

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

DEVICOR MEDICAL PRODUCTS, INC.)	
)	
Plaintiff,)	C.A. No. 10-1060-GMS
)	
v.)	
)	DEMAND FOR JURY TRIAL
BIOPSY SCIENCES, LLC.)	
)	
Defendant.)	

SECOND AMENDED COMPLAINT

Plaintiff Devicor[®] Medical Products, Inc. (“Devicor”) brings this action against Defendant Biopsy Sciences, LLC (“Biopsy Sciences”) and alleges as follows:

PARTIES

1. Devicor is a corporation registered in Delaware with its principal place of business at 300 E-Business Way, Sharonville, Ohio 45241.
2. On information and belief, Biopsy Sciences is a corporation organized under the laws of Florida with its principal place of business at 4900 Creekside Drive, Suite C, Clearwater, Florida 33760.

JURISDICTION AND VENUE

3. This action is for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and seeks damages and injunctive relief. This is also an action seeking damages for false patent marking under 35 U.S.C. § 292, as amended by the Leahy-Smith America Invents Act, Publ. L. 112–29, H.R. 1249 (enacted Sept. 16, 2011). The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. This Court has personal jurisdiction over Biopsy Sciences because, *inter alia*, Biopsy Sciences conducts substantial business in this forum, including: (i) deriving substantial revenue from sales of goods in this District, including significant revenue derived from sales of infringing goods as alleged herein; (ii) regularly doing or soliciting business, including contracting to supply goods and services with businesses and individuals in this District, including goods and services that encompass the infringing goods, as alleged herein; and (iii) engaging in other persistent, systematic, and continuous courses of conduct in this District. The courts of Delaware have jurisdiction over Biopsy Sciences under 10 Del. C. § 3104.

5. Venue is proper pursuant to 28 U.S.C. § 1391(b) and § 1400(b). On information and belief, Biopsy Sciences has transacted business in this District, and has committed and/or induced acts of patent infringement in this District.

BACKGROUND

6. Devicor Medical Products, Inc., is a global medical products company dedicated to the investment in, and development of, technologies that facilitate minimally invasive medical procedures. Among the medical products that Devicor develops and markets are devices in the minimally invasive breast biopsy market.

7. Typically, when a patient undergoes a biopsy, a small piece of tissue is removed. For any given biopsy procedure, a subsequent examination of the biopsy site is often needed. Thus, there is an important need to determine the location of the biopsy site. Inserting a marker at the biopsy site is one way to determine the location of the biopsy site at a subsequent examination.

8. Devicor offers a family of marker products for vacuum-assisted and core needle breast biopsy procedures, visible under imaging modalities, to radiographically mark a biopsy site.

9. Biopsy Sciences offers for sale, sells, and has sold competitor breast biopsy site markers and devices in this District and throughout the United States. For example, Biopsy Sciences's HydroMARK[®] line of products includes breast biopsy site markers. Upon information and belief, a reasonable opportunity for discovery will show that at least the HydroMARK breast biopsy site markers infringe one or more claims of Devicor's asserted patents.

10. Devicor and Biopsy Sciences are direct competitors. They promote their products to the same actual and potential customers and offer their products for sale through the same or similar retail, distribution, and Internet channels.

PATENTS IN SUIT

11. On August 7, 2001, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 6,270,464 ("the '464 patent"), entitled "Biopsy Localization Method and Device." The '464 patent's inventors are Richard E. Fulton, III and William R. Dubrul. Devicor is the owner of all right, title, and interest in the '464 patent. A true and correct copy of the '464 patent is attached hereto as Exhibit 1.

12. On March 12, 2002, the USPTO issued U.S. Patent No. 6,356,782 ("the '782 patent"), entitled "Subcutaneous Cavity Marking Device and Method." The '782 patent's inventors are D. Laksen Sirimanne, Douglas S. Sutton, Natalie V. Fawzi, and Gail Lebovic. Devicor is the owner of all right, title, and interest in the '782 patent. A true and correct copy of the '782 patent is attached hereto as Exhibit 2.

13. On March 2, 2004, the USPTO issued U.S. Patent No. 6,699,205 (“the ’205 patent”), entitled “Biopsy Localization Method and Device.” The ’205 patent’s inventors are Richard E. Fulton, III and William R. Dubrul. The ’205 patent has been subject to reexamination but the claims asserted in this Complaint have not been reexamined. Devicor is the owner of all right, title, and interest in the ’205 patent. A true and correct copy of the ’205 patent is attached hereto as Exhibit 3.

14. On June 12, 2007, the USPTO issued U.S. Patent No. 7,229,417 (“the ’417 patent”), entitled “Methods for Marking a Biopsy Site.” The ’417 patent’s inventors are Seth A. Foerster, Fred H. Burbank, Mark A. Ritchart, and Elias A. Zerbouni. The ’417 patent has been subject to reexamination but the claim asserted in this Complaint has not been reexamined. Devicor is the owner of all right, title, and interest in the ’417 patent. A true and correct copy of the ’417 patent is attached hereto as Exhibit 4.

15. On December 1, 2009, the USPTO issued U.S. Patent No. 7,625,397 (“the ’397 patent”), entitled “Methods for Defining and Marking Tissue.” The ’397 patent’s inventors are Seth A. Foerster, Fred H. Burbank, Mark A. Ritchart, and Elias A. Zerbouni. Devicor is the owner of all right, title, and interest in the ’397 patent. A true and correct copy of the ’397 patent is attached hereto as Exhibit 5.

16. On February 26, 2002, the USPTO issued U.S. Patent No. 6,350,244 (“the ’244 patent”), entitled Bioabsorbable [sic] Markers for Use in Biopsy Procedures.” The ’244 patent lists John S. Fisher as the inventor and Biopsy Sciences, LLC as the assignee. A true and correct copy of the ’244 patent is attached hereto as Exhibit 7.

17. On July 15, 2003, the USPTO issued U.S. Patent No. 6,592,608 (“the ’608 patent”), entitled “Bioabsorbable Sealant.” The ’608 patent lists John S. Fisher, Frederick Ahari,

and Lucjan J. J. Hronowski as inventors and Biopsy Sciences, LLC as the assignee. A true and correct copy of the '608 patent is attached hereto as Exhibit 8.

18. On February 7, 2006, the USPTO issued U.S. Patent No. 6,994,712 (“the '712 patent”), entitled “Bioabsorbable Marker Having External Anchoring Means.” The '712 patent lists John S. Fisher and Frederick Ahari as inventors and Biopsy Sciences, LLC as the assignee. A true and correct copy of the '712 patent is attached hereto as Exhibit 9.

FIRST CAUSE OF ACTION
INFRINGEMENT OF U.S. PATENT NO. 6,270,464

19. Devicor realleges and incorporates by reference the allegations of paragraphs 1-17 herein.

20. On information and belief, Biopsy Sciences has infringed and continues to infringe, directly and/or indirectly by way of inducement and/or contributory infringement, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. § 271, one or more claims of the '464 patent by making, having made, using, importing, selling, and/or offering for sale in the United States one or more biopsy markers that embody the invention claimed in the '464 patent, or that use and/or incorporate the claimed invention, including, by way of example and without limitation, the HydroMARK line of products.

21. Biopsy Sciences has specifically induced and continues to induce others to infringe the '464 patent in violation of 35 U.S.C. § 271 by encouraging and facilitating others to perform actions known by Biopsy Sciences to be acts of infringement of the '464 patent with intent that those performing the acts infringe the '464 patent. Biopsy Sciences, upon information and belief, *inter alia*, advertises regarding the HydroMARK line of products, publishes datasheets and promotional literature describing the use and operation of those products, creates

and/or distributes information on the operation and use of those products, and offers support and technical assistance to its customers, including physicians who use the products.

22. Biopsy Sciences also contributes to infringement of the '464 patent in violation of 35 U.S.C. § 271 by selling within the United States, offering for sale within the United States, and/or importing components, including the HydroMARK line of products, and the non-staple constituent parts of those products, that embody a material part of the invention described in the '464 patent. These products are known by Biopsy Sciences to be especially made or especially adapted for use in infringement of the '464 patent and are not staple articles or commodities suitable for substantial, non-infringing use.

23. By infringing the '464 patent, Biopsy Sciences has caused and will continue to cause Devicor to suffer damages in an amount to be determined at trial.

24. By way of its past and continued acts of infringement of Devicor's patents, Biopsy Sciences has caused, and will continue to cause, Devicor irreparable injury and damages, including but not limited to, lost profits and diminution of the rights granted under Devicor's patents.

25. Devicor will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Biopsy Sciences is enjoined from infringing Devicor's '464 patent.

26. Upon information and belief, Biopsy Sciences's infringement of the '464 patent is willful and Devicor should be awarded increased damages pursuant to 35 U.S.C. § 284 and attorneys fees pursuant to 35 U.S.C. § 285.

SECOND CAUSE OF ACTION
INFRINGEMENT OF U.S. PATENT NO. 6,356,782

27. Devicor realleges and incorporates by reference the allegations of paragraphs 1-25 herein.

28. On information and belief, Biopsy Sciences has infringed and continues to infringe, directly and/or indirectly by way of inducement and/or contributory infringement, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. § 271, one or more claims of the '782 patent by making, having made, using, importing, selling, and/or offering for sale in the United States one or more biopsy markers that embody the invention claimed in the '782 patent, or that use and/or incorporate the claimed invention, including, by way of example and without limitation, the HydroMARK line of products.

29. Biopsy Sciences has specifically induced and continues to induce others to infringe the '782 patent in violation of 35 U.S.C. § 271 by encouraging and facilitating others to perform actions known by Biopsy Sciences to be acts of infringement of the '782 patent with intent that those performing the acts infringe the '782 patent. Biopsy Sciences, upon information and belief, *inter alia*, advertises regarding the HydroMARK line of products, publishes datasheets and promotional literature describing the use and operation of those products, creates and/or distributes information on the operation and use of those products, and offers support and technical assistance to its customers, including physicians who use the products.

30. Biopsy Sciences also contributes to infringement of the '782 patent in violation of 35 U.S.C. § 271 by selling within the United States, offering for sale within the United States, and/or importing components, including the HydroMARK line of products, and the non-staple constituent parts of those products, that embody a material part of the invention described in the '782 patent. These products are known by Biopsy Sciences to be especially made or especially adapted for use in infringement of the '782 patent and are not staple articles or commodities suitable for substantial, non-infringing use.

31. By infringing the '782 patent, Biopsy Sciences has caused and will continue to cause Devicor to suffer damages in an amount to be determined at trial.

32. By way of its past and continued acts of infringement of Devicor's patents, Biopsy Sciences has caused, and will continue to cause, Devicor irreparable injury and damages, including but not limited to, lost profits and diminution of the rights granted under Devicor's '782 patent.

33. Devicor will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Biopsy Sciences is enjoined from infringing Devicor's patents.

34. Upon information and belief, Biopsy Sciences's infringement of the '782 patent is willful and Devicor should be awarded increased damages pursuant to 35 U.S.C. § 284 and attorneys fees pursuant to 35 U.S.C. § 285.

THIRD CAUSE OF ACTION
INFRINGEMENT OF U.S. PATENT NO. 6,699,205

35. Devicor realleges and incorporates by reference the allegations of paragraphs 1-33 herein.

36. On information and belief, Biopsy Sciences has infringed and continues to infringe, directly and/or indirectly by way of inducement and/or contributory infringement, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. § 271, claims 8, 18, and 27 of the '205 patent, which are not under reexamination, by making, having made, using, importing, selling, and/or offering for sale in the United States one or more biopsy markers that embody the invention claimed in the '205 patent, or that use and/or incorporate the claimed invention, including, by way of example and without limitation, the HydroMARK line of products.

37. Biopsy Sciences has specifically induced and continues to induce others to infringe the '205 patent in violation of 35 U.S.C. § 271 by encouraging and facilitating others to perform actions known by Biopsy Sciences to be acts of infringement of the '205 patent with intent that those performing the acts infringe the '205 patent. Biopsy Sciences, upon information and belief, *inter alia*, advertises regarding the HydroMARK line of products, publishes datasheets and promotional literature describing the use and operation of those products, creates and/or distributes information on the operation and use of those products, and offers support and technical assistance to its customers, including physicians who use the products.

38. Biopsy Sciences also contributes to infringement of the '205 patent in violation of 35 U.S.C. § 271 by selling within the United States, offering for sale within the United States, and/or importing components, including the HydroMARK line of products, and the non-staple constituent parts of those products, that embody a material part of the invention described in the '205 patent. These products are known by Biopsy Sciences to be especially made or especially adapted for use in infringement of the '205 patent and are not staple articles or commodities suitable for substantial, non-infringing use.

39. By infringing the '205 patent, Biopsy Sciences has caused and will continue to cause Devicor to suffer damages in an amount to be determined at trial.

40. By way of its past and continued acts of infringement of Devicor's patents, Biopsy Sciences has caused, and will continue to cause, Devicor irreparable injury and damages, including but not limited to, lost profits and diminution of the rights granted under Devicor's '205 patent.

41. Devicor will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Biopsy Sciences is enjoined from infringing Devicor's patents.

42. Upon information and belief, Biopsy Sciences's infringement of the '205 patent is willful and Devicor should be awarded increased damages pursuant to 35 U.S.C. § 284 and attorneys fees pursuant to 35 U.S.C. § 285.

FOURTH CAUSE OF ACTION
INFRINGEMENT OF U.S. PATENT NO. 7,229,417

43. Devicor realleges and incorporates by reference the allegations of paragraphs 1-41 herein.

44. On information and belief, Biopsy Sciences has infringed and continues to infringe, directly and/or indirectly by way of inducement and/or contributory infringement, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. § 271, claim 16 of the '417 patent, which is not under reexamination, by making, having made, using, importing, selling, and/or offering for sale in the United States one or more biopsy markers that embody the invention claimed in the '417 patent, or that use and/or incorporate the claimed invention, including, by way of example and without limitation, the HydroMARK line of products.

45. Biopsy Sciences has specifically induced and continues to induce others to infringe the '417 patent in violation of 35 U.S.C. § 271 by encouraging and facilitating others to perform actions known by Biopsy Sciences to be acts of infringement of the '417 patent with intent that those performing the acts infringe the '417 patent. Biopsy Sciences, upon information and belief, *inter alia*, advertises regarding the HydroMARK line of products, publishes datasheets and promotional literature describing the use and operation of those products, creates and/or distributes information on the operation and use of those products, and offers support and technical assistance to its customers, including physicians who use the products.

46. Biopsy Sciences also contributes to infringement of the '417 patent in violation of 35 U.S.C. § 271 by selling within the United States, offering for sale within the United States,

and/or importing components, including the HydroMARK line of products, and the non-staple constituent parts of those products, that embody a material part of the invention described in the '417 patent. These products are known by Biopsy Sciences to be especially made or especially adapted for use in infringement of the '417 patent and are not staple articles or commodities suitable for substantial, non-infringing use.

47. By infringing the '417 patent, Biopsy Sciences has caused and will continue to cause Devicor to suffer damages in an amount to be determined at trial.

48. By way of its past and continued acts of infringement of Devicor's patents, Biopsy Sciences has caused, and will continue to cause, Devicor irreparable injury and damages, including but not limited to, lost profits and diminution of the rights granted under Devicor's '417 patent.

49. Devicor will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Biopsy Sciences is enjoined from infringing Devicor's patents.

50. Upon information and belief, Biopsy Sciences's infringement of the '417 patent is willful and Devicor should be awarded increased damages pursuant to 35 U.S.C. § 284 and attorneys fees pursuant to 35 U.S.C. § 285.

FIFTH CAUSE OF ACTION
INFRINGEMENT OF U.S. PATENT NO. 7,625,397

51. Devicor realleges and incorporates by reference the allegations of paragraphs 1-49 herein.

52. On information and belief, Biopsy Sciences has infringed and continues to infringe, directly and/or indirectly by way of inducement and/or contributory infringement, literally and/or under the doctrine of equivalents, in violation of 35 U.S.C. § 271, one or more claims of the '397 patent by making, having made, using, importing, selling, and/or offering for

sale in the United States one or more biopsy markers that embody the invention claimed in the '397 patent, or that use and/or incorporate the claimed invention, including, by way of example and without limitation, the HydroMARK line of products.

53. Biopsy Sciences has specifically induced and continues to induce others to infringe the '397 patent in violation of 35 U.S.C. § 271 by encouraging and facilitating others to perform actions known by Biopsy Sciences to be acts of infringement of the '397 patent with intent that those performing the acts infringe the '397 patent. Biopsy Sciences, upon information and belief, *inter alia*, advertises regarding the HydroMARK line of products, publishes datasheets and promotional literature describing the use and operation of those products, creates and/or distributes information on the operation and use of those products, and offers support and technical assistance to its customers, including physicians who use the products.

54. Biopsy Sciences also contributes to infringement of the '397 patent in violation of 35 U.S.C. § 271 by selling within the United States, offering for sale within the United States, and/or importing components, including the HydroMARK line of products, and the non-staple constituent parts of those products, that embody a material part of the invention described in the '397 patent. These products are known by Biopsy Sciences to be especially made or especially adapted for use in infringement of the '397 patent and are not staple articles or commodities suitable for substantial, non-infringing use.

55. By infringing the '397 patent, Biopsy Sciences has caused and will continue to cause Devicor to suffer damages in an amount to be determined at trial.

56. By way of its past and continued acts of infringement of Devicor's patents, Biopsy Sciences has caused, and will continue to cause, Devicor irreparable injury and damages,

including but not limited to, lost profits and diminution of the rights granted under Devicor's '397 patent.

57. Devicor will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Biopsy Sciences is enjoined from infringing Devicor's patents.

58. Upon information and belief, Biopsy Sciences's infringement of the '397 patent is willful and Devicor should be awarded increased damages pursuant to 35 U.S.C. § 284 and attorneys fees pursuant to 35 U.S.C. § 285.

SIXTH CAUSE OF ACTION
FALSE PATENT MARKING OF U.S. PATENT NO. 6,350,244

59. Devicor realleges and incorporates by reference the allegations of paragraphs 1-57 herein.

60. This is a claim for false marking under 35 U.S.C. § 292.

61. Biopsy Sciences makes, uses, offers for sale, sells, supplies, causes to be supplied, in the State of Delaware and/or elsewhere in the United States, the HydroMARK line of products. Biopsy Sciences has in the past marked, or caused to be marked, and, upon information and belief, presently marks, or causes to be marked HydroMARK products with a patent that does not cover these products. (D.I. 10 at 2-3, 11-12).

62. The HydroMARK packaging states: "Covered by one or more of the following patents and other pending patents: 5410016, 6060582, 6083524, 6162241, 6177095, 6350244, 6592608, 6605294, 6790185, 6994712."¹

63. These ten patent numbers listed on the HydroMARK packaging have various assignees and issue dates as listed below:

¹ Ex. 6, true and correct copies of the packaging for HydroMark models 4010-01-08-T1, 4010-02-15-T3, and 4010-04-09-T3.

5,410,016 (Board of Regents, The University of Texas System, Apr. 25, 1995);
6,060,582 (Board of Regents, The University of Texas System, May 9, 2000);
6,083,524 (Focal, Inc., Jul. 4, 2000);
6,162,241 (Focal, Inc., Dec. 19, 2000);
6,177,095 (Focal, Inc., Jan. 23, 2001);
6,350,244 (Biopsy Sciences, LLC, Feb. 26, 2002);
6,592,608 (Biopsy Sciences, LLC, Jul. 15, 2003);
6,605,294 (Incept LLC, Aug. 12, 2003);
6,790,185 (Biopsy Sciences, LLC, Sep. 14, 2004); and
6,994,712 (Biopsy Sciences, LLC, Feb. 7, 2006).

64. According to Biopsy Sciences, it only started “advertising, marketing, and selling its [HydroMARK] products in January 2009.” (D.I. 8-2 at 1). As shown above, all of the patents marked on the HydroMARK packaging issued before January 2009.

65. Upon information and belief, Biopsy Sciences is a sophisticated company and has experience applying for, obtaining, and maintaining patents, and therefore knows that patents provide a scope of patent protection that is governed by the claims of the patent.

66. Upon information and belief, Biopsy Sciences employs outside intellectual property counsel.²

67. Further underscoring its legal sophistication as to patent matters, Biopsy Sciences is listed as the assignee for approximately twelve U.S. patents.³

² See, e.g., Ex. 7, '244 patent; Ex. 8, '608 patent; Ex. 9, '712 patent.

³ Ex. 10, <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetacgi/nph-adv.htm&r=0&p=1&f=S&l=50&Query=an%2Fbiopsy+and+sciences%0D%0A&d=PTXT>

68. The inventor listed on the '244 patent, John S. Fisher, is experienced with patent matters. In particular, Biopsy Sciences's website states that "Dr. Fisher holds over 25 U.S. and EU patents and patent applications."⁴ Dr. Fisher co-founded Biopsy Sciences in 2000 and is currently its Chief Executive Officer.⁵ Upon information and belief, Biopsy Sciences (itself or by its representatives) performed an analysis to determine which patents to list on its HydroMARK packaging.

69. Upon information and belief, when Biopsy Sciences (itself or by its representatives) performed its analysis to determine which patents to list on the HydroMARK packaging, Biopsy Sciences knew that the HydroMARK products lacked essential elements covered by the '244 patent.

70. The '244 patent is entitled "Bioabsorbable [sic] Markers For Use In Biopsy Procedures." Independent claims 1, 3, and 6 of the '244 patent cover more than one marker, claiming, among other things, "a plurality of markers," "a plurality of marker retaining means in said marker carrier," and/or "said marker carrier having a plurality of recesses of uniform predetermined depth formed in an outer surface thereof for respectively holding said plurality of markers."⁶

71. Biopsy Sciences publishes an instructional video on its website demonstrating the HydroMARK product.⁷ The video does not show the HydroMARK marker having "a plurality of markers," "a plurality of marker retaining means in said marker carrier," and/or "said marker carrier having a plurality of recesses of uniform predetermined depth formed in an outer surface

⁴ Ex. 11, <http://www.hydromark.com/hydromark/Company.aspx>.

⁵ *Id.*

⁶ Ex. 7, '244 patent, col. 5, lns. 47-48, 54-55; col. 6, ln. 17, lns. 31-34, ln. 57, and lns. 66-67.

⁷ <http://www.hydromark.com/hydromark/How.aspx>.

thereof for respectively holding said plurality of markers.”⁸ To the contrary, the Biopsy Sciences video shows the HydroMARK having just one marker.⁹ Moreover, the Biopsy Sciences website describes the HydroMARK as a single marker containing stainless steel or titanium.¹⁰ That the HydroMARK markers contain stainless steel or titanium also conflicts with the ’244 patent’s specification which states that “Markers **16** are nonmetallic.”¹¹ Accordingly, the ’244 patent unmistakably does not cover the HydroMARK because at least the “a plurality of markers,” “a plurality of marker retaining means in said marker carrier,” and/or “said marker carrier having a plurality of recesses of uniform predetermined depth formed in an outer surface thereof for respectively holding said plurality of markers” claim elements are not met.

72. Despite performing an analysis on the patents and providing an instructional video about the HydroMARK, Biopsy Sciences, nevertheless, marked and, upon information and belief, continues to mark every HydroMARK package with the ’244 patent.

73. On information and belief, Biopsy Sciences, with knowledge that the HydroMARK is not covered by the ’244 patent, marked and, upon information and belief, continues to mark the HydroMARK with the ’244 patent with the intent of deceiving the public.

74. Biopsy Sciences knows, or reasonably should know (itself or by its representatives), that marking the HydroMARK line of products with a patent that does not cover the HydroMARK will deceive the public.

⁸ *Id.*

⁹ *Id.*

¹⁰ Ex. 12, <http://www.hydromark.com/hydromark/AboutHydroMARK.aspx> (“HydroMARK is a water-soluble polyethylene glycol-based hydrogel, which contains a **central marker** of stainless steel or titanium.”) (emphasis added).

¹¹ Ex. 7, ’244 patent, col. 3., ln. 30.

75. Biopsy Sciences knows, or reasonably should know (itself or by its representatives), that marking the HydroMARK line of products with a patent that does not cover the HydroMARK is a violation of 35 U.S.C. § 292.¹²

76. Each mismarked patent on the HydroMARK package is likely to, or at least has the potential to, discourage or deter others from commercializing a competing product, thereby deterring innovation and stifling competition in the marketplace generally and between Biopsy Sciences and Devicor specifically.

77. Biopsy Sciences has wrongfully and illegally advertised patent monopolies which it does not possess, and, as a result, upon information and belief, has likely benefitted in at least maintaining its market share with respect to the HydroMARK products in the marketplace.

78. For at least the reasons provided herein, and/or for other reasons which will be later evidenced, each mismarked patent which is marked on a product likely, or at least potentially, deceives the public and contributes to the public harm.

79. For at least the reasons provided herein, and/or for other reasons which will be later evidenced, each '244 patent number which is mismarked on a Biopsy Sciences product has stifled Devicor's competition with Biopsy Sciences and has caused Devicor competitive injury.

80. Biopsy Sciences knew or reasonably should have known that each HydroMARK package it has marked and sold or caused to be sold is not covered by the '244 patent. Thus, each time Biopsy Sciences has intentionally marked a HydroMARK package with a patent that does not cover the article such as described above, Biopsy Sciences has committed at least one

¹² Biopsy Sciences knew or should have known that each instance of false marking of a HydroMARK product was a violation of 35 U.S.C. § 292, in effect up to and including September 15, 2011. Biopsy Sciences also knew or should have known that each instance of false marking of HydroMARK was and is a continuing violation of 35 U.S.C. § 292, as amended by the Leahy-Smith America Invents Act, Publ. L. 112-29, H.R. 1249 (enacted Sept. 16, 2011).

“offense” as defined in 35 U.S.C. § 292(a), and has caused Devicor a “competitive injury” as defined in 35 U.S.C. § 292(b), as amended. Devicor is entitled to recover damages adequate to compensate for this injury.

81. For at least the reasons set forth herein, and/or for other reasons which will later be evidenced, Biopsy Sciences has falsely marked and, upon information and belief, continues to falsely mark its products, with the intent to deceive the public and the effect of causing competitive injury to Devicor, in violation of 35 U.S.C. § 292.

SEVENTH CAUSE OF ACTION
FALSE PATENT MARKING OF U.S. PATENT NO. 6,592,608

82. Devicor realleges and incorporates by reference the allegations of paragraphs 1-81 herein.

83. This is a claim for false marking under 35 U.S.C. § 292.

84. Biopsy Sciences makes, uses, offers for sale, sells, supplies, causes to be supplied, in the State of Delaware and/or elsewhere in the United States, the HydroMARK line of products. Biopsy Sciences has in the past marked, or caused to be marked, and, upon information and belief, presently marks, or causes to be marked HydroMARK products with a patent that does not cover these products. (D.I. 10 at 2-3, 11-12).

85. The HydroMARK packaging states: “Covered by one or more of the following patents and other pending patents: 5410016, 6060582, 6083524, 6162241, 6177095, 6350244, 6592608, 6605294, 6790185, 6994712.”¹³

86. These ten patent numbers listed on the HydroMARK packaging have various assignees and issue dates as listed below:

¹³ Ex. 6, true and correct copies of the packaging for HydroMark models 4010-01-08-T1, 4010-02-15-T3, and 4010-04-09-T3.

5,410,016 (Board of Regents, The University of Texas System, Apr. 25, 1995);
6,060,582 (Board of Regents, The University of Texas System, May 9, 2000);
6,083,524 (Focal, Inc., Jul. 4, 2000);
6,162,241 (Focal, Inc., Dec. 19, 2000);
6,177,095 (Focal, Inc., Jan. 23, 2001);
6,350,244 (Biopsy Sciences, LLC, Feb. 26, 2002);
6,592,608 (Biopsy Sciences, LLC, Jul. 15, 2003);
6,605,294 (Incept LLC, Aug. 12, 2003);
6,790,185 (Biopsy Sciences, LLC, Sep. 14, 2004); and
6,994,712 (Biopsy Sciences, LLC, Feb. 7, 2006).

87. According to Biopsy Sciences, it only started “advertising, marketing, and selling its [HydroMARK] products in January 2009.” (D.I. 8-2 at 1). As shown above, all of the patents marked on the HydroMARK packaging issued before January 2009.

88. Upon information and belief, Biopsy Sciences is a sophisticated company and has experience applying for, obtaining, and maintaining patents, and therefore knows that patents provide a scope of patent protection that is governed by the claims of the patent.

89. Upon information and belief, Biopsy Sciences employs outside intellectual property counsel.¹⁴

90. Further underscoring its legal sophistication as to patent matters, Biopsy Sciences is listed as the assignee for approximately twelve U.S. patents.¹⁵

¹⁴ See, e.g., Ex. 7, '244 patent; Ex. 8, '608 patent; Ex. 9, '712 patent.

¹⁵ Ex. 10, <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetacgi%2FPTO%2Fsearch-adv.htm&r=0&p=1&f=S&l=50&Query=an%2Fbiopsy+and+sciences%0D%0A&d=PTXT>

91. Two of the inventors listed on the '608 patent, John S. Fisher and Frederick Ahari, are experienced with patent matters. In particular, Biopsy Sciences's website states that "Dr. Fisher holds over 25 U.S. and EU patents and patent applications."¹⁶ Dr. Fisher co-founded Biopsy Sciences in 2000 and is currently its Chief Executive Officer.¹⁷ Similarly, Mr. Ahari, Biopsy Sciences's Chief Technology Officer, is well versed in patent matters by virtue of being an inventor "on over 20 issued and filed patent applications involving novel and unique technologies in medical device applications."¹⁸

92. Upon information and belief, Biopsy Sciences (itself or by its representatives) performed an analysis to determine which patents to list on its HydroMARK packaging.

93. Upon information and belief, when Biopsy Sciences (itself or by its representatives) performed its analysis to determine which patents to list on the HydroMARK packaging, Biopsy Sciences knew that the HydroMARK products lacked essential elements covered by the '608 patent.

94. More specifically, sole claim 1 of the '608 patent requires, among other things, the step of "pre-hydrating said dehydrated plug by introducing a liquid-fluid solution into said lumen of said coaxial needle before displacing said prehydrated plug from said lumen."¹⁹

95. Biopsy Sciences publishes an instructional video on its website demonstrating the use of the HydroMARK product.²⁰ Biopsy Sciences, however, does not instruct "prehydrating" the HydroMARK marker in this video or anywhere else on its website.²¹ To the contrary, the Biopsy Sciences website states that the HydroMARK is hydrated after it is deployed into the

¹⁶ Ex. 11, <http://www.hydromark.com/hydromark/Company.aspx>.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Ex. 8, '608 patent, col. 14, lns. 15-19, col. 12, lns. 40-49.

²⁰ <http://www.hydromark.com/hydromark/How.aspx>.

²¹ *Id.*

patient's body.²² Accordingly, the '608 patent unmistakably does not cover the HydroMARK because at least the "prehydrating" claim element is not met.

96. Despite performing an analysis on the patents and providing an instructional video on the use of the HydroMARK, Biopsy Sciences, nevertheless, marked and, upon information and belief, continues to mark every HydroMARK package with the '608 patent.

97. On information and belief, Biopsy Sciences, with knowledge that the HydroMARK is not covered by the '608 patent, marked and, upon information and belief, continues to mark the HydroMARK with the '608 patent with the intent of deceiving the public.

98. Biopsy Sciences knows, or reasonably should know (itself or by its representatives), that marking the HydroMARK line of products with a patent that does not cover the HydroMARK will deceive the public.

99. Biopsy Sciences knows, or reasonably should know (itself or by its representatives), that marking the HydroMARK line of products with a patent that does not cover the HydroMARK is a violation of 35 U.S.C. § 292.²³

100. Each mismarked patent on the HydroMARK package is likely to, or at least has the potential to, discourage or deter others from commercializing a competing product, thereby deterring innovation and stifling competition in the marketplace generally and between Biopsy Sciences and Devicor specifically.

²² Ex. 13, <http://www.hydromark.com/hydromark/Benefits.aspx> ("The marker expands in length and diameter **after** it is deployed . . .") (emphasis added); Ex. 12, <http://www.hydromark.com/hydromark/AboutHydroMARK.aspx> ("HydroMARK absorbs greater than 90% water **after** hydration.") (emphasis added).

²³ See *supra*, note 12.

101. Biopsy Sciences has wrongfully and illegally advertised patent monopolies which it does not possess, and, as a result, upon information and belief, has likely benefitted in at least maintaining its market share with respect to the HydroMARK products in the marketplace.

102. For at least the reasons provided herein, and/or for other reasons which will be later evidenced, each mismarked patent which is marked on a product likely, or at least potentially, deceives the public and contributes to the public harm.

103. For at least the reasons provided herein, and/or for other reasons which will be later evidenced, each '608 patent number which is falsely marked on a Biopsy Sciences product has stifled Devicor's competition with Biopsy Sciences and has caused Devicor competitive injury.

104. Biopsy Sciences knew or reasonably should have known that each HydroMARK package it has marked and sold or caused to be sold is not covered by the '608 patent. Thus, each time Biopsy Sciences intentionally marks a HydroMARK package with a patent that does not cover the article such as described above, Biopsy Sciences has committed at least one "offense" as defined in 35 U.S.C. § 292(a), and has caused Devicor a "competitive injury" as defined in 35 U.S.C. § 292(b), as amended. Devicor is entitled to recover damages adequate to compensate for this injury.

105. For at least the reasons set forth herein, and/or for other reasons which will later be evidenced, Biopsy Sciences has falsely marked and, upon information and belief, continues to falsely mark its products, with the intent to deceive the public and the effect of causing competitive injury to Devicor, in violation of 35 U.S.C. § 292.

EIGHTH CAUSE OF ACTION
FALSE PATENT MARKING OF U.S. PATENT NO. 6,994,712

106. Devicor realleges and incorporates by reference the allegations of paragraphs 1-105 herein.

107. This is a claim for false marking under 35 U.S.C. § 292(b).

108. Biopsy Sciences makes, uses, offers for sale, sells, supplies, causes to be supplied, in the State of Delaware and/or elsewhere in the United States, the HydroMARK line of products. Biopsy Sciences has in the past marked, or caused to be marked, and, upon information and belief, presently marks, or causes to be marked HydroMARK products with a patent that does not cover these products. (D.I. 10 at 2-3, 11-12).

109. The HydroMARK packaging states: "Covered by one or more of the following patents and other pending patents: 5410016, 6060582, 6083524, 6162241, 6177095, 6350244, 6592608, 6605294, 6790185, 6994712."²⁴

110. These ten patent numbers listed on the HydroMARK packaging have various assignees and issue dates as listed below:

5,410,016 (Board of Regents, The University of Texas System, Apr. 25, 1995);

6,060,582 (Board of Regents, The University of Texas System, May 9, 2000);

6,083,524 (Focal, Inc., Jul. 4, 2000);

6,162,241 (Focal, Inc., Dec. 19, 2000);

6,177,095 (Focal, Inc., Jan. 23, 2001);

6,350,244 (Biopsy Sciences, LLC, Feb. 26, 2002);

6,592,608 (Biopsy Sciences, LLC, Jul. 15, 2003);

²⁴ Ex. 6, true and correct copies of the packaging for HydroMark models 4010-01-08-T1, 4010-02-15-T3, and 4010-04-09-T3.

6,605,294 (Incept LLC, Aug. 12, 2003);

6,790,185 (Biopsy Sciences, LLC, Sep. 14, 2004); and

6,994,712 (Biopsy Sciences, LLC, Feb. 7, 2006).

111. According to Biopsy Sciences, it only started “advertising, marketing, and selling its [accused] products in January 2009.” (D.I. 8-2 at 1). As described above, all of the patents marked on the HydroMARK packaging issued before January 2009.

112. Upon information and belief, Biopsy Sciences is a sophisticated company and has experience applying for, obtaining, and maintaining patents, and therefore knows that patents provide a scope of patent protection that is governed by the claims of the patent.

113. Upon information and belief, Biopsy Sciences employs outside intellectual property counsel.²⁵

114. Further underscoring its legal sophistication as to patent matters, Biopsy Sciences is listed as the assignee for approximately twelve U.S. patents.²⁶

115. The two inventors listed on the '712 patent, John S. Fisher and Frederick Ahari, are experienced with patent matters. In particular, Biopsy Sciences's website states that “Dr. Fisher holds over 25 U.S. and EU patents and patent applications.”²⁷ Dr. Fisher co-founded Biopsy Sciences in 2000 and is currently its Chief Executive Officer.²⁸ Similarly, Mr. Ahari, Biopsy Sciences's Chief Technology Officer, is well versed in patent matters by virtue of being

²⁵ See, e.g., Ex. 7, '244 patent; Ex. 8, '608 patent; Ex. 9, '712 patent.

²⁶ Ex. 10, <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&u=%2Fnetacgi/nph-adv.htm&r=0&p=1&f=S&l=50&Query=an%2Fbiopsy+and+sciences%0D%0A&d=PTXT>

²⁷ Ex. 11, <http://www.hydromark.com/hydromark/Company.aspx>.

²⁸ *Id.*

an inventor “on over 20 issued and filed patent applications involving novel and unique technologies in medical device applications.”²⁹

116. Upon information and belief, Biopsy Sciences (itself or by its representatives) performed an analysis to determine which patents to list on its HydroMARK packaging.

117. Upon information and belief, when Biopsy Sciences (itself or by its representatives) performed its analysis to determine which patents to list on the HydroMARK packaging, Biopsy Sciences knew that the HydroMARK products lacked essential elements covered by the '712 patent.

118. More specifically, the '712 patent is entitled “Bioabsorbable Marker Having External Anchoring Means.” Indeed, the '712 patent’s specification states that the invention relates to a “bioabsorbable marker having **an anchoring means** that is not bioabsorbable and that **is external** to the bioabsorbable part of the marker.”³⁰ Moreover, each of the independent claims (1, 5, 6, 11, 12, 18, 20, 25, 26, 31, 32, 37, 38, and 46) covers “an anchoring means” that is “external” to the bioabsorbable part of the marker. In particular, each of the independent claims covers at least “a straight configuration attachment means,” “a clip,” “an attachment means,” “a barb means,” and/or “a barbed anchor.”³¹

119. Biopsy Sciences publishes an instructional video on its website demonstrating the use of the HydroMARK product.³² Notably, the video does not show any “anchoring means”

²⁹ *Id.*

³⁰ Ex. 9, '712 patent, col. 1, lns. 8-10 (emphases added).

³¹ Ex. 9, '712 patent, col. 19, ln. 35 – col. 20, ln. 10, col. 20, ln. 19 – col. 21, ln. 28, col. 21, ln. 38 – col. 23, ln. 38, col. 23, ln. 54 – col. 25, ln. 4, col. 25, lns. 11-65, col. 26, ln. 7 – col. 27, ln. 61, col. 28, ln. 3 – col. 29, ln. 27, col. 29, ln. 36 – col. 30, ln. 27, and col. 30, lns. 43-55.

³² <http://www.hydromark.com/hydromark/How.aspx>.

such as “a straight configuration attachment means,” “a clip,” “an attachment means,” “a barb means,” “a barbed anchor,” or any equivalents thereof as claimed in the ’712 patent.³³

120. Accordingly, the ’712 patent unmistakably does not cover the HydroMARK because at least the “a straight configuration attachment means,” “a clip,” “an attachment means,” “a barb means,” and/or “a barbed anchor,” claim elements are not met.

121. Despite performing an analysis on the patents and providing an instructional video about the use of the HydroMARK, Biopsy Sciences, nevertheless, marked the HydroMARK package with the ’712 patent.

122. On information and belief, Biopsy Sciences, with knowledge that the HydroMARK is not covered by the ’712 patent, marked and, upon information and belief, continues to mark the HydroMARK with the ’712 patent with the intent of deceiving the public.

123. Biopsy Sciences knows, or reasonably should know (itself or by its representatives), that marking the HydroMARK line of products with a patent that does not cover the HydroMARK will deceive the public.

124. Biopsy Sciences knows, or reasonably should know (itself or by its representatives), that marking the HydroMARK line of products with patents that do not cover the HydroMARK is a violation of 35 U.S.C. § 292.³⁴

125. Each mismarked patent on the HydroMARK package is likely to, or at least has the potential to, discourage or deter others from commercializing a competing product, thereby deterring innovation and stifling competition in the marketplace generally and between Biopsy Sciences and Devicor specifically.

³³ *Id.*

³⁴ *See supra*, note 12.

126. For at least the reasons set forth herein, Biopsy Sciences has wrongfully and illegally advertised patent monopolies which it does not possess, and, as a result, upon information and belief, has likely benefitted in at least maintaining its market share with respect to the HydroMARK products in the marketplace.

127. For at least the reasons provided herein, and/or for other reasons which will be later evidenced, each mismarked patent which is marked on a product likely, or at least potentially, deceives the public and contributes to the public harm.

128. For at least the reasons provided herein, and/or for other reasons which will be later evidenced, each '712 patent number which is falsely marked on a Biopsy Sciences product has stifled Devicor's competition with Biopsy Sciences and has caused Devicor competitive injury.

129. Biopsy Sciences knew or reasonably should have known that each HydroMARK package it has marked and sold or caused to be sold is not covered by the '712 patent. Thus, each time Biopsy Sciences intentionally marks a HydroMARK package with a patent that does not cover the article such as described above, Biopsy Sciences has committed at least one "offense" as defined in 35 U.S.C. § 292(a), and has caused Devicor a "competitive injury" as defined in 35 U.S.C. § 292(b), as amended. Devicor is entitled to recover damages adequate to compensate for this injury.

130. For at least the reasons set forth herein, and/or for other reasons which will later be evidenced, Biopsy Sciences has falsely marked and, upon information and belief, continues to mark its products, with the intent to deceive the public and the effect of causing competitive injury to Devicor, in violation of 35 U.S.C. § 292.

PRAYER FOR RELIEF

WHEREFORE, Devicor prays that this Court:

A. Enter judgment in favor of Devicor that Biopsy Sciences directly and/or indirectly infringes claims of each of the five Devicor patents identified above;

B. Enter judgment enjoining Biopsy Sciences from selling, offering to sell, making, using, or importing any product that infringes any claim of any of the five Devicor patents identified above;

C. Enter judgment finding that Biopsy Sciences violated 35 U.S.C. § 292;

D. Award Devicor damages pursuant to 35 U.S.C. § 292(b), as amended, including costs and pre- and post-judgment interest;

E. Award Devicor damages pursuant to 35 U.S.C. § 284, including costs and pre- and post-judgment interest;

F. Award Devicor treble damages under 35 U.S.C. § 284 as a result of Biopsy Sciences's willful infringement of Devicor's patents;

G. Declare this case exceptional under 35 U.S.C. § 285 and award Devicor reasonable attorneys' fees, costs, and expenses; and

H. Award Devicor such other relief as the Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Devicor demands a trial by jury on all issues so triable.

October 7, 2011

BAYARD, P.A.

/s/ Richard D. Kirk
Richard D. Kirk (rk0922)
Stephen B. Braerman (sb4952)
222 Delaware Avenue, Suite 900
P.O. Box 25130
Wilmington, DE 19899
(302) 655-5000
rkirk@bayardlaw.com
sbraerman@bayardlaw.com

Of Counsel:

Janine A. Carlan
Aziz Burgy
Arent Fox LLP
1050 Connecticut Avenue, NW
Washington, DC 20036-5339
(202) 857-6000

Attorneys for Devicor Medical Products, Inc.