

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ATLANTA DIVISION**

ERBE USA, INC.,	)	
	)	
	)	
Plaintiff and	)	
Counterclaim-Defendant,	)	
	)	
v.	)	Civ. Action No. 1:11-cv-01480-AT
	)	
BYRNE MEDICAL, INC. and	)	
MINNTECH CORPORATION,	)	<b>SECOND AMENDED</b>
	)	<b>COMPLAINT</b>
Defendants,	)	
Counterclaim-Plaintiffs,	)	
and Counter-Counterclaim Defendants,	)	Jury Trial Demanded
	)	
v.	)	
	)	
ALAN SMITH,	)	
	)	
Counterclaim-Defendant	)	
and Counter-Counterclaim Plaintiff.	)	

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**ERBE USA, INC.’S SECOND AMENDED COMPLAINT**

Plaintiff ERBE USA, Inc. (“ERBE”) hereby files this Second Amended Complaint against Defendants Byrne Medical, Inc., k/n/a DMB Holdings, Inc., (“Byrne”) and Minntech Corporation (“Minntech”) (collectively “Defendants”), as follows:

### **NATURE OF ACTION**

1. This complaint comprises five causes of action. There are two false marking actions in which ERBE seeks damages sufficient to compensate for its competitive injury, two unfair competition actions in which ERBE seeks damages amounting to no less than Defendants' profits from its sales of two different products, and a declaratory judgment action in which ERBE seeks a declaration that the claims of U.S. Patent No. 6,210,322 ("the '322 patent") are invalid. Because this is an exceptional case, ERBE also seeks its attorneys' fees.

### **JURISDICTION AND VENUE**

2. The false marking actions arise under the United States Patent Act, codified at 35 U.S.C. § 1 *et seq.*, and in particular, 35 U.S.C. § 292, the unfair competition actions arise under the Lanham Act, codified at 15 U.S.C. § 1051 *et seq.*, and in particular, 15 U.S.C. §§ 1117(a) and 1125(a), and the declaratory judgment action arises under the Declaratory Judgments Act, 28 U.S.C. § 2201 *et seq.*, and under the United States Patent Act, 35 U.S.C., § 1 *et seq.*

3. This Court has original jurisdiction over the subject matter of the false marking actions under 28 U.S.C. §§ 1331, 1332 and 1338(a), the unfair competition actions under 28 U.S.C. §§ 1331, 1332, 1338(a) and 1338(b), and the declaratory judgment action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

4. This Court has personal jurisdiction over Byrne because, on information and belief, Byrne has transacted business in this District, has committed acts of false marking and unfair competition in this District, and continues to commit acts of false marking and unfair competition in this District.

5. This Court has personal jurisdiction over Minntech because, on or about August 1, 2011, Minntech purchased the assets and the liabilities of Byrne, and by doing so expressly assumed the liability of this pending action, therefore acquiescing to this Court's jurisdiction. Moreover, on information and belief, Minntech has transacted business in this District.

6. Venue is proper under 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b) because, on information and belief, Byrne has transacted business in this District, has committed acts of false marking and unfair competition in this District, and has established minimum contacts within this District, and Minntech, by assuming the liability of this pending action, has consented to venue in this District.

**PARTIES**

7. ERBE is a corporation organized and existing under the laws of the State of Georgia, with its corporate headquarters and principal place of business at 2225 Northwest Parkway, Marietta, Georgia 30067.

8. On information and belief, Byrne is a corporation organized under the laws of the State of Texas, with its corporate headquarters and principal place of business at 3150 Pollok Drive, Conroe, Texas 77303.

9. On information and belief, Minntech is a corporation organized under the laws of the State of Minnesota, with its corporate headquarters and principal place of business at 14605 28th Avenue, North, Minneapolis, Minnesota 55447.

**FACTUAL BACKGROUND**

10. ERBE sells endoscopic irrigation systems manufactured by ERBE Elektromedizin GmbH, including the ERBE EIP™ 2 Irrigation Pump System, in the United States.

11. Defendants manufacture and sell endoscopic irrigation systems and disposable products for endoscopic irrigation in the United States. Defendants' disposable products include its EndoGator™ Irrigation Tubing (Part

No. 100130) (“the EndoGator tube set”) and its Endo SmartCap® Tubing (Part Nos. 100145 and 100145 CO<sub>2</sub>) (“the SmartCap product”).

12. The EndoGator tube set is an irrigation tubing set for an endoscopic lavage system whereas the SmartCap product is a water bottle adaptor that facilitates the cleaning of a lens of an endoscope during medical procedures.

13. Approximately seven years ago, Byrne and ERBE entered into a distribution agreement (“the Agreement”) that allowed ERBE to distribute and sell tube sets and other certain disposable products manufactured by Byrne to purchasers of the ERBE irrigation pump systems. The Agreement did not allow ERBE to distribute and sell the SmartCap product to its customers.

14. Pursuant to the Agreement, Byrne manufactured a specific version of its EndoGator tube set for ERBE that was in ERBE’s color scheme and included ERBE’s trademarks. This ERBE specific version is packaged, marketed and sold as the ERBEFLO™ Endoscopy Pump Tubing/Cap Set (“the ERBEFLO tube set”).

15. At the time Byrne and ERBE entered into the Agreement, representatives of Byrne told ERBE that its EndoGator tube set was manufactured according to at least one U.S. patent application – which, on information and

belief, later issued as the '322 patent. Upon information and belief, Byrne also told third parties that it had patent protection for the EndoGator tube set.

16. For example, upon information and belief, Byrne warned Boston Scientific that it had patent protection for its tube set, and because of that warning Boston Scientific did not manufacture tube sets for its Spyglass technology.

17. Moreover, as part of its marketing of its EndoGator tube set, Byrne distributed advertisements, a copy of which is attached as Exhibit A, indicating that the EndoGator tube set was protected by a pending U.S. patent application. Additionally, Byrne marked, and upon information and belief Defendants continue to mark, the boxes in which EndoGator tube sets are shipped with the phrase "Patent:6210322B1", as shown in Exhibit B.

18. Through Byrne's communications with ERBE and others, its advertisements claiming that the EndoGator tube set was protected by U.S. patents and/or pending patent applications, and its marking the packaging for its EndoGator tube set with a U.S. patent number, potential manufacturers of competitive products and customers of the EndoGator tube set – including ERBE – believed the EndoGator tube set was protected by a U.S. patent.

19. Similarly, upon information and belief, Byrne informed actual and potential competitors that its SmartCap product was covered by the ‘322 patent. In fact, Byrne’s website stated that the SmartCap product was protected by the ‘322 patent, as shown in Exhibit C.

20. For example, upon information and belief, because of Byrne’s claims of patent protection for its SmartCap product, U.S. Endoscopy took pains to design its AquaShield™ product around the SmartCap product.

21. Over time, Byrne has continuously reminded the market – including ERBE and U.S. Endocopy – of its exclusive patent rights.

### **THE ‘322 PATENT**

22. The ‘322 patent, which is assigned to Byrne and entitled “Adaptor for the Connection of a Water Bottle to an Endoscope,” was filed on October 5, 1998 and granted on April 3, 2001. A true and correct copy of the ‘322 patent is attached as Exhibit D.

23. The ‘322 patent has nine claims and is directed to a water bottle adaptor that has, among other features, an inner tube and an outer tube, where the inner tube extends through the outer tube and an air passing annulus is formed

between the exterior surface of the inner tube and the interior surface of the outer tube.

24. As filed, claim 1 of the '322 patent – the only independent claim of the '322 patent – only required a water bottle adaptor that has an inner tube extending through an outer tube, where an air annulus is formed between the exterior surface of the inner tube and the interior surface of the outer tube. However, as filed, claim 1 was rejected in light of prior art that disclosed such a configuration.

25. To overcome the rejection, claim 1 was amended to additionally require that the water bottle adapter include a permanent fitting affixed to one end of the tubing (opposite the cap) with a removable adaptor attached to it.

26. According to the prosecution history of the '322 patent, it is this specific structure of a permanent fitting affixed to one end of the tubing with a removable adaptor attached to it that the U.S. Patent and Trademark Office (“PTO”) found patentable.

27. Therefore for an article to be covered by the '322 patent, it must have at least an inner tube extending through an outer tube such that an air annulus is formed between the exterior surface of the inner tube and the interior surface of



the outer tube and a permanent fitting affixed to one end of the tubing with a removable adaptor attached to it.

### **BYRNE'S DISPOSABLE PRODUCTS**

28. The EndoGator tube set has a single tube, i.e., not a tube within a tube, extending from a water bottle cap. Because the EndoGator tube set does not have a tube within a tube, it does not have an inner tube extending through an outer tube. Consequently, the EndoGator tube set does not also have an air annulus formed between two tubes.

29. Moreover, there is not a permanent fitting affixed to one end of the tubing (opposite the cap) with a removable adaptor attached to it.

30. Since the EndoGator tube set does not have all of the limitations found in claim 1 of the '322 patent, neither claim 1, nor any of its dependent claims, i.e., claims 2-9, cover the EndoGator tube set. Thus, with regard to the '322 patent, the EndoGator tube set is an unpatented product.

31. The SmartCap product is a water bottle adaptor that has an inner tube extending through an outer tube, where an air passing annulus is formed between the exterior surface of the inner tube and the interior surface of the outer

tube. However, the SmartCap product does not have a removable adaptor attached to a permanent fitting affixed to one end of the tubing.

32. Since the SmartCap product does not have a removable adaptor attached to a permanent fitting affixed to one end of the tubing required by claim 1 of the '322 patent, neither claim 1, nor dependent claims 2-9 cover the Smart Cap product. Thus, with regard to the '322 patent, the SmartCap product is an unpatented product.

33. As set out above, the EndoGator tube set and the SmartCap product are structurally different and on information and belief, Defendants know or should know, that the '322 patent is directed towards a particular tube arrangement.

34. On information and belief, Byrne is aware of the differences between its EndoGator tube set and SmartCap product. Defendants know or should know that the EndoGator tube set does not have a tube within a tube and, consequently, does not provide an air annulus, while the SmartCap product has an inner tube extending through an outer tube such that an air passing annulus is formed between the exterior surface of the inner tube and the interior surface of the outer tube.

35. On information and belief, Defendants know or should know that since the '322 patent requires a particular tube arrangement and its EndoGator tube set and SmartCap product have structurally distinct tube arrangements, both products cannot be covered by the one independent claim of the '322 patent.

36. On information and belief, Byrne, with knowledge of the structural differences – not to mention their different functional uses – between its EndoGator tube set and Smart Cap product, marketed and marked both products as being covered by the '322 patent. By doing so, Byrne deceived, and Defendants continue to deceive, the public and ERBE.

### **CONTROVERSY BETWEEN THE PARTIES**

37. On June 30, 2010, Byrne informed ERBE that it was terminating the Agreement, effective December 31, 2010. ERBE believed that the Agreement could not be terminated until July 31, 2011.

38. Once Byrne announced it was terminating the Distribution Agreement, ERBE discovered that Byrne was selling ERBE products at prices not in accordance with the Distribution Agreement.

39. ERBE also discovered that Byrne was selling products directly to ERBE's customers, another violation of the Distribution Agreement.

40. Along with certain other things ERBE discovered regarding Byrne's actions in the tube set marketplace, these two discoveries led to a contentious business relationship between ERBE and Byrne. To stop what it believed to be serious and on-going material breaches of the Agreement, pursuant to the terms of the Agreement, ERBE filed an Arbitration proceeding to resolve issues related to the termination date of the Agreement and the breaches of contract claims.

41. While seeking to resolve its contractual dispute with Byrne, ERBE began to investigate how it could continue to supply disposable endoscopic irrigation products, including ERBEFLO tube sets, to its long standing customers.

42. Because of the '322 patent, most third party manufacturers were unwilling to manufacture a product similar to the EndoGator tube set. Similarly, ERBE's internal R&D team was hesitant to develop a replacement for the ERBEFLO tube sets.

43. Similarly, ERBE realized that in order to protect its customer base for endoscopic irrigation products, it needed a competitive product to the SmartCap product. Therefore, ERBE began to investigate how it could provide such a product.

44. Again, because of the '322 patent, third party manufacturers were hesitant to manufacture a product similar to the SmartCap product.

45. ERBE and Byrne dismissed the Arbitration with prejudice upon agreeing that the Agreement would not terminate until July 31, 2011 and that Byrne would cease breaching the Agreement.

46. After settling the Arbitration, the parties attempted to extend the Agreement past July 31, 2011. To this end, the parties met in Byrne's offices in Conroe, Texas on March 2, 2011.

47. At that meeting, Donnie Byrne, President of Byrne, introduced the ERBE representatives to his lawyer, Betsy McKernan, and stated that U.S. Endoscopy's AquaShield™ product was very close to his patents, and that he would take legal action against anyone who came any closer to his patents.

48. Mr. Byrne further elaborated how he Byrne had put together a legal fund and set up offices for Ms. McKernan, and a legal assistant so that Byrne could aggressively defend its exclusive patent rights.

49. After this meeting, ERBE concluded that it could probably not continue a relationship with Byrne. ERBE was also convinced that Byrne intended

to aggressively assert its '322 patent against third parties that Byrne felt came close to its patents.

50. After ERBE concluded not to extend its relationship with Byrne, ERBE located a new manufacturer for its tube sets. ERBE introduced its ERBEFLO 2 product line at the Digestive Disease Week exposition in Chicago, Illinois, and the Society of Gastroenterology Nurses and Associates meeting in Indianapolis, Indiana.

51. Included within this product line is the ERBEFLO 2 tube set which is substantially similar to the EndoGator product and the ERBEFLO product that was manufactured for ERBE by Byrne. Sales of the ERBEFLO 2 tube sets will commence in September 2011.

52. Recently, ERBE's internal R&D team completed development of a single product – the ERBE CLEVERCAP™ Tubing Set (“CleverCap product”) – that can replace the combination of both the EndoGator tube set and the SmartCap product.

53. ERBE's sales force began showing the CleverCap product to customers on April 22, 2011 and on May 8, 2011, ERBE formally introduced its CleverCap product to the industry at the Digestive Disease Week exposition in

Chicago, Illinois, and the Society of Gastroenterology Nurses and Associates meeting in Indianapolis, Indiana.

54. On July 26, 2011, ERBE began shipping its CleverCap product to customers.

55. The CleverCap product is a water bottle adaptor that has an inner tube extending through an outer tube, where an air passing annulus is formed between the exterior surface of the inner tube and the interior surface of the outer tube.

56. While the CleverCap product does not have a removable adaptor attached to a permanent fitting affixed to one end of the tubing, on information and belief, Byrne maintains that its SmartCap product, having the same configuration as the CleverCap product, is covered by the '322 patent.

57. Thus, having now introduced two new products into the market that Byrne, on information and belief, believes are covered by the '322 patent and knowing that Byrne intends to defend its exclusive patent rights, ERBE reasonably believes Byrne will assert its alleged exclusive patent rights against one or both of ERBE's two new products.

58. ERBE's apprehension that it will be sued by Byrne for patent infringement is magnified because of the contentious business relationship between ERBE and Byrne.

**FIRST CLAIM FOR RELIEF**

(False Marking)

59. ERBE incorporates by reference the allegations contained in paragraphs 1 through 58 above.

60. ERBE, as a direct competitor, brings this action pursuant to 35 U.S.C. § 292(b) because it has suffered direct competitive injury because of Byrne's false marking.

61. The EndoGator tube set does not possess all of the limitations required by the claims of the '322 patent, and therefore, in regards to the '322 patent, the EndoGator tube set is an unpatented product.

62. Byrne knew or reasonably should have known that falsely marking the unpatented EndoGator tube set with the '322 patent is in violation of 35 U.S.C. § 292(a).



63. By marketing and selling its unpatented EndoGator tube set – and more specifically by marking its packaging as being covered by the claims of the ‘322 patent – Byrne has knowingly and intentionally falsely marked the EndoGator tube set, in violation of 35 U.S.C. § 292(a).

64. ERBE and the public have been, and continue to be, intentionally deceived and injured by Byrne’s intentional false marking of the EndoGator tube set.

65. By wrongfully and illegally claiming that the EndoGator tube set was a patented product, the consuming public has paid higher prices for EndoGator tube sets and ERBE has lost profits from sales of its ERBEFLO tube sets.

66. Because it suppressed competition, thereby harming ERBE and the public, ERBE is entitled to damages sufficient to compensate for its competitive injury, as set forth in 35 U.S.C. § 292(b).

## **SECOND CLAIM FOR RELIEF**

(False Advertising)

67. ERBE incorporates by reference the allegations contained in paragraphs 1 through 66 above.

68. By falsely representing that its EndoGator tube set was a patented product, Byrne has made false representations in commercial advertisements, in violation of 15 U.S.C. § 1125(a).

69. By making false statements of facts in commercial advertisements, Byrne is deceiving the public including consumers, competitors and ERBE as to the nature, characteristics and quality of its EndoGator tube set in violation of 15 U.S.C. § 1125(a).

70. By deceiving the public and ERBE, Byrne materially influenced ERBE's purchasing and competitive decisions, in violation of 15 U.S.C. § 1125(a) and its false advertising has increased the profits from the sales of its EndoGator tube sets and diverted profits from ERBE to Byrne.

71. ERBE has been, and continues to be, injured by Defendants' misrepresentation of its EndoGator tube sets in violation of 15 U.S.C. § 1125(a) and ERBE is entitled to Defendants' profits from the sale of its EndoGator tube sets and damages sustained by ERBE because of Defendants' violation of 15 U.S.C. § 1125(a).

**THIRD CLAIM FOR RELIEF**

(False Marking)

72. ERBE incorporates by reference the allegations contained in paragraphs 1 through 71 above.

73. ERBE, as a direct competitor, brings this action pursuant to 35 U.S.C. § 292(b) because it has suffered direct competitive injury because of Byrne's false marking.

74. The SmartCap product does not possess all of the limitations required by the claims of the '322 patent, and therefore, in regards to the '322 patent, the SmartCap product is an unpatented product.

75. Byrne knew or reasonably should have known that falsely marking the unpatented SmartCap product with the '322 patent is in violation of 35 U.S.C. § 292(a).

76. By marketing and selling its unpatented SmartCap product – and more specifically by marking its website as being covered by the claims of the '322 patent – Byrne has knowingly and intentionally falsely marked the SmartCap product, in violation of 35 U.S.C. § 292(a).

77. ERBE and the public have been, and continue to be, intentionally deceived and injured by Byrne's intentional false marking of the SmartCap product.

78. By wrongfully and illegally claiming that the SmartCap product was a patented product, the consuming public has paid higher prices for the SmartCap.

79. Because it suppressed competition, thereby harming ERBE and the public, ERBE is entitled to damages sufficient to compensate for its competitive injury, as set forth in 35 U.S.C. § 292(b).

#### **FOURTH CLAIM FOR RELIEF**

(False Advertising)

80. ERBE incorporates by reference the allegations contained in paragraphs 1 through 79 above.

81. By falsely representing that its Smart Cap product was a patented product, Byrne has made false representations in commercial advertisements, in violation of 15 U.S.C. § 1125(a).

82. By making false statements of facts in commercial advertisements, Byrne is deceiving the public including consumers, competitors and ERBE as to the nature, characteristics and quality of its SmartCap product in violation of 15 U.S.C. § 1125(a).

83. By deceiving the public and ERBE, Byrne materially influenced ERBE's purchasing and competitive decisions, in violation of 15 U.S.C. § 1125(a) and its false advertising has increased the profits from the sales of its SmartCap product.

84. ERBE has been, and continues to be, injured by Defendants' misrepresentation of its SmartCap products in violation of 15 U.S.C. § 1125(a) and ERBE is entitled to Defendants' profits from the sale of its SmartCap products and damages sustained by ERBE because of Defendants' violation of 15 U.S.C. § 1125(a).

#### **FIFTH CLAIM FOR RELIEF**

(Declaration of Invalidity)

85. ERBE incorporates by reference the allegations contained in paragraphs 1 through 84 above.

86. On information and belief, all of the claims of the '322 patent are invalid because they fail to satisfy one or more of the requirements of patentability specified in 35 U.S.C. § 1 *et seq.*, including but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112.

87. As recited above, the prior art of record to the '322 patent disclosed a water bottle adaptor having an inner tube extending through an outer tube, where the inner tube forms an air annulus between the exterior surface of the inner tube and the interior surface of the outer tube. Additional prior art, not cited by the PTO, discloses a removable adaptor body.

88. Because all of the allegedly patentable limitations of claim 1 of the '322 patent, are disclosed in the prior art, claim 1 is anticipated and/or rendered obvious by the prior art and therefore invalid.

89. Since the prior art likewise discloses each of the limitations of claims 2-9, each of the limitations of claims 1-9 are anticipated and/or rendered obvious by the prior art, and consequently are invalid.

90. Because of the history between the parties, including Byrne's assertions that the SmartCap product is protected by a patent, and ERBE's introduction of its CleverCap product, an actual, substantial and immediate

controversy exists between ERBE and Byrne as to whether the claims of the '322 patent are valid, as Byrne presumably contends, or invalid, as ERBE contends.

91. The parties' recent history further demonstrates the sufficient immediacy of the controversy warrant issuance of a declaratory judgment.

92. Pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, ERBE is therefore entitled to a declaration that the claims of the '322 patent are invalid.

### **DEMAND FOR JURY TRIAL**

93. ERBE hereby demands trial by jury on all issues.

### **PRAYER FOR RELIEF**

WHEREFORE, ERBE prays for the following relief:

1. Pursuant to 35 U.S.C. § 292, a Judgment that Byrne has falsely marked its EndoGator tube set, and an Order that Defendants not commit further acts of false marking;

2. Pursuant to 35 U.S.C. § 292, damages sufficient to compensate for its competitive injury, or such alternative amount as the Court deems appropriate for Defendants' acts of false marking;

3. Pursuant to 15 U.S.C. § 1125, a Judgment that Byrne has committed acts of unfair competition, and an Order that Defendants not commit further acts of unfair competition;

4. Pursuant to 15 U.S.C. § 1117, an award to ERBE of Defendants' profits, damages suffered by ERBE and the costs of this action as a result of Defendants' acts of unfair competition;

5. Pursuant to 15 U.S.C. § 1117, an award to ERBE of its attorneys' fees incurred in this action;

6. Pursuant to 28 U.S.C. §§ 2201 and 2202, a Judgment that the claims of the '322 patent are invalid; and

7. Such other and further relief as this Court deems just and proper.

Dated: November 3, 2011

Respectfully submitted,

By s/Christine S. Tenley



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v.	)	
	)	
ALAN SMITH,	)	
	)	
Counterclaim-Defendant	)	
and Counter-Counterclaim Plaintiff.	)	

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**CERTIFICATE OF SERVICE**

I certify that on this 3rd day of November I have electronically filed the foregoing ERBE USA, INC.’S SECOND AMENDED COMPLAINT with the Clerk of Court using the CM/ECF System, which will automatically send email notification of such filing to the following attorneys of record:

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