

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

Hologic, Inc., a Delaware corporation; and
Cytoc Surgical Products, LLC, a Delaware
limited liability company,

Plaintiffs,

v.

Minerva Surgical, Inc., a Delaware
corporation

Defendant.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Minerva Surgical, Inc. (“Defendant”), Plaintiffs Hologic, Inc. (“Hologic”), and Cytoc Surgical Products, LLC (“Cytoc”; collectively “Plaintiffs”) by its attorneys, allege as follows:

NATURE OF THE ACTION

1. In this action, Plaintiffs Hologic and Cytoc allege that Defendant infringes U.S. Patent Nos. 6,872,183 (“the ‘183 Patent”), 8,998,898 (“the ‘898 Patent”), and 9,095,348 (“the ‘348 Patent” collectively “the Patents-in-Suit”).

PARTIES

2. Plaintiff Hologic is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Hologic is a leader in women’s health care including diagnostics, screening, and imaging, as well as medical intervention and treatment.

3. Plaintiff Cytoc is a limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at 250 Campus Drive,

Marlborough, Massachusetts, 01752. Cytoc is a leader in designing, developing, and selling medical devices for the treatment of excessive or abnormal endometrial bleeding. Cytoc is a wholly owned subsidiary of Hologic and the owner by assignment of the '183, '898, and '348 Patents.

4. On information and belief, Defendant Minerva is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 101 Saginaw Drive, Redwood City, CA, 94063.

JURISDICTION AND VENUE

5. This action arises under the Patent Laws of the United States, Title 35 of the United States Code.

6. This Court has subject matter jurisdiction over the causes of action asserted herein pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over the Defendant. On information and belief, Defendant has had systematic and continuous contacts with this District, regularly transacts business within this District, and regularly avails themselves of the benefits of this District. On information and belief, Defendant, directly or through intermediaries (including sales agents and others), use, offer for sale, sell, imports and/or distributes to others for such purposes, endometrial ablation products for the treatment of abnormal uterine bleeding, in the United States and this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b)–(c) as, among other reasons, Defendant is subject to personal jurisdiction in this District and a substantial part of the events giving rise to the claims occurred in this District.

BACKGROUND

9. Plaintiffs Hologic and Cytoc are leading developers, manufacturers, and suppliers of medical devices dedicated to helping medical care professionals deliver superior healthcare to their patients. One such medical product that Cytoc makes and distributes is the NovaSure[®] endometrial ablation system, a system designed to, among other things, remove the endometrial lining of the uterus and control abnormal uterine bleeding. The NovaSure[®] system has been used to treat more than two million woman since it was approved for use by the FDA in 2001. The novel design (*e.g.*, using radiofrequency impedance-based technology allowing for fast treatment time with no hormonal pretreatment required) of the NovaSure[®] system allows medical care professionals to quickly, efficiently, and comfortably control abnormal uterine bleeding.

10. Plaintiffs have made significant investments into the research, development, and testing of safe tissue ablation, including the technology embodied by the NovaSure[®] endometrial ablation system.

11. Plaintiffs have made significant investments into bringing the product to market.

12. To protect these investments, Cytoc applied for and obtained a number of patents, including the '183, '898, and '348 Patents.

13. On information and belief, Defendant has been directly competing with Plaintiffs since at least August, 2015, by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use the Minerva Endometrial Ablation Device. A true and correct copy of the Minerva Endometrial Ablation System Operator's manual which can be obtained from the FDA website (http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140013d.pdf)

or from Defendant's website (<http://www.minervasurgical.com/health-care-professionals/clinical-study-data/#downloadifu>) is attached as Exhibit A.

COUNT I

(Defendant's Infringement of the '183 Patent)

14. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

15. On March 29, 2005, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '183 Patent, entitled "System and Method for Detecting Perforations in a Body Cavity," to Russel M. Sampson, Mike O'Hara, Csaba Truckai, and Dean T. Miller as inventors. A true and correct copy of the '183 Patent is attached as Exhibit B.

16. Cytoc is the assignee and lawful owner of all right, title, and interest in and to the '183 Patent.

17. Plaintiffs have complied with the notice requirements of 35 U.S.C. § 287 with respect to products that they manufacture and sell under the '183 Patent.

18. Defendant has had knowledge of the '183 Patent since at least the filing of this Complaint and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the Minerva Endometrial Ablation System would infringe one or more claims of the '183 Patent.

19. On information and belief, Defendant was aware that Plaintiffs' NovaSure[®] system embodied the claimed invention of the '183 Patent and knew or should have known that Defendant's products, including the Minerva Endometrial Ablation System, infringed one or more claims of the '183 Patent due to their substantially similar designs.

20. On information and belief, Defendant has infringed and continues to infringe, literally and/or through the doctrine of equivalents, the '183 Patent in violation of 35 U.S.C. § 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use products, services, methods, or processes that are covered by at least claims 1-7, 9, 11, and 13-15 of the '183 Patent. On information and belief, such devices include, but are not limited to, the Minerva Endometrial Ablation System.

21. On information and belief, Defendant has indirectly infringed and continues to indirectly infringe the '183 Patent in violation of 35 U.S.C. § 271. On information and belief, Defendant's customers directly infringe at least claims 1-7, 9, 11, and 13-15 of the '183 Patent by practicing the claimed method. On information and belief, Defendant has knowingly induced infringement and has had a specific intent to induce infringement of the '183 Patent by their activities relating to the marketing, sales, support, and distribution of the Minerva Endometrial Ablation System, including, for example without limitation, providing through Defendant's website video and print instructions to use the Minerva Endometrial Ablation System in a manner that infringes one or more claims of the '183 Patent. On information and belief, Defendant has contributed to infringement by selling and/or offering to sell within the United States, or importing into the United States, the Minerva Endometrial Ablation System knowing the same to be especially made or especially adapted for use in the infringement of one or more claims of the '183 patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

22. On information and belief, Defendant's infringement has been and continues to be willful, making this an exceptional case under 35 U.S.C. § 285 and entitling Plaintiffs to treble damages under 35 U.S.C. § 284.

23. As a result of Defendant's infringement of the '183 Patent, Plaintiffs have suffered and continues to suffer damages.

24. Defendant's infringement of the '183 Patent has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such infringing acts.

COUNT II

(Defendant's Infringement of the '898 Patent)

25. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

26. On April 7, 2015, the USPTO duly and legally issued the '898 Patent, entitled "Moisture Transport System for Contact Electrocoagulation" to Csaba Truckai, Russel M. Sampson, Stephanie Squarcia, Alfonso L. Ramirez, Estela Hilario, and David C. Auth as inventors. A true and correct copy of the '898 Patent is attached as Exhibit C.

27. Cytoc is the assignee and lawful owner of all right, title, and interest in and to the '898 Patent.

28. Plaintiffs have complied with the notice requirements of 35 U.S.C. § 287 with respect to products that it manufactures and sells under the '898 Patent.

29. Defendant has had knowledge of the '898 Patent since at least the filing of this complaint and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the Minerva Endometrial Ablation System would infringe one or more claims of the '898 Patent.

30. On information and belief, Defendant was aware that Plaintiffs' NovaSure[®] system embodied the claimed invention of the '898 Patent and knew or should have known that

Defendant's products, including the Minerva Endometrial Ablation System, infringed one or more claims of the '898 Patent due to their substantially similar designs.

31. On information and belief, Defendant has infringed and continues to infringe, literally and/or through the doctrine of equivalents, the '898 Patent in violation of 35 U.S.C. § 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use products, services, methods, or processes that are covered by at least claims 1-6, 8, and 14-16 of the '898 Patent. On information and belief, such devices include, but are not limited to, the Minerva Endometrial Ablation System.

32. On information and belief, Defendant has indirectly infringed and continues to indirectly infringe the '898 Patent in violation of 35 U.S.C. § 271. On information and belief, Defendant's customers directly infringe at least claims 1-6, 8, and 14-16 of the '898 Patent by practicing the claimed method. On information and belief, Defendant has knowingly induced infringement and have had a specific intent to induce infringement of the '898 Patent by their activities relating to the marketing, sales, support, and distribution of the Minerva Endometrial Ablation System, including, for example without limitation, providing video and print instructions to use the Minerva Endometrial Ablation System in a manner that infringes one or more claims of the '898 Patent. On information and belief, Defendant has contributed to infringement by selling and/or offering to sell within the United States, or importing into the United States, the Minerva Endometrial Ablation System knowing the same to be especially made or especially adapted for use in the infringement of one or more claims of the '898 patent and not a staple article or commodity of commerce suitable for substantial noninfringing use.

33. On information and belief, Defendant's infringement has been and continues to be willful, making this an exceptional case under 35 U.S.C. § 285 and entitling Plaintiffs to treble damages under 35 U.S.C. § 284.

34. As a result of Defendant's infringement of the '898 Patent, Plaintiffs have suffered and continues to suffer damages.

35. Defendant's infringement of the '898 Patent has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such infringing acts.

COUNT III

(Defendant's Infringement of the '348 Patent)

36. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

37. On August 4, 2015, the USPTO duly and legally issued the '348 Patent, entitled "Moisture Transport System for Contact Electrocoagulation" to Csaba Truckai, Russel M. Sampson, Stephanie Squarcia, Alfonso L. Ramirez, and Estela Hilario as inventors. A true and correct copy of the '348 Patent is attached as Exhibit D.

38. Cytoc is the assignee and lawful owner of all right, title, and interest in and to the '348 Patent.

39. Plaintiffs have complied with the notice requirements of 35 U.S.C. § 287 with respect to products that it manufactures and sells under the '348 Patent.

40. Defendant has had knowledge of the '348 Patent since at least the filing of this complaint and knew or should have known that the sale, offer for sale, use, manufacture, and/or

importation of the Minerva Endometrial Ablation System would infringe one or more claims of the '348 Patent.

41. On information and belief, Defendant was aware that Plaintiffs' NovaSure[®] system embodied the claimed invention of the '348 Patent and knew or should have known that Defendant's products, including the Minerva Endometrial Ablation System, infringed one or more claims of the '348 Patent due to their substantially similar designs.

42. On information and belief, Defendant has infringed and continues to infringe, literally and/or through the doctrine of equivalents, the '348 Patent in violation of 35 U.S.C. § 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use products that are covered by at least claims 1, 3, and 8-10 of the '348 Patent. On information and belief, such devices include, but are not limited to, the Minerva Endometrial Ablation System.

43. On information and belief, Defendant has indirectly infringed and continues to indirectly infringe the '348 Patent in violation of 35 U.S.C. § 271. On information and belief, Defendant's customers directly infringe at least claims 1, 3, and 8-10 of the '348 Patent by using the claimed apparatus. On information and belief, Defendant has knowingly induced infringement and have had a specific intent to induce infringement of the '348 Patent by their activities relating to the marketing, sales, support, and distribution of the Minerva Endometrial Ablation System, including, for example without limitation, providing video and print instructions to use the Minerva Endometrial Ablation System in a manner that infringes one or more claims of the '348 Patent. On information and belief, Defendant has contributed to infringement by selling and/or offering to sell within the United States, or importing into the United States, the Minerva Endometrial Ablation System knowing the same to be especially

made or especially adapted for use in the infringement of one or more claims of the '348 patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

44. On information and belief, Defendant's infringement has been and continues to be willful, making this an exceptional case under 35 U.S.C. § 285 and entitling Plaintiffs to treble damages under 35 U.S.C. § 284.

45. As a result of Defendant's infringement of the '348 Patent, Plaintiffs have suffered and continues to suffer damages.

46. Defendant's infringement of the '348 Patent has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such infringing acts.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

1. Judgment in favor of Plaintiffs Hologic and Cytec, and against Defendant Minerva Surgical, Inc., that Defendant has and continues to directly infringe and induce infringement of one or more claims of the '183 Patent;

2. Judgment in favor of Plaintiffs Hologic and Cytec, and against Defendant Minerva Surgical, Inc., that Defendant's infringement of the '183 Patent has been and continues to be willful;

3. Judgment in favor of Plaintiffs Hologic and Cytec, and against Defendant Minerva Surgical, Inc., that Defendant has and continues to directly infringe and induce infringement of one or more claims of the '898 Patent;

4. Judgment in favor of Plaintiffs Hologic and Cytoc, and against Defendant Minerva Surgical, Inc., that Defendant's infringement of the '898 Patent has been and continues to be willful;

5. Judgment in favor of Plaintiffs Hologic and Cytoc, and against Defendant Minerva Surgical, Inc., that Defendant has and continues to directly infringe and induce infringement of one or more claims of the '348 Patent;

6. Judgment in favor of Plaintiffs Hologic and Cytoc, and against Defendant Minerva Surgical, Inc., that Defendant's infringement of the '348 Patent has been and continues to be willful;

7. A preliminary and permanent injunction against Defendant Minerva Surgical, Inc. for infringement of the Patents-in-Suit;

8. Judgment awarding Plaintiffs Hologic and Cytoc damages adequate to compensate for Defendant Minerva Surgical, Inc.'s infringement of the Patents-in-Suit in an amount to be proven at trial, together with pre-judgment and post-judgment interest and costs, as fixed by the Court;

9. Judgment enhancing the damages due to Defendant Minerva Surgical, Inc.'s willful infringement, pursuant to 35 U.S.C. § 284;

10. Judgment declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Hologic and Cytoc their attorneys' fees and costs incurred in prosecuting its claims; and

11. Such other relief as this Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury in this action on all issues so triable.

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