

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ALKERMES, INC.,
Plaintiff,

v.

ALKEUS PHARMACEUTICALS, INC.,
Defendant.

Civil Action No.

COMPLAINT AND DEMAND
FOR JURY TRIAL

The plaintiff, Alkermes, Inc. (“Alkermes” or “plaintiff”), for its complaint against the defendant, Alkeus Pharmaceuticals, Inc. (“Alkeus” or “defendant”), states that:

NATURE OF THE ACTION

1. In this action the plaintiff Alkermes seeks to recover damages and to obtain a preliminary and permanent injunction for the defendant’s trademark infringement under the Lanham Act and at common law; for the defendant’s infringement of Alkermes’ federally registered trademark; for the defendant’s infringement of Alkermes’ trade names; for the defendant’s false designation of origin; for dilution under 15 U.S.C. § 1125(c); for dilution under Mass. Gen. Laws ch. 110H, § 13; for the defendant’s unfair competition; and for unfair and deceptive acts and practices under Mass. Gen. Laws ch. 93A, §§ 2 and 11.

JURISDICTION AND VENUE

2. This court has jurisdiction of the subject matter of this action under 28 U.S.C. §§ 1331 and 1338, the Lanham Act, Title 15 of the United States Code, and principles of supplemental jurisdiction, 28 U.S.C. § 1367.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)-(c).

THE PARTIES

4. The plaintiff, Alkermes, Inc., is a Pennsylvania corporation with a place of business at 852 Winter Street, Waltham, Massachusetts 02451.

5. The defendant, Alkeus Pharmaceuticals, Inc., is a Delaware corporation with a place of business at 1 Marina Park Drive, Boston, Massachusetts 02210.

FACTUAL BACKGROUND

6. The plaintiff, Alkermes, Inc., has been engaged in developing pharmaceutical products based on innovative drug technologies since at least 1987.

7. On September 16, 2011, Alkermes, Inc. and Elan Drug Technologies, the drug formulation and manufacturing business unit of Elan Corporation, plc, were combined to form a new company. The businesses were combined under an entity incorporated in Ireland and headquartered in Dublin, Alkermes plc, which, with the consent of Alkermes, Inc., adopted the Alkermes trade name. Alkermes plc has a diversified portfolio of more than 20 commercial drug products spanning a range of major diseases, such as schizophrenia, addiction, diabetes, and multiple sclerosis. Alkermes plc is listed on the Nasdaq stock exchange under the ticker symbol “ALKS.” Alkermes, Inc. operates as a wholly owned subsidiary of Alkermes plc. With the consent of Alkermes, Inc., the other operating subsidiaries of Alkermes plc have adopted and use Alkermes as part of their trade names.

8. Alkermes also has an extensive pipeline of proprietary drug candidates, many in late-stage development.

9. Alkermes was incorporated as a Pennsylvania corporation with the name “Alkermes, Inc.” on July 13, 1987.

10. Alkermes was registered to conduct business in the Commonwealth of Massachusetts on February 26, 1988.

11. Since 1987, the plaintiff has used “Alkermes, Inc.,” and “Alkermes” as corporate names and trade names to identify the company.

12. The Alkermes, Inc. and Alkermes trade names are widely recognized in the pharmaceutical industry.

13. The plaintiff established www.alkermes.com as a web address for its business at least as early as 1995 and has used this web address continuously from 1995 to the present.

14. Alkermes began using ALKERMES as a mark in commerce at least as early as 1991 for pharmaceutical preparations.

15. Alkermes has used the ALKERMES mark continuously for pharmaceutical products from 1991 to present.

16. As a result of its longstanding use, Alkermes has developed strong common law rights in the mark ALKERMES.

17. In the United States, Alkermes owns numerous trademark registrations for the mark ALKERMES, covering a variety of pharmaceutical products.

18. On August 18, 1995, Alkermes applied for federal registration of the ALKERMES trademark. A registration issued on July 30, 1996 as U.S. Registration No. 1,990,007. The ALKERMES trademark is registered on the Principal Register of the United States Patent and Trademark Office for polymer-based drug delivery formulations for clinical use. This trademark registration is incontestable. A true and accurate copy of this registration is attached hereto and made a part hereof as Exhibit A.

19. On July 5, 2001, Alkermes applied for federal registration of the ALKERMES trademark. A registration issued on September 17, 2002 as U.S. Registration No. 2,622,243. The ALKERMES trademark is registered on the Principal Register of the United States Patent and Trademark Office for polymer-based drug delivery formulations for clinical use and pharmaceutical products, namely, injectable drug delivery formulations used as facilitating agents for other pharmaceutical preparations. This trademark registration is incontestable. A true and accurate copy of this registration is attached hereto and made a part hereof as Exhibit B.

20. On July 11, 2000, Alkermes applied for federal registration of the ALKERMES trademark. A registration issued on January 27, 2004 as U.S. Registration No. 2,808,988. The ALKERMES trademark is registered on the Principal Register of the United States Patent and Trademark Office for pharmaceutical products, namely, injectable drug delivery formulations used as a facilitating agent for other pharmaceuticals. This trademark registration is incontestable. A true and accurate copy of this registration is attached hereto and made a part hereof as Exhibit C.

21. On March 4, 2010, Alkermes applied for federal registration of the ALKERMES trademark. A registration issued on January 18, 2011 as U.S. Registration No. 4,139,550. The ALKERMES trademark is registered on the Principal Register of the United States Patent and Trademark Office for pharmaceutical preparations and compounds, namely, small molecules and chemical compounds for use in opioid modulation; pharmaceutical preparations and compounds for use in treating addiction, substance abuse and dependence, reward disorders, CNS disorders, pain and constipation; and prodrugs for medical use, namely, antipsychotics for use in treating CNS disorders. A true and accurate copy of this registration is attached hereto and made a part hereof as Exhibit D.

22. Alkermes uses a naming convention for its pharmaceutical products and candidates that consists of the letters ALKS followed by one or more numbers. Examples of these pharmaceutical products and candidates include ALKS 33 (an opioid modulator); ALKS 5461 (a combination mu-opioid partial agonist and a mu-opioid antagonist); ALKS 9070 and ALKS 9072 (aripiprazole lauroxil); ALKS 7106 (an opioid modulator); and ALKS 3831 (an orally administered combination of an atypical antipsychotic and a potent mu-opioid antagonist).

23. Alkermes uses the ALKS naming convention to identify its pharmaceutical products during clinical trials, regulatory submissions, and press releases.

24. As a result of use and registration, Alkermes has rights in the trade names Alkermes and Alkermes, Inc., in the trademark and service mark ALKERMES, in the domain name www.alkermes.com, and in the product designation “ALKS,” alone or in combination with a number (hereinafter “trade names, trademark, and service mark”).

25. Those in the prescription pharmaceutical industry have come to recognize “ALKERMES” as indicating the products and services of Alkermes as a result of the goodwill and expanding reputation of the trade names, trademark, and service mark associated with a wide variety of drug delivery products that emanate from Alkermes. The products associated with “ALKERMES” have continued to expand over the years, and Alkermes has continued this expansion into additional fields such as new molecular entity pharmaceuticals, including single agents, prodrugs, and orthogonal combinations of drugs.

26. The ALKERMES mark, trade names, and ALKS product designation are distinguished and widely known in the pharmaceutical industry as distinctly connected with Alkermes.

27. Those in the prescription pharmaceutical industry have come to recognize the product designation ALKS as the prefix for Alkermes' pharmaceutical products.

28. Those in the prescription pharmaceutical industry have come to recognize the trade names Alkermes and Alkermes, Inc. as referring to the plaintiff Alkermes.

29. The prescription pharmaceutical and healthcare industries are highly competitive. Therefore, it is critical that Alkermes protect its trade names, trademark, and service mark and police against any confusingly similar uses by others.

30. Alkermes' trade names, trademark, and service mark are valuable assets of Alkermes.

31. To develop and achieve a competitive advantage, Alkermes relies on the reputation that it has developed for high-quality products.

32. The strength of Alkermes' trade names, trademark, and service mark is due to Alkermes' consistent emphasis on providing innovative and distinctive products and services in the prescription pharmaceutical industry.

33. Under United States trademark laws, Alkermes' rights in Alkermes' trade names, trademark, and service mark give Alkermes exclusive rights of use throughout the United States in connection with its various products and services and in connection with related products and services, as well as products and services that are likely to be confused with those of Alkermes.

34. Alkermes' rights specifically include rights to preclude any other person or entity from using any identical or confusingly similar trade names, trademark, and service mark in connection with products or services that may be confused with those of Alkermes.

35. Alkermes would be damaged by any diminution in the strength of any of its trade names, trademark, and service mark.

36. The defendant is a clinical stage company that is developing prescription pharmaceutical products.

37. Corporate records show that Alkeus was incorporated in Delaware on March 3, 2010 and was registered to do business in Massachusetts on December 19, 2011.

38. The defendant is using “Alkeus Pharmaceuticals, Inc.” and “Alkeus” as trade names for its business.

39. The defendant is using www.alkeus.com as a web address for its business.

40. Alkeus has adopted the convention “ALK,” followed by a number, which it has used at least for its pharmaceutical products in connection with preclinical research, presentations, publications, press releases, grant proposals, and pending clinical trials.

41. The defendant’s lead drug candidate is an investigational medicine designed for oral delivery, designated as ALK-001. Alkeus has completed animal trials with ALK-001 and has received FDA clearance to start human clinical trials with ALK-001.

42. Alkeus is currently recruiting volunteers for a study of its drug compound ALK-001.

43. On information and belief, Alkeus has sought or will be seeking employees with backgrounds and experience that are similar to those of Alkermes’ employees, in the greater Boston area, where both parties are located.

44. On information and belief, the defendant is using or intends to use Alkeus and Alkeus Pharmaceuticals, Inc. to identify Alkeus as the source for products in clinical trials by using these company identifiers on packaging for products shipped in interstate commerce for clinical trials.

45. On information and belief, Alkeus is using or intends to use “ALKEUS” in ways that are trademark or service mark use, at least as part of clinical trials for Alkeus products.

46. The defendant’s actions, including the uses of Alkeus, Inc. and Alkeus as trade names, the use of ALKEUS as a trademark and service mark, the use of ALK as a product designation, and the use of www.alkeus.com as a web address (hereinafter “the defendant’s infringing activities”) infringe the rights of Alkermes in its trade names, trademark, and service mark.

47. The defendant’s infringing activities, in connection with its pharmaceutical business, conflict with and overlap the trade name, trademark, and service mark rights of Alkermes.

48. The defendant’s infringing activities create a likelihood of confusion or mistake among consumers concerning the origin of products and services of Alkermes and the defendant.

49. This likelihood of confusion has been increased by the defendant’s recent activity, which has heightened its profile as a pharmaceutical company, including Alkeus’ announcement that it received a grant from the U.S. Food and Drug Administration for “Phase 1 Study of ALK001 for the Treatment of Stargardt Disease,” Alkeus’ statement on its website that “Alkeus intends to start a clinical trial in patients with Stargardt disease in 2013,” and Alkeus’ publication of preclinical results using “ALK-001” in the 2014 Annual Meeting Abstracts of the Association for Research in Vision and Ophthalmology.

50. Those in the pharmaceutical industry are likely to mistakenly identify Alkeus as related to Alkermes.

51. Indeed, there is a high likelihood that people in the pharmaceutical industry will be confused into thinking that Alkeus, which combines the first four letters of the name

Alkermes, “ALKE,” with the suffix “US,” is a U.S. division or subsidiary of Alkermes, particularly because both Alkermes and Alkeus are located in the greater Boston area.

52. The defendant’s use of ALKEUS will lead consumers and others in the prescription pharmaceutical industry to improperly conclude that the defendant and the defendant’s products and services are associated with Alkermes or have a common origin with the products of Alkermes.

53. The likelihood of confusion or mistake that has been and that will be caused by the defendant’s actions is high because Alkermes’ products and Alkeus’ products are both used in the pharmaceutical industry.

54. The likelihood of confusion or mistake that has been and that will be caused by the defendant’s actions is high because the trade name and mark ALKEUS sounds similar to Alkermes’ registered mark ALKERMES, starts with the same four letters, and ends with the same letter.

55. Indeed, upon information and belief, one or more of the pharmaceutical delivery platforms of Alkermes could be used for Alkeus’ ALK-001 product.

56. Alkermes adopted and used its trade names, trademark, and service mark, federally registered the ALKERMES mark, and used the web address www.alkermes.com years before Alkeus began its infringing activities.

57. In May 2012, before the defendant had begun to expand its use of the trade name and mark ALKEUS and the product designation ALK in publications, on its website, and in connection with clinical trials, Alkermes notified the defendant of Alkermes’ rights in the Alkermes’ trade names, trademark, and service mark, and advised the defendant to discontinue use of “ALKEUS” and the ALK product designation.

58. In May 2012, defendant could have easily changed its trade names and mark with a minimum of business impact to it as a newly formed pharmaceutical company.

59. The defendant did not change its trade name, mark, and product designation as a result of the discussions with Alkermes that took place in 2012. Instead, the defendant continued to build a company with the Alkeus trade name and the ALK product designation throughout the U.S. pharmaceutical community, increasing the likelihood of confusion between the products of services of Alkermes and those of the defendant.

60. On March 31, 2014, Alkermes' counsel sent a letter to inform the defendant that its continued and expanded use of "Alkeus" as a mark, trade name and domain name, and use of the ALK product designation were likely to cause confusion with Alkermes' federally registered ALKERMES trademark. The letter also gave further notice to the defendant of Alkermes' rights and the defendant's infringement and requested that the defendant stop using Alkeus as a trademark, as a trade name, and as a domain name.

61. Despite further communication, the defendant has neglected or refused to cease its infringing activities.

62. The defendant's infringing activities have caused and will continue to cause irreparable harm to Alkermes.

COUNT I

(Infringement of Plaintiff Alkermes' Common Law Mark)

63. The plaintiff Alkermes repeats and realleges paragraphs 1 through 62 of this complaint as if they were fully set forth.

64. The defendant has infringed and is infringing Alkermes' common law rights in the ALKERMES mark.

65. Alkermes has been and is being damaged by the defendant's infringement of its common law rights.

66. Alkermes has suffered and will continue to suffer irreparable injury due to the above described activities of the defendant if the defendant is not preliminarily and permanently enjoined.

COUNT II

(Infringement of Plaintiff Alkermes' Federally Registered Mark)

67. The plaintiff Alkermes repeats and realleges paragraphs 1 through 66 of this complaint as if they were fully set forth.

68. The defendant's actions were and are in violation of 15 U.S.C. § 1114(1).

69. The defendant has infringed and is infringing the plaintiff Alkermes' federally registered ALKERMES trademark, bearing U.S. Registration Nos. 1,990,007; 2,622,243; 2,808,988; and 4,139,550.

70. Alkermes has been and is being damaged by the defendant's infringement of its federally registered mark.

71. Alkermes has suffered and will continue to suffer irreparable injury due to the above described activities of the defendant if the defendant is not preliminarily and permanently enjoined.

COUNT III

(Trade Name Infringement)

72. The plaintiff Alkermes repeats and realleges paragraphs 1 through 71 of this complaint as if they were fully set forth.

73. The defendant infringed and is infringing Alkermes' trade names Alkermes and Alkermes, Inc.

74. Alkermes has been and is being damaged by the defendant's infringement of Alkermes' trade names.

75. Alkermes has suffered and will continue to suffer irreparable injury due to the above described activities of the defendant if the defendant is not preliminarily and permanently enjoined.

COUNT IV

(False Designation of Origin)

76. The plaintiff Alkermes repeats and realleges paragraphs 1 through 75 of this complaint as if they were fully set forth.

77. The defendant's actions were and are in violation of 15 U.S.C. § 1125(a) (Lanham Act § 43(a)), which imposes liability for the use in commerce of any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person.

78. Alkermes has been and is being damaged as a result of the defendant's violation of 15 U.S.C. § 1125(a).

79. Alkermes has suffered and will continue to suffer irreparable injury due to the above described activities of the defendant if the defendant is not preliminarily and permanently enjoined.

COUNT V

(Dilution under 15 U.S.C. §1125(c))

80. Alkermes repeats and realleges paragraphs 1 through 79 of this complaint as if they were fully set forth.

81. Alkermes' ALKERMES mark has become famous in the prescription pharmaceutical industry, as that term is used and defined in 15 U.S.C. § 1125(c).

82. The defendant's commercial use of the mark ALKEUS; the trade name ALKEUS; the web addresses www.alkeus.com, alone and in combination, in commerce has caused and continue to cause dilution of the distinctive quality of Alkermes' mark in violation of 15 U.S.C. § 1125(c).

83. Alkermes has been damaged by the defendant's dilution of the distinctive quality of Alkermes' famous mark.

84. Alkermes has suffered and will continue to suffer irreparable injury due to the above described activities of the defendant if the defendant is not preliminarily and permanently enjoined.

COUNT VI

(Dilution under Mass. Gen. Laws ch. 110H, § 13)

85. Alkermes repeats and realleges paragraphs 1 through 84 of this complaint as if they were fully set forth.

86. The defendant's use in commerce of the trade name and mark ALKEUS, the designation ALK, and the web address www.alkeus.com, alone and in combination, is causing a likelihood of injury to Alkermes' business reputation and of dilution of the distinct quality of its ALKERMES mark.

87. By reason of the foregoing, Alkermes is entitled to relief under Mass. Gen. Laws ch. 110H, § 13.

COUNT VII

(Unfair Competition)

88. The plaintiff Alkermes repeats and realleges paragraphs 1 through 87 of this complaint as if they were fully set forth.

89. The defendant, by its actions, has engaged and is engaging in unfair competition.

90. Alkermes has been and is being damaged by the defendant's engagement in unfair competition.

91. Alkermes has suffered and will continue to suffer irreparable injury due to the above described activities of the defendant if the defendant is not preliminarily and permanently enjoined.

COUNT VIII

(Unfair or Deceptive Acts of Practices under Mass. Gen. Laws ch. 93A, §§ 2 and 11)

92. The plaintiff Alkermes repeats and realleges paragraphs 1 through 91 of this complaint as if they were fully set forth.

93. At all times relevant hereto, the plaintiff and defendant were engaged in trade or commerce.

94. The defendant's foregoing conduct constitutes unfair competition with Alkermes and unfair or deceptive acts and practices as provided in and declared unlawful under Mass. Gen. Laws ch. 93A, §2.

95. The defendant's actions described herein and their use and employment of the foregoing unfair and deceptive acts or practices were performed willfully and knowingly.

96. As a result of the above-described unfair or deceptive acts or practices, Alkermes sustained injury.

WHEREFORE, the plaintiff, Alkermes, Inc., demands judgment:

A. Preliminarily and permanently enjoining the defendant, Alkeus Pharmaceuticals, Inc., from utilizing ALKEUS, or any confusingly similar term, directly or indirectly, to promote its goods or services;

B. Preliminarily and permanently enjoining the defendant, Alkeus Pharmaceuticals, Inc., from using, directly or indirectly, Alkeus Pharmaceuticals, Inc., Alkeus, or any confusingly similar term, as a trade name for its company including, but not limited to, as a web address, part of a web address, or part of an email address;

C. Preliminarily and permanently enjoining the defendant, Alkeus Pharmaceuticals, Inc., from diluting, directly or indirectly, the distinctive quality of the plaintiff Alkermes' ALKERMES mark;

D. Preliminarily and permanently enjoining the defendant, Alkeus Pharmaceuticals, Inc., from using, directly or indirectly, the web address www.alkeus.com;

E. Preliminarily and permanently enjoining the defendant, Alkeus Pharmaceuticals, Inc., from using, directly or indirectly, the product designation ALK, ALKS, or any confusingly similar term.

F. Preliminarily and permanently enjoining the defendant, Alkeus Pharmaceuticals, Inc., from engaging, directly or indirectly, in unfair methods of competition with the plaintiff Alkermes;

G. Determining and awarding the plaintiff Alkermes damages resulting from the defendant's infringement of the plaintiff Alkermes' common law trademark and service mark rights, as alleged in Count I of the complaint, plus interest, costs, and attorneys' fees;

H. Determining and awarding the plaintiff Alkermes damages resulting from the defendant's infringement of the plaintiff Alkermes' federally registered mark, in violation of 15 U.S.C. § 1114(1), as alleged in Count II of the complaint, plus interest, costs, and attorneys' fees;

I. Determining and awarding the plaintiff Alkermes damages resulting from the defendant's infringement of the plaintiff's trade names, as alleged in Count III of the complaint, plus interest, costs, and attorneys' fees;

J. Determining and awarding the plaintiff Alkermes damages resulting from the defendant's violation of 15 U.S.C. § 1125(a), as alleged in Count IV of the complaint, plus interest, costs, and attorneys' fees;

K. Determining and awarding the plaintiff Alkermes damages resulting from the defendant's dilution of the plaintiff's famous mark in violation of 15 U.S.C. § 1125(c), as alleged in Count V of the complaint, plus interest, costs, and attorneys' fees;

L. Determining and awarding the plaintiff Alkermes damages from the defendant's violation of Mass. Gen. Laws ch. 110H, § 13, as alleged in Count VI of the complaint, plus interest, costs, and attorneys' fees;

M. Determining and awarding the plaintiff Alkermes damages resulting from the defendant's unfair competition with the plaintiff Alkermes, as alleged in Count VII of the complaint, plus interest, costs, and attorneys' fees;

N. Awarding the plaintiff Alkermes three times its actual damages, pursuant to 15 U.S.C. § 1117(a), arising out of the defendant's willful violation under 15 U.S.C. § 1114(1) of the plaintiff's rights in its registered mark;

O. Awarding the plaintiff Alkermes three times its actual damages, pursuant to 15 U.S.C. § 1117(a), arising out of the defendant's acts of willful unfair competition under 15 U.S.C. § 1125(a), and trademark dilution under 15 U.S.C. § 1117(c);

P. Awarding the plaintiff Alkermes its costs and disbursements incurred in this action, including reasonable attorneys' fees pursuant to 15 U.S.C. § 1117(a).

Q. Determining and awarding the plaintiff Alkermes, pursuant to Mass. Gen. Laws ch. 93A, § 11, treble the amount of its damages resulting from the defendant's unfair competition with Alkermes and unfair or deceptive acts and practices declared unlawful in Mass. Gen. Laws ch. 93A, §2, as alleged in Count VIII of the complaint, plus interest, costs, and attorneys' fees; and

R. Granting such other and further relief as this Court may deem just and proper.

THE PLAINTIFF DEMANDS A TRIAL BY JURY.

ALKERMES, INC.

By its attorneys,

/s/ John L. DuPre'

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