

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

W. L. GORE & ASSOCIATES, INC.,)	
)	
Plaintiff,)	C.A. No. _____
)	
v.)	
)	
AGA MEDICAL CORP. and AGA MEDICAL)	JURY TRIAL DEMANDED
HOLDINGS, INC.,)	
)	
Defendants.)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff W. L. Gore & Associates, Inc. (“Gore”) hereby alleges for its Complaint for Declaratory Judgment against Defendants AGA Medical Corp. and AGA Medical Holdings, Inc. (collectively “AGA”), on personal knowledge as to its own activities and on information and belief as to the activities of others, as follows:

A. NATURE OF THIS ACTION

1. Plaintiff Gore seeks a Declaratory Judgment that the Gore[®] Septal Occluder medical device does not infringe any valid and enforceable claim of U.S. Patent No. 5,725,552 (“the ’552 patent”) and U.S. Patent No. 5,944,738 (“the ’738 patent”) pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, and for such other relief as the Court deems just and proper.

B. THE PARTIES

2. Plaintiff Gore is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 555 Paper Mill Road, Newark, Delaware 19711. Gore was founded in 1958, and its fluoropolymer products provide innovative solutions

throughout various industries, including medical products, next-generation electronics, and high-performance fabrics such as “GORE-TEX®.”

3. On information and belief, Defendant AGA Medical Corp. is a corporation organized and existing under the laws of the State of Minnesota with its principal place of business at 5050 Nathan Lane North, Plymouth, MN 55442. AGA Medical Corp. markets its products through a network of distributors or sales agents throughout the United States, including the state of Delaware and this district.

4. On information and belief, Defendant AGA Medical Holdings, Inc. (collectively with AGA Medical Corp., “AGA”), is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 5050 Nathan Lane North, Plymouth, MN 55442, and is the parent of AGA Medical Corp., which is a wholly owned subsidiary. AGA Medical Holdings, Inc., can be served with process through its registered agent, The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801.

C. JURISDICTION AND VENUE

5. Gore brings this action pursuant to the Federal Declaratory Judgment Statutes 28 U.S.C. §§ 2201-2202, which cause of action arises under the United States Patent Laws, Title 35 of the United States Code.

6. This Court has exclusive subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. On information and belief, AGA Medical Corp. is subject to personal jurisdiction in Delaware because of AGA Medical Corp.’s threats of patent infringement directed at Gore, which is located in the State of Delaware, and AGA Medical Corp.’s other activities in Delaware that are distinct from the foregoing threats of infringement including, without limitation, its

frequent contacts within the State of Delaware and its conducting of substantial and regular business in Delaware through the marketing and sales of AGA Medical Corp.'s products in Delaware, including by substantial sales of products it alleges are covered by the '552 patent or the '738 patent.

8. On information and belief, AGA Medical Holdings, Inc. is subject to personal jurisdiction in Delaware because it has submitted itself to the jurisdiction of courts in Delaware by virtue of its incorporation under Delaware law.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

D. BACKGROUND

10. Since 1975, Plaintiff Gore has sold and continues to sell medical devices containing a unique inventive polymer material—expanded polytetrafluoroethylene (ePTFE) also commonly referred to as “GORE-TEX®.” Gore currently has a number of life-saving medical devices that incorporate ePTFE.

11. Among these medical devices, Gore manufactures and sells septal occluders that incorporate innovative solutions and life-saving technology to patients suffering from certain serious heart defects. Septal defects are serious life-threatening conditions in which patients have holes between the chambers of the heart. Septal occluders are medical devices that are implanted within the heart via catheter to close these holes and to treat the septal defects without the need for open heart surgery.

12. Gore currently offers the GORE® HELEX Septal Occluder medical device that utilizes ePTFE. The GORE® HELEX Septal Occluder medical device has been widely

recognized by medical professionals and provides advantages to patients in many circumstances, including for use in the closure of atrial septal defects in infants and children.

13. The novelty of the GORE[®] HELEX Septal Occluder medical device has been recognized on several occasions by the United States Patent and Trademark Office, which has issued four patents to Gore covering the GORE[®] HELEX Septal Occluder.

14. Defendant AGA has commercialized a line of AMPLATZER[®] occluders, which are indicated for the occlusion of atrial septal defects in secundum position or patients who have undergone a fenestrated fontan procedure and who now require closure of the fenestration. Patients indicated for atrial septal defect closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (*i.e.*, 1.5:1 degree of left-to-right shunt or RV enlargement). On information and belief, those devices were first approved by the FDA on or about December 2001.

E. PATENTS

15. U.S. Patent No. 5,725,552 is entitled “Percutaneous Catheter Directed Intravascular Occlusion Devices,” and bears an issue date of March 10, 1998. A copy of the ’552 patent is attached hereto as Exhibit 1.

16. U.S. Patent No. 5,944,738 is entitled “Percutaneous Catheter Directed Constricting Occlusion Device,” and bears an issue date of August 31, 1999. A copy of the ’738 patent is attached hereto as Exhibit 2.

17. Both the ’552 patent and the ’738 patent are assigned on their face to AGA Medical Corp. On information and belief, Defendant AGA Medical Corp. is the owner of the ’552 patent. In the Minnesota Action (defined below), Defendant AGA Medical Corp. claims it is the owner of the ’738 patent.

F. EXISTENCE OF AN ACTUAL CONTROVERSY

18. There is an actual controversy within the jurisdiction of this Court under 28 U.S.C. §§ 2201 and 2202.

19. On information and belief, AGA has marked its AMPLATZER® occluders with the '552 patent and the '738 patent. Because AGA marks its own products with these patents, Gore believes future infringement litigation with AGA would likely include the '552 patent and the '738 patent.

1. MINNESOTA ACTION

20. On August 24, 2010, AGA, by and through its wholly-owned subsidiary AGA Medical Corp., brought a patent infringement action against Gore in the United States District Court for the District of Minnesota (Case No. 0:10-cv-3734 (JNE/JSM)) (“the Minnesota Action”). In the Minnesota Action, AGA accused Gore of infringing and continuing to infringe one of its patents because of Gore’s activities relating to the life-saving GORE® HELEX Septal Occluder. AGA is seeking, *inter alia*, a permanent injunction to prevent patient access to the life-saving GORE® HELEX Septal Occluder. A true and correct copy of that Complaint is attached hereto as Exhibit 3.

21. The only asserted patent in the Minnesota Action is the '738 patent.

22. On January 18, 2011, AGA served preliminary infringement contentions in the Minnesota Action that accuse the GORE® HELEX Septal Occluder as the only allegedly infringing Gore medical device.

23. The Gore® Septal Occluder medical device was not and is not accused by AGA of infringement in the Minnesota Action.

24. The Minnesota Action has been pending for over nine months and has advanced into fact discovery with significant document production by the parties (scheduled to be substantially complete by June 22), and is about to enter the claim construction or *Markman* process.

2. GORE[®] SEPTAL OCCLUDER MEDICAL DEVICE

25. Gore has invested and continues to invest substantial resources to develop life-saving technology. Such technologies include septal occluders, including the Gore[®] Septal Occluder medical device. The GORE[®] HELEX Septal Occluder and the new Gore[®] Septal Occluder medical device are separate products that each require separate FDA approval and have different structures. The Gore[®] Septal Occluder medical device is not commercially available in the United States at this time, and the U.S. Food & Drug Administration has not approved the Gore[®] Septal Occluder medical device for sale in this country.

26. From March 31 to April 2, 2011, a conference entitled the 8th International Workshop on Interventional Pediatric Cardiology was held in Milan, Italy (the “Milan Conference”). Several AGA representatives, including CEO John Barr, attended the Milan conference. AGA had a large presence at the conference and sponsored a trade show booth.

27. On April 1, 2011, during the Milan conference, Dr. M. Carminati gave a presentation that described a next generation or 5-wire septal occluder, being developed by Gore to an audience of hundreds of attendees. The next generation or 5-wire septal occluder, referred to in Dr. Carminati’s presentation, is the Gore[®] Septal Occluder medical device.

28. On June 10, 2011, the Gore[®] Septal Occluder medical device received its “CE” mark, European regulatory approval that is required for commercial sales in Europe.

29. On June 15, 2011, Dr. Lars Sondergaard implanted the Gore[®] Septal Occluder medical device in a patient at Rigshospital, Copenhagen, Denmark. The Gore[®] Septal Occluder medical device was implanted into a 50 year old patient to treat a patent foramen ovale (PFO) defect in his heart.

30. On June 16, 2011, Dr. Sondergaard implanted two additional Gore[®] Septal Occluder medical devices in patients, again at Rigshospital, Copenhagen, Denmark. In a four year old child, the Gore[®] Septal Occluder medical device was implanted for fenestrated fontan closure in the heart. In a 44 year old patient, the Gore[®] Septal Occluder medical device was implanted to treat a PFO defect in the heart.

31. Attempts by Defendant AGA to interrupt, prevent or limit Gore's activities relating to the Gore[®] Septal Occluder medical device will cause or are likely to cause Gore substantial injury and harm.

3. AGA'S ATTEMPTS TO INJECT THE GORE[®] SEPTAL OCCLUDER MEDICAL DEVICE INTO THE MINNESOTA ACTION

32. On April 7, 2011, after the Milan Conference, AGA's litigation counsel in the Minnesota Action sent an e-mail to Gore's litigation counsel confirming that AGA was and is aware of the Milan Conference presentation and asked to obtain litigation discovery from Gore relating to that device.

33. On April 11, 2011, AGA served its Second Set of Requests for Production of Documents and Things on Gore in the Minnesota Action seeking, among other things, discovery on the Gore[®] Septal Occluder medical device.¹ For example, AGA's Document Request No. 31 sought:

All documents and things relating to each version of a Gore five-wire occluder frame design, including without limitation the "5 Wire Occluder Frame

¹ AGA refers to the Gore[®] Septal Occluder medical device as the "Five-Wire occluder."

designed for optimal closure,” as demonstrated, described or disclosed at any conference, presentation or meeting since 2009, including documents and things sufficient to describe the structure and operation of each such design.

34. On May 6, 2011, AGA served an “amended” Rule 30(b)(6) Deposition Notice of Gore, which added new topic 16, as follows:

The structure, function and operation of the Gore Five-Wire Occluder Device prior to implantation, during implantation, and after implantation.

35. On May 11, 2011, Gore served its objections to the discovery requests and refused to provide the requested documents and things relating to the Gore[®] Septal Occluder medical device. The Gore[®] Septal Occluder medical device was not included in AGA’s infringement contentions; it was not, and is not, part of the Minnesota Action.

36. Also on May 11, 2011, AGA’s counsel in the Minnesota Action requested an “immediate” meet and confer to discuss Gore’s refusal to provide the requested discovery on the Gore[®] Septal Occluder medical device.

37. On May 12, 2011, the parties held a meet and confer to discuss various discovery issues. AGA’s counsel again requested discovery regarding the Gore[®] Septal Occluder medical device. AGA requested that Gore agree to a waiver of any possible laches defense that Gore might raise in a potential future patent infringement action brought by AGA against the Gore[®] Septal Occluder medical device.

38. On May 23, 2011, counsel for AGA sent counsel for Gore an email again indicating that AGA still sought information on the Gore[®] Septal Occluder medical device and it would seek a court ruling as to whether Gore would have to disclose the information to AGA.

39. On May 31, 2011, counsel for AGA and Gore again met and conferred regarding various discovery disputes. During this process, AGA’s litigation counsel confirmed that it was seeking a stipulation from Gore waiving any possible laches defense that Gore might raise in a

potential future patent infringement action brought by AGA against the Gore[®] Septal Occluder medical device.

40. On June 3, 2011, AGA served its Fifth Set of Requests for Production of Documents and Things on Gore in the Minnesota Action seeking, among other things, discovery on the Gore[®] Septal Occluder medical device. For example, AGA's Document Request No. 47 sought:

To the extent not already produced, all documents and things relating to ... the 5-Wire Septal Occluder, including analyses, communications, correspondence, discussions, evaluations, investigations, memoranda, meeting minutes, reports, statements, studies, or tests.

41. On information and belief, AGA has sought discovery regarding the Gore[®] Septal Occluder medical device in the Minnesota Action in an attempt to show that the Gore[®] Septal Occluder medical device could also be accused of infringement in the Minnesota Action. On information and belief, AGA would seek to enjoin patient access to Gore[®] Septal Occluder medical devices in a future patent infringement action.

42. The Gore[®] Septal Occluder medical device has not infringed and does not infringe, either directly or indirectly, any valid and enforceable claim of the '552 or '738 patents, either literally or under the doctrine of equivalents. However, as a result of AGA's past litigious conduct against Gore and its implied threats to accuse the Gore[®] Septal Occluder medical device as an infringement, as described above, a substantial controversy exists between the parties which is of sufficient immediacy and reality to warrant declaratory relief. Absent a declaration of non-infringement and/or invalidity of the claims of the '552 and '738 patents, AGA will continue to threaten Gore, *e.g.*, with the assertion of the '552 or '738 patents against the Gore[®] Septal Occluder medical device, as a means to intimidate Gore and the doctors seeking to implant the medical device, and thereby cause Gore irreparable injury and damage.

43. Because the structures of the GORE[®] HELEX Septal Occluder and Gore[®] Septal Occluder medical device differ, the issues in the Minnesota Action regarding the GORE[®] HELEX Septal Occluder differ from the issues presented here regarding the Gore[®] Septal Occluder medical device. Additionally, the '552 patent is not part of the Minnesota Action even though AGA contends it too covers septal occluder technology (including its own AMPLATZER[®] line of products).

44. This is an exceptional case within the meaning of 35 U.S.C. § 285.

COUNT I

Declaratory Judgment of Non-Infringement of the Claims of the '552 Patent

45. Plaintiff Gore hereby repeats and realleges the allegations in paragraphs 1-44 of this Complaint as if fully set forth herein.

46. The Gore[®] Septal Occluder medical device has not infringed and does not infringe, directly or indirectly, any valid and enforceable claim of the '552 patent, either literally or under the doctrine of equivalents.

47. As a result of the acts described in the foregoing paragraphs, there is a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

48. A judicial declaration that Gore does not infringe any claim of the '552 patent is necessary and appropriate at this time so that Gore can ascertain its rights and duties with respect to the manufacturing and marketing of the Gore[®] Septal Occluder medical device. Gore is entitled to a declaration and judgment that its Gore[®] Septal Occluder medical device does not infringe any claim of the '552 patent.

COUNT II

Declaratory Judgment of Patent Invalidity of the Claims of the '552 Patent

49. Plaintiff Gore hereby repeats and realleges the allegations in paragraphs 1-48 of this Complaint as if fully set forth herein.

50. The '552 patent claims are invalid for failure to meet the conditions of patentability and/or otherwise comply with one or more of 35 U.S.C. §§ 100 *et seq.*, 101, 102, 103 and 112.

51. As a result of the acts described in the foregoing paragraphs, there is a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

52. A judicial declaration that the '552 patent claims are invalid for failure to comply with one or more of the requirements of Title 35 of the United States Code is necessary and appropriate at this time so that Gore can ascertain its rights and duties with respect to the manufacturing and marketing of the Gore[®] Septal Occluder medical device. Gore is entitled to a declaration and judgment that the '552 patent claims are invalid under the Patent Act, 35 U.S.C. § 100, *et seq.*

COUNT III

Declaratory Judgment of Non-Infringement of the Claims of the '738 Patent

53. Plaintiff Gore hereby repeats and realleges the allegations in paragraphs 1-52 of this Complaint as if fully set forth herein.

54. The Gore[®] Septal Occluder medical device has not infringed and does not infringe, directly or indirectly, any valid and enforceable claim of the '738 patent, either literally or under the doctrine of equivalents.

55. As a result of the acts described in the foregoing paragraphs, there is a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

56. A judicial declaration that Gore does not infringe any claim of the '738 patent is necessary and appropriate at this time so that Gore can ascertain its rights and duties with respect to the manufacturing and marketing of the Gore[®] Septal Occluder medical device. Gore is entitled to a declaration and judgment that its Gore[®] Septal Occluder medical device does not infringe any claim of the '738 patent.

COUNT IV

Declaratory Judgment of Patent Invalidity of the Claims of the '738 Patent

57. Plaintiff Gore hereby repeats and realleges the allegations in paragraphs 1-56 of this Complaint as if fully set forth herein.

58. The '738 patent claims are invalid for failure to meet the conditions of patentability and/or otherwise comply with one or more of 35 U.S.C. §§ 100 *et seq.*, 101, 102, 103 and 112.

59. As a result of the acts described in the foregoing paragraphs, there is a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

60. A judicial declaration that the '738 patent claims are invalid for failure to comply with one or more of the requirements of Title 35 of the United States Code is necessary and appropriate at this time so that Gore can ascertain its rights and duties with respect to the manufacturing and marketing of the Gore[®] Septal Occluder medical device. Gore is entitled to a

declaration and judgment that the '738 patent claims are invalid under the Patent Act, 35 U.S.C. § 100, *et seq.*

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Gore respectfully requests that the Court enter judgment in favor of Gore granting the following relief:

- (i) A declaration that the Gore[®] Septal Occluder medical device has not infringed and does not infringe any valid and enforceable claim of the '552 patent;
- (ii) A declaration that the '552 patent claims are invalid for failure to meet the condition for patentability and/or otherwise comply with the requirements of 35 U.S.C. §§ 100 *et seq.*, 101, 102, 103 and 112;
- (iii) A declaration that the Gore[®] Septal Occluder medical device has not infringed and does not infringe any valid and enforceable claim of the '738 patent;
- (iv) A declaration that the '738 patent claims are invalid for failure to meet the condition for patentability and/or otherwise comply with the requirements of 35 U.S.C. §§ 100 *et seq.*, 101, 102, 103 and 112;
- (v) A declaration that Gore has the right to manufacture and market the Gore[®] Septal Occluder medical device without any threat or other interference whatsoever against Gore by AGA, based on or arising out of the ownership of the '552 patent and/or the '738 patent;
- (vi) An injunction against AGA and its officers, agents, servants, employees, attorneys, and others in active concert or participation with them from asserting infringement or instituting or continuing any legal action for infringement of the

'552 patent or the '738 patent against Gore or its manufacturers, distributors, customers or end users of their products;

- (vii) An order declaring that this is an exceptional case and awarding Gore its costs, expenses, disbursements and reasonable attorney fees under 35 U.S.C. § 285 and all other applicable statutes, rules and common law;
- (viii) An order awarding pre-judgment and post-judgment interest on all damages, attorneys' fees, expenses, and costs awarded to Gore; and
- (ix) Such other and further relief as the Court may deem just and proper.

JURY DEMAND

In accordance with Rule 38 of the Federal Rules of Civil Procedure and Rule 38.1 of the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, Plaintiff Gore respectfully demands a jury trial of all issues triable to a jury in this action.

ASHBY & GEDDES

/s/ Steven J. Balick

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