringement claims under the Cabilly II patent against companies who have made and sold antibody products that were produced using recombinant methods similar to the recombinant methods used by Lilly to make Erbitux.

5. In public statements, Defendant Genentech has specifically identified the Erbitux product as a potential competitor to one of Genentech's own products, and has stated that it expects to be involved in future litigation relating to the enforcement of the Cabilly II patent. *See* Genentech, Inc. (2009), 10-K Annual Report 2008, Retrieved from SEC EDGAR at 13, 25, 39.

6. In response to the Defendants' position that ImClone required a license under the Cabilly Patents to make and sell two antibody products, including a product produced by a similar process as Erbitux, ImClone entered into an agreement with Genentech on January 25, 2005 under which it received, *inter alia*, a non-exclusive license to the Cabilly Patents to make, have made, use, sell and have sold, offer for sale, import and export substances which, but for the license, may infringe one or more claims of the Cabilly Patents (the "Genentech Agreement"). As a result of Eli Lilly and Company's acquisition of ImClone in 2008, Eli Lilly and Company became a licensee to the Cabilly Patents and remains a licensee to date.

7. Lilly has paid, and Genentech has accepted, royalties on sales of Erbitux under the Genentech Agreement.

8. Based on the allegations detailed below, Lilly contends that it has no obligation to pay royalties on the sales of Erbitux, or on any other therapeutic, on any of the Cabilly Patents due to the Cabilly Patents being invalid, unenforceable, and, in any event, not infringed by Lilly.

9. Defendants' past acts and public statements show that Defendants believe

therapeutics like Erbitux fall within the scope of the Cabilly Patents, that Defendants believe they are entitled to royalties on the Cabilly Patents, and that Defendants intend to pursue an aggressive litigation policy to protect against alleged infringement of the Cabilly Patents. *See* ¶¶ 106-118 *infra*. Indeed, prior to Lilly's acquisition of ImClone, ImClone temporarily ceased payments of royalties for the license to the Cabilly Patents under the Genentech Agreement and Genentech threatened to pursue litigation against ImClone for this temporary failure to pay royalties. As such, a real, immediate, and substantial dispute exists between the parties concerning the Cabilly Patents for which Lilly now seeks declaratory relief, specifically, whether the manufacture, importation, offer to sell, sale, or use of Erbitux in the United States infringes any valid and enforceable claim of the Cabilly Patents.

THE PARTIES

10. Plaintiff Eli Lilly and Company is an Indiana corporation having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly and Company is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

11. Plaintiff ImClone Systems LLC is a Delaware limited liability company having its principal place of business at 440 Route 22 East, Bridgewater, New Jersey 08807. ImClone Systems LLC is a wholly owned subsidiary of Eli Lilly and Company.

12. Defendant Genentech is a Delaware corporation having its principal place of business at 1 DNA Way, South San Francisco, California 94080-4990.

13. Defendant City of Hope is a California not-for-profit organization having its principal place of business in Duarte, California. On information and belief, City of Hope has a place of business in this District at 55 Hawthorne Street, Suite 450, San Francisco, California, 94105.

14. On information and belief, Genentech and City of Hope are co-assignees of the Cabilly Patents.

JURISDICTION AND VENUE

15. 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 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).

16. This Court has personal jurisdiction over Genentech based on its principal place of business in California and also based on Genentech consenting to jurisdiction of this Court in the Genentech Agreement. 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 California.

17. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 (b), (c), and (d) 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. In addition, pursuant to the Genentech Agreement, Genentech stipulated and agreed that any disputes arising out of or related to the Genentech Agreement must be brought in this District.

INTRADISTRICT ASSIGNMENT

18. A substantial part of the events or omissions giving rise to the claims occurred in the San Francisco Division.

The Cabilly II Patent Interference

19. On March 25, 1983, Michael Boss, John Kenton, John Emtage, and Clive Wood (the "Celltech applicants") filed their initial application for a patent in the United Kingdom (the "British Patent Application"), presumptively entitling the patent to priority on that date.

20. On March 28, 1989, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,816,397 (the "Boss patent"), which arose from the March 25, 1983 British Patent Application, with Celltech Ltd. ("Celltech") listed as assignee.

21. On April 8, 1983, Shmuel Cabilly, Herbert Heyneker, William Holmes, Arthur Riggs, and Ronald Wetzel (the "Cabilly applicants") filed a patent application in the PTO ("the Cabilly I application") that issued on March 28, 1989, as U.S. Patent 4,816,567 (the "Cabilly I patent"). Messrs. Heyneker, Holmes, and Wetzel were affiliated with Genentech, and Messrs.

Cabilly and Riggs were affiliated with City of Hope. The Cabilly applicants assigned their rights to Genentech and the City of Hope.

22. Before the Cabilly I patent issued, the Cabilly applicants filed a continuation application that claimed priority to the Cabilly I application (the "Cabilly II application"). The Cabilly applicants copied claims from the Boss patent into their then-pending Cabilly II application in order to provoke the PTO Board of Patent Appeals and Interferences ("the Board") to declare an interference proceeding to determine who was entitled to priority for the invention claimed in the Boss patent.

23. In February 1991, the Board declared an interference between the pending Cabilly II application and the Boss patent on the grounds that both the Boss patentees and the Cabilly applicants claimed the same purported invention.

24. Celltech argued that the subject matter at issue in the interference fell "under the doctrine of conception and simultaneous reduction to practice because of the unpredictability of the technology." *Cabilly v. Boss*, 55 U.S.P.Q.2d 1238, 1256 (B.P.A.I. 1998). According to the Boss patentees, therefore, conception of the invention could not occur without an actual reduction to practice of the invention.

25. As discussed below, Defendants, the Cabilly applicants, and their representatives, disagreed, arguing, while under a duty of candor to the PTO, that it would be sufficient to establish a complete conception of the subject matter of the claimed invention merely by showing inventor testimony evidencing nothing more than a strategy for reduction to practice for constructing a bacterial strain for coexpression of both heavy and light chain genes for coexpression of an immunoglobulin molecule.

26. Notably, after termination of the interference, but during subsequent reexamination proceedings related to the Cabilly II patent, while also under a duty of candor to the PTO, Defendants took a diametrically opposed position and made inconsistent representations to the PTO and to the examiners. The Reexamination examiners were: Examiners Padmashri Ponnaluri, Deborah D. Jones, Bennett Celsa, and Evelyn M. Huang.[1] Defendants were aware that the

[1] Examiner Huang replaced primary examiner Celsa during the course of the Reexamination.

Reexamination examiners had not previously been involved in any aspect of the Cabilly II patent prosecution, including the interference proceeding, or the parent Cabilly I patent prosecution, and that the examiners would have thus expected candor to accurately describe any conflicting statements or "mistakes" in the decades-long, and many-thousands-of-pages-long, file wrapper histories. As more fully detailed below, Defendants acted with intent to deceive the PTO by making contradictory factual assertions at a stage of prosecution when the PTO was unable to fully consider the effects of the new and inconsistent positions on patentability. For example, Cabilly applicants, Heyneker and Riggs, testified during the interference proceedings and in subsequent litigation regarding the Cabilly II patent that co-transformation of heavy and light chains in a single host cell was "quite doable" and "had a good chance" of success as of the priority date. By contrast, in attempting to overcome a final obviousness-type double patenting rejection during reexamination, Defendants represented that the subject matter of the claimed invention was a "pioneering advance" in a nascent field of art, *i.e.*, that the claimed invention was made "during the infancy of the biotechnology industry" and that at the time, skilled workers "had only begun to scratch the surface of the understandings necessary to realize [the] potential" of genetic engineering. This inconsistency in Defendants' positions and representations to the PTO is but one example of an extensive pattern of like behavior, detailed more fully below, that evidences Defendants' knowing and deliberate intent to deceive the PTO into allowing the Cabilly II and III patents.

27. During the interference and in subsequent prosecution, the factual misrepresentations made by Defendants went well beyond attorney argument and included percipient witness declarations by Cabilly applicants Shmuel Cabilly, William E. Holmes, Arthur D. Riggs, Ronald D. Wetzel, and other Genentech scientists, including Paul J. Carter, Michael B. Mumford, L. Jeanne Perry, Michael W. Rey, and City of Hope scientist John E. Shively, concerning their interpretations of scientific data and scientific publications. These misrepresentations, detailed *infra*, were extensive and, when viewed as a whole, demonstrate a pattern of behavior that evidences Defendants' intent to violate their duty of candor and to deceive the PTO into issuing the Cabilly II patent. As set out further below, this information was

material to the prosecution and reexamination of the Cabilly II patent, particularly since Defendants knew that positions they took during the interference were diametrically opposed to and inconsistent with the positions they then took during the reexamination.

28. As set out further below, the misrepresentations and withheld information were material to the prosecution and the reexamination of the Cabilly II patent and to the interference, particularly since Defendants' counsel knew that positions they took during the interference were diametrically opposed to and inconsistent with the factual positions they then took during the reexamination. The misrepresentations and withheld information would have been material to the PTO's examination of the Cabilly II claims and, for several reasons, the PTO would not have issued the Cabilly II patent had it known the complete and accurate factual record at the appropriate time. The demonstrated pattern of deception described herein, by making inaccurate representations to the PTO during prosecution, by hiding information from the PTO and the public, and by repeatedly failing to make the necessary inquiry into the underlying facts and circumstances of the case at the appropriate times, evidences inequitable conduct in the prosecution of the Cabilly II patent.

29. The PTO rejected Defendant's arguments raised in the interference regarding the state of the art and the sufficiency of the disclosure to show a completed conception and reduction to practice. Thus, after seven years of adversarial proceedings in the PTO, on August 13, 1998, the Board found that the Boss patentees were entitled to priority over the Cabilly applicants. *See Cabilly v. Boss*, 55 U.S.P.Q.2d 1238 (B.P.A.I. 1998). In its ruling, the Board stated explicitly that "[w]e agree with Boss *et al.* that on the record before us, this case is one where conception and reduction to practice must be concurrent." *Id.* at 1256. The Board concluded that "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. Rather the evidence of record establishes that Riggs had but a research plan." *Id.* (internal citation omitted).

30. The Board concluded that the Cabilly applicants had failed to establish conception or reduction to practice of the claimed inventions prior to March 25, 1983, the filing date of the Boss patent. According to the Board, "there is no evidence that immunoglobulins, multiple chain

proteins, had been produced by recombinant DNA techniques from a single host cell prior to March 25, 1983." 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 a complete conception." *Id.* The Final Decision therefore indicated that the Cabilly applicants were "not entitled to a patent." *Id.*

Defendants' Civil Action to Appeal PTO Board Decision

31. After losing in the PTO, on October 9, 1998, Genentech filed an action under 35 U.S.C. § 146 against Celltech, the owner of the Boss patent, to appeal the decision of the Board awarding priority to the Boss patent. *Genentech, Inc. v. Celltech Ltd.*, 3:1998-cv-03926 (N.D. Cal. Oct. 9, 1998).

32. Celltech answered the complaint and alleged the affirmative defenses of priority of invention by Celltech and a lack of corroboration by Genentech. Specifically, Celltech alleged that "Genentech should not recover on its claim because Genentech has failed to present sufficient evidence to corroborate any alleged conception or alleged actual reduction to practice."

33. While pursuing that action, in early 2000 (two years after Celltech's allegations of affirmative defenses regarding a lack of corroboration and nine years after the PTO declared an interference to decide the ultimate question of priority of invention), Defendants, through counsel R. Danny Huntington and potentially others, first requested that Dr. Shmuel Cabilly, the lead Cabilly applicant, produce documents in his possession potentially relevant to the question of priority. Dr. Cabilly produced for the first time a purported draft patent application dated February 25, 1983 (the "February Draft Cabilly II Application") from his files in Israel. It is not clear in which country this uncorroborated February Draft Cabilly II Application originated. Though Dr. Cabilly alleges to have had the February Draft Cabilly II Application in his possession at all times since leaving City of Hope, Dr. Cabilly has testified that Defendants never asked him to produce the draft application until after termination of the interference, during the civil action, about nine years into the dispute, and approximately seventeen years after the alleged invention.

34. According to Defendants, the February Draft Cabilly II Application established that the Cabilly applicants had conceived of the invention 30 days before the priority date accorded to the Boss patent, based on the filing date for Boss's March 25, 1983 British Patent Application.

35. Taking full advantage of this belated unearthing of evidence, Genentech moved for summary judgment that it was entitled to priority of invention over Celltech. Genentech argued that, because the February Draft Cabilly II application contained every element of the claimed invention, and was dated earlier than the Boss British Patent Application of March 25, 1983, Genentech should be awarded priority of invention.

36. Because the interference turned on evidence of this exact issue, *i.e.*, whether the Cabilly applicants could establish priority of invention prior to March 25, 1983, it is implausible that Defendants and Dr. Cabilly were not aware of the need for evidence of conception and reduction to practice that would have pre-dated the Boss British Patent Application during the seven-year-long interference proceeding. The implausibility of Defendants having made no prior request for such evidence from the lead named inventor over all those years is reinforced by Dr. Cabilly's testimony in the form of sworn declarations to the PTO during the interference. There, Dr. Cabilly testified about documents evidencing his work and that of the other Cabilly applicants that was allegedly performed during February 1983 but never mentioned a February draft patent application. The PTO's ruling denying Cabilly priority and awarding the patent to Boss hinged on the lack of corroborated evidence (and in particular written corroboration) that would have supported the Cabilly applicants' story regarding the February 1983 time frame. In its ruling, the Board stated that "[s]tatements in the brief cannot take the place of evidence in the record" and specifically cited Dr. Cabilly as himself failing to provide adequate written corroboration of his testimony regarding "any date the work was done." *Cabilly v. Boss*, 55 U.S.P.Q.2d 1238, 1250-51 (B.P.A.I. 1998).

37. Based on the Board's view that the Cabilly applicants failed to proffer sufficient written documentation as corroboration of their alleged invention prior to March 25, 1983, and because the later-produced February Draft Cabilly II Application purports to provide the much-

needed proof of conception that was lacking throughout the entire seven-year interference proceeding, any reliance on the truth of Defendants' and Dr. Cabilly's representations regarding the February 25, 1983 Draft Cabilly II Application is not reasonable. Dr. Cabilly had worked with Defendants' counsel, R. Danny Huntington, on the priority case during the interference. Dr. Cabilly had previously submitted multiple sworn declarations on the exact subject of conception and reduction to practice and produced notebooks and other information concerning the development of expression vectors and their alleged use to cotransform single cells to express heavy and light chains, yet he failed to disclose the February Draft Cabilly II Application during the entire course of the interference.

38. From this evidence, the single most reasonable inference is that Defendants' counsel, R. Danny Huntington, and Dr. Cabilly knew or should have known that the February Draft Cabilly II application did not, in fact, support a finding of conception, *see* ¶¶ 39-40, 50-53 *infra*, and that they withheld the February Draft Cabilly II application with an intent to deceive the PTO.

39. Celltech responded by demonstrating that the February Draft Cabilly II Application fell short of satisfying the legal requirements for conception, in that it did not set forth each and every element of the invention. In fact the February Draft Cabilly II application had a section heading entitled "Reconstitution [refolding] of Antibody from Recombinant K and Gamma Chains," for which the corresponding section body was left completely blank. Therefore, the February Draft Cabilly II Application that formed the entire basis of Genentech's claim to priority in the District Court action had absolutely no description or enabling teaching as to a critical part of the purported invention. In particular, the February Draft Cabilly II Application failed to describe or enable a single embodiment for producing functional antibodies in a single host cell. In other words, the February Draft Cabilly II Application exposed the fact that Defendants had neither successfully made an antibody as of February 1983, nor had they conceived of how to do so at that time. Celltech also pointed out that Genentech had changed its basic theory of conception and reduction to practice from what it had asserted before the PTO.

40. Cabilly applicant Wetzel did not disagree with Celltech's statements regarding the

February Draft Cabilly II Application's infirmities, *i.e.*, that it showed Cabilly did not have a complete conception of the alleged invention by the February 25, 1983 date. In fact, upon information and belief, Cabilly applicant Wetzel did not remember being involved with any work underlying the alleged Cabilly II invention at the time the February Draft Cabilly II application was prepared, nor could Wetzel identify anything in the February Draft Cabilly II application that was representative of his work on reconstitution of separate heavy and light chains into a complete immunoglobulin molecule. In fact, upon information and belief, Wetzel stated affirmatively, in a August 5, 2008 deposition: "I have no memory of [the February Draft Cabilly II] application."

41. An intent to deceive the PTO on the issue of priority by Defendants, the Cabilly applicants, and their representatives, specifically Defendants' counsel, R. Danny Huntington, and Dr. Cabilly, is the most reasonable inference to be drawn from the fact that the February Draft Cabilly II application was found and disclosed only to the District Court and not the PTO at the appropriate time during the first interference. Not only should the veracity and authenticity of the February Draft Cabilly II application itself have been called into question by this late and selective disclosure, but its existence and contents were directly contradictory to evidence and testimony Defendants previously presented to the PTO. Defendants did not inform the District Court or the PTO of such contradictions when the February Draft Cabilly II application was disclosed. In 1999, Dr. Cabilly was deposed and testified under oath that he had "no notes prior to April 30th" that show a co-transformation of heavy and light chains. Dr. Cabilly also affirmatively swore that "I couldn't find any evidence of coexpression of the FAB fragment" at any time in February or March, 1983. An intent to deceive the PTO is the only plausible inference to be drawn from the entirely contradictory misrepresentations of material fact regarding conception, reduction to practice, and fundamentally, the patentability of the Cabilly II patent.

42. Genentech argued that the February Draft Cabilly II Application contained at least as much detail as Celltech's own March 25, 1983 British Patent Application, and moved for summary judgment that Celltech was not entitled to the March 25, 1983 priority date in view of

the February Draft Cabilly II Application.

43. Celltech challenged Genentech's Summary Judgment Motion and prevailed.

44. Despite prevailing on Summary Judgment and with a clear indication that its Boss patent had priority over the Cabilly applicants' pending application, Celltech elected to enter into a settlement agreement with Genentech wherein Celltech received royalty payments and other considerations including future revenue streams when the term of patent protection for the technology originally claimed in the Boss patent was extended until 2018 instead of expiring in 2006.

45. The agreement was reduced to writing by Defendants and Celltech no later than March 6, 2001. Genentech and Celltech entered into the "Settlement Agreement Between Genentech, Inc. and Celltech Chiroscience Limited," the "Amended and Restated License Agreement Between Genentech, Inc. and Celltech Chiroscience Limited" and another license agreement with Celltech, the terms of which were negotiated concurrently. Genentech and Celltech entered into at least the following additional agreements: the "Settlement Negotiation and Alternative Dispute Resolution Agreement," dated September 18, 2000; and two untitled agreements between Genentech and Celltech, each of which is dated March 1, 1991, and, as pleaded by other parties challenging the Cabilly Patents, it was stated that each agreement contained a provision that stated that the parties "anticipate that an interference proceeding may be instituted in the United States Patent and Trademark Office involving the Boss and Cabilly patents and patent applications and patents related thereto" and that they "shall enter into an interference settlement agreement with the objective of resolving issues of priority."

46. According to public statements made by Celltech and the proposed order submitted to the Court, Defendants and Celltech entered into the above settlement agreements with bad faith intent to deceive the PTO and the Court as illustrated by the fact that the agreements called for Celltech to concede priority to Defendants. Celltech did so, notwithstanding the fact that it had just defeated Defendants' summary judgment motions and that Celltech had established priority in the PTO after a seven-year-long interference proceeding with the Board awarding priority judgment in Celltech's favor.

47. The agreements required Defendants to make Celltech whole by paying Celltech for the royalties it would have received at least under the remaining term of the Boss Patent and other consideration. Such payment made by Defendants to Celltech, as well as other consideration, provided Celltech all the benefits it would have received had it preserved the victory it obtained in the interference at the PTO. According to UCB S.A., Belgium which acquired Celltech in 2004, the settlement agreements confirm that this consideration in fact did flow from Defendants to Celltech, in various forms, including giving Celltech "preferential access" to the soon-to-be-issued Cabilly II patent, and "royalty" payments to Celltech in exchange for agreeing to allow cancellation of the Boss Patent claims. *See* Exhibit E (Press Release stating that "By this settlement, Celltech will be compensated by Genentech in terms of income from sales of products which would otherwise have been covered by the Boss patent until its normal expiry date in 2006. Celltech has also secured rights to Genentech's Cabilly patent for its products."). Upon information and belief, the terms of this agreement represent Defendants' intent to deceive the PTO by circumventing the PTO's ability to meritoriously award patent rights and instead unknowingly sanction the parties' intentions to unlawfully divide and allocate the market for methods of making immunoglobulins based on patent rights that are now set to expire in 2018—twelve years longer than after the issued Boss Patent would have expired.

48. As admitted by one of the Cabilly applicants, Herbert L. Heyneker, Genentech's strategy was and always had been to limit competition. According to Cabilly applicant Heyneker, Genentech said, "Look, you get those licenses [only] in a certain field. *We will not put a competitor in place*." Herbert L. Heyneker, Ph.D., *Molecular Geneticist at UCSF and Genentech, Entrepreneur in Biotechnology*, an oral history conducted by Sally Smith Hughes, Ph.D. in 2002, Regional Oral History Office, The Bancroft Library, University of California, Berkeley, 2004 at 188. (Emphasis added.) The agreement between Defendants and Celltech was part of Defendants' overall deceptive and inequitable strategy—to illegally limit competition and provide preferential access to Celltech in exchange for sharing the commercial antibody market. In Cabilly applicant Heyneker's words, "if you want to express antibodies in a heterologous system—so not in a natural environment but in bacteria or fungi or eukaryotic cells—you have to knock on Genentech's

door." *Id.* at 146.

49. On March 6, 2001, the parties to that action filed a notice of settlement and joint request for entry of settlement instruments with the District Court and lodged a Proposed Order Regarding Resolution of Interference purportedly resolving the Defendants' dispute with Celltech. The proposed order contained as a purported finding the demonstrably false assertion that Defendants had won the priority dispute, based upon the February Draft Cabilly II Application proving conception prior to the Boss patent. The District Court plainly relied upon these false statements when signing its Order Regarding Resolution of Interference. An intent to deceive the District Court and the PTO is the single most reasonable inference to be drawn from Defendants' counsel deliberately including these false statements in the Notice of Settlement and Joint Request for Entry of Settlement Instruments to persuade the Court to sign the Order without conducting a hearing and rendering its own findings of fact on the issue.

50. Indeed, Celltech previously argued explicitly to the Board during the interference that a strategy or plan for producing antibodies in the manner described in the February Draft Cabilly II Application was insufficient to support a finding of priority, and the Board agreed. It was not until after the Board ruled against Defendants on this basis that Defendants purportedly unearthed the February Draft Cabilly II Application and argued its alleged teaching to the District Court. Had the February Draft Cabilly II Application been presented during the interference, the Board would have properly evaluated the February Draft Cabilly II Application for corroborated evidence of conception and reduction to practice, as well as for descriptive support for the interference count. For example, as set forth in the Board's decision awarding priority to Boss, Cabilly was required to demonstrate a "successful experiment." *Cabilly v. Boss*, 55 U.S.P.Q.2d 1238, 1239 (B.P.A.I. 1998). But the February Draft Cabilly II Application did not show such success. Had Cabilly presented the February Draft Cabilly II Application to the Board, this same logic of needing to demonstrate a successful experiment would have precluded the Board from awarding priority to Cabilly.

51. For example, Celltech's expert, Dr. Dennis Burton, stated in his expert report that "[e]xpression of the heavy and light chains from cotransformed *E. coli* host cells as described in

Genentech's patent application does not produce correctly folded Ig [immunoglobulin] molecules or immunologically functional Ig fragments . . .. [A]s of March 25, 1983, a scientist of ordinary skill in the art would not, without extensive experimentation, have been able to arrive at refolding conditions capable of generating an immunologically functional protein. Indeed, even after extensive experimentation, proper folding conditions may not have been possible to find. Genentech never determined such refolding conditions."

52. Celltech's expert, Dr. Jonathan Weissman, likewise opined during the District Court action that Defendants failed to demonstrate a successful experiment. He stated that "[b]ecause they did not determine the conditions needed to refold the expression product of the cotransformed *E.coli* cells into immunoglobulin molecules, Genentech's inventors never completed conception of the count. The refolding example given in Genentech's patent application would not enable another scientist to correctly refold an immunoglobulin molecule or produce an immunologically functional molecule."

53. Defendants indirectly agreed with Dr. Burton's and Dr. Weissman's assessments of the inadequacy of the Cabilly applicants' disclosure. Specifically, while admitting that the February Draft Cabilly II Application contained a similar level of detail as Celltech's March 25, 1983 British Patent Application, Defendants also asserted that the "British Application was 'not sufficient' to teach one of ordinary skill how to make and use the invention, because . . . the '[f]olding of an immunoglobulin is a difficult problem,'" and that, as a matter of law, Celltech was "not entitled to a priority date based on its [March] 25, 1983 British application," a position Defendants supported by reference to Celltech's expert, Dr. Burton.

54. Defendants' knowing and deliberate decision to seek an Order directing the issuance of the Cabilly II patent, with no further review by the PTO, was intended to deceive the PTO and the District Court and, upon information and belief, was carried out with the specific purpose of ensuring issuance of a patent that would not have issued following any meaningful scrutiny by the PTO. Upon information and belief, Defendants acted in concert with Celltech and a private consultant to ensure that the District Court would not scrutinize the basis for the parties' settlement. Further, the settlement was designed to ensure that the PTO could not meaningfully

examine the February Draft Cabilly II Application and that Defendants (and Celltech) would now have a total of 29 years of protection for the patented technology. Specifically, instead of the Boss patent expiring in 2006, the Cabilly II Patent was set to expire in 2018.

55. Accordingly, 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 over the Celltech applicants for the identical inventions previously claimed in the Boss patent. *See* Exhibit E. The precise terms of the settlement agreement are confidential and are unknown to Lilly.

56. After the District Court entered its judgment in the Cabilly/Boss interference pursuant to the terms of the settlement, the Board issued an opinion in which it expressed concerns on the record about the settlement. Among other things, the Board noted that the agreement effectively created a 29-year patent: "We will note that if a patent is issued to Cabilly, its term will begin to run now and the public has already been subject to patent rights of Boss since 1989, and that the interference has been pending since 1991." *Cabilly v. Boss*, Interference No. 102,572, 2001 WL 1585450, n.7 (B.P.A.I. July 25, 2001).

57. The Board also expressed concern that Celltech had seemingly abandoned a winning position. In particular, there was no indication that Celltech had raised with the District Court the issue of whether Defendants' newly discovered February Draft Cabilly II Application should have been precluded from evidence because Defendants had not shown that they were diligent in locating this evidence during the more than seven-year interference proceeding before the PTO. *Cabilly*, 2001 WL 1585450, at n.7.

58. If the Board's decision in favor of the Boss patent had not been reversed as a result of the Genentech-Celltech agreement, the Boss patent would have expired in 2006, and the public would thereafter have been free to use the inventions as now claimed in the Cabilly II patent. Instead, Defendants received the Cabilly II patent, which is not set to expire until 2018. Consequently, due to the private Genentech-Celltech agreement, Defendants have ostensibly extended their power to exclude others from making, using, or selling technology originally

claimed in the Boss patent until 2018, more than 35 years after their filing of their original patent application in 1983, and more than 12 years after the expiration of the Boss patent.

59. According to Genentech's 2009 Form 10-K filing for the year ending 2008, Defendants received $256 million in royalties on the Cabilly II patent in 2007 and $298 million in royalties on this patent in 2008. In short, two years after the original expiration date of the Boss patent, Genentech received over $550 million in royalties on the inventions claimed in the Boss patent. Genentech continues to receive substantial royalties on the Cabilly Patents to this day.

Defendants' Failure to Timely Submit Settlement Agreement to PTO

60. Under 35 U.S.C. § 135(c), any agreement to settle a patent interference must be filed with the PTO before the interference terminates, because, as explained by the Senate Report related to this legislation, "[i]nterference proceedings may be terminated in a manner hostile to the public interest by using patent interference settlement agreements as a means of restricting competition," and "[t]o make such a practice more difficult the bill requires the filing of such agreements" with the Board. *See Moog Inc. v. Pegasus Laboratories, Inc.*, 521 F.2d 501, 506 (6th Cir. 1975) (quoting S. Rept. No. 2169, 87th Cong., 2d Sess., Reported in 2 U.S. Code Cong. & Admin. News, pp. 3286, 3289 (1962)). Indeed, the public interest in mitigating anticompetitive patent interference settlements is so strong that failure to provide a copy of any settlement agreement to the PTO under 35 U.S.C. § 135(c) before the interference terminates "shall render permanently unenforceable such agreement or understanding and any patent of such parties involved in the interference or any patent subsequently issued on any application of such parties so involved."

61. By plain application of this statute, therefore, Defendants were required by law to file with the Board all instruments relating to the settlement of the Boss-Cabilly interference, by a date no later than the termination of the interference. This includes the settlement documents, and any related collateral or underlying agreements, that accompanied Defendants' and Celltech's sealed filing of the Notice of Settlement and Joint Request for Entry of Settlement Instruments in the District Court proceedings. The interference terminated on March 16, 2001, which was the date the District Court entered its Judgment and Order Regarding Resolution of Interference.

62. On July 25, 2001, more than four months after the District Court entered the March 16th Order and Judgment, the Board issued an Order notifying Defendants that, "if there is a settlement agreement, attention is directed to 35 U.S.C. § 135(c)." On information and belief, the Board's Order constituted notice that no settlement agreements had been filed and that the statutory deadline for submitting these agreements had not been met. As a result, the Cabilly II patent would be unenforceable by operation of 35 U.S.C. § 135(c).

63. Upon information and belief, Defendants had no intention of ever filing the settlement agreement with the Board to avoid any scrutiny of the collusive settlement agreement that was designed to extend the patent term of the claimed invention beyond the projected 2006 expiration date of the Boss patent.

64. Indeed, upon information and belief, both Defendants and Celltech were well aware at that time that the settlement agreement would raise red flags for the antitrust and other regulatory authorities and third parties, as indicated, by Celltech's statement to a mediator during negotiation of the settlement agreement that "settlement of this dispute may draw scrutiny from the Department of Justice or the FTC as well as third parties."

65. Moreover, to this day, Defendants continue to deny access to the terms of the settlement agreement to any party that has petitioned for access to the agreements, either to the PTO or during the course of any litigation. Defendants have filed oppositions to public requests under the Freedom of Information Act for parties to gain access to the settlement agreement, and Defendants have argued against releasing the settlement agreements to parties in the course of discovery involving the Cabilly II patent.

66. Defendants' counsel filed with the PTO a Contingent Petition for Acceptance of Settlement Agreement ("Contingent Petition"). Because Defendants had failed to file the settlement agreement by the statutory deadline, a showing of "good cause" to the Director of the PTO was required for the late filing to be considered by the PTO. *See* 35 U.S.C. § 135(c) (the PTO Director may "on a showing of good cause for failure to file within the time prescribed, permit the filing of the agreement or understanding during the six-month period subsequent to the termination of the interference as between the parties to the agreement or understanding.").

67. This Contingent Petition was not received by the PTO until September 24, 2001, more than six months after the interference terminated on March 16, 2001. Thus, Defendants failed to comply with the requirements of 35 U.S.C. § 135(c) for failing to timely file the settlement agreements prior to the resolution of the interference, and for failing to timely file their Petition with the Director alleging "good cause" for the delay in filing the settlement agreements. Defendants, through their attorneys, knowingly, deliberately, and with intent to deceive the PTO averred that they were "not aware of the [settlement] Agreement until a time subsequent to the time for taking an appeal…."

68. The assertion that Defendants were "not aware of the [settlement] Agreement" was false. To the contrary, Defendants had submitted numerous settlement-related documents with the Board only weeks earlier. On March 6, 2001, Genentech filed the Notice of Settlement and Joint Request for Entry of the Settlement Instruments in the U.S. District Court (N.D. California). On June 1, 2001, Genentech filed additional settlement documents with the PTO but not the one pertaining to the Notice of Settlement filed with the District Court on March 6, 2001. It was not until September 24, 2001, after the Interference had been terminated, and more than six months after initially filing the Notice of the same agreement in the District Court, that Genentech filed the agreement with the PTO.

69. Because Defendants failed to comply with the requirements of 35 U.S.C. § 135(c), the Cabilly II patent is permanently unenforceable by operation of 35 U.S.C. § 135(c).

70. The affirmative material misrepresentations that Defendants made to the Director in its Contingent Petition, *i.e.*, that Defendants were not aware that the interference had terminated and were "not aware of the [settlement] Agreement," were intended to deceive the PTO regarding Defendants' failure to comply with the statutory requirements of 35 U.S.C. § 135(c). The statement of purported good cause as required to be filed in the Contingent Petition to the Director was false and made with the fraudulent intent to deceive the Director into accepting the late filing of settlement documents.

71. But for Defendants' knowing and deliberate misrepresentations, the Director would not have accepted Defendants' late filing of the agreement. In the Board's "Decision on

Petition for Late Filing of Interference Settlement Under 37 C.F.R. § 1.666(c)," dated September 19, 2002, the PTO Chief Judge Bruce H. Stoner, Jr., held that "[a]fter a review of the record, the settlement agreement accompanying this petition is accepted as timely filed," necessarily finding a showing of good cause to permit the untimely filing of the agreement under 35 U.S.C. § 135(c). Such review demonstrated that, per the requirements of the statute, the truthfulness or falsity of the reason for the late filing was material to the Board such that it conducted a review of the petition and the record to evaluate and rule on the merits of the petition. Indeed, given the PTO's limited statutory discretion to accept late settlement filings only "on a showing of good cause for failure to file within the time prescribed," the Board necessarily would have found Defendants' misrepresentations that the Cabilly applicants' attorneys were "not aware" of the settlement agreement, or when the interference terminated, as highly material. The PTO was statutorily required to condition any late acceptance of the documents on proof of "good cause," and Defendants' false justification for the late filing necessarily negates any good cause. Defendants acted with intent to deceive the Board into accepting a late-filed agreement based on fraudulently attesting that there was a good cause basis to accept the agreement. The misrepresentations are but-for material because, had the Board known of Defendants' deceptive intent in getting the Board to accept the late filing, through false statements made by its attorneys, this bad faith would have prohibited the Board from accepting the agreement and would have rendered the Cabilly II patent permanently unenforceable. The Board would not have accepted the late-filed settlement agreement or issued the Cabilly II patent but for Defendants' fraud.

72. Deceptive intent is also the single most reasonable inference to be drawn from the evidence that Defendants' counsel, R. Danny Huntington, misrepresented material information concerning his knowledge of the settlement agreement itself, given Mr. Huntington's prior involvement as Genentech's litigation counsel during the District Court proceedings. Moreover, Mr. Huntington's allegation that he was "not aware" of the settlement agreement until after the termination of the interference is implausible given his long-standing role in the case and given evidence that such documents were previously served upon him. Regardless, Defendant Genentech was obviously aware of the settlement agreement and was statutorily required to file a

copy of the agreement with the PTO.

73. Because Defendants, through their aforementioned counsel, failed to comply with the requirements of 35 U.S.C § 135(c), both the agreement and the Cabilly II patent itself are permanently unenforceable by statute.

The Cabilly II Patent Obtained By Inequitable Conduct

74. Once the Cabilly applicants won the interference and were awarded priority over the Boss patent by way of the settlement with Celltech, the PTO resumed further examination of the Cabilly II application.

75. Defendants' counsel knowingly, and with the intent to deceive the PTO, affirmatively made false statements to the new PTO examiner during prosecution of the Cabilly II application beginning in October 2001. The PTO examiner, Philip Gambel, had issued a rejection of the pending claims of the Cabilly II application, directed to methods of expressing heavy and light chains in a single host cell, as being patentably indistinct for obviousness-type double patenting over the issued claims in the Cabilly I patent, which were directed to methods of expressing heavy or light chains in a single cell. Defendants' prosecution counsel, Sharon Crane and Wendy Lee, in an interview with Examiner Gambel, falsely stated that the obviousness-type double patenting rejection did not apply in view of a restriction requirement. As documented in an October 4, 2001 Interview Summary by Examiner Phillip Gambel, Defendants' attorneys, Ms. Crane and Ms. Lee, falsely represented that the PTO restricted the claims of the Cabilly I application to heavy and light chains in a single host cell versus heavy or light chains in a single host cell to overcome the obviousness-type double patenting rejection of the Cabilly II application over the Cabilly I application.

76. Defendants' counsel knowingly, and with intent to deceive the PTO, represented to Examiner Gambel that the obviousness-type double patenting rejection was overcome by a requirement for a restriction in the Cabilly I application, which was never issued during prosecution of Cabilly I. Further, the Cabilly II application is a continuation of the Cabilly I, and not a divisional application, as is also required to overcome a double patenting rejection. *See* 35 U.S.C. § 121 and MPEP 804.01 (prohibiting double patenting rejections only in a divisional

application filed as a result of a PTO requirement for restriction). Nonetheless, the October 4, 2001 Interview Summary by Examiner Gambel confirms in writing that Defendants' counsel made that statement. They did so despite knowing that the restriction requirement they relied on was, in fact, made in the Cabilly II application, not the Cabilly I application, which is irrelevant to the question of obviousness-type double patenting of Cabilly II over Cabilly I, and they did so despite knowing that the Cabilly II application was not a divisional of the Cabilly I application. Defendants' counsel, therefore, knew that the Cabilly II application was not subject to the protections of 35 U.S.C. § 121 against a rejection for obviousness-type double patenting. Yet Defendants' counsel misrepresented the facts to Examiner Gambel in a knowing and willful attempt to deceive the PTO into issuing the Cabilly II patent.

77. Defendants' counsel's misrepresentation is highly material because Defendants' counsel did not offer any substantive challenge to the rejection other than the reliance on a non-existent restriction requirement. Thus, the PTO would not have withdrawn the double patenting rejection but for this attestation by Defendants' counsel, and the PTO would have maintained the rejection that the claims of the Cabilly II application were unpatentable over the Cabilly I patent claims. In other words, Defendants' misrepresentation to the PTO during the late-stage interview in Cabilly II prosecution was material because the PTO would not have allowed the pending claims of the Cabilly II application, or would have required a terminal disclosure, had the PTO been aware that there was no restriction requirement issued during prosecution of the Cabilly I patent.

78. An intent to deceive the PTO is the single most reasonable inference to be drawn from this evidence, given that Ms. Crane and Ms. Lee should have known as a basic matter of patent law that a restriction requirement in the Cabilly II application was entirely irrelevant to addressing a double patenting rejection over the prior Cabilly I application. Moreover, Ms. Crane and Ms. Lee had been involved in the prosecution of the Cabilly II application throughout its long and extensive history and should have been well aware that the Cabilly II application was a continuation application, not a divisional application. The most reasonable inference from Ms. Crane and Ms. Lee's actions is, therefore, one of deceptive intent. Defendants' counsel

breached their duty of candor and good faith in dealing with the PTO and thereby committed inequitable conduct.

79. Defendants, through their aforementioned counsel and the Cabilly applicants, also made directly contradictory statements regarding a key prior art reference, Valle, distinguishing it before the PTO because it taught the use of mRNA (messenger RNA), rather than DNA. Yet, Defendants' counsel made statements to the PTO that directly contradicted statements they had made to the European Patent Office ("EPO") when challenging the validity of the European counterpart to the Boss patent in an EPO opposition proceeding, a post-grant procedure allowing for the challenging of a granted European patent. Defendants knowingly and deliberately took fundamentally inconsistent positions in the PTO from that which they took in the EPO regarding the Valle reference. In a filing before the PTO in 1991, Defendants' patent prosecution attorney, Max D. Hensley, represented that the Valle article was not invalidating prior art with respect to the Cabilly II application because it disclosed work using mRNA rather than DNA. Specifically, Defendants asserted that "[w]ork of this sort is readily distinguishable from the instant claims in that the oocytes are not transformed with DNA, but instead are used to transiently express mRNA preparations." *See* Sept. 20, 1991 IDS at 2.

80. But in challenging certain claims of the European Boss patent which contained method claims of similar scope to the Boss application filed in the U.S., especially with respect to the use of DNA in these method claims, Defendants' attorney, John David Brown, took the exact opposite position, representing that Valle was invalidating prior art based on directly contradictory factual assertions regarding the distinction between mRNA, which was used in the Valle article, and DNA, which was claimed in the European Boss patent: "[i]n view of the broad implications evidenced by the Abstract, the fact that the actual experiment was performed with microinjected mRNAs is not relevant. In any event, because the messenger RNA carries the information from DNA to the ribosomal sites of protein synthesis, it is functionally equivalent to DNA." *See* Genentech's April 19, 1994 Notice of Opposition at 17.

81. Defendants' representations to the PTO purporting to distinguish their claims involving DNA over the Valle reference also stand at odds with their representations to the EPO

regarding another significant prior art reference, Colman, *et al.*, "Interactions of mouse immunoglobulin chains within Xenopus oocytes," J. Mol. Biol. 160(3): 459-74 (1982). Specifically, in attacking the European Boss patent, Defendants' attorney, Mr. Brown, represented that the Colman reference "clearly discloses the expression of complete immunoglobulin molecules in eukaryotic cells, into which mRNAs encoding Ig heavy and light chains were introduced separately." *See* Genentech's April 19, 1994 Notice of Opposition at 21.

82. An intent to deceive is the most reasonable inference to be drawn from the evidence given the focus of the Valle and Colman references in prior proceedings involving Defendants. But for Defendants' material omissions during prosecution regarding the positions they took in other proceedings, the PTO would not have issued the Cabilly II claims directed to producing immunoglobulin molecules by co-expressing two chains in eukaryotic cells.

83. Defendants also failed to comply with Defendants' obligation, under MPEP § 2004(13), to "highlight those documents which have been specifically brought to [the] applicant's attention and/or are known to be of [the] most significance." To the contrary, Defendants never alerted the PTO to any particular reference, purposely hiding or failing to cite some of the most relevant documents to patentability.

84. Defendants also failed to disclose material information submitted to the EPO during opposition proceedings regarding Defendants' European counterpart patent to the Cabilly I patent, which contained claims of similar scope to the U.S. Cabilly II patent. In May 2001, the EPO's Technical Board of Appeal issued a decision (the "EPO Decision") in which it limited Defendants' patent to a sole claim of a non-glycosylated chimeric immunoglobulin species and found that the specification did not enable the production of an antibody in any eukaryotic host cell, and determined that Defendants were not entitled to claim any process, let alone a process for producing antibodies in mammalian cells. EPO Decision, May 14, 2001 at 5 & 18.

85. The EPO decision and other information from those proceedings was material because it was relevant to the patentability of the claims of the then-pending Cabilly II application. Upon information and belief, Defendants and their representatives, including patent prosecution attorneys such as Ms. Crane, concealed this information knowingly, deliberately, and

with specific intent to deceive the PTO. As a direct result of Defendants' withholding of material information, withholding of inconsistent statements, and mischaracterizations, the Cabilly II patent issued in its current form when it otherwise would not have survived the reexamination procedure.

86. Defendants also committed inequitable conduct before the PTO by making additional statements about the Cabilly invention during reexamination that were fundamentally inconsistent with statements Defendants previously made, including at least during the interference and during prosecution of the Cabilly I patent.

87. For example, in an attempt to demonstrate priority over the Boss patent during the interference, Defendants characterized their invention by stating that, prior to the Boss patent's priority date, "Cabilly had transformed a single host cell with the DNA of at least the variable regions of the heavy and light chains of an Ig molecule, and had independently expressed the DNA of those chains to obtain separate molecules. As such, Cabilly had reduced the invention of Count 1 to practice. While not required by Count 1, Cabilly had also proceeded prior to the filing date of the Boss British priority document to produce reconstituted Ig antibodies and had demonstrated their antigen binding activity." Defendants further stated that "[t]he invention of Count 1 does not require that an active antibody be produced directly." Defendants went on to state that "Boss contends that Count 1 requires that an active product, (*i.e.*, an active immunoglobulin molecule consisting of 4 separate chains) be produced directly. However, this requirement is not an element of the Count. . . Count 1 describes a process for producing an Ig molecule or an immunologically functional Ig fragment, comprising the steps of (i) transforming a single host cell with the DNA sequences for the heavy and light chains of an immunoglobulin molecule, and (ii) expressing both of the heavy and light chains as separate molecules in the single host cell. Nowhere in Count 1 does the language specify that these separate heavy and light chain molecules must associate to form active antibody molecules within the single transformed cell." (Emphases in original.)

88. By contrast, during reexamination of the Cabilly II patent, Defendants, through patent prosecution attorneys such as Jeffery Kushan, and relying on the declaration of Dr. Steven

McKnight, represented to the PTO that claim 1 of the Cabilly II patent, which is identical to the count in the interference, "require[s] three separate steps: (i) a host cell must be transformed with immunoglobulin heavy and light chain DNA sequences; (ii) the DNA sequences must be independently expressed (transcribed and translated) by the host cell to produce polypeptides; and (iii) the polypeptides must be assembled to form an immunoglobulin molecule or an immunologically functional immunoglobulin fragment ('fragment')."

89. Thus, when attempting to establish priority of the invention over the Boss patent, Defendants asserted to the PTO that the Cabilly II invention as captured in the count did not require that an active antibody be produced and that the invention consisted of two steps: (1) transforming a host cell with heavy and light chain DNA, and (2) expressing both the heavy and light chains as separate molecules. When trying to distinguish their invention over the prior art during reexamination, however, Defendants asserted to the PTO that the claimed invention included three steps, including assembly of an immunoglobulin molecule or an immunologically functional immunoglobulin fragment. Defendants, the Cabilly applicants, and Defendants' counsel knew or should have known of these inconsistent representations based on their prolonged involvement in prosecution of the Cabilly patents and failed to disclose these prior inconsistent statements with the specific intent to deceive the PTO. This information was material to at least the reexamination of the Cabilly II patent because it related fundamentally to the scope of the invention as compared to the prior art. But for Defendants' inequitable conduct, the Cabilly II patent would not have survived the reexamination.

90. Finally, Defendants made representations during the reexamination that were fundamentally inconsistent with the sworn testimony of the Cabilly applicants themselves. Most notably, in order to prove conception during the interference proceedings, Cabilly applicants, Heyneker and Riggs, testified during the interference proceedings and in subsequent litigation regarding the Cabilly II patent that co-transformation of heavy and light chains in a single host cell was "quite doable" and "had a good chance" of success as of the priority date. By contrast, in order to overcome an obviousness rejection during reexamination, Defendants represented that co-transformation of heavy and light chains in a single host cell was "unpredictable" as of the

priority date. This information was material to the reexamination of the Cabilly II patent because, among other things, it related fundamentally to the knowledge of one of skill in the art and the obviousness of the Cabilly II claims over the prior art. Defendants knew or should have known of these material inconsistent representations based on their prolonged involvement in prosecution of the Cabilly II patent and related proceedings, and Defendants made these misrepresentations with specific intent to deceive the PTO.

The Cabilly II Patent Reexamination

91. On May 13 and December 23, 2005, two separate requests for reexamination of the Cabilly II patent were filed by third parties.

92. The PTO concluded that the prior art submitted by the requestors raised substantial new questions of patentability with respect to each of the claims of the Cabilly II patent and commenced separate reexamination proceedings on July 7, 2005 and January 23, 2006. *See* Decision Granting *Ex Parte* Reexamination, Reexamination Control No. 90/007,542 (July 7, 2005); Decision Granting *Ex Parte* Reexamination, Reexamination Control No. 90/007,859 (January 23, 2006). The separate reexamination proceedings were merged on June 6, 2006.

93. In an Advisory Action on July 19, 2008, the PTO maintained its final rejection of the claims in the Cabilly II patent as invalid for reasons including obviousness-type double patenting. *Ex Parte* Reexamination Advisory Action, Reexamination Control Nos. 90/007,859 and 90/007,542 (July 19, 2008).

94. In response to the final rejection, Defendants filed an Appeal Brief on December 9, 2008.

95. During Reexamination, the examiners could not consider the issue of priority with respect to the Boss patent, and they had a limited ability to consider issues under 35 U.S.C. § 112. Defendants thus had ample reason to withhold inconsistent statements throughout regular prosecution, which if provided would have lead to a rejection/denial on the issues of lack of written description and/or non-enablement, but Defendants were free to disclose them during the reexaminations.

96. The PTO issued a February 23, 2009 Notice of Intent to Issue a Reexamination

Certificate on February 23, 2009, confirming claims 1-20 and 33-36, allowing amended claims 21, 27 and 32, and confirming claims 22-26 and 28-31 as dependent on amended claims 21, 27 and 32. On May 19, 2009, the PTO issued an *Ex Parte* Reexamination Certificate.

97. An intent to deceive the PTO is the most reasonable inference to be drawn from the evidence that Defendants withheld inconsistent statements during examination and that they contradicted earlier factual assertions during reexamination, a stage of prosecution when the PTO was unable to fully consider the effects of the new/inconsistent positions in several respects. For one, Defendants knew that the Reexamination examiners were limited to considering the issue of validity over the prior art and they had a very limited ability to consider issues of written description, enablement, or any other grounds for patentability under 35 U.S.C. § 112. Defendants, however, made representations during reexamination that were fundamentally inconsistent with their representations made during regular examination. For example, Cabilly applicants, Heyneker and Riggs, testified during the interference proceedings and in subsequent litigation regarding the Cabilly II patent that co-transformation of heavy and light chains in a single host cell was "quite doable" and "had a good chance" of success as of the priority date. By contrast, during reexamination, Defendants represented that co-transformation of heavy and light chains in a single host cell was "unpredictable" as of the priority date. This representation was material to the reexamination of the Cabilly II patent because, among other things, it related fundamentally to the knowledge of one of skill in the art and the obviousness of the Cabilly II claims over the prior art. Defendants knew or should have known of these material inconsistent representations based on their prolonged involvement in prosecution of the Cabilly II patent and related proceedings, and Defendants made these misrepresentations with specific intent to deceive the PTO.

98. The decision following reexamination of the patent by the PTO was the direct result of Defendants' knowing and deliberate misrepresentations, omissions, and inconsistencies, as well as other affirmative egregious misconduct detailed above, but for which the Cabilly II patent would not have survived.

Defendants' Admissions Regarding State of the Art in April 1983

99. In order to overcome the PTO's obviousness-type double patenting rejections during the reexamination, Defendants made a number of admissions in their December 2008 Appeal Brief regarding the state of the art prior to the filing of the Cabilly II patent application in April 1983. According to Defendants, the state of the art prior to the April 1983 filing of the Cabilly patent application was as follows:

a. "[I]n April 1983, the biological mechanisms that controlled expression of foreign DNA and assembly of proteins were not well understood. This lack of understanding was especially true for eukaryotic genes, which were known to be far more complex than prokaryotic genes. As Dr. Harris, one of Owners' experts in this case, explained in his 1983 review paper, 'it is clear that not all the rules governing the expression of cloned genes have been elaborated and those rules that do exist are still largely empirical.'" (Appeal Brief at 20).

b. "In early April of 1983, the field of genetic engineering was still developing . . . . A relatively small number of proteins had been made by recombinant DNA technology. Almost all of those were relatively simple monomeric (*i.e.*, one polypeptide chain) proteins." (Appeal Brief Appendix at B551 [Harris Decl.]).

c. "As of April 1983, insulin was the only 'multimeric' protein that had been made using genetic engineering." (Appeal Brief at 21).

d. "Several experts with actual experience in the field of the invention in April 1983 explained that those references cited by the Examiner that include experimental results show a significant amount of unpredictability in achieving success in simpler experiments than what is required by the '415 patent claims." (Appeal Brief at 28).

e. "[S]uccessful production of immunoglobulins was highly dependent on the sequence of expression and levels at which the two immunoglobulin genes

were expressed." (Appeal Brief at 63).

f. "[L]evels of expression of each immunoglobulin gene could affect production of the other immunoglobulin polypeptide." (Appeal Brief at 63)

g. "Such a person would have been familiar with the many complications of producing eukaryotic polypeptides in bacterial host cells known by April 1983." (Appeal Brief at 73).

h. "I believe a person of ordinary skill in the art, in early April of 1983, would have thought that successful expression of two immunoglobulin proteins in one transformed host cell would have been unpredictable and that assembly of the two proteins into an immunoglobulin tetramer would have been even more unpredictable." (Appeal Brief Appendix at B224 [McKnight Decl.])

i. "Experimental results would have been important to a person of ordinary skill in the art in April 1983 because many of the biological mechanisms that controlled expression of foreign DNA and assembly of proteins were not well understood at that time." (Appeal Brief Appendix at B376 [Second McKnight Decl.]).

j. "Each of these papers shows that successful transformation and expression of even one foreign immunoglobulin gene in a lymphoid host cell could not be reasonably expected in April 1983. I do not believe these references can be read as suggesting that something even more challenging — expressing <u>two</u> different foreign immunoglobulin genes in one transformed cell — would have been something that could be predictably achieved at that time." (Appeal Brief Appendix at B382 [Second McKnight Decl.]) (Emphasis in original).

k. ". . . I disagree with the suggestion, that by early April 1983, my *PNAS* paper had made routine or predictable the task of expressing exogenous immunoglobulin light and heavy chain genes in the same cell. In later

> experiments, I attempted to use the techniques described in the *PNAS* paper to introduce and express single Ig genes into other lymphoid cell lines. Most of these experiments failed to produce stable transfectants. Thus, my experience was that using the same transfection and selection conditions described in the *PNAS* paper with other cell lines or other Ig genes did not routinely yield stable transformants containing even a single exogenous Ig gene." (Appeal Brief Appendix at B391 [Rice Decl.]).

100. In this light, the Cabilly II patent specification failed to contain adequate written description of the purported invention, and to adequately describe the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use the same.

101. Indeed, as described in ¶¶ 39-40, 50-53 *supra*, the expression of heavy and light chains from cotransformed *E. coli* host cells as described in the Cabilly II patent application does not produce correctly folded Ig molecules or immunologically functional Ig fragments and Genentech may have never determined such refolding conditions. Indeed, the February Draft Cabilly II Application does not describe and does not enable a single process for producing functional antibodies, and had a section heading entitled "Reconstitution [refolding] of Antibody from Recombinant K and Gamma Chains," for which the corresponding section body was left completely blank.

102. As such, the Cabilly II patent is invalid under 35 U.S.C. § 112, ¶ 1, for failure to satisfy the written description, and/or enablement requirements.

LILLY'S ERBITUX® (CETUXIMAB) PRODUCT

103. Erbitux® (cetuximab) is an epidermal growth factor receptor ("EGFR") antagonist, first approved by the U.S. Food and Drug Administration ("FDA") in 2004 for treatment of colorectal cancer and in 2006 for treatment of head and neck cancer.

104. Erbitux is a chimeric (mouse/human) monoclonal antibody that binds to the ligand-binding domain of EGFR, a receptor linked to the growth and development of many human cancers, including those of the head and neck, colon, and rectum.

105. Following these FDA approvals, Lilly, in partnership with BMS, has begun marketing and selling Erbitux in the United States, physicians have begun prescribing Erbitux, and patients have begun taking Erbitux to treat the above-mentioned forms of cancer.

LILLY'S DISPUTE WITH GENENTECH REGARDING THE CABILLY PATENTS

106. Through its statements and actions, Genentech has made clear to the biopharmaceutical industry generally, and to Lilly specifically, that it contends that the claims of the Cabilly Patents effectively preclude others from commercially manufacturing recombinant monoclonal antibodies without Genentech's permission. 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."

Genentech Awarded Critical Antibody Patent," *Nature Biotechnology*, vol. 20, p. 108 (Feb. 2002).

107. According to Defendants, the manufacturing method claimed in the Cabilly II patent is "the backbone of recombinant antibody production in the biotech industry." *Centocor, Inc. v. Genentech, Inc.*, Case No. 2:08-cv-03573-MRP-JEM (C.D. Cal.), 3/24/09 (Opening Brief of Claim Construction at 2).

108. Genentech has asserted the Cabilly II patent in litigation against other manufacturers of recombinant monoclonal antibodies, including MedImmune, Inc. ("MedImmune"), Centocor Ortho Biotech Inc. ("Centocor"), Human Genome Sciences ("HGS"), and GlaxoSmithKline LLC ("GSK"). On information and belief, the recombinant methods used by Lilly to produce Erbitux are similar to the recombinant methods used by MedImmune, Centocor, HGS, and GSK to produce their monoclonal antibody products, Synagis®, ReoPro®, Remicade®, Benlysta®, and Arzerra®.

109. On information and belief, Genentech contends that the process and certain

starting materials used to produce Erbitux infringe one or more claims of the Cabilly Patents.

110. For example, both Lilly's Erbitux and MedImmune's Synagis are produced by genetically engineering mammalian host cells to produce the desired antibody in cell culture. Erbitux is produced by genetically engineering mammalian host cells to produce cetuximab in cell culture.

111. On information and belief, Synagis is also produced by genetically engineering mammalian host cells to produce the desired antibody in cell culture. On further information and belief, MedImmune's Synagis and GSK's Arzerra products are manufactured using the same or similar transformation and manufacturing process that is used to manufacture Erbitux. Lilly is informed and believes that Genentech contends that the methods used to produce Erbitux infringe one or more claims of the Cabilly Patents.

112. On information and belief, Genentech has also alleged that the corresponding recombinant methods and starting materials used to produce its Avastin® antibody product fall within the scope of the Cabilly Patents. Like Erbitux, on information and belief, Genentech's Avastin is produced by genetically engineering mammalian host cells to produce the desired antibody in cell culture. If Genentech contends that the manufacturing process to produce Avastin for Genentech falls within the scope of the Cabilly Patents, then Lilly is informed and believes that Genentech also contends that the manufacturing process used to produce Erbitux for Lilly also falls within the scope of the Cabilly Patents.

113. Since Defendants have consistently alleged that the use of well-known, conventional recombinant methods to produce monoclonal antibodies in mammalian cell culture is within the scope of claims of the Cabilly Patents and have asserted the patents against others who are similarly situated to Lilly, Defendants' prior statements and conduct necessarily establish an actual and substantial dispute between Lilly and Defendants regarding the invalidity, unenforceability, and noninfringement of claims of the Cabilly Patents.

114. In addition to the statements and conduct directed at others, Defendants, in particular Genentech, have made statements and engaged in conduct directed at Lilly that create a real and immediate dispute between the parties regarding the Cabilly Patents.

115. Genentech has made public statements about pursuing an aggressive litigation policy to protect its products against competition and to protect against alleged infringement of the Cabilly II patent claims in its 2009 Form 10-K filing for the year ending 2008 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."

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 . . . ."

116. In early 2009, Genentech made public statements specifically identifying Erbitux as an imminent competitor to Genentech's products Avastin and Tarceva® in its filings with the Securities and Exchange Commission.

117. Taken together, Genentech's statements that it will enforce its intellectual property, specifically the Cabilly Patents, to defend its products against competing products, and its contention that Lilly's Erbitux will be a competitor with Genentech's antibody products of Avastin and Tarceva, establish that a real and immediate dispute exists between parties with adverse legal interests concerning the Cabilly Patents.

118. Based on the allegations detailed above, Lilly contends that it has no obligation to pay royalties on the sales of Erbitux, or on any other therapeutic, on any of the Cabilly Patents due to the Cabilly Patents being invalid and unenforceable, and, in any event, not infringed by Lilly. As such, a real, immediate, and substantial dispute exists between the parties concerning

the Cabilly Patents for which Lilly now seeks declaratory relief.

FIRST CAUSE OF ACTION

CABILLY II PATENT INVALIDITY

119. Lilly incorporates the allegations of paragraphs 1 through 118 as if fully set forth herein.

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

121. The Cabilly II patent is invalid because it is anticipated and/or obvious under 35 U.S.C. §§ 102 and 103.

122. The Cabilly II patent is invalid based on the statutory double patenting under 35 U.S.C. § 101 and/or the judicially created doctrine of obviousness-type double patenting.

123. The Cabilly II patent is invalid under 35 U.S.C. § 112, for failure to satisfy the written description, and/or enablement requirements.

124. Lilly seeks a declaratory judgment that the Cabilly II patent is invalid under 35 U.S.C. §§ 101, 102, 103 and/or 112 and/or under the judicially created doctrine of obviousness-type double patenting.

125. Lilly also seeks a declaratory judgment that the Cabilly II patent is anticipated and invalid under 35 U.S.C. § 102(g). Specifically, the Board ruled that the Cabilly applicants were not entitled to priority based on their lack corroborated evidence of conception and reduction to practice.

126. In the appeal of the Board's Decision under 35 U.S.C. § 146, Cabilly provided no independent corroboration verifying that the February Draft Cabilly II Application was generated prior to the Boss British Priority Application. Moreover, even if the February Draft Cabilly II Application was generated prior to the Boss British Priority Application, it does not demonstrate that the Cabilly applicants reduced key elements of the claimed invention to practice or had conceived of means for doing so. As such, Genentech has yet to present any corroborating independent evidence of prior conception and reduction to practice of the interference count at issue in the first interference that would have entitled the Cabilly applicants to priority over the

Boss Application.

127. In the alternative, the February Draft Cabilly II Application originated from Israel. Under the version of 35 U.S.C. §1 04 that was controlling at that time, "an applicant for a patent or a patentee may not establish a date of invention by reference to or knowledge of use thereof, or other activity with respect thereto, in a foreign country." Under 35 U.S.C. § 104, applicants or patentees could not establish a date of invention based on evidence of activity or knowledge of use thereof in a foreign country, such as Israel, that was dated before January 1, 1996.

128. Accordingly, the District Court's reliance of the February Draft Cabilly II Application was improper and impermissible. Once the February Draft Cabilly II Application is properly disregarded, the record is completely devoid of the Cabilly applicants providing any type of corroborating evidence to establish a priority date earlier than the Boss patent. Accordingly, the Cabilly II patent is invalid under 35 U.S.C. § 102(g).

SECOND CAUSE OF ACTION

CABILLY III PATENT INVALIDITY

129. Lilly incorporates the allegations of paragraphs 1 through 128 as if fully set forth herein.

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

131. The Cabilly III patent is invalid because it is anticipated and/or obvious under 35 U.S.C. §§ 102 and 103.

132. The Cabilly III patent is invalid based on the statutory double patenting under 35 U.S.C. § 101 and/or the judicially created doctrine of obviousness-type double patenting.

133. The Cabilly III patent is invalid under 35 U.S.C. § 112, for failure to satisfy the written description, and/or enablement requirements.

134. Lilly seeks a declaratory judgment that the Cabilly III patent is invalid under 35 U.S.C. §§ 101, 102, 103 and/or 112 and/or under the judicially created doctrine of obviousness-type double patenting.

THIRD CAUSE OF ACTION

CABILLY II PATENT NON-INFRINGEMENT

135. Lilly incorporates the allegations of paragraphs 1 through 134 as if fully set forth herein.

136. An actual controversy has arisen and now exists between the parties concerning whether Lilly's manufacturing process or importation or sale of Erbitux infringes any valid and enforceable claim of the Cabilly II patent.

137. Lilly seeks a declaratory judgment that making, using, importing, offering to sell, and selling Erbitux does not and will not infringe any valid and enforceable claim of the Cabilly II patent.

FOURTH CAUSE OF ACTION

CABILLY III PATENT NON-INFRINGEMENT

138. Lilly incorporates the allegations of paragraphs 1 through 137 as if fully set forth herein.

139. An actual controversy has arisen and now exists between the parties concerning whether Lilly's manufacturing process or importation or sale of Erbitux infringes any valid and enforceable claim of the Cabilly III patent.

140. Lilly seeks a declaratory judgment that making, using, importing, offering to sell, and selling Erbitux does not and will not infringe any valid and enforceable claim of the Cabilly III patent.

FIFTH CAUSE OF ACTION

UNENFORCEABILITY UNDER 35 U.S.C. § 135(c)

141. Lilly incorporates the allegations of paragraphs 1 through 140 as if fully set forth herein.

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

143. The Cabilly II patent is unenforceable under 35 U.S.C. § 135(c). On information and belief, Defendants failed to timely provide a copy of any settlement agreement to the PTO

under 35 U.S.C. § 135(c) before the interference terminated in March 2001.

144. Under 35 U.S.C. § 135(c), this failure "render[s] permanently unenforceable such agreement or understanding and any patent of such parties involved in the interference or any patent subsequently issued on any application of such parties so involved."

145. In the alternative, even if Defendants complied with 35 U.S.C. § 135(c) by timely submitting a Petition to showing good cause for late submission of the settlement agreements, Defendants' Petition did not rise to the level of "good cause." Thus, Cabilly II is permanently unenforceable for failure to comply with 35 U.S.C § 135(c).

146. Because Defendants failed to comply with the requirements of 35 U.S.C § 135(c), by statute, the Cabilly II patent is permanently unenforceable.

147. Lilly seeks a declaratory judgment that the Cabilly II patent is unenforceable due Defendants' failure to comply with the requirements of 35 U.S.C § 135(c).

SIXTH CAUSE OF ACTION

UNENFORCEABILITY DUE TO INEQUITABLE CONDUCT

148. Lilly incorporates the allegations of paragraphs 1 through 147 as if fully set forth herein.

149. An actual controversy has arisen and now exists between the parties concerning the enforceability of the Cabilly Patents.

150. Defendants controlled and/or had knowledge of the prosecution of the Cabilly II and III applications, and are therefore accountable for the knowing and deliberate misstatements and omissions set out above, both during prosecution of the Cabilly II application itself and during prosecution of the very closely related Cabilly III application, which shares the same parent application, the same inventors, the same specification, and virtually identical claims.

151. As set out above, during examination of the Cabilly II application, its interference, and its reexamination, and while under a duty of candor to the PTO, Defendants knowingly and deliberately deceived the PTO in a variety of material ways, including, among other things, failing to inform the PTO of inconsistent positions the Defendants took on prior art and enablement issues in other proceedings, such as the European Opposition to the Boss European

Counterpart to the United States Boss Patent, as well as during at least the first Cabilly/Boss interference.

152. In addition, because Defendants failed to comply with 35 U.S.C. § 135(c) requiring that they file any agreement to settle a patent interference before the interference terminates, both the settlement Agreement with Celltech and the Cabilly patents are permanently unenforceable. But for Defendants' knowing and deliberate misrepresentations, the PTO would not have accepted Defendants' late filing of the settlement Agreement, and the Cabilly II patent (and the related Cabilly III patent) would be unenforceable.

153. Because much of the aforementioned egregious misconduct occurred during the Cabilly II prosecution, it also renders the closely-related Cabilly III patent unenforceable for inequitable conduct through the doctrine of infectious unenforceability. Defendants' inequitable conduct in prosecuting the Cabilly II patent permeated and had an immediate and necessary relation to the Cabilly III patent, which has a direct and descendant relationship with the Cabilly II patent. Indeed, the prior inequitable conduct was necessary for the Cabilly III patent to issue at all.

154. The conduct set out above constitutes inequitable conduct, by itself and/or through the doctrine of infectious unenforceability.

155. Lilly seeks a declaratory judgment that the Cabilly II patent is unenforceable due to Defendants' inequitable conduct.

156. Lilly seeks a declaratory judgment that the Cabilly III patent is also unenforceable due to Defendants' inequitable conduct, directly, and/or through infectious unenforceability.

SEVENTH CAUSE OF ACTION

LILLY OWES NO ROYALTIES

157. Lilly incorporates the allegations of paragraphs 1 through 156 as if fully set forth herein.

158. An actual controversy has arisen and now exists between the parties concerning whether Lilly has any obligation to pay royalties to Defendants and/or whether Lilly is entitled to recoup royalties paid to Defendants if the Cabilly Patents are deemed to be invalid or

unenforceable.

159. If the Cabilly Patents are declared to be invalid or unenforceable, Lilly is entitled to a declaratory judgment that Lilly owes no royalties to Genentech and/or City of Hope.

PRAYER FOR RELIEF

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

1. Declaring that Lilly does not infringe any valid claim of either the Cabilly II patent or the Cabilly III patent;
2. Declaring the Cabilly II patent and the Cabilly III patent invalid;
3. Declaring the Cabilly II patent and the Cabilly III patent unenforceable;
4. Declaring that the manufacture, use, sale, offer to sell, or importation of Lilly's Erbitux product does not infringe any valid and enforceable claim of the Cabilly II patent or the Cabilly III patent;
5. Awarding Lilly damages at least equivalent to any unjust enrichment enjoyed by Genentech and/or City of Hope;
6. Awarding Lilly damages at least equivalent to any amounts received by Genentech and/or City of Hope as royalties or other license fees due on account of the Cabilly II patent or the Cabilly III patent;
7. Enjoining Genentech and City of Hope from enforcing the Cabilly II patent or the Cabilly III patent;
8. Awarding Lilly its costs and attorneys' fees;
9. Declaring Lilly's case to be exceptional and awarding Lilly its attorneys' fees and expenses under 35 U.S.C. § 285; and
10. Awarding Lilly such other relief as the Court deems just and proper.

Dated: February 28, 2013

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

By _____
DANIEL JOHNSON, JR.

Attorneys for Plaintiffs
ELI LILLY AND COMPANY and
IMCLONE SYSTEMS LLC

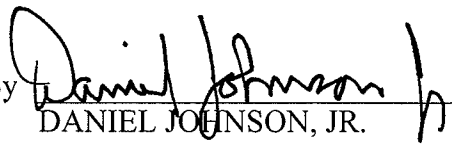
DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38 and Civil L.R. 3-6, Plaintiffs hereby request a trial by jury.

Dated: February 28, 2013

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

By 
DANIEL JOHNSON, JR.

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ELI LILLY AND COMPANY and
IMCLONE SYSTEMS LLC