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Richard W. Wisking
Clerk, U.S. District Court
Northern District of California
San Jose

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

EMC

CEPHEID,

Plaintiff,

v.

ROCHE MOLECULAR SYSTEMS, INC. and
F. HOFFMANN-LA ROCHE LTD.,

Defendants.

CASE NO.

CV 12-04411

COMPLAINT FOR
DECLARATORY JUDGMENT

DEMAND FOR JURY TRIAL

1 **COMPLAINT**

2 Plaintiff Cepheid, by and through its undersigned attorneys, hereby alleges as follows:

3 **NATURE OF THE ACTION**

4 1. Cepheid brings this action under the Federal Declaratory Judgment Act, 28 U.S.C. §§
5 2201 and 2202, for a declaratory judgment of (a) invalidity, expiration, and non-infringement of
6 United States Patent No. 5,804,375 ("the '375 patent"); and (b) invalidity, unenforceability,
7 expiration, and non-infringement of United States Patent No. 6,127,155 ("the '155 patent").

8 2. A copy of the '375 patent is attached as Exhibit A, and a copy of the '155 patent is
9 attached as Exhibit B.

10 **THE PARTIES**

11 3. Cepheid is a corporation organized and existing under the laws of California with its
12 principal place of business at 904 Caribbean Drive, Sunnyvale, California 94089.

13 4. On information and belief, Defendant Roche Molecular Systems, Inc. ("RMS") is a
14 corporation organized and existing under the laws of Delaware, with its principal place of business at
15 4300 Hacienda Drive, Pleasanton, California 94588. On information and belief, RMS owns the '375
16 and '155 patents.

17 5. On information and belief, Defendant F. Hoffmann-La Roche Ltd. ("Hoffmann") is a
18 corporation organized and existing under the laws of Switzerland with its principal place of business
19 at Grenzacherstrasse 124, CH-4070 Basel, Switzerland.

20 6. Collectively, RMS and Hoffmann will be referred to as "Roche."

21 **JURISDICTION AND VENUE**

22 7. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§
23 1331, 1338, 2201, and 2202.

24 8. RMS is engaged in the substantial, continuous, and systematic transaction of business
25 in this judicial district. Hoffmann is an alien that has acted in this judicial district on behalf of itself
26 and RMS with respect to the events that give rise to the claims against Roche. Accordingly, venue is
27 proper in this judicial district pursuant to 28 U.S.C. § 1391.
28

FACTUAL BACKGROUND

15. In a letter to Cepheid dated July 1, 2011, RMS contended that Cepheid's sale of unlicensed Xpert kits is covered by claim 21 of the '375 patent, that Cepheid was required by the

1 License Agreement to cease manufacture or sale of unlicensed Xpert kits, and that Cepheid should
2 pay royalties based on the sale of unlicensed Xpert kits.

3 16. On April 24, 2012, RMS sent to Cepheid an RMS and Hoffman "Term Sheet" for a
4 license under the "Licensed Patents," including the '155 patent, with rights to "make, offer to sell
5 and sell [licensee's] Complete Diagnostic Kits . . .," only so long as the kit is "not covered by any
6 ROCHE patents, [specifically including the '375 patent]."

7 **COUNT I**
8 **(For a Declaratory Judgment that the '375 Patent is Expired and Invalid)**

9 17. Cepheid re-alleges and incorporates by reference, as if fully set forth herein, the
10 allegations contained in paragraphs 1 through 16.

11 18. Because RMS has contended that the '375 patent is valid and necessary for Cepheid's
12 products and because, as shown below, the '375 patent is expired and invalid, a conflict of asserted
13 rights has arisen and a justiciable controversy exists between Cepheid and RMS with regard to
14 whether the claims of the '375 patent are (a) expired and (b) invalid.

15 19. On May 6, 2011, a third-party (not affiliated with Cepheid and not supported or
16 solicited to act by Cepheid) filed an *ex-parte* reexamination request relating to the '375 patent. On
17 July 20, 2011, the United States Patent and Trademark Office ("PTO") granted that reexamination
18 request, finding that a substantial new question of patentability had been raised as to every claim of
19 the '375 patent.

20 20. On July 5, 2011, RMS submitted a request to the PTO to reissue the '375 patent. On
21 July 6, 2011, RMS filed a Preliminary Amendment that added limitations to the independent claims
22 of the '375 patent.

23 21. On January 19, 2012, the PTO issued an Office Action in the reexamination
24 proceeding, rejecting several of the claims of the '375 patent as unpatentable in view of prior art, and
25 rejecting all of the claims of the '375 patent as unpatentable due to non-statutory double patenting.

26 22. On May 3, 2012, in the reexamination proceeding, RMS filed an Amendment and
27 Response Under 37 C.F.R. §1.530 that added limitations to the independent claims of the '375
28 patent. Also on May 3, 2012, RMS filed another Preliminary Amendment in the reissue application.

1 Roche stated that after entry of the two amendments of May 3, 2012, the claims in the reissue
2 application were identical to the claims in the reexamination proceeding.

3 23. On May 17, 2012, RMS filed at the PTO a renewed petition to merge the reissue
4 application and the reexamination proceeding, and on July 13, 2012, the PTO granted RMS's
5 petition.

6 24. One or more claims of the '375 patent are invalid for at least the following reasons:
7 (a) because the alleged invention is anticipated under 35 U.S.C. § 102; (b) because the alleged
8 invention is obvious in view of the prior art under 35 U.S.C. § 103; and (c) because the specification
9 fails to satisfy the requirements of 35 U.S.C. § 112. In addition, one or more claims of the '375
10 patent are invalid under non-statutory double patenting, and expired no later than August 6, 2010, in
11 view of one or more patents commonly owned by RMS, including United States Patent Nos.
12 5,210,015 and 5,487,972, either alone or in combination with prior art. Accordingly, for at least
13 these reasons, Cepheid is entitled to a declaratory judgment that the '375 patent is expired and
14 invalid.

15 **COUNT II**
16 **(For a Declaratory Judgment that the '375 Patent is Not Infringed)**

17 25. Cepheid re-alleges and incorporates by reference, as if fully set forth herein, the
18 allegations contained in paragraphs 1 through 24.

19 26. Because RMS has contended that the '375 patent is valid and necessary for Cepheid's
20 products, and because the '375 patent is not infringed, a conflict of asserted rights has arisen and a
21 justiciable controversy exists between Cepheid and RMS with regard to whether the claims of the
22 '375 patent are not infringed.

23 27. Cepheid has not infringed and will not infringe, either directly or indirectly, any valid
24 or enforceable claim of the '375 patent by importing, making, having made, offering for sale, or
25 selling its Xpert kits, or on any other basis. Accordingly, for at least these reasons, Cepheid is
26 entitled to a declaratory judgment that the '375 patent is not infringed.
27
28

COUNT III
(For a Declaratory Judgment that the '155 Patent is
Expired, Unenforceable, and Invalid)

28. Cepheid re-alleges and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 27.

29. Because RMS has contended that the '155 patent is valid and necessary for Cepheid's products and because, as shown below, the '155 patent is expired, unenforceable, and invalid, a conflict of asserted rights has arisen and a justiciable controversy exists between Cepheid and RMS with regard to whether the claims of the '155 patent are (a) expired; (b) unenforceable; and (c) invalid.

30. One or more claims of the '155 patent are invalid for at least the following reasons: (a) because the alleged invention is obvious in view of the prior art under 35 U.S.C. § 103, and (b) because the specification fails to satisfy the requirements of 35 U.S.C. § 112. In addition, one or more claims of the '155 patent are invalid under non-statutory double patenting, and expired no later than December 26, 2006, in view of one or more patents commonly owned by RMS, including United States Patent No. 4,889,818 ("the '818 patent"), either alone or in combination with prior art. Accordingly, for at least these reasons, Cepheid is entitled to a declaratory judgment that the '155 patent is expired and invalid.

31. The '155 patent is not enforceable because, as shown below, it was procured through false declarations and egregious misrepresentations in its specification and prosecution history. Accordingly, for at least the reasons shown below, Cepheid is entitled to a declaratory judgment that the '155 patent is unenforceable.

The '155 Patent is a Descendant of the Unenforceable '818 Patent

32. The '155 patent is a descendant of the '818 patent, which was judicially found to have been procured through inequitable conduct.

33. In 1993, RMS along with another Roche-related entity (Hoffmann-LaRoche, Inc.) brought suit against Promega Corp. in the United States District Court for the Northern District of California alleging infringement of the '818 patent. *Hoffmann-La Roche, Inc. v. Promega Corp.*, No. C-93-1748, 1999 U.S. Dist. LEXIS 19059 (N.D. Cal. Dec. 7, 1999) ("*Roche I*"). After a bench

1 trial on inequitable conduct, the district court found that the applicants for the '818 patent, through
2 their attorney Kevin Kaster, had made intentional material misrepresentations to the PTO to mislead
3 and to deceive the PTO and held that the '818 patent was unenforceable.

4 34. RMS appealed the *Roche I* judgment to the United States Court of Appeals for the
5 Federal Circuit. In 2003, the Federal Circuit affirmed multiple grounds of inequitable conduct and
6 remanded for a determination of whether those grounds were sufficient to hold the '818 patent
7 unenforceable. *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354 (Fed. Cir. 2003)
8 (*"Roche II"*).

9 35. On remand, the district court held the '818 patent unenforceable based on its findings
10 that the applicants committed inequitable conduct by:

11 "making misleading statements regarding the relative fidelity of Taq as compared to
12 the prior art enzymes;"

13 "claiming that Taq purified by the method taught in Example VI had a specific
14 activity of 250,000 units/mg;"

15 "presenting Example VI as though it had been performed when, in fact, it had not
16 been performed;"

17 "making deceptive, scientifically unwarranted comparisons between the specific
18 activity of the claimed enzyme and the specific activity reported by Chien et al. and
19 Kaledin et al.;"

20 "claiming that Taq purified according to the method taught in Example VI yielded a
21 single 88 kd band on an SDS PAGE mini-gel and"

22 "claiming that the Taq produced was free from nuclease contamination."

23 *Hoffmann-La Roche, Inc. v. Promega Corp.*, 319 F. Supp. 2d 1011, 1016 (N.D. Cal. 2004) (*"Roche*
24 *III"*). The parties subsequently settled, and the case was dismissed with prejudice against RMS and
25 its co-plaintiff.

26 36. After the '818 patent was held unenforceable because of inequitable conduct, RMS
27 and a number of other Roche-related entities faced an antitrust class action lawsuit based on RMS's
28 enforcement of the '818 patent. *Molecular Diagnostics Labs. v. Hoffmann-La Roche, Inc. et al.*,
1:04-cv-01649-HHK (D.D.C.). According to public documents, RMS and its co-plaintiffs reportedly
settled that lawsuit in 2008 for \$33,000,000.

1 37. As explained below, the inequitable conduct that occurred in the '818 patent also
2 occurred in the preparation and prosecution of the '155 patent application.

3 **The '155 Patent's Named Inventors**

4 38. The initial named co-inventors on the '818 patent are David Gelfand, Susanne Stoffel,
5 Frances Lawyer, and Randall Saiki. The '818 patent issued in 1989.

6 39. The application that became the '155 patent was filed in 1992 as a continuation of a
7 1989 application that was subsequently abandoned (collectively, "the '155 patent application"). On
8 information and belief, in 1991, Roche acquired all right, title, and interest in the '155 patent
9 application and controlled its prosecution thereafter.

10 40. The co-inventors originally named in the '155 patent application were the same as the
11 four initially named co-inventors on the '818 patent, but the inventor list was subsequently changed
12 to remove Frances Lawyer. Thus, the three named inventors for the '155 patent are David Gelfand,
13 Susanne Stoffel, and Randall Saiki.

14 **False Declarations Submitted to the PTO**

15 41. During prosecution of the '155 application, the PTO rejected numerous pending
16 claims on the basis of a product information sheet of Molecular Biology Resources ("MBR product
17 information"), which pre-dated the earliest applicable filing date. PTO Paper # 7, September 4,
18 1990, at 4-6. In response to the PTO's rejection based on the MBR product information, the named
19 inventors submitted two declarations.

20 42. The first declaration was submitted by named inventor David Gelfand. PTO Paper #
21 10, February 11, 1991. In that declaration, Gelfand declared that he and his co-inventors had
22 reduced their claimed invention to practice well before the date of the MBR product information,
23 and that evidence of their reduction to practice was shown by a *Taq* polymerase purification protocol
24 that was attached to the declaration. *Id.* The applicants' attorney, Kevin Kaster, requested that the
25 PTO withdraw its rejection in view of the declaration. PTO Paper # 9, February 11, 1991, at 6. The
26 PTO found this first declaration inadequate on the grounds that, among other things, it was not
27 signed by all the named inventors. PTO Paper # 11, May 3, 1991, at 2.
28

43. The second declaration was, as a result, submitted by all of the named inventors, i.e., David Gelfand, Susanne Stoffel, and Randall Saiki. Declaration accompanying PTO Paper # 20, April 24, 1992. In that declaration, all of the named inventors declared that they had reduced their claimed invention to practice well before the date of the MBR product information, and that evidence of their reduction to practice was shown by a *Taq* polymerase purification protocol that David Gelfand had previously submitted, and the inventors attached another copy to their declaration. *Id.* The applicants' attorney, now David Highet, again requested that the PTO withdraw its rejection in view of the declaration, contending that the product of the attached protocol was "exactly" what was claimed in application Claim 1 and arguing that the declaration "should be accorded more evidentiary significance than the posturing of a party involved in a dispute" because the declaration was made "with the knowledge that willful false statements could result in . . . invalidation of any patent issuing from the present application." PTO Paper # 20, April 24, 1992, at 2-10. The PTO Examiner found the second declaration inadequate on substantive grounds. PTO Paper # 21, July 15, 1992, at 3-5.

44. RMS and the inventors failed to disclose to the PTO that the *Taq* polymerase purification protocol, which was attached to the first and second declarations, was never performed. Reexam of the '155 patent, Application Serial No. 90/007,416 (the "'155 Reexam'"), Fourth IDS, December 6, 2005, at 3-4.

45. Relying in part on the second declaration, the PTO Board of Patent Appeals and Interferences reversed the rejections based on the MBR product information. PTO Paper # 38, July 30, 1999, at 2-4, 8. The PTO issued a Notice of Allowability (PTO Paper # 40, October 6, 1999) and the '155 patent subsequently issued.

46. Upon information and belief, both declarations were material to examination by the PTO, were made with the intent to deceive the PTO, and render the '155 patent unenforceable due to inequitable conduct.

Intentional Misrepresentations to the PTO

47. During the prosecution of the '155 application, the PTO rejected numerous claims on the basis of publications by Kaledin. PTO Paper # 7, September 4, 1990, at 6-7.

1 48. As had been done previously in the '818 patent prosecution, the applicants
 2 distinguished Kaledin on the grounds that their claims required a "purified" enzyme whereas
 3 Kaledin's enzyme was "crude." *See* PTO Paper # 21, July 15, 1992, at 6. *See also*, PTO Paper # 32,
 4 July 11, 1994, at 12, stating that the Kaledin enzyme "is a crude preparation, comparable in activity
 5 to 1.5% of the purity of [Applicants'] teaching."

6 49. During the prosecution of the '155 patent, the applicants, through their agent Stacey
 7 Sias, relied on the prosecution history of the '818 patent to support their purported distinction,
 8 stating:

9 The pending claims, however, are directed to a purified enzyme composition. The
 10 Patent Office has previously determined that the purified enzyme compositions
 11 provided by the present application are novel and non-obvious in view of the crude
 partially degraded preparations of Kaledin *et al.* (see U.S. Patent No. 4,889,818,
 which issued from the grandparent to the present application).

12 PTO Paper # 24, January 19, 1993, at 10.

13 50. In *Roche I*, the district court found that the representations made in the '818 patent
 14 prosecution and in the '818 specification about the alleged purity of the claimed invention were
 15 intentional misrepresentations. *Roche I*, 1999 U.S. Dist. LEXIS 19059, at *24-26. The district court
 16 also found that the comparison made in the '818 patent prosecution about the specific activity of the
 17 claimed invention and the prior art was deceptive and improper. *Id.* at *26-28. The Federal Circuit
 18 affirmed these findings. *Roche II*, 323 F.3d at 1363-69.

19 51. Upon information and belief, these false representations were material, were made
 20 with the intent to deceive the PTO, and render the '155 patent unenforceable due to inequitable
 21 conduct.

22 **False Example XIII in the '155 Patent Application**

23 52. The applicants, including named inventors David Gelfand, Susanne Stoffel, and
 24 Randall Saiki, included a false and deceitful example of a purification protocol in the specification of
 25 the '155 patent application. Specifically, the applicants wrote Example XIII in the past tense and, on
 26 information and belief, did so to deceive the PTO into believing that the protocol had been
 27 performed when it had not been performed.

1 53. RMS has admitted that Example XIII of the '155 patent application corresponds to
2 Example VI of the '818 patent. '155 Reexam, Fourth IDS, December 6, 2005, at 3-4.

3 54. In *Roche I*, the district court found that inventors David Gelfand and Susanne Stoffel
4 never actually performed Example VI of the '818 patent. *Roche I*, 1999 U.S. Dist. LEXIS 19059, at
5 *21, 23, 37, and 45. The Federal Circuit affirmed this finding. *Roche II*, 323 F.3d at 1364.

6 55. In *Roche I*, the district court found that the Example VI of the '818 patent had been
7 written in the past tense in order to deceive the PTO into believing that the protocol had been
8 performed. *Roche I*, 1999 U.S. Dist. LEXIS 19059, at *25-26. The Federal Circuit affirmed this
9 finding. *Roche II*, 323 F.3d at 1365-66.

10 56. Just as the same applicants had previously written Example VI of the '818 patent in
11 the past tense, the applicants wrote Example XIII of the '155 patent application in the past tense and,
12 on information and belief, did so to deceive the PTO into believing that the protocol had been
13 performed when it had not been performed.

14 57. RMS has admitted that Example XIII of the '155 patent application was not practiced
15 by the named inventors. '155 Reexam, Fourth IDS, December 6, 2005, at 4. In *Roche I*, the district
16 court found that the use of the past tense itself evidenced an intent to deceive the PTO. *Roche I*,
17 1999 U.S. Dist. LEXIS 19059, at *25-26:

18 Gelfand understood that when experiments are described using the past tense,
19 the author represents that the procedures described have actually been performed as
20 written and the results reported have actually been achieved using those procedures.
21 Stoffel also understood that a scientist using the past tense represents that the
22 experiment described has actually been performed. The inventors were aware of the
23 materiality of reporting Example VI in the past tense, without indicating that it was
24 prophetic.

25 ... the court finds that Example VI was written in the past tense in order to
26 deceive the PTO into believing that it had actually been performed. The fact that
27 Example VI may have been a superior method of purification is irrelevant; it had not
28 been performed as written, the inventors knew that it had not been performed as
written and they understood the significance of using the past tense to describe
experiments. Under these circumstances, the court finds that the inventors'
misrepresentation was intentional.

58. Upon information and belief, Example XIII was material, was presented with the
intent to deceive the PTO, and renders the '155 patent unenforceable due to inequitable conduct.

Had RMS's Deceit Been Timely Disclosed to the PTO, the '155 Patent Would Have Expired Prior to 2008

59. Subsequent to the October 6, 1999 Notice of Allowability of the '155 patent, RMS, through its attorney Douglas Petry, sought to disclose to the PTO the pre-trial and post-trial briefs from *Roche I*, while at the same time contending that the misrepresentations and omissions alleged with respect to the '818 patent were not relevant to the patentability of the claims in the '155 patent application. PTO Paper # 41, October 7, 1999, at 7-8. The PTO refused to consider the information presented because RMS had failed to comply with the requirements for a disclosure made after a Notice of Allowability. PTO Paper # 42, January 14, 2000. Those requirements included a certification that the material being submitted was not known to RMS more than three months before the submission. 37 C.F.R. § 1.97(e). On information and belief, RMS had the pre-trial briefs in its possession for more than nine months before it sought to disclose them to the PTO and had the post-trial briefs in its possession for at least five months before seeking to disclose them to the PTO.

60. RMS, through its attorneys Jennifer Gordon and Margaret Brivanlou, petitioned the PTO to waive the requirements for a disclosure made after a Notice of Allowability, arguing that to make the disclosure without a waiver would require RMS to file a continuation application, which would cause the resulting '155 patent to terminate in 2007. Petition, December 7, 1999, at 4. The PTO dismissed the petition for a waiver, noting that RMS had not offered any explanation for its "protracted delay" in bringing the items to the attention of the PTO. PTO Paper # 44, April 14, 2000, at 2.

61. Also subsequent to the Notice of Allowability, RMS submitted to the PTO the opinion of the district court in *Roche I* holding that the '818 patent was unenforceable for inequitable conduct. PTO Paper No. 46, December 27, 1999. The PTO allowed RMS to make this submission, which was presented to the PTO within three weeks of the *Roche I* decision. *Id.*; PTO Paper No. 49, July 17, 2000. RMS did not supply any of the factual material underlying the opinion, even though that material had been in RMS's possession prior to submitting the opinion. Third Supplemental IDS, December 27, 1999, at 2.

62. Inequitable conduct is not a criterion for patentability that is considered by the PTO and the PTO "does not investigate and reject original or reissue applications [for inequitable

conduct] under 37 CFR 1.56.” Manual of Patent Examining Procedure § 2010 (7th ed. 1998) (explaining that a “court, with subpoena power, is presently the best forum to consider duty of disclosure issues under the present evidentiary standard for finding an ‘intent to mislead’”). Accordingly, the PTO could not take RMS’s inequitable conduct under consideration in deciding whether to allow the ’155 patent.

63. RMS was aware of the findings of inequitable conduct rendering the ’818 patent unenforceable and acknowledged during reexamination of the ’155 patent, through its attorney Jennifer Gordon, that the statements that had led to unenforceability of the ’818 patent were “similar to” statements made in the ’155 patent prosecution. ’155 Reexam, Fourth IDS, December 6, 2005, at 2-5.

64. Upon information and belief, but for (a) submitting material false declarations with the intent to deceive the PTO; (b) making material false representations with the intent to deceive the PTO; and (c) presenting, with the intent to deceive the PTO, an example written in the past tense when that example had not been performed; the ’155 patent would never have been allowed to issue at all and, if it had been allowed, it would have had an expiration date prior to 2008.

COUNT IV
(For a Declaratory Judgment that the ’155 Patent is Not Infringed)

65. Cepheid re-alleges and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 64.

66. Because RMS has contended that the ’155 patent is valid and necessary for Cepheid’s products, and because the ’155 patent is not infringed, a conflict of asserted rights has arisen and a justiciable controversy exists between Cepheid and RMS with regard to whether the claims of the ’155 patent are not infringed.

67. Cepheid has not infringed and will not infringe, either directly or indirectly, any valid or enforceable claim of the ’155 patent by importing, making, having made, offering for sale, or selling its Xpert kits, or on any other basis. Accordingly, for at least these reasons, Cepheid is entitled to a declaratory judgment that the ’155 patent is not infringed.

PRAYER FOR RELIEF

Wherefore, Plaintiff Cepheid prays for judgment against Defendants, and respectfully requests that this Court:

A. Declare that United States Patent Nos. 5,804,375 and 6,127,155 are invalid, and in any event, under non-statutory double patenting cannot be enforced after their expiration on August 6, 2010, and December 26, 2006, respectively;

B. Declare that Cepheid has not infringed, and is not infringing, United States Patent Nos. 5,804,375 or 6,127,155;

C. Declare that United States Patent No. 6,127,155 is unenforceable due to inequitable conduct;

D. Declare this case exceptional under 35 U.S.C. § 285 and award Cepheid its costs, disbursements, and attorneys' fees in connection with this action;


E. Award Cepheid any other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Cepheid demands a trial by jury on all matters so triable.

Dated: August 21, 2012

Respectfully submitted,

By: 

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