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Attorneys for Plaintiff
AFFYMETRIX, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AFFYMETRIX, INC., a Delaware corporation,

Plaintiff,

v.

MULTILYTE LTD., a British corporation,

Defendant.

Civil Case No. C03 3779 WHA

FOURTH AMENDED COMPLAINT FOR DECLARATORY JUDGMENT

DEMAND FOR JURY TRIAL

Plaintiff AFFYMETRIX, INC. ("Affymetrix") alleges as follows:

PARTIES

1. Plaintiff Affymetrix is a Delaware corporation with its principal place of business at 3380 Central Expressway, Santa Clara, California 95051.

2. On information and belief, Defendant MULTILYTE LTD. ("Multilyte") is a British corporation (Company No. 02290281) with its registered place of business at Queens House, 55-56 Lincolns Inn Fields, London WC2A 3NA, United Kingdom. Multilyte has its principal place of business at Division of Molecular Endocrinology, University College London Medical School, Mortimer Street, London W1N 8AA, United Kingdom. Multilyte is the assignee of at least eight (8) United States patents listing Roger P. Ekins ("Ekins") as an inventor (collectively, the "Multilyte patents"). Ekins has represented himself to be "Chief Executive" of Multilyte. Ekins is also emeritus professor in the division of molecular endocrinology at the University College of London Medical School.

JURISDICTION

3. This is an action arising under the patent laws of the United States, Title 35 of the United States Code, Section 1 *et seq*. and the Declaratory Judgment Act, Title 28 of the United States Code, Sections 2201 and 2202. The Court has jurisdiction over the subject matter of this action pursuant to Title 28 of the United States Code, Sections 1331, 1337, 1338, and 1367.

4. This Court has personal jurisdiction over Multilyte because Multilyte has engaged in sufficient contacts with the State of California to satisfy both the requirements of due process and Rule 4(k)(2) of the Federal Rules of Civil Procedure. Multilyte has intentionally engaged in contacts with California involving the Multilyte patents. These contacts include directing multiple written and oral communications to Affymetrix in California regarding Affymetrix's business and Multilyte's patents (discussed below). Multilyte, by its counsel, also entered into a mutual non-disclosure agreement with Affymetrix that is governed by California law relating to the potential licensing of the Multilyte patents. Multilyte further established contacts by engaging in extensive negotiations with Affymetrix relating to Multilyte patents and concurrently threatening to sue Affymetrix for infringement of those patents. During the course of the

negotiations, representatives of Multilyte, including Ekins and Multilyte's consultant, Hans Berger ("Berger"), personally traveled to California on at least two occasions to meet with representatives of Affymetrix. Ekins and Berger, as well as other representatives of Multilyte, also had many telephone conversations and email exchanges with representatives of Affymetrix regarding licensing the Multilyte patents. Multilyte has also represented to Affymetrix that it has engaged in similar business discussions with other biotech companies in an effort to license or sell the Multilyte patents.

VENUE

5. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)-(d).

INTRADISTRICT ASSIGNMENT

6. Under Local Rule 3-2(c), this action for declaratory judgment shall be assigned on a district-wide basis. For this reason, Plaintiff originally did not list a division of the Court in its original Complaint. The present action has now been assigned to the San Francisco division.

GENERAL ALLEGATIONS

7. Affymetrix pioneered the commercial market for DNA ("GeneChip®") microarray systems used by life sciences researchers. Affymetrix GeneChip® microarrays are the leading commercial application in this field. GeneChip® microarrays consist of many known sequences of DNA attached to a substrate that bind to genetic sequences in experimental samples. Researchers use Affymetrix's GeneChip® microarrays to analyze a particular gene, groups of genes, or a whole genome of an organism.

8. Multilyte has alleged that Affymetrix, by making and selling the GeneChip® microarray systems, infringes the following patents:

A) U.S. Patent No. 5,432,099 (the "'099 patent"), issued on July 11, 1995, entitled "Determination of ambient concentration of several analytes."

B) U.S. Patent No. 5,599,720 (the "'720 patent"), issued on February 4, 1997, entitled "Measurement of analyte concentration."

C) U.S. Patent No. 5,807,755 (the "'755 patent"), issued on September 15, 1998, entitled "Determination of ambient concentrations of several

analytes." This patent is a continuation-in-part of the '099 patent. Per the parties' stipulation, dated October 17, 2003, Multilyte agreed that it will not allege infringement of its other issued United States patents based on present Affymetrix products and services.

9. A true and correct copy of each of the Multilyte patents is attached hereto as Exhibits A through C.

10. On or about April 8, 2002, Ekins wrote to Ms. Susan Siegel ("Siegel"), President of Affymetrix, regarding the Multilyte patents. In this letter, Ekins suggested that Affymetrix consider a license to Multilyte's United States patents and their foreign equivalents.

11. On June 14, 2002, Multilyte, by and through its counsel, entered into a "Mutual Non-Disclosure Agreement" with Affymetrix. Multilyte agreed, with respect to the Mutual Non-Disclosure Agreement, to be bound by the laws of the State of California.

12. Thereafter, on at least two occasions, Ekins came to California, once accompanied by Berger, to meet with representatives of Affymetrix discuss a license to the Multilyte patents. Ekins and Berger also engaged in license discussions with Affymetrix representatives by telephone and email. At all times during these discussions, Berger had apparent authority to act on behalf of Multilyte on all licensing-related issues.

13. Recently, Affymetrix stated to Multilyte that it had many concerns about taking a license to the Multilyte patents. In response, on July 18, 2003, Berger wrote to Dr. Rob Lipshutz, Affymetrix's Senior Vice President of Corporate Development and Licensing, stating:

> In the circumstances, we do not consider that there is anything to be gained by continuing these protracted negotiations any longer. We have therefore instructed our lawyers to prepare the necessary papers to begin patent infringement proceedings. These proceedings will be issued and served without further notice, unless we hear from you with an acceptable offer by 5:30pm Austrian time on Friday 25 July 2003.

14. On or about July 23, 2003, Dr. Stephen Fodor ("Fodor"), the Chairman of the Board and Chief Executive Officer of Affymetrix, contacted Ekins and suggested that the parties meet again in September to discuss a potential license and that the parties agree not file any lawsuits in the meantime. Ekins agreed to Fodor's proposal.

AFFYMETRIX, INC.

15. However, on July 28, 2003, Ekins sent an email to Fodor and stated that Multilyte could not wait until September for further discussions and stated that Multilyte's would commence legal proceedings against Affymetrix by August 8, 2003.

16. On or about August 5, 2003, Siegel contacted Ekins to try to obtain more time so that the companies could have a further face-to-face meeting to discuss potential prior art to the Multilyte patents. Based on these discussions, Affymetrix and Multilyte agreed to meet in the following week to have further discussions regarding the Multilyte patents.

17. When Siegel contacted Ekins on August 12, 2003, in the course of their conversation, Ekins informed her that Multilyte had commenced legal proceedings in Europe against Affymetrix. When Siegel asked Ekins about the nature of the proceeding and where it was filed, Ekins responded that his legal advisors had told him that he could not share that information with Affymetrix. Affymetrix subsequently learned that Multilyte filed an infringement action in Düsseldorf, Germany, against Affymetrix, alleging infringement of European patents equivalent to the U.S. '099 (EP 0 304 202) and '720 (EP 0 134 215) patents. Multilyte filed the complaint on July 18, 2003.

18. By virtue of Multilyte's explicit threats of an imminent patent infringement lawsuit and commencement of legal proceedings in Germany on patents equivalent to ones at issue in this action, Affymetrix has a reasonable apprehension that it will face a patent infringement suit based on the Multilyte patents.

19. Affymetrix denies that it infringes any valid and enforceable claim of any of the Multilyte patents.

20. An actual and justiciable controversy exists between Multilyte and Affymetrix concerning whether Affymetrix infringes any valid claim of the Multilyte patents. Affymetrix now seeks a declaratory judgment that the claims of the Multilyte patents are invalid and that Affymetrix does not infringe any valid claim of the Multilyte patents.

FIRST CLAIM FOR RELIEF

(Invalidity and Non-Infringement of U.S. Patent 5,432,099)

21. Affymetrix incorporates by reference paragraphs 1 through 20 as though fully set forth herein.

22. Affymetrix is not directly infringing, contributorily infringing, or actively inducing others to infringe any valid claim of the '099 patent as properly construed.

23. On information and belief, the '099 patent is invalid and void under at least the provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

SECOND CLAIM FOR RELIEF

(Invalidity and Non-Infringement of U.S. Patent 5,599,720)

24. Affymetrix incorporates by reference paragraphs 1 through 23 as though fully set forth herein.

25. Affymetrix is not directly infringing, contributorily infringing, or actively inducing others to infringe any valid claim of the '720 patent as properly construed.

26. On information and belief, the '720 patent is invalid and void under at least the provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD CLAIM FOR RELIEF

(Invalidity and Non-Infringement of U.S. Patent 5,807,755)

27. Affymetrix incorporates by reference paragraphs 1 through 26 as though fully set forth herein.

28. Affymetrix is not directly infringing, contributorily infringing, or actively inducing others to infringe any valid claim of the '755 patent as properly construed.

29. On information and belief, the '755 patent is invalid and void under at least the provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

FOURTH CLAIM FOR RELIEF

(Unenforceability of U.S. Patent 5,599,720)

30. Affymetrix incorporates by reference paragraphs 1 through 29 as though fully set forth herein.

31. Upon information and belief, during the prosecution of the '720 patent, Multilyte and Ekins knowingly failed to cite to the United States Patent and Trademark Office ("PTO") several references and other prior art that were material to the claimed subject matter of the '720 patent and were known to them.

32. For example, Multilyte and Ekins failed to cite Ekins' 1981 publication *Towards Immunoassays of Greater Sensitivity, Specificity and Speed: An Overview*, published in MONOCLONAL ANTIBODIES AND DEVELOPMENTS IN IMMUNOASSAY 3, 19 (Alberto Albertini and Roger Ekins eds., 1981), during the prosecution of the '720 patent. The Ekins 1981 publication was material to the claimed subject matter of the '720 patent because it described the existence of commercially-available immunoassay kits, and also described assays that used trace amounts of binding agent (*e.g.*, 5% or less) relative to analyte. Moreover, the Ekins' 1981 publication occurred more than one year before the filing of any of the patents-in-suit, and is therefore prior art under 35 U.S.C. 102(b).

33. The kits known by Ekins at the time of his 1981 publication included kits sold by Baxter-Travenol (Parsons), Amersham (Midgley and Wilkins), Lapetit, and Corning. Upon information and belief, each of these prior art kits was known to Ekins at the time he filed the applications that led to the patents-in-suit. Multilyte and Ekins failed to cite any of these kits to the PTO during the prosecution of the '720 patent.

34. In the 1981 publication, Ekins described assays that used trace amounts of binding agent (*e.g.*, 5% or less) relative to analyte. This description was particularly material given the arguments Ekins made to distinguish prior art cited during prosecution of the '720 patent. For example, Ekins stated in a declaration:

> The examiner's reliance on Ekins '687 in support of the §102(b) rejection is manifestly misplaced. Ekins '687 fails to identically describe a sample volume independent assay **using an amount of binding agent that binds less than about 5% of the analyte** that is expected to be present and having no binding protein present in the sample, in accordance with the present invention. Thus, Ekins '687 does not provide evidence of lack of novelty such as to support a 35 U.S.C. §102 rejection.

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Prelim. Am. of Sept. 14, 1994, at p. 2 (emphasis added). Upon information and belief, the Ekins 1981 publication refutes and is inconsistent with this statement by Ekins and was therefore highly material to patentability. Ekins plainly knew about the Ekins 1981 publication because he was the author. Upon information and belief, Ekins acted with deceptive intent when he concealed his 1981 publication from the PTO while at the same time making arguments for patentability that were refuted by and inconsistent with information described in his 1981 article. A true and correct copy of the Ekins 1981 publication is attached hereto as Exhibit D, and a true and correct copy of the above-noted preliminary amendment is attached hereto as Exhibit E.

35. As another example, if the asserted claims cover DNA hybridization technology, Mulitlyte and Ekins failed to cite Maniatis *et al*., *Molecular Cloning: A Laboratory Manual* (1982) ("Maniatis"), a standard molecular biology laboratory manual, during the prosecution of the '720 patent. Upon information and belief, Maniatis was published in January 1982, and provided laboratory protocols adapted from well-known scientific publications at that time, *see, e.g.*, Southern, E., *Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis*, *J. Mol. Biol.* 98:503 (1975); St. John, T.P. and Davis, R.W., *Isolation of galactose-inducible DNA sequences from Saccaromyces cerevisiae by differential plaque filter hybridization*, *Cell* 16:443 (1979). Maniatis is a widely-known manual of techniques for nucleic acid manipulations that is commonly used by researchers in biochemistry and molecular biology. For example, in Chapter 10 (pages 310-61), Maniatis describes hybridization of DNA or RNA immobilized on filters to radioactive probes to determine whether a nucleic acid sequence of interest is present and the relative concentration of a nucleic acid of interest from one sample to another. At pages 382-89, Maniatis describes the "Southern" procedure for hybridizing DNA or RNA to DNA fragments transferred to a solid membrane, again to determine whether a sequence of interest is present.

36. Several of the claims of the '720 patent recite methods for determining the concentration of an analyte in a solution using the same steps described in the Maniatis and Southern references. Upon information and belief, Maniatis and Southern were material to patentability because Maniatis or Southern each establishes, by itself or in combination with other

information, a prima facie case of unpatentability of one or more of the claims of the '720 patent. Upon information and belief, Multilyte and/or Ekins had knowledge of the Maniatis and Southern references and, as a result, should have cited Maniatis and Southern to the PTO during the prosecution of the '720 patent. Upon information and belief, Ekins acted with deceptive intent when he concealed the Maniatis and Southern references from the PTO while at the same time making arguments for patentability that were refuted by and inconsistent with information described in Maniatis and Southern. A true and correct copy of relevant sections of Maniatis is attached hereto as Exhibit F, and a true and correct copy of the Southern article is attached hereto as Exhibit G.

37. Accordingly, on information and belief, the '720 patent is unenforceable as a result of Multilyte's and Ekins' inequitable conduct during the prosecution of the '720 patent by failing to disclose material references and prior art known to them and/or mischaracterizing the prior art.

FIFTH CLAIM FOR RELIEF

(Unenforceability of U.S. Patent 5,432,099)

38. Affymetrix incorporates by reference paragraphs 1 through 37 as though fully set forth herein.

39. Upon information and belief, during the prosecution of the '099 patent, Multilyte and Ekins knowingly failed to cite to the PTO information, several references, and other prior art that were material to the claimed subject matter of the '099 patent and were known to them, including commercially available free hormone measurement kits, the Ekins 1981 publication, the Maniatis publication, a 1984 publication co-authored by Ekins, and information regarding the financial interest of a person who submitted a declaration on behalf of Multilyte.

40. The kits known by Ekins at the time of his 1981 publication included kits sold by Baxter-Travenol (Parsons), Amersham (Midgley and Wilkins), Lapetit, and Corning. Upon information and belief, each of these prior art kits was known to Ekins at the time he filed the applications that led to the patents-in-suit. Multilyte and Ekins failed to cite any of these kits to the PTO during the prosecution of the '099 patent.

41. With regard to the Ekins 1981 publication, which described assays that used trace amounts of binding agent (*e.g.*, 5% or less) relative to analyte, this prior art was particularly material given the arguments Ekins made to distinguish prior art cited during prosecution of the '099 patent. For example, Ekins stated in a declaration:

> Before the present invention, there was, as far as I am aware, no disclosure or suggestion of an assay – whether of so-called competitive or non-competitive design – using less than 0.1V/K moles of binding agent.

42. Upon information and belief, the Ekins 1981 publication refutes and is inconsistent with this statement by Ekins and was therefore highly material to patentability. Ekins plainly knew about the Ekins 1981 publication because he was the author. Upon information and belief, Ekins acted with deceptive intent when he concealed his 1981 publication from the PTO while at the same time making arguments for patentability that were refuted by and inconsistent with information described in his 1981 article. A true and correct copy of the above-noted Ekins declaration is attached hereto as Exhibit H.

43. As another example, if the asserted claims cover DNA hybridization technology, Mulitlyte and Ekins failed to cite Maniatis *et al*., *Molecular Cloning: A Laboratory Manual* (1982) ("Maniatis"), a standard molecular biology laboratory manual, during the prosecution of the '099 patent. Upon information and belief, Maniatis was published in January 1982, and provided laboratory protocols adapted from well-known scientific publications at that time, *see, e.g.*, Southern, E., *Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis, J. Mol. Biol.* 98:503 (1975); St. John, T.P. and Davis, R.W., *Isolation of galactose-inducible DNA sequences from Saccaromyces cerevisiae by differential plaque filter hybridization*, *Cell* 16:443 (1979). Maniatis is a widely-known manual of techniques for nucleic acid manipulations that is commonly used by researchers in biochemistry and molecular biology. For example, in Chapter 10 (pages 310-61), Maniatis describes hybridization of DNA or RNA immobilized on filters to radioactive probes to determine whether a nucleic acid sequence of interest is present and the relative concentration of a nucleic acid of interest from one sample to another. At pages 382-89, Maniatis describes the "Southern" procedure for hybridizing DNA or

RNA to DNA fragments transferred to a solid membrane, again to determine whether a sequence of interest is present.

44. Several of the claims of the '099 patent recite methods for determining the concentration of an analyte in a solution using the same steps described in Maniatis. Upon information and belief, Maniatis and Southern were material to patentability because Maniatis or Southern each establishes, by itself or in combination with other information, a prima facie case of unpatentability of one or more of the claims of the '099 patent. Upon information and belief, Multilyte and/or Ekins had knowledge of the Maniatis and Southern references and, as a result, should have cited Maniatis and Southern to the PTO during the prosecution of the '099 patent. Upon information and belief, Ekins acted with deceptive intent when he concealed the Maniatis and Southern references from the PTO while at the same time making arguments for patentability that were refuted by and inconsistent with information described in Maniatis and Southern. A true and correct copy of relevant sections of Maniatis is attached hereto as Exhibit F, and a true and correct copy of the Southern article is attached hereto as Exhibit G.

45. Multilyte and Ekins also failed to disclose another Ekins publication during the prosecution of the '099 patent, namely, Dakubu, S., Ekins, R., Jackson, T., and Marshall, N.J., *High Sensitivity, Pulsed-Light, Time-Resolved Fluoroimmunoassay;* published in Practical Immunoassay, W. Butt (Ed.), Marcel Dekker, Inc. pp. 71-101 (1984). This publication by Dakubu and Ekins, et al. was material to the claimed subject matter of the '099 patent because the authors described arrays of different antibodies of differing specificity that could rapidly measure multiple analytes in the same sample. This article was published more than one year before the filing date of the '099 patent, and is therefore prior art under 35 U.S.C. § 102(b). A true and correct copy of the Dakubu and Ekins, et al. 1984 publication is attached hereto as Exhibit I.

46. During the prosecution of the '099 patent, Multilyte and Ekins also submitted a declaration from Ivan Roitt in support of the patentability of the pending application to the Patent and Trademark Office, but failed to disclose Roitt's financial interest in Multilyte. Dr. Roitt argued in this declaration that the pending claims were patentable over two patents, Ekins '031 and Chang '570. Nowhere in the Roitt declaration or in the accompanying "Supplemental

Response To First Official Action" did Multilyte or Ekins disclose that Roitt was a director of Multilyte and that he owned shares of Multilyte. The Patent and Trademark Office would have considered Roitt's financial interest in Multilyte material in evaluating Roitt's declaration and, therefore, Multilyte and Ekins failed to disclose material information to the Patent and Trademark Office. Upon information and belief, Multilyte and Ekins acted with deceptive intent when failing to disclose Roitt's financial interest in Multilyte to the PTO.

47. Accordingly, on information and belief, the '099 patent is unenforceable as a result of Multilyte's and Ekins' inequitable conduct during the prosecution of the '099 patent by failing to disclose material references, information, and prior art known to them and/or mischaracterizing the prior art.

SIXTH CLAIM FOR RELIEF

(Unenforceability of U.S. Patent 5,807,755)

48. Affymetrix incorporates by reference paragraphs 1 through 45 as though fully set forth herein.

49. Upon information and belief, the '755 patent is unenforceable as a result of Multilyte's and Ekins' failure to satisfy their duty of disclosure to the PTO and/or their engaging in inequitable conduct during the prosecution of the '755 patent by failing to disclose material references and prior art known to them, failing to disclose the existence of commercially available kits known to them, including kits sold by Baxter-Travenol (Parsons), Amersham (Midgley and Wilkins), Lapetit, and Corning, and/or mischaracterizing the prior art.

50. The '755 patent is related as a continuation-in-part of the '099 patent. Like the '099 patent, the '755 patent is directed to methods for determining ambient analyte concentration. Because of the relatedness of the subject matter of the '755 and the '099 patents, inequitable conduct during prosecution of the '099 patent also renders the '755 patent unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Affymetrix prays for the following relief:

A. As to the First through Third Claims for Relief, that the Court enter a declaratory judgment that the manufacture, use, sale, or offer for sale of the Affymetrix GeneChip® microarray systems does not infringe any valid claim of the Multilyte patents; and that

i. The manufacture, use, sale, or offer for sale of the Affymetrix GeneChip® microarray systems does not constitute an inducement to infringe or contributory infringement of any valid claim of the Multilyte patents; and

ii. The claims of the Multilyte patents are invalid;

B. As to the Fourth through Sixth Claims for Relief, that the Court enter a declaratory judgment that each of U.S. Patent 5,432,099, U.S. Patent 5,599,720, and U.S. Patent 5,807,755 is unenforceable as a result of Multilyte's and Ekins' engaging in inequitable conduct during the prosecution of these patents;

C. That this Court enter a judgment that this is an exceptional case under 35 U.S.C. § 285;

D. That this Court award Affymetrix its costs, expenses, and attorneys' fees in this action; and

E. For such other, further, or different relief that Affymetrix may be entitled to as a matter of law or equity, or that the Court otherwise deems just and proper.

Dated: April 7, 2004

GEORGE A. RILEY
JOHN C. KAPPOS
DIANE K. WONG
O'MELVENY & MYERS LLP

MICHAEL J. MALECEK
GEORGE C. YU
DANIEL R. REED
AFFYMETRIX, INC.

By: _____
John C. Kappos

Attorneys for Plaintiff
AFFYMETRIX, INC.

AFFYMETRIX, INC.

CERTIFICATION OF INTERESTED ENTITIES OR PERSONS

Pursuant to Civil Local Rule 3-16, the undersigned certifies that as of this date, AXA Financial owns more than 10% of Plaintiff's Affymetrix's common stock. Other than AXA Financial and the named parties, to the best of the undersigned's knowledge, there is no other interest to report.

Dated: April 7, 2004

MICHAEL J. MALECEK
GEORGE C. YU
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AFFYMETRIX, INC.

By:_____
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DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Affymetrix hereby demands a trial by jury of any and all issues triable by a jury in this action.

Dated: April 7, 2004

MICHAEL J. MALECEK
GEORGE C. YU
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