

competition actions in which ERBE seeks damages amounting to no less than Byrne's 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. 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.

PARTIES

6. 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.

7. 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.

FACTUAL BACKGROUND

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

9. Byrne manufactures and sells endoscopic irrigation systems and disposable products for endoscopic irrigation in the United States. Byrne's disposable products include its EndoGator™ Irrigation Tubing (Part No. 100130) ("the EndoGator tube set") and its Endo SmartCap® Tubing (Part Nos. 100145 and 100145 CO₂) ("the SmartCap product").

10. 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.

11. Approximately seven years ago, Byrne and ERBE entered into a distribution agreement ("the Agreement") that allowed ERBE to distribute and sell EndoGator tube sets and other certain disposable products manufactured by Byrne to purchasers of the ERBE irrigation pump systems.

12. 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 of the EndoGator tube set is sold as the ERBEFLO™ Endoscopy Pump Tubing/Cap Set ("the ERBEFLO tube set").

13. 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 other entities involved in endoscopic irrigation that it had patent protection for the EndoGator tube set.

14. 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 continues to mark, the boxes in which it ships its EndoGator tube sets with the phrase “Patent:6210322B1”, as shown in Exhibit B.

15. 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.

16. On June 30, 2010, Byrne informed ERBE that it was terminating the Agreement. Pursuant to the terms of the Agreement, ERBE filed an Arbitration proceeding to resolve disputes related to the termination date of the Agreement and certain breach of contract claims. ERBE and Byrne dismissed the Arbitration with prejudice upon agreeing that the Agreement would not terminate until July 31, 2011.

17. 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.

18. 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.

19. At the time Byrne and ERBE entered into the Agreement, Byrne was selling its SmartCap product. However, the Agreement did not allow ERBE to distribute and sell the SmartCap product to its customers.

20. Once Byrne announced it was terminating the Agreement, 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.

21. Because Byrne's website stated that the SmartCap product was protected by the '322 patent, as shown in Exhibit C, third party manufacturers were hesitant to manufacture a product similar to the SmartCap product.

22. Recently, ERBE's internal R&D team completed development of a single product – the ERBE CLEVERCAP™ Tubing Set (“CleverCap product”) – that replaces both the EndoGator tube set and the SmartCap product. ERBE's sales force began showing the CleverCap product to customers on April 22, 2011.

23. On May 8, 2011, ERBE will formally introduce 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, and expects to begin shipping its CleverCap product to customers in June 2011.

THE '322 PATENT

24. 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.

25. 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.

26. 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.

27. 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.

28. 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.

29. 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

30. 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.

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

32. 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.

33. 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.

34. 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.

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

36. On information and belief, Byrne is aware of the differences between its EndoGator tube set and SmartCap product. Byrne knows 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.

37. On information and belief, Byrne knows 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.

38. 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 continues to deceive, the public and ERBE.

FIRST CLAIM FOR RELIEF

(False Marking)

39. ERBE incorporates by reference the allegations contained in paragraphs 1 through 38 above.

40. 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.

41. 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.

42. 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).

43. 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).

44. 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.

45. 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.

46. Because it suppressed competition, thereby harming ERBE and the public, Byrne should be fined \$500.00 for each instance of false marking, as set forth in 35 U.S.C. § 292(b).

SECOND CLAIM FOR RELIEF

(False Advertising)

47. ERBE incorporates by reference the allegations contained in paragraphs 1 through 46 above.

48. 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).

49. 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).

50. 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.

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

THIRD CLAIM FOR RELIEF

(False Marking)

52. ERBE incorporates by reference the allegations contained in paragraphs 1 through 51 above.

53. 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.

54. 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.

55. 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).

56. 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).

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

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

59. Because it suppressed competition, thereby harming ERBE and the public, Byrne should be fined \$500.00 for each instance of false marking, as set forth in 35 U.S.C. § 292(b).

FOURTH CLAIM FOR RELIEF

(False Advertising)

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

61. 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).

62. 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).

63. 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.

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

FIFTH CLAIM FOR RELIEF

(Declaration of Invalidity)

65. ERBE incorporates by reference the allegations contained in paragraphs 1 through 64 above.

66. 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.

67. 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.

68. 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.

69. 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.

70. 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.

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

72. 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

73. 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 Byrne not commit further acts of false marking;

2. Pursuant to 35 U.S.C. § 292, a civil fine of \$500, or such alternative amount as the Court deems appropriate, one-half of which shall be paid to ERBE, for each instance 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 Byrne not commit further acts of unfair competition;

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

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Respectfully submitted,

By s/Christine S. Tenley

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