UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

AGA Medical Corporation.,

Plaintiff,

v.

Civil Action # 04-4486 JMR/FLN

Nitinol Medical Technologies, Inc.,
d/b/a/ NMT Medical, Inc, and
Lloyd A. Marks

Defendants.

COMPLAINT FOR DECLARATORY RELIEF

For its complaint against Nitinol Medical Technologies, Inc. ("NMT") and Lloyd A. Marks (hereinafter referred to collectively as "Defendants"), Plaintiff AGA Medical Corp. states and alleges as follows:

PARTIES

1. Plaintiff, AGA Medical Corp. ("AGA") is a corporation duly organized and existing under the laws of the State of Minnesota with its principal place of business in Golden Valley, Minnesota.

2. NMT is a corporation organized and existing under the laws of the State of Massachusetts, with its principal place of business in Boston, Massachusetts.

3. Lloyd A. Marks is a resident of the state of New Jersey.

JURISDICTION

4. This is a claim for, among other things, a declaratory judgment of patent invalidity and non-infringement.

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5. This Court has jurisdiction over AGA's federal claims by virtue of the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

6. This Court has personal jurisdiction over the Defendants. NMT knowingly and intentionally exploits the Minnesota market through advertising and sales of its products. Mr. Marks knowingly and intentionally exploits the Minnesota market through the royalties he receives under his exclusive licensing agreement with NMT.

VENUE

7. A substantial part of the events or omissions giving rise to AGA's cause of action occurred in this judicial district.

8. By reasons of the foregoing, venue of this action is proper in this Court pursuant to the provisions of 28 U.S.C. § 1391(b).

COUNT I : INVALIDITY AND NON-INFRINGEMENT OF PATENT

9. AGA restates Paragraphs 1-8 of this Complaint.

10. Lloyd A. Marks claims to be the owner of U.S. Patent No. 5,108,420 issued on April 28, 1992, attached hereto as Exhibit A (the "'420 Patent"). NMT claims to own an exclusive license under the '420 patent.

11. As a result of the acts set forth below, an actual justiciable controversy exists between Defendants and AGA with respect to the validity of the '420 Patent and Defendants' claims that AGA's products infringe the '420 Patent.

12. On December 10, 1998, Defendants commenced litigation in the U.S. District Court for the District of Massachusetts against AGA for infringement of the '420 Patent (hereinafter referred to as "the Massachusetts Litigation"). The Massachusetts Litigation was

captioned Nitinol Medical Tech v. AGA Medical Corp., 98-cv-12506-NG. A copy of the Complaint is attached hereto as Exhibit B.

13. On April 25, 2001, the District Court stayed the Massachusetts Litigation pending a reexamination of the '420 patent by the United States Patent and Trademark Office. A copy of the Order staying the Prior Litigation is attached hereto as Exhibit C. On December 1, 2003, the District Court of Massachusetts dismissed the litigation without prejudice. A copy of the Order dismissing the litigation is attached as Exhibit D.

14. During the reexamination of the '420 Patent, the Patent Office Examiner rejected the claims. However, on August 19, 2004, the Patent and Trademark Office Board of Appeals purportedly reversed the examiner's rejection.

15. On September 7, 2004, Defendants issued a press release in which John E. Ahern, the President and CEO of NMT declared:

> "[t]he Board of Appeals decision represents an important step in our patent infringement efforts against AGA. As a medical technology innovator, NMT Medical has developed and obtained the rights to an impressive portfolio of patents and intellectual property that we will continue to defend aggressively."

(emphasis added). A copy of the September 7th press release is attached as Exhibit E.

16. AGA's position has consistently been that it has not infringed the '420 Patent and that the '420 Patent is invalid and unenforceable.

17. By virtue of the exchanges outlined above, there is a substantial and continuing justiciable controversy between AGA and Defendants as to Defendants' rights in the '420 Patent, the validity and enforceability of the '420 Patent, and as to AGA's continuing right to make, use and sell its products.

18. AGA contends that the claims for the '420 Patent, including any claims which may have survived reexamination, are not infringed by AGA.

19. In the alternative, AGA contends that the claims for the '420 Patent, including any claims which may have survived reexamination, are invalid, unenforceable, and void since they have not and may not be duly or legally issued for many reasons including, without limitation, that each are invalid, unenforceable, and void given the statutory requirements of 35 U.S.C. §§ 102, 103 or 112 for one or more of the following reasons:

a. The patentee did not invent the subject matter patented, nor did he make any invention or discovery, either novel, original, or otherwise, within the meaning of United States Code, Title 35;

b. The alleged invention was made by another in this country before the patentee's alleged invention, and such other person had not abandoned, suppressed, or concealed it;

c. The patent does not particularly point out and distinctly claim the part, improvement, method, steps, or combination that the patentee claims as his invention, as required by Title 35, United States Code;

d. The specification does not contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it most nearly connected, to make, construct, compound and/or use the same, and the description does not adequately explain the principle or the best mode in which the patentee contemplated applying the principle so as

to distinguish it from other inventions, as required by Title 35, United States Code;

e. The claims, and each of them, of the patent are excessively vague and indefinite and do not distinctly point out and define the invention;

f. The claims, and each of them, are not directed to patentable combinations, but are directed to mere aggregations of parts or steps, means, or elements which were matters of common knowledge in the art to which said patent relates before the alleged invention and more than one year prior to the date of the application for the patent;

g. In light of the prior art at the time the alleged invention was made, the subject matter as claimed in the patent would have been obvious to one skilled in the art to which the alleged invention relates and does not constitute patentable invention;

h. The alleged invention or discovery was disclosed in a U.S. patent to another, the application for which was filed before the alleged invention by the patentee of the Patents-in-Suit;

i. More than one year prior to the filing of the original application which matured into the Patents-in-Suit, the alleged invention was patented or described in printed

publications in this or in foreign countries, or was in public use, or on sale in this country;

j. Before the alleged invention or discovery of the patentee, the alleged invention was known or used by others than the alleged inventor and was on sale in this country and was patented or described in a printed publication in this or in foreign countries.

20. AGA further avers that any claims of the '420 Patent, including any claims which may have survived reexamination, which may be held to be valid are so restricted in scope that AGA has not infringed said claims.

21. As a result of the proceedings in the U.S. Patent and Trademark Office during the prosecution of the applications and reexamination proceedings for the '420 Patent and the admissions and representations made in the proceedings by or on behalf of the applicant, Defendants are estopped under the doctrine of prosecution history estoppel and may not now seek or maintain a construction for the claims of the '420 Patent, were the same otherwise possible, to cover or embrace any products made, used, or sold by AGA.

22. The Patent Statutes provide, in part, that during a reexamination proceeding in the Patent and Trademark Office "[n]o proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding..." 35 U.S.C. § 305 (2003). Because none of the original claims of the '420 patent cover AGA's products or conduct AGA cannot be found ti infringe any claim added or amended during reexamination.

23. AGA has not done any act or thing and is not proposing to do any act or thing in violation of any rights validly belonging to Defendants under any patent owned by Defendants.

The '420 Patent is invalid and unenforceable, and not infringed by AGA, and AGA is not liable for infringement of said patents.

PRAYER

WHEREFORE, AGA prays that:

1. Entry of judgment providing:

a. A declaration that Defendants is without right or authority to threaten or maintain suit against AGA for alleged infringement of the '420 Patent, including any claims which may have survived reexamination.

b. A declaration that the claims of '420 Patent, including any claims which may have survived reexamination, are invalid, unenforceable and void in law.

c. A declaration that the claims of '420 Patent, including any claims which may have survived reexamination, are not infringed by AGA.

d. AGA be awarded its costs and attorneys fees related to this suit.

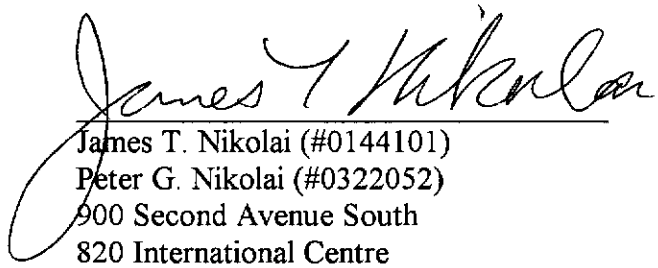
e. Preliminary and permanent injunctive relief enjoining Defendants, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with it who receive actual notice of the injunction from initiating infringement litigation or threatening AGA or any of its customers, dealers, agents, servants, or employees, or any perspective or present sellers, dealers, or users of AGA's products, with infringement litigation, or charging any of them verbally or in writing with infringement of the '420 Patent because of the manufacture, use, sale, or offering for sale of the AGA's products.

2. All other relief that the Court may deem appropriate.

Respectfully submitted,

Dated: October 13, 2004

NIKOLAI & MERSEREAU, P.A.



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