

JUDGE GARDEPHE

10 CV 4673

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

THE ESTÉE LAUDER COMPANIES, INC.,
and APPLIED GENETICS INCORPORATED
DERMATICS,

Plaintiffs,

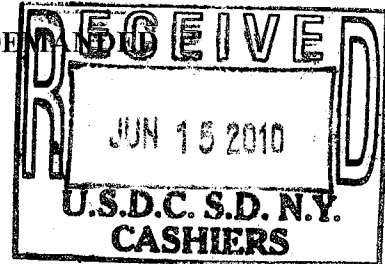
-against-

OXIS INTERNATIONAL, INC.,

Defendant.

CIVIL ACTION NO. _____

JURY TRIAL DEMAND _____



COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs The Estée Lauder Companies, Inc. and Applied Genetics Incorporated Dermatics, as and for their Complaint herein, state as follows:

THE PARTIES

1. The Estée Lauder Companies, Inc. ("Estée Lauder") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 767 5th Avenue, New York, New York 10153.

2. Applied Genetics Incorporated Dermatics ("AGI") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 7 Corporate Center Drive, Melville, New York 11747. AGI is a wholly owned subsidiary of Estée Lauder.

3. Upon information and belief, Defendant Oxis International, Inc. ("Oxis") is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 468 N. Camden Drive, 2nd Floor, Beverly Hills, California 90210.

JURISDICTION AND VENUE

4. This action arises under the Acts of Congress relating to patents, 35 U.S.C. §§ 1 *et seq.*, and under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. This Court has subject matter jurisdiction under the provisions of 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Oxis because it has transacted business in New York out of which the causes of action arise.

6. Venue is proper in this judicial district under 28 U.S.C. § 1391(b).

FACTUAL ALLEGATIONS

Background of Companies' Relationship

7. In the early to mid-1990s, AGI and Oxis entered into a series of non-disclosure agreements under which each agreed to share with the other confidential information related to shared areas of interest.

8. On or about October 31, 1994, Dr. Daniel Yarosh, then-president of AGI, met with Anna Barker, then-president of Oxis, at the Grand Hyatt Hotel in New York City to discuss their mutual interest in L-ergothioneine, and AGI's interest in L-ergothioneine for use in cosmetics.

9. Upon information and belief, Oxis owns a patent that claims one particular method for synthesizing L-ergothioneine, among the multiple methods that exist. (U.S. Pat. No. 5,438,151 ("the '151 patent").)

10. In 1996, AGI and Oxis entered into a Material Supply Agreement ("MSA") under which Oxis agreed to supply AGI with L-ergothioneine, and AGI agreed to disclose the results of its research with L-ergothioneine to Oxis.

11. In February of 1997, AGI and Oxis entered into an agreement that amended and modified the MSA. Oxis and AGI both assumed additional obligations. The parties agreed to negotiate in good faith to establish mutually acceptable terms for any patents jointly developed.

12. Two patents naming Dr. Yarosh as the sole inventor eventually issued and have been a long-standing source of dispute between the parties: U.S. Pat. No. 6,103,746 ("the '746 patent") and U.S. Pat. No. 6,479,533 ("the '533 patent") (collectively, "the mitochondria patents").

13. Between 1997 and 2003, Oxis supplied L-ergothioneine to AGI. During the time period between 1993 and 2006, the two companies had business dealings in New York.

14. In or about 2003, Oxis unilaterally terminated its business relationship with AGI, thereby depriving AGI of its source of L-ergothioneine.

15. AGI subsequently identified another supplier of L-ergothioneine, and purchased L-ergothioneine from that outside manufacturer. The outside manufacturer used a manufacturing method to produce L-ergothioneine that is different from, and unrelated to, the process disclosed and claimed in the '151 patent.

16. On or about November 3, 2006, Dr. Yarosh met with Dr. Marvin Hausman, then CEO and President of Oxis, in New York City at LaGuardia Airport to discuss reaching resolution of outstanding disputes between AGI and Oxis.

17. On April 4, 2007, after Oxis had repeatedly contacted AGI's customers and misrepresented the scope and ownership of patents related to L-ergothioneine, AGI filed a declaratory judgment action against Oxis in the Eastern District of New York. (07-cv-1441, Dkt. No. 1.) Oxis filed an Answer in that action on June 11, 2007, and also asserted counterclaims. (07-cv-1441, Dkt. No. 9.) Oxis alleged that AGI infringed the '151 patent and the '746 patent.

AGI filed a Reply to Oxis' counterclaims in that action on July 2, 2007. (07-cv-1441, Dkt. No. 14.)

18. In September of 2007, AGI and Oxis stipulated to a dismissal, without prejudice, of the action in the Eastern District of New York, because they desired to pursue non-binding mediation. (07-cv-1441, Dkt. No. 17.)

19. Upon information and belief, Oxis and AGI reached a settlement agreement in principle as to rights to the '151, '746 and '533 patents, but did not execute a final settlement agreement.

20. Upon information and belief, Oxis did nothing between 2007 and 2009 to attempt enforce the rights that it claims under the patents.

21. Estée Lauder acquired AGI in 2008. Estée Lauder has, and continues, to purchase L-ergothioneine from AGI's outside manufacturer. The outside manufacturer continues to use a manufacturing method to produce L-ergothioneine that is different from, and unrelated to, the process disclosed and claimed in the '151 patent.

22. After a prolonged period of silence, Oxis contacted Estée Lauder in June of 2009, demanding that Estée Lauder disclaim any ownership rights in the '746 and '533 patents. Estée Lauder has not done so.

23. Upon information and belief, after contacting Estée Lauder, Oxis announced its intention to "vigorously defend" its patents "against any potential infringer no matter how large or small they may be."

The '151 Patent

24. United States Patent No. 5,438,151 ("the '151 patent") relates to a process for the preparation of L-ergothioneine, a naturally-occurring molecule with antioxidant properties.

25. Estée Lauder and AGI purchase L-ergothioneine that is synthesized in a manner that is different from, and unrelated to, the process disclosed and claimed in the '151 patent.

26. Upon information and belief, Oxis is aware that the L-ergothioneine that is purchased by Estée Lauder and AGI is synthesized in a manner that is different from, and unrelated to, the process disclosed and claimed in the '151 patent.

27. Nonetheless, based on communications with Oxis and others, Estée Lauder and AGI have reason to believe that Oxis is alleging that Estée Lauder and AGI have infringed, and continue to infringe, the '151 patent.

28. Estée Lauder and AGI deny that they have infringed, contributed to the infringement, or induced others to infringe any valid and enforceable claim of the '151 patent.

The Mitochondria Patents

The '746 Patent

29. United States Patent No. 6,103, 746 ("the '746 patent") is directed to methods and compositions using L-ergothioneine for the protection of mitochondria, which are subcellular organelles found in most eukaryotic cells.

30. Oxis purports to own the '746 patent. Estée Lauder and AGI deny that Oxis owns the '746 patent.

31. The '746 patent arose out of work performed in New York by the sole inventor on the '746 patent, Dr. Daniel Yarosh, who was then president of AGI. The '746 patent matured out of provisional patent application 60/038,749 ("the provisional patent application") and patent application 09/026,198 ("the '746 patent application").

32. Under the terms of a written agreement between AGI and Oxis, including all modifications thereof, as well as the course of dealing between AGI and Oxis, Dr. Yarosh was the sole owner of the provisional patent application and the '746 patent application.

33. Dr. Yarosh assigned the provisional patent application and the '746 patent application to AGI on July 30, 1998. The assignments were recorded at the U.S. Patent and Trademark Office ("PTO") on July 31, 1998.

34. In August of 1998, counsel for AGI and Dr. Yarosh informed Oxis that Dr. Yarosh believed that the '746 patent application should be abandoned, and that a more comprehensive application filed by AGI, patent application 09/026,875 ("the abandoned patent application"), should be prosecuted instead.

35. Oxis did not abandon the prosecution of the '746 patent application as the inventor, Dr. Yarosh, requested.

36. In September of 1998, Oxis filed a declaration and power of attorney at the PTO with regard to the '746 patent application, purporting to act as an agent of Dr. Yarosh and signing on his behalf. Oxis' representation to the PTO was misleading. Oxis knew that it was not authorized to act on behalf of Dr. Yarosh, or to represent itself as Dr. Yarosh's agent.

37. In September of 1998, Oxis filed misleading disclosures to the PTO regarding the ownership of the provisional patent application and the '746 patent application. Oxis submitted a written agreement between Oxis and AGI to the PTO that allegedly assigned ownership of the provisional patent application and the '746 patent application to Oxis, which is referred to herein as the Material Supply Agreement or MSA. The MSA was executed in 1996. Oxis failed to disclose a 1997 modification of the MSA to the PTO. Under the terms of the MSA, as amended, Dr. Yarosh had sole ownership of the provisional patent application and the '746 patent application.

38. In December of 1998, the PTO rejected all pending claims of the '746 patent application under 35 U.S.C. § 103. The Examiner stated that L-ergothioneine was shown by the

prior art to be an antioxidant, and that L-ergothioneine “would be expected to be equally beneficial to the entire cell including the mitochondria.”

39. In March of 1999, counsel for Oxis, Klauber & Jackson, told the Examiner that the beneficial effects of antioxidants known for entire cells were not extendable to mitochondria, and that a skilled artisan would not be able to correlate protective effects of a particular antioxidant on whole cells with a corresponding protection of the mitochondria.

40. Counsel for Oxis failed to disclose to the Examiner the results of an international, prior art search that was performed in connection with a related application under the Patent Cooperation Treaty, PCT/US98/03352, which they were also prosecuting. The PCT application and the international search report had been published over six months earlier, in August of 1998. (WO 98/36748.) The international search report identified numerous pieces of prior art that were not disclosed to the Examiner during prosecution of the '746 patent application, even though counsel for Oxis filed an IDS with the PTO in November of 1998.

41. In particular, counsel for Oxis failed to disclose the Kawano reference to the Examiner, which counsel knew was material to the prosecution of the '746 patent application. The Kawano reference, published in 1983, discloses that L-ergothioneine has an effect on the mitochondria. Specifically, Kawano discloses that L-ergothioneine increases the activity of a mitochondrial enzyme, Mn-superoxide dismutase.

42. The Kawano reference directly contradicts representations that counsel for Oxis made to the Examiner during prosecution of the '746 patent application. Contrary to what they told the Examiner in March of 1999, a skilled artisan would have been able to correlate protective effects of a particular antioxidant, L-ergothioneine, on whole cells with a corresponding protection of the mitochondria.

43. In September of 1999, Oxis filed an assignment of the provisional patent application and the '746 patent application to Oxis with the PTO, purporting to act as an agent of Dr. Yarosh and signing on his behalf. Oxis' representation to the PTO was misleading. Oxis knew that it was not authorized to act on behalf of Dr. Yarosh, or to represent itself as Dr. Yarosh's agent.

44. The '746 patent issued on August 15, 2000, incorrectly identifying Oxis as the assignee on the face of the patent. Oxis voluntarily abandoned the '746 patent in 2008, subsequently claiming that it had "unintentionally" delayed making payment of a maintenance fee.

45. Estée Lauder and AGI purchase L-ergothioneine from their outside manufacturer to include in certain of their cosmetic products. Estée Lauder also sells L-ergothioneine to customers in the cosmetic industry, for use in the customers' products, through a third-party distributor.

46. Based on communications with Oxis and others, Estée Lauder and AGI have reason to believe that Oxis is alleging that Estée Lauder and AGI have infringed, and continue to infringe, the '746 patent.

47. Estée Lauder and AGI deny that they have infringed, contributed to the infringement, or induced others to infringe any valid and enforceable claim of the '746 patent.

The '533 Patent

48. United States Patent No. 6,479,533 ("the '533 patent") is directed to methods for using L-ergothioneine for the protection of mitochondria in eukaryotic cells that are intermingled with prokaryotic organisms, when the mixture is exposed to radiation or reactive oxygen species to inactivate the prokaryotic organisms.

49. Oxis purports to own the '533 patent. Estée Lauder and AGI deny that Oxis owns the '533 patent.

50. The '533 patent arose out of work performed in New York by the sole inventor on the '533 patent, Dr. Daniel Yarosh, who was then president of AGI. The '533 patent matured out of the provisional patent application, patent application 09/026,875 ("the abandoned patent application") and divisional patent application 09/452,585 ("the '533 patent application").

51. Under the terms of a written agreement between AGI and Oxis, including all modifications thereto, as well as the course of dealing between AGI and Oxis, Dr. Yarosh was the sole owner of the provisional patent application, the abandoned patent application and the '533 patent application.

52. Dr. Yarosh assigned the provisional patent application and the abandoned patent application (parent application to the divisional application) to AGI on July 30, 1998. The assignments were recorded at the PTO on July 31, 1998.

53. Unlike the provisional patent application and the '746 patent application, the abandoned patent application and the '533 patent application were prosecuted by counsel for AGI.

54. During prosecution of the abandoned patent application, counsel for AGI became aware of an international, prior art search that was performed in connection with the prosecution of a related application under the Patent Cooperation Treaty, PCT/US98/03352, published as WO 98/36748. Counsel for AGI disclosed the international prior art search to the PTO in May of 1999.

55. The '533 patent issued on November 12, 2002, correctly identifying AGI as the assignee on the face of the patent.

COUNT I

DECLARATORY JUDGMENT OF ESTOPPEL AND/OR LACHES

56. Estée Lauder and AGI hereby restate and reallege the allegations set forth in paragraphs 1-55.

57. The dispute between Oxis and AGI-Estée Lauder over the '151, '746 and/or '533 patents dates back over a decade, to at least the late 1990s.

58. For at least the last six years, AGI has purchased L-ergothioneine from a supplier other than Oxis. AGI has used L-ergothioneine in its products and has supplied L-ergothioneine to the cosmetic industry.

59. After Oxis made repeated misrepresentations to AGI's customers, AGI filed a declaratory judgment action in 2007 in an attempt to finally resolve this dispute.

60. Oxis agreed to the dismissal of that lawsuit in 2007.

61. AGI and Oxis reached an agreement in principle regarding the '151, '746 and '533 patents after the 2007 lawsuit was dismissed.

62. Upon information and belief, after AGI and Oxis reached their agreement in principle regarding the '151, '746 and '533 patents, Oxis remained silent.

63. Estée Lauder purchased AGI in 2008. Oxis voluntarily abandoned the '746 patent in 2008, subsequently claiming that it had "unintentionally" delayed making payment of a maintenance fee.

64. Relying upon Oxis' silence, Estée Lauder and AGI continued to purchase L-ergothioneine to include in certain of their cosmetic products. Estée Lauder and AGI also continued to supply L-ergothioneine to customers in the cosmetic industry, for use in the customers' products, through a third-party distributor.

65. After a prolonged period of silence, during which Estée Lauder and AGI believed that the dispute with Oxis was over, Oxis again approached Estée Lauder and AGI in 2009, demanding that they disclaim any ownership rights in the '746 and '533 patents.

66. Estée Lauder and AGI are entitled to a declaration that Oxis is barred by estoppel and/or laches from taking any action against Estée Lauder and AGI, or their customers, based on the '151, '746 or '533 patents. As to the '746 patent, Oxis is barred by estoppel and/or laches for at least the additional reason that they relinquished the '746 patent in 2008.

67. Estée Lauder and AGI are further entitled to a declaration that Oxis is barred by estoppel and/or laches from challenging Estée Lauder and AGI's ownership interests in the '746 and '533 patents.

COUNT II

DECLARATORY JUDGMENT REGARDING THE '151 PATENT

68. Estée Lauder and AGI hereby restate and reallege the allegations set forth in paragraphs 1-55.

69. Estée Lauder and AGI have reason to believe that Oxis is alleging that Estée Lauder and AGI have infringed, and continue to infringe, either directly or indirectly, via contributory infringement or inducement of infringement, the '151 patent.

70. Estée Lauder and AGI do not infringe either directly or indirectly, via contributory infringement or inducement of infringement, the '151 patent.

71. Estée Lauder and AGI are entitled to a declaration that they do not infringe either directly or indirectly, via contributory infringement or inducement of infringement, any valid and enforceable claim of the '151 patent.

COUNT III

DECLARATORY JUDGMENT REGARDING THE '746 PATENT

72. Estée Lauder and AGI hereby restate and reallege the allegations set forth in paragraphs 1-55.

73. Estée Lauder and AGI have reason to believe that Oxis is alleging that Estée Lauder and AGI have infringed, and continue to infringe, either directly or indirectly, via contributory infringement or inducement of infringement, the '746 patent.

74. Estée Lauder and AGI do not infringe either directly or indirectly, via contributory infringement or inducement of infringement, the '746 patent.

75. Estée Lauder and AGI are entitled to a declaration that they do not infringe either directly or indirectly, via contributory infringement or inducement of infringement, any valid and enforceable claim of the '746 patent.

COUNT IV

**THE '746 PATENT IS UNENFORCEABLE BY OXIS FOR
INEQUITABLE CONDUCT BY OXIS**

76. Estée Lauder and AGI hereby restate and reallege the allegations set forth in paragraphs 1-55.

77. On information and belief, the claims of the '746 patent are unenforceable by Oxis for inequitable conduct by Oxis because, during prosecution of the '746 patent, Oxis and its patent counsel, Klauber & Jackson, made affirmative misrepresentations of material facts and failed to disclose known material information to the PTO with the intent to deceive.

Oxis Misrepresented The Ownership Of The '746 Patent Application To The PTO

78. During prosecution of the '746 patent, in order to falsely demonstrate that it owned the '746 patent application, Oxis submitted to the PTO the Material Supply Agreement ("MSA") between Oxis and AGI that had been executed in 1996.

79. Oxis deliberately withheld from the PTO the 1997 amendment to the MSA that established that Oxis did not own the '746 patent application, and, to the contrary, that Dr. Yarosh owned the '746 patent application.

80. Oxis intended to deceive the PTO when it withheld the 1997 amendment to the MSA.

81. Further, during prosecution of the '746 patent, Oxis filed assignment documents with the PTO that assigned the application to Oxis, purporting to act as an agent of Dr. Yarosh and signing on his behalf. Oxis' representation to the PTO was misleading. Oxis knew that it was not authorized to act on behalf of Dr. Yarosh, or to represent itself as Dr. Yarosh's agent.

82. Oxis intended to deceive the PTO when it misrepresented itself as Dr. Yarosh's agent and executed assignment documents on his behalf.

83. Because Oxis failed to disclose the 1997 amendment to the MSA to the PTO, and because Oxis misrepresented that it was Dr. Yarosh's agent when it filed assignment documents on Dr. Yarosh's behalf, the '746 patent issued with an indication that it is assigned to Oxis.

Oxis Failed To Disclose Material Prior Art To The PTO

84. During prosecution of the '746 patent, counsel for Oxis failed to disclose the Kawano reference, published in 1983, to the Examiner.

85. Counsel for Oxis was aware of Kawano because Kawano was identified in an international search report for a related, PCT application that they were also prosecuting.

86. Counsel for Oxis was aware that Kawano was material to the prosecution of the '746 patent application because, to overcome a rejection under 35 U.S.C. § 103, Oxis argued to the PTO that the beneficial effects of antioxidants known for entire cells were not extendable to mitochondria, and that a skilled artisan would not be able to correlate protective effects of a particular antioxidant on whole cells with a corresponding protection of the mitochondria.

87. Kawano is material because it discloses that L-ergothioneine has an effect on a mitochondrial enzyme, Mn-superoxide dismutase. Thus, Kawano directly contradicts the argument for patentability that was made by Oxis' counsel.

88. Upon information and belief, counsel for Oxis intended to deceive the PTO when they failed to submit the Kawano reference.

JURY DEMAND

89. Estée Lauder and AGI request a jury trial on all issues triable of right by a jury.

PRAYER FOR RELIEF

WHEREFORE, Estée Lauder and AGI pray for judgment as follows:

1. A declaration that Oxis is barred by estoppel and/or laches from taking any action against Estée Lauder and AGI, or their customers, based on the '151, '746 or '533 patents;
2. A declaration that Oxis is barred by estoppel and/or laches from challenging Estée Lauder and AGI's ownership interests in the '746 and '533 patents.
3. A declaration that Estée Lauder and AGI have not, and are not, infringing either directly or indirectly, via contributory infringement or inducement of infringement, any valid and enforceable claim of the '151 patent;
4. A declaration that Estée Lauder and AGI have not, and are not, infringing either directly or indirectly, via contributory infringement or inducement of infringement, any valid and enforceable claim of the '746 patent;

5. A declaration that the claims of the '746 patent are unenforceable by Oxis for inequitable conduct by Oxis and its counsel;

6. That Estée Lauder and AGI be awarded their costs, disbursements and attorneys' fees herein in accordance with the terms of the Agreement and with Title 35 U.S.C. § 285; and

7. That Estée Lauder and AGI be awarded such other relief as this Court may deem just and equitable.

Dated: June 15, 2010

Respectfully submitted,

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.



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