#### UNITED STATES DISTRICT COURT

#### DISTRICT OF MASSACHUSETTS

DIOMED, INC.,	)
Plaintiff, v.	) ) CIVIL ACTION NO.: 04-10019-RGS
ANGIODYNAMICS, INC.,	)
Defendant.	)
AND	)
ANGIODYNAMICS, INC.,	)
Counterclaim-Plaintiff, v.	) ) )
DIOMED, INC. AND ENDOLASER, LLC,	)
Counterclaim-Defendants.	) JUNE 1, 2004

## <u>DEFENDANT ANGIODYNAMICS, INC.'S FIRST AMENDED</u> <u>ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS</u>

Defendant AngioDynamics, Inc. ("AngioDynamics" or "Defendant") submits this First Amended Answer, Affirmative Defenses and Counterclaims in response to the Complaint and Demand For Jury Trial of Plaintiff Diomed, Inc. ("Diomed" or "Plaintiff"), dated January 6, 2004, alleges as follows: <sup>1</sup>

Pursuant to the Joint Schedule entered by Judge Stearns on May 10, 2004 in this action, the parties have until June 1, 2004 to amend the pleadings.

#### **ANSWER**

- 1. AngioDynamics lacks the knowledge or information necessary to respond to the allegations of paragraph 1 relating to Plaintiff's incorporation and address and thus is deemed to deny the allegations of paragraph 1.
- 2. AngioDynamics admits the allegations of paragraph 2, which paragraph relates to AngioDynamics' incorporation and address.
- 3-13. AngioDynamics lacks the knowledge or information necessary to respond to the allegations of paragraphs 3 through 13, which paragraphs relate to Plaintiff Diomed's allegations of its own activities and the significance thereof, and therefore the allegations of paragraph 3 through 13 are deemed denied.
- 14. AngioDynamics denies the allegations of paragraph 14, which paragraph asserts infringement by AngioDynamics. However, AngioDynamics admits that it and Diomed are competitors.
- 15-18. AngioDynamics admits the allegations of paragraphs 15 through 18 which relate to jurisdiction and venue.

## Count 1 And The Allegations of Infringement of U.S. Patent No. 6,398,777

- 19. AngioDynamics repeats its answers to paragraphs 1 through 18, which paragraphs are realleged in paragraph 19.
- 20. AngioDynamics lacks knowledge or information necessary to respond to the allegations of claim 20 concerning Plaintiff's alleged rights in the '777 patent. However, AngioDynamics admits that a copy of the '777 patent and the Certificate of Correction issued by the United States Patent And Trademark Office are attached to the Complaint.
- 21. AngioDynamics admits the allegations of paragraph 21; which paragraph relates to products sold by AngioDynamics.
- 22. AngioDynamics admits the allegations of paragraph 22; which paragraph relates to AngioDynamics' training program.
- 23. AngioDynamics denies the allegations of paragraph 23; which paragraph relates to allegations of contributory infringement and inducing infringement. AngioDynamics specifically denies that it has infringed or contributorily infringed or induced infringement of the '777 patent.

- 24. AngioDynamics denies the allegations of paragraph 24; which paragraph relates to continuing infringement.
- 25. AngioDynamics denies the allegations of paragraph 25; which paragraph relates to allegations of knowing and willful infringement.
- 26. AngioDynamics denies the allegations of paragraph 26; which paragraph assumes infringement and alleges that Plaintiff has suffered damages.
- 27. AngioDynamics denies the allegations of paragraph 27; which paragraph asserts that alleged infringement has caused Plaintiff irreparable harm.

## <u>AFFIRMATIVE DEFENSES</u>

Further answering, AngioDynamics states:

#### First Affirmative Defense

The claims of the '777 patent, depending on the scope asserted for them, are invalid either because they are anticipated under 35 U.S.C. Section 102 by the prior art or are rendered obvious under 35 U.S.C. Section 103 by the prior art.

### **Second Affirmative Defense**

If any claim of the '777 patent were to be so interpreted or so expanded in scope as to embrace product sold by AngioDynamics or methods employed by AngioDynamics, the claim would be invalid for each or both of the following reasons, namely:

- (a) the subject matter of the claim as a whole, as it would then stand, would have been obvious, at the time the purported invention was made, to a person having ordinary skill in the art to which said subject matter pertains; and
- (b) with respect to the subject matter of the claim as it would then stand, the patentees did not invent any new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof.

### **Third Affirmative Defense**

With respect to the features and collection of features relating to the endovascular laser device and method as disclosed in the '777 patent, AngioDynamics has used only those which the public is free to use by reason of patents, publications and publicly known and used practices of legally effective date prior to any date available on behalf of said patent.

## **Fourth Affirmative Defense**

If any claim of the '777 patent were to be so interpreted as to embrace the products sold by AngioDynamics, the claim would be invalid for failure to point out subject matter which the patentees regard as their invention.

### Fifth Affirmative Defense

By reason of words and acts on the part of the patentees and their legal representatives in prosecution of the application for the '777 patent, Plaintiff is estopped or otherwise barred from asserting that any claim of said patent has a scope that would cover any product sold by AngioDynamics.

#### Sixth Affirmative Defense

Claims 1-8 of the '777 patent are invalid under 35 U.S.C. Section 112.

### **Seventh Affirmative Defense**

AngioDynamics has not infringed and is not now infringing the '777 patent.

## **Eighth Affirmative Defense**

During prosecution of the '777 patent application from August 13, 1999 through June 4, 2002, the inventors and/or those associated with the filing and prosecution of the patent application, committed inequitable conduct or fraud by knowingly withholding, and otherwise failing to bring to the attention of the U.S. Patent & Trademark Office prior art that was material to patentability, thereby rendering the '777 patent unenforceable.

WHEREFORE, AngioDynamics prays judgment as set out below.

### **ANGIODYNAMICS' COUNTERCLAIMS**

#### **Parties**

- 1. Counterclaim-Plaintiff AngioDynamics is a Delaware Corporation with a place of business at 603 Queensbury Avenue, Queensbury, New York 12804.
- 2. Upon information and belief, Counterclaim-Defendant Diomed is a Delaware Corporation with a place of business at One Dundee Park, Suite 5/6, Andover, Massachusetts 10810. Upon information and belief, Counterclaim-Defendant Diomed is involved in the manufacture, distribution, and marketing of products for the laser treatment of veins in interstate commerce throughout the United States, including Massachusetts.
- 3. Upon information and belief, Counterclaim-Defendant Endolaser Associates, LLC is a limited liability company of Delaware, having a place of business at 327 East 65<sup>th</sup> Street, New York, New York 10021 ("Endolaser"). Upon information and belief, Counterclaim-Defendant Endolaser has collaborated with Counterclaim-Defendant Diomed in connection with the manufacture, distribution and sales of products for the laser treatment of veins.

#### **Jurisdiction And Venue**

4. These Counterclaims are for a Declaratory Judgment of non-infringement, invalidity of patent and unenforceability of patent pursuant to 28 U.S.C. §§ 2201 and 2202, arising from an actual controversy between AngioDynamics and Counterclaim-Defendants concerning the alleged infringement, invalidity and unenforceability of the '777 patent and violation of the antitrust laws of the United States, 15 U.S.C. §§ 1, 2, and 15.

- 5. This Court has jurisdiction over these Counterclaims for a declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, and 1338(a) and for antitrust violations pursuant to 15 U.S.C. § 22.
- 6. This Court also has supplemental jurisdiction over these Counterclaims under 28 U.S.C. § 1367(a) because they arise out of the same transaction and occurrence alleged in Diomed's Complaint and are so related to the claims alleged therein as to form a part of the same case or controversy within the meaning of Article III of the United States Constitution.

## AngioDynamics' First Counterclaim Against Counterclaim-Defendants (Declaratory Judgment of Non-Infringement of Patent)

- 7. AngioDynamics repeats and re-alleges the allegations in paragraphs 1-6 above as if fully set forth herein.
- 8. Counterclaim-Defendant Diomed purports to be and on information and belief is an owner of the '777 patent.
- 9. Counterclaim-Defendant Endolaser Associates, LLC is an owner of the '777 patent. Upon information and belief, Endolaser's purpose has been and continues to be to exploit the '777 patent, Endolaser is obligated to identify to Diomed alleged infringers of the '777 patent, to assist and otherwise collaborate in bringing and in maintaining suit against such alleged infringers, and is entitled to share in recoveries against infringers.

- 10. Diomed filed suit in this Court against AngioDynamics, and upon information and belief, in collaboration and with the assistance of Endolaser, for alleged infringement of the '777 patent on grounds that AngioDynamics has, and continues to, allegedly infringe, contributorily infringe, and/or induce infringement of the '777 patent by making, using, offering to sell, and selling its ELVS Procedure Kit, and by inducing others to use the ELVS Procedure Kit through a training program.
- 11. Based upon actions undertaken by Counterclaim-Defendants, AngioDynamics is under a reasonable apprehension that Counterclaim-Defendants will continue to seek to enforce their alleged rights in the '777 patent against AngioDynamics or its customers.
- 12. AngioDynamics' activities in connection with making, using, offering to sell, and selling its ELVS Procedure Kit, and inducing others to use the ELVS Procedure Kit through a training program, or otherwise, do not infringe, contributorily infringe or induce infringement of any claim of the '777 patent.

## AngioDynamics' Second Counterclaim Against Counterclaim-Defendants (Declaratory Judgment of Invalidity of Patent)

- 13. AngioDynamics repeats and re-alleges the allegations in paragraphs 1-12 above as if fully set forth herein.
- 14. One or more claims of the '777 patent sought to be enforced against AngioDynamics in this action is invalid under one or more provisions of 35 U.S.C. Sections 102, 103 and/or 112.

## AngioDynamics' Third Counterclaim Against Counterclaim-Defendants (Declaratory Judgment of Patent Unenforceability)

- 15. AngioDynamics repeats and re-alleges the allegations in paragraphs 1-14 above as if fully set forth herein.
- 16. The '777 patent identifies Luis Navarro, Nestor Navarro, Carlos Bone Salat, Joaquina Fructuso Gomez, and Robert J. Min as its inventors ("the inventors").
- 17. Upon information and belief, inventors Luis Navarro, Nestor Navarro, Carlos Bone Salat and Joaquina Fructuso Gomez assigned their interest in the '777 patent to Endolaser Associates, LLC, and inventor Robert J. Min assigned his interest in the '777 patent to Diomed.
- 18. In 1989, Dr. Ken Biegeleisen published a paper in *Phlebologie* entitled "Use of the venoscope for treatment of varicose veins" ("the Biegeleisen Paper").
- 19. In September 1999, Dr. Carlos Bone Salat, one of the inventors of the '777 patent, published a paper entitled "Endoluminal treatment of the varices with Laser of Diode" ("the Salat Paper"). In his paper, Dr. Salat referenced the Biegeleisen Paper.
- 20. In November 1999, the inventors filed their First Information Disclosure Statement in the United States Patent & Trademark Office in connection with the '777 patent application.

- 21. In September 2000, the inventors filed their Second Information Disclosure Statement in the United States Patent & Trademark Office in connection with the '777 patent application.
- 22. The inventors failed to disclose the Biegeleisen Paper as prior art in their Information Disclosure Statements. The Biegeleisen Paper contains information material to the patentability of the '777 patent application.
- 23. Such nondisclosure should have been cited and disclosed as being material prior art and was clearly within the purview of the inventors' knowledge.
- 24. During prosecution of the '777 patent application from August 13, 1999 through June 4, 2002, the inventors and/or those associated with the filing and prosecution of the patent application, committed inequitable conduct or fraud by knowingly withholding, and otherwise failing to bring to the attention of the U.S. Patent & Trademark Office prior art that was material to patentability, including without limitation, the 1989 Biegeleisen Paper.
- 25. As a result of the inequitable conduct committed by the inventors and/or those associated with the filing and prosecution of the '777 patent application, the '777 patent is unenforceable.

# AngioDynamics' Fourth Counterclaim Against Counterclaim-Defendants (Violation of Sections 1, 2, and 15 of the Sherman Antitrust Act, 15 U.S.C. §§ 1, 2 and 15)

- 26. AngioDynamics repeats and re-alleges the allegations in paragraphs 1-25 above as if fully set forth herein.
- 27. Shortly after initiating this action in the United States District Court for the District of Massachusetts against its competitor AngioDynamics, and upon information and belief, Counterclaim-Defendants Diomed and Endolaser collaborated and otherwise conspired in bringing two additional lawsuits against other competitors, Total Vein Solutions, LLC and Vascular Solutions, Inc., in the same District, alleging infringement of the '777 patent.
- 28. Prior to and since filing these lawsuits, Counterclaim-Defendants Diomed and Endolaser knew or reasonably should have known that they did not have a good faith basis to initiate and to continue such actions because the '777 patent was invalid and/or unenforceable. Such suits were and are objectively baseless.
- 29. On January 7, 2004, March 4, 2004, and April 5, 2004, respectively, Counterclaim-Defendant Diomed widely disseminated press releases touting the patent infringement actions brought against AngioDynamics, Vascular Solutions, Inc., and Total Vein Solutions, LLC.
- 30. By and through the aforesaid acts, the Counterclaim-Defendants intended to achieve monopoly power in the field of disposable procedure kits for the treatment of varicose veins by endovascular laser techniques in the United States ("the relevant market").

- 31. By and through the aforesaid acts, the Counterclaim-Defendants engaged in exclusionary conduct to further such intent to achieve monopoly power in the relevant market.
- 32. As a direct and proximate result of Counterclaim-Defendants' monopolistic and anti-competitive conduct, there exists a dangerous probability that the Counterclaim-Defendants will achieve monopoly power within the relevant market.
- 33. By virtue of the foregoing acts of harassment and threats of, and the continued prosecution of suits for, patent infringement made against AngioDynamics and its competitors, when the Counterclaim-Defendants knew or should have known that the '777 patent is invalid and/or unenforceable, Counterclaim-Defendants have committed acts of patent misuse and have conspired to unlawfully restrain trade within the relevant market and have conspired with the specific intent to accomplish an unlawful and anticompetitive result, all in violation of federal antitrust laws.
- 34. As a result of Counterclaim-Defendants' patent misuse and attempts to monopolize and restrain trade, AngioDynamics has been damaged in an amount which is unknown and cannot at the present time be ascertained.

## AngioDynamics' Fifth Counterclaim Against Counterclaim-Defendants (Patent Misuse)

35. AngioDynamics repeats and re-alleges the allegations in paragraphs 1-34 above as if fully set forth herein.

- 36. By virtue of the foregoing acts of harassment and threats of further or continued patent infringement suits made by Diomed, and Endolaser in collaboration with Diomed, when Counterclaim-Defendants have known, or should have known, that the '777 patent is unenforceable and/or invalid, Counterclaim-Defendants have committed acts of patent misuse.
- 37. As a result of Counterclaim-Defendants' acts of patent misuse, the '777 patent is unenforceable.

## AngioDynamics' Sixth Counterclaim Against Counterclaim-Defendants (Violation of Massachusetts General Law ch. 93A)

- 38. AngioDynamics repeats and re-alleges the allegations in paragraphs 1-37 above as if fully set forth herein.
- 39. At all times material to this action, Counterclaim-Defendants have and were engaged in trade or commerce in the Commonwealth of Massachusetts and compete against AngioDynamics in the Commonwealth of Massachusetts.
- 40. At all times relevant to these Counterclaims, the actions of Counterclaim-Defendants described herein, including but not limited to initiating and maintaining three actions in the United States District Court for the District of Massachusetts based on a patent which Counterclaim-Defendants have known, or should have known to be unenforceable and/or invalid, and issuing related press releases, constitute unfair and deceptive acts in violation of Mass. Gen. Law ch. 93A § 1 et seq.

- 41. At all times relevant to these Counterclaims, the Counterclaim-Defendants' actions in violation of Mass. Gen. Law ch. 93A were done recklessly, intentionally and willfully.
- 42. At all times relevant to these Counterclaims and as a result of the Counterclaim-Defendants' violation of Mass. Gen. Law. ch. 93A, AngioDynamics has been harmed.
- 43. As a result of Counterclaim-Defendants' violation of the unfair competition laws of the Commonwealth of Massachusetts, AngioDynamics has been damaged in an amount which is unknown and cannot at the present time be ascertained

#### **Demand for Jury Trial**

1. AngioDynamics demands trial by jury on all claims asserted herein.

### **Prayer for Relief**

WHEREFORE, Counterclaim-Plaintiff, AngioDynamics, demands judgment in its favor and against Counterclaim-Defendants as follows:

- 1. that United States Patent No. 6,938,777 is not infringed;
- 2. that United States Patent No. 6,938,777 is invalid;
- 3. that United States Patent No. 6,938,777 is unenforceable;
- 4. that AngioDynamics be awarded damages in the amount to be determined at trial, including a claim for treble damages pursuant to 15 U.S.C. § 15 and Mass. Gen. L. 93A § 11;
- 5. that AngioDynamics be awarded its attorneys' fees pursuant to 15 U.S.C. § 15 and Mass. Gen. L. ch. 93A § 11;

- 6. that costs and reasonable attorneys' fees be awarded AngioDynamics in connection with this suit; and
- 7. that AngioDynamics be granted such other and further relief as this Court may find just and proper.

Dated: June 1, 2004

I hereby certify that a true copy of the above document was served upon the attorney of record for the Plaintiff and Counterclaim-Defendants by regular mail on

June 1, 2004.

Mark/D. Giarratana

**DEFENDANT** 

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