

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUTERA, INC.,)
)
Plaintiff,)
) C.A. No. _____
v.)
)
PALOMAR MEDICAL TECHNOLOGIES,)
INC. and THE GENERAL HOSPITAL)
CORPORATION,)
)
Defendant.)

COMPLAINT

Plaintiff, Cutera, Inc. (“Cutera”) alleges as follows:

NATURE OF ACTION

1. This action is for a declaratory judgment that United States Patent No. 5,595,568 (“the ‘568 Patent”) and United States Patent No. 5,735,844 (“the ‘844 Patent”) are invalid, void, unenforceable, and not infringed by Cutera. True and correct copies of the ‘568 Patent and the ‘844 Patent are attached hereto as Exhibits A and B, respectively.

THE PARTIES

2. Cutera is a Delaware corporation having its principal place of business at 3240 Bayshore Boulevard, Brisbane, California 94005.

3. Upon information and belief, Palomar Medical Technologies, Inc. (“Palomar”) is a Delaware corporation with its principal place of business at 82 Cambridge Street, Burlington, Massachusetts 01830. Upon information and belief, Palomar is the exclusive licensee of the ‘568 Patent and the ‘844 Patent.

4. Upon information and belief, The General Hospital Corporation (“General”) is a not-for-profit corporation, with its principal place of business at 55 Fruit Street, Boston, Massachusetts 02114. Upon information and belief, General is the assignee and owner of the ‘568 Patent and ‘844 Patent.

JURISDICTION AND VENUE

5. This action arises under the Patent Laws of the United States (35 U.S.C. § 1 et seq.), and the laws authorizing actions for declaratory judgment in the courts of the United States, Title 28 of the United States Code, sections 2201, 2202. Defendants’ conduct has, and continues to, put Cutera under a reasonable and serious apprehension of imminent suit under the ‘568 Patent and ‘844 Patent. Based on the allegations set forth in paragraphs 8 through 63, there is a conflict of asserted rights between the parties and an actual controversy exists between Cutera and Defendants with respect to the infringement, validity, scope and enforceability of the ‘568 Patent and ‘844 Patent.

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c).

FIRST CLAIM FOR RELIEF

Declaratory Judgment of Noninfringement of the ‘568 Patent

8. Cutera repeats and realleges each and every allegation contained in paragraphs 1 through 7 hereof with the same force and effect as if fully set forth herein.

9. Defendants contend that Cutera's "products using pulsed light technology for hair removal" infringe the '568 Patent.

10. Cutera contends that such products do not infringe the '568 Patent.

11. Accordingly, an actual controversy exists between Cutera and Defendants as to the infringement of the '568 Patent. Cutera desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time in order that the parties may ascertain their respective rights and duties.

SECOND CLAIM FOR RELIEF
Declaratory Judgment of Invalidity of the '568 Patent

12. Cutera repeats and realleges each and every allegation contained in paragraphs 1 through 7 hereof with the same force and effect as if fully set forth herein.
13. Defendants claim that the '568 Patent is valid.

14. Cutera contends that the '568 Patent is invalid under 35 U.S.C. §§ 102, 103 and/or 112.

15. Accordingly, an actual controversy exists between Cutera and Defendants as to the validity of the '568 Patent. Cutera desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time in order that the parties may ascertain their respective rights and duties.

THIRD CLAIM FOR RELIEF

Declaratory Judgment of Unenforceability of the '568 Patent

16. Cutera repeats and realleges each and every allegation contained in paragraphs 1 through 7 hereof with the same force and effect as if fully set forth herein.

17. Defendants claim that the '568 Patent is enforceable.

18. Cutera contends that the '568 Patent is unenforceable by reason of inequitable conduct committed by Defendants, the named inventors of the '568 Patent and the '844 Patent, and/or their attorneys (collectively and individually, the "Applicants") during prosecution of the '568 Patent before the United States Patent and Trademark Office ("PTO").

19. In particular, the Applicants failed to disclose to the PTO certain prior art and information material to the application for the '568 Patent, including information about the Spectrum Medical Technologies, Inc. ("Spectrum") Q-switched ruby laser device, the RD-1200. Upon information and belief, the RD-1200 was on sale, and informational brochures and operator manuals for its operation were publicly available as early as 1989. The RD-1200 laser system's informational brochures and operator's manuals are highly material to the subject matter claimed in the '568 Patent because, inter alia, they disclose a laser device utilizing an articulated arm and transparent device in contact with a skin region of a patient, and further disclose the simultaneous removal of multiple hairs from a skin region of a patient while leaving the skin region substantially free of injury. Furthermore, the brochures and operator's manuals for the RD-1200 laser system disclose specific wavelength, radiation pulse energy, and radiation field parameters claimed in the '568 Patent.

20. Applicants had knowledge of the RD-1200 laser system and its informational brochures and operator's manuals prior to and during prosecution of the '568 Patent and, upon information and belief, failed to disclose the reference with intent to deceive.

21. On or about December 7, 1995, while the application for the '568 Patent was pending before the PTO, Spectrum and Palomar applied to the Food and Drug Administration (the "FDA") for permission to distribute and market a model RD-1200H Normal Mode Ruby Laser – later renamed EpiLaser® - for hair removal. On information and belief, the EpiLaser® was an embodiment covered by the then-pending application that matured into the '568 Patent. In their application to the FDA, Spectrum and Palomar contended that the EpiLaser® was equivalent in design and function to the RD-1200 laser system, and product information on the RD-1200 laser system was enclosed in the application to the FDA, including brochures and an operator's manual. Palomar employees involved in the FDA application were also involved in the application that matured into the '568 Patent.

22. Despite the materiality of the RD-1200 laser system, including its informational brochures and operator's manuals, and the Applicants' knowledge of this prior art prior to and during prosecution of the '568 Patent, the Applicants did not disclose this information to the PTO. The '568 Patent is, therefore, unenforceable by reason of the Applicants' inequitable conduct.

23. The Applicants also failed to disclose to the PTO a prior art publication by Leon Goldman M.D., entitled *Comparison of the Biomedical Effects of the Exposure of Human Tissues to Low and High Energy Lasers*, ANNALS OF THE

NEW YORK ACADEMY OF SCIENCES, 122:2, pp. 802-831 (1965) (“Goldman65”). The Goldman65 publication is highly material to the subject matter claimed in the ‘568 Patent because, inter alia, it discloses the delivery of normal-mode ruby laser pulses to a skin region of a patient using special glass rods in contact with the skin region and resulting in the simultaneous removal of multiple hairs. Furthermore, the Goldman65 publication discloses specific wavelength, radiation pulse, radiation pulse energy, and radiation field parameters claimed in the ‘568 Patent.

24. Applicants had knowledge of the Goldman65 publication prior to and during prosecution of the ‘568 Patent and, upon information and belief, failed to disclose such publication with intent to deceive.

25. In 1982, R. Rox Anderson, M.D., the first named inventor on the face of the ‘568 Patent, co-authored a publication entitled *Lasers in Dermatology Provide a Model for Exploring New Applications in Surgical Oncology*, INTERNATIONAL ADVANCES IN SURGICAL ONCOLOGY, 5:341-358 (1982) (“1982 Lasers in Dermatology”), which disclosed various applications of laser technology in dermatology and, in which Dr. Anderson explicitly cited the Goldman65 publication.

26. Despite the materiality of the Goldman65 publication, and the Applicants’ knowledge of this prior art prior to and during prosecution of the ‘568 Patent, the Applicants did not disclose this information to the PTO. The ‘568 Patent is, therefore, unenforceable by reason of such inequitable conduct.

27. Furthermore, on March 30, 1995, in connection with the prosecution of the patent application for the ‘568 Patent, David J. Glass, Associate Director for Patents, of General, submitted a declaration to the PTO asserting

General's entitlement to 'small-entity status' and, accordingly General's entitlement to pay reduced fees to the PTO. Mr. Glass declared, inter alia, that no rights to the invention claimed in the application were held by any person, other than the inventor, who could not qualify for small entity status. Lastly, Mr. Glass acknowledged his duty "to file, in this application or Patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee."

28. On August 18, 1995, General granted Palomar an exclusive license to, inter alia, the patent application for the '568 Patent. On information and belief, Palomar did not qualify for small entity status and, accordingly, such license terminated General's small-entity status.

29. On August 21, 1996, the PTO mailed to the Applicants a 'Notice of Allowance and Issue Fee Due.' In the Notice, the PTO instructed the Applicants to "[r]eview the SMALL ENTITY status . . . [and to] verify [their] SMALL ENTITY status." (emphasis in original).

30. Despite Palomar's exclusive license to rights in the application for the '568 Patent, on August 30, 1996, the Applicants submitted their fee certificate, again claiming small entity status. Upon information and belief, at least as of August 30, 1996, the Applicants did not qualify for small entity status.

31. Despite the Applicants' knowledge that they did not qualify for small entity status, they claimed and, upon information and belief, continue to claim, such status in connection with the payment of the issue fee and continued maintenance fees for the '568 Patent. Moreover, upon information and belief, the

Applicants claimed, and continue to claim, such small entity status with intent to deceive. The '568 Patent is, therefore, unenforceable by reason of such inequitable conduct.

32. By reason of the facts set forth in Paragraphs 16 through 31, hereof, an actual controversy exists between Cutera and Defendants as to the enforceability of the '568 Patent. Cutera desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time in order that the parties may ascertain their respective rights and duties.

FOURTH CLAIM FOR RELIEF
Declaratory Judgment of Noninfringement of the '844 Patent

33. Cutera repeats and realleges each and every allegation contained in paragraphs 1 through 7 hereof with the same force and effect as if fully set forth herein.

34. Defendants claim that Cutera's "products using pulsed light technology for hair removal" infringe the '844 Patent.

35. Cutera contends that such products do not infringe the '844 Patent.

36. Accordingly, an actual controversy exists between Cutera and Defendants as to the infringement of the '844 Patent. Cutera desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time in order that the parties may ascertain their respective rights and duties.

FIFTH CLAIM FOR RELIEF

Declaratory Judgment of Invalidity of the '844 Patent

37. Cutera repeats and realleges each and every allegation contained in paragraphs 1 through 7 hereof with the same force and effect as if fully set forth herein³⁸. Defendants claim that the '844 Patent is valid.

39. Cutera contends that the '844 Patent is invalid under 35 U.S.C. §§ 102, 103 and/or 112.

40. Accordingly, an actual controversy exists between Cutera and Defendants as to the validity of the '844 Patent. Cutera desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time in order that the parties may ascertain their respective rights and duties.

SIXTH CLAIM FOR RELIEF

Declaratory Judgment of Unenforceability of the '844 Patent

41. Cutera repeats and realleges each and every allegation contained in paragraphs 1 through 7 hereof with the same force and effect as if fully set forth herein⁴². Defendants claim that the '844 Patent is enforceable.

43. Cutera contends that the '844 Patent is unenforceable by reason of inequitable conduct committed by Defendants, the named inventors of the "568 Patent and the '844 Patent, and/or their attorneys (collectively and individually, the "Applicants") during prosecution of the '844 Patent before the United States Patent and Trademark Office ("PTO").

44. The '844 Patent is unenforceable by reason of inequitable conduct committed by the Applicants during prosecution of the '844 Patent before the

PTO. In particular, the Applicants failed to disclose to the PTO certain material prior art, including a publication authored by James G. Kuhns et al. M.D., entitled *Laser Injury in Skin*, 17 LABORATORY INVESTIGATION, 1 (1967) (“Kuhns”). The Kuhns publication is highly material to the subject matter claimed in the ‘844 Patent because, inter alia, it recites a combination of laser wavelength, fluence and pulse duration that the Applicants alleged to the PTO was not disclosed in the prior art, and the reference describes the use of a laser to selectively damage hair follicles and vaporize hair.

45. Applicants had knowledge of the Kuhns publication prior to and during prosecution of the ‘844 Patent and, upon information and belief, failed to disclose the reference with intent to deceive.

46. A copy of the Kuhns publication was provided to Ronald Kransdorf, Defendants’ outside patent counsel, during the week of October 13, 1997, while the patent application for the ‘844 Patent was pending before the PTO.

47. At the time Mr. Kransdorf received the Kuhns reference, the application for the ‘844 Patent had been allowed by the patent examiner and substantive examination of the application was complete. Although the Applicants could have submitted the Kuhns reference to the PTO, doing so in the way required by the PTO rules would have resulted in the PTO withdrawing the ‘844 Patent application from issue. Such a procedure would have certainly delayed – and, given the substantial materiality of the Kuhns publication, could have prevented – issuance of the ‘844 Patent, thereby frustrating Palomar’s efforts to obtain licensing revenue.

48. Mr. Kransdorf discussed the Kuhns publication with individuals employed by Palomar, and a decision was made to not submit the Kuhns reference to the PTO.

49. In addition, Dr. Anderson's 1982 Lasers in Dermatology publication, referred to in paragraph 25 hereof, cited the Kuhns publication.

50. Despite the materiality of the Kuhns publication and the Applicants' knowledge of such publication prior to and during prosecution of the application for the '844 Patent, the Applicants did not disclose the Kuhns publication to the PTO. The '844 Patent is, therefore, unenforceable by reason of the Applicants' inequitable conduct.

51. Applicants also failed to disclose to the PTO the Goldman65 publication that is referred to in paragraph 23 hereof. The Goldman65 publication is highly material to the subject matter claimed in the '844 Patent because, inter alia, it discloses the delivery of normal-mode ruby laser pulses to a skin region of a patient using special glass rods in contact with the skin region and resulting in the simultaneous removal of multiple hairs. Furthermore, Goldman65 discloses specific wavelength, radiation pulse, radiation pulse energy, and radiation field parameters claimed in the '844 Patent.

52. Applicants had knowledge of the Goldman65 publication prior to and during prosecution of the application for the '844 Patent and, upon information and belief, failed to disclose such publication with intent to deceive.

53. Dr. Anderson's 1982 Lasers in Dermatology publication, referred to in paragraph 25 hereof, cited the Goldman65 publication.

54. Despite the materiality of the Goldman65 publication, and the Applicants' knowledge of this prior art publication prior to and during prosecution of the application for the '844 Patent, the Applicants did not disclose this information to the PTO. The '844 Patent is, therefore, unenforceable by reason such inequitable conduct.

55. Applicants further failed to disclose to the PTO a publication by Ohshiro et al., entitled *Treatment by Ruby Laser Beams in the Field of Dermatology*, JAPAN MEDICAL NEWS, Vol. 2768 (May 14, 1977) ("Ohshiro77"). The Ohshiro77 publication is highly material to the subject matter claimed in the '844 Patent because, inter alia, it discloses the delivery of normal-mode ruby laser pulses to hairy skin within the fluence, wavelength, and pulse duration parameters claimed in the '844 Patent. The Ohshiro77 publication also discloses removing more than one hair at the same time from an area of skin, and further discloses an applicator that is adapted to be in pressure contact with a portion of the skin surface in a skin region.

56. The Ohshiro77 publication is also inconsistent with the Applicants' representation to the PTO, during prosecution of the '844 Patent, that the combination of "specific wavelength, fluence and duration limitations" in claim 27 of that Patent was not disclosed in the prior art.

57. Upon information and belief, the Applicants had knowledge of the Ohshiro77 publication prior to and during prosecution of the application for the '844 Patent and, upon information and belief, failed to disclose the reference with intent to deceive.

58. Despite the materiality of the Ohshiro77 publication, and the Applicants' knowledge of this prior art publication prior to and during prosecution of

the application for the '844 Patent, the Applicants did not disclose this information to the PTO. The '844 Patent is, therefore, unenforceable by reason of such inequitable conduct.

59. Furthermore, the Applicants failed to disclose to the PTO a publication by Ohshiro et al., entitled *The Ruby and Argon Lasers in the Treatment of Naevi*, Ann. ACAD. MED. SINGAPORE, 12:388-395 (1983) ("Ohshiro83"). The Ohshiro83 publication is highly material to the subject matter claimed in the '844 Patent because, inter alia, it discloses the delivery of normal-mode ruby laser pulses to hairy skin within the fluence, wavelength, and pulse duration parameters claimed in the '844 Patent. The Ohshiro83 publication also discloses removing more than one hair at the same time from an area of skin, and further discloses a laser beam head in pressure contact with a portion of the skin surface in a skin region.

60. The Ohshiro83 publication is also inconsistent with the Applicants' representation to the PTO, during prosecution of the application for the '844 Patent, that the combination of "specific wavelength, fluence and duration limitations" in claim 27 of that Patent was not disclosed in the prior art.

61. Upon information and belief, the Applicants had knowledge of the Ohshiro83 publication prior to and during prosecution of the application for the '844 Patent and, upon information and belief, failed to disclose the publication with intent to deceive.

62. Despite the materiality of the Ohshiro83 publication, and the Applicants' knowledge of this prior art publication prior to and during prosecution of the application for the '844 Patent, the Applicants did not disclose this information to

the PTO. The '844 Patent is, therefore, unenforceable by reason of such inequitable conduct.


63. By reason of the facts set forth in paragraphs 41 through 62, an actual controversy exists between Cutera and Defendants as to the enforceability of the '844 Patent. Cutera desires a judicial determination and declaration of the respective rights and duties of the parties herein. Such a determination and declaration is necessary and appropriate at this time in order that the parties may ascertain their respective rights and duties.

WHEREFORE, Cutera respectfully requests that the Court:

- A. Enter an Order declaring that Cutera has not, and does not, infringe, directly or indirectly, any valid and enforceable claim of the '568 Patent or the '844 Patent;
- B. Enter an Order declaring that the claims of the '568 Patent and the '844 Patent are invalid;
- C. Enter an Order declaring that the '568 Patent and the '844 Patent are unenforceable;
- D. Enter an order enjoining Defendants and each of their employees, agents, alter egos, attorneys and/or any person in active concert or participation with them from instituting any action or otherwise claiming that the '568 Patent or the '844 Patent are valid, enforceable, or infringed by Cutera;
- E. Enter an order declaring this an exceptional case pursuant to 35 U.S.C. § 285, and awarding Cutera its attorney fees, costs, and expenses; and

F. Grant to Cutera such other and further relief as the Court may deem just and appropriate.

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