IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THOMAS A. SIMONIAN,

Plaintiff,

v.

BAXTER HEALTHCARE CORP.,

Defendant.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR FALSE PATENT MARKING

Plaintiff THOMAS A. SIMONIAN ("Plaintiff"), by his attorneys, hereby complains against Defendant BAXTER HEALTHCARE CORP. ("Defendant") as follows:

I.
NATURE OF THE CASE

1. This is a *qui tam* action on behalf of the public for false patent marking under 35 U.S.C. §292.

2. As set forth below, Defendant has violated 35 U.S.C. §292(a), by marking certain of its prescription pharmaceutical products with United States Patent Number 4,757,006 ("the '006 Patent"), United States Patent No. 4,891,319 ("the '319 Patent"), United States Patent No. 4,640,834 ("the '834 Patent") and United States Patent No. 4,388,232 ("the '232 Patent") (collectively, "the Expired Patents"), even though the '006 Patent has been expired since December 10, 2006, the '319 Patent has been expired since January 2, 2007, the '834 Patent has been expired since February 26, 2005 and the '232 Patent has been expired since May 5, 2002. On information and belief, Defendant marks certain of its pharmaceutical products with the Expired Patents with the intent to deceive the public and to gain a competitive advantage in the market.

3. Plaintiff seeks an award of monetary damages against Defendant pursuant to 35 U.S.C. §292(b) of up to $500 for each offense, with one-half going to the use of the United States and the other half going to the person bringing the action.

II.
THE PARTIES

4. Plaintiff is an individual residing in Geneva, Illinois.

5. Defendant BAXTER HEALTHCARE CORP. is a Corporation established under the laws of the State of Delaware with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.

6. Upon information and belief, Defendant is a leading manufacturer and producer of pharmaceutical products throughout the world. In particular, Defendant currently sells, for example, but not limited to: (1) ADVATE®, (2) ARTISS®, (3) BEBULIN VH®, (4) FEIBA VH®, (5) FLOSEAL®, and (6) TISSEEL®.

7. Upon information and belief, as of June 1, 1999, the U.S. Food and Drug Administration ("the FDA") began requiring the distribution of patient labeling, called Medication Guides, for certain products that may post a serious and significant public health concern requiring distribution of FDA approved patient medication information for the purpose of providing information necessary for patients to use their prescription medications safely and effectively (see http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1998_register&docid=fr01de98-24.pdf, last viewed March 3, 2010).

8. According to 21 CFR 201.56, human prescription drugs must contain certain labeling information. Specifically, the labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug. Moreover, the labeling

must be informative and accurate and neither promotional in tone nor false or misleading in any particular. The labeling must also contain the drug's full prescribing information.

9. Upon information and belief, the required labeling pursuant 21 CFR 201.56 is provided as part of the packaging for the prescription drug, such as, in the form of a product insert.

10. ADVATE® is currently advertised on Defendant's website (see http://www.baxter.com/patients_and_caregivers/products/advate.html, last viewed March 4, 2010). Defendant's website further includes prescribing information for the ADVATE® product (see http://www.advate.com/pdf/advate_pi.pdf, last viewed March 4, 2010). A copy of the prescribing information is attached hereto as Exhibit A.

11. ARTISS® is currently advertised on Defendant's website (see http://www.baxter.com/healthcare_professionals/products/index.html?t=azorder, last viewed March 4, 2010). Defendant's website further includes prescribing information for the ARTISS® product (see http://www.baxter.com/downloads/healthcare_professionals/products/ARTISS_PI.pdf, last viewed March 4, 2010). A copy of the prescribing information is attached hereto as Exhibit B.

12. BEBULIN VH® is currently advertised on Defendant's website (see http://www.baxter.com/healthcare_professionals/products/bebulin_vh.html, last viewed March 4, 2010). Defendant's website further includes prescribing information for the BEBULIN VH® product (see http://www.thereforyou.com/pdf/bebulin-vh_pi.pdf, last viewed March 4, 2010). A copy of the prescribing information for BEBULIN VH®is attached hereto as Exhibit C.

13. FEIBA VH® is currently advertised on Defendant's website (see http://www.baxter.com/healthcare_professionals/products/feiba_vh.html, last viewed March 4,

2010). Defendant's website further includes prescribing information for the FEIBA VH® product (see http://www.thereforyou.com/pdf/feiba-pi.pdf, last viewed March 4, 2010). A copy of the prescribing information is attached hereto as Exhibit D.

14. FLOSEAL® is currently advertised on Defendant's website (see http://www.baxter.com/healthcare_professionals/products/floseal.html, last viewed March 4, 2010). Defendant's website further includes prescribing information for the FLOSEAL® product (see http://www.baxter.com/downloads/healthcare_professionals/products/FLOSEAL_5mL_Instructions_For_Use.pdf, last viewed March 4, 2010). A copy of the prescribing information is attached hereto as Exhibit E.

15. TISSEEL® is currently advertised on Defendant's website (see http://www.baxter.com/healthcare_professionals/products/index.html?t=azorder, last viewed March 4, 2010). Defendant's website further includes prescribing information for the TISSEEL® product (see http://www.baxter.com/downloads/healthcare_professionals/products/Tisseel_PI.pdf, last viewed March 4, 2010). A copy of the prescribing information is attached hereto as Exhibit F.

16. Upon information and belief, Defendant is a sophisticated company and has many decades of experience applying for, obtaining, and litigating patents.

17. Upon information and belief, Defendant has previously accused companies of patent infringement.

18. As a sophisticated company, upon information and belief, that has previous litigated or overseen litigation of patent infringement cases and who regularly prosecutes or oversees patent prosecution, Defendant (by itself or by its representatives) knows, or reasonably should know, of the requirements of 35 U.S.C. §292.

III.
JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

20. Venue properly lies in the Northern District of Illinois pursuant to 28 U.S.C. §§ 1391(c), and 1395(a), because Defendant resides in this District, and because Defendant's falsely marked products were and are offered for sale and sold in this District.

21. This Court has personal jurisdiction over Defendant because it resides in this District and because Defendant has sold and continues to sell its falsely marked products, in Illinois and in this District and/or in the stream of commerce with knowledge that they would be sold in Illinois and in this District. Upon information and belief, such sales by Defendant are substantial, continuous, and systematic.

IV.
COUNT I - FALSE MARKING OF THE '006 PATENT

22. Plaintiff incorporates paragraphs 1-21 as if fully set forth herein.

23. When a patent expires, all prospective rights in the patent terminate irrevocably. Therefore, a product marked with an expired patent is not currently protected by such expired patent.

24. Defendant by itself or by its representatives cannot genuinely believe that a patent does not expire and that prospective patent rights apply even after its expiration.

25. The '006 Patent, entitled "Human factor VIII: C Gene and Recombinant Methods for Production," was filed on October 28, 1983, issued on July 12, 1988 and was originally set to expire on July 12, 2005. However, the U.S. Patent & Trademark Office issued a Certificate of Extension for 516 days, thereby extending the patent term until December 10, 2006. A true and

correct copy of the '006 Patent, including the Certificate of Extension, is attached hereto as Exhibit G.

26. The Abstract of the '006 Patent states as follows:

> *"The protein having factor VIII:C procoagulant activity has been produced by culturing a cell transformed with a recombinant expression vector encoding the gene for that activity."*

27. Upon information and belief, Defendant has in the past or currently is responsible for marking the product packaging or product inserts of, at least, its ADVATE® product with the '006 Patent with the knowledge that the '006 Patent has expired.

28. The false patent marking for the ADVATE® product is found on the product insert. (*See* Exhibit A)

29. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '006 Patent marked on the ADVATE® product has expired.

30. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the ADVATE® product is not covered by the expired '006 Patent marked on such product because an expired patent has no prospective rights.

31. Upon information and belief, Defendant intentionally included the expired '006 Patent in the patent markings of the ADVATE® product, in an attempt to deter competitors from using the same or similar pharmaceuticals.

32. Upon information and belief, Defendant marks the ADVATE® product with the expired '006 Patent for the purpose of deceiving the public into believing that something contained in or embodied in the product is covered by or protected by the expired '006 patent.

33. Each false marking on the ADVATE® product is likely to, or at least has the potential to, discourage or deter persons and companies from commercializing competing products.

34. Through its product packaging inserts and website, Defendant has wrongfully and illegally advertised patent rights which it does not possess and, as a result, has benefitted commercially and financially by maintaining false statements of patent rights.

35. Upon information and belief, Defendant knows, or reasonably should know, that marking the ADVATE® product with false patent statements was and is illegal under Title 35 United States Code. At a minimum, Defendant had and has no reasonable basis to believe that its use of the false markings was or is proper or otherwise permitted under federal law.

36. Upon information and belief, Defendant's marking of its ADVATE® product with the expired '006 Patent, as described above and/or as will be further later evidenced, has wrongfully quelled competition with respect to such products to an immeasurable extent thereby causing harm to the United States in an amount which cannot be readily determined.

37. Upon information and belief, for at least the reasons set forth herein, Defendant has wrongfully and illegally advertised patent rights which it does not possess, and, as a result, has likely benefitted in at least maintaining its considerable market share with respect to the herein described ADVATE® product in the market place.

38. The instances of false marking alleged in Count I of this Complaint are representative and not meant to be exhaustive.

39. For at least the reasons provided herein, and/or for reasons which will be later evidenced, each instance of false marking contributes to causing harm to the Plaintiff, the United States and the general public.

40. Thus, each expired patent marked on a product, directly or in connection with the packaging or advertising thereof, multiplied by the number of products and/or packaging materials on which it appears is a separate "offense" pursuant to 35 U.S.C. §292(a).

V.
COUNT II- False Marking of the '319 Patent

41. Plaintiff incorporates paragraphs 1-40 as if fully set forth herein.

42. The '319 Patent, entitled "Protection of Proteins and the like," was filed on July 9, 1986 (PCT Filed), issued on January 2, 1990 and expired on January 2, 2007. A true and correct copy of the '319 Patent, including the Certificate of Extension, is attached hereto as Exhibit H.

43. The Abstract of the '319 Patent states as follows:

> *"Sensitive proteins and other macromolecules, such as enzymes, antibodies, antigens, serum complement, fluorescent proteins, vaccine components, polysaccharides such as agarose etc, can be preserved by drying at ambient temperature and at atmospheric pressure in the presence of trehalose. A porous matrix impregnated with trehalose is provided as a receiver for a blood or other liquid sample to be dried."*

44. Upon information and belief, Defendant has in the past or currently is responsible for marking the product packaging or product inserts of, at least, its ADVATE® product with the '319 Patent with the knowledge that the '319 Patent has expired.

45. The false patent marking for the ADVATE® pharmaceutical product is found on the product insert. (*See* Exhibit A)

46. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '319 Patent marked on the ADVATE® pharmaceutical product has expired.

47. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the ADVATE® product is not covered by the expired '319 Patent marked on such product because an expired patent has no prospective rights.

48. Upon information and belief, Defendant intentionally included the expired '319 Patent in the patent markings of the ADVATE® product in an attempt to deter competitors from using the same or similar pharmaceutical products.

49. Upon information and belief, Defendant marks the ADVATE® product with the expired '319 Patent for the purpose of deceiving the public into believing that something contained in or embodied in the product is covered by or protected by the expired '319 Patent.

50. Each false marking on the ADVATE® product is likely to, or at least has the potential to, discourage or deter persons and companies from commercializing competing products.

51. Through its product packaging inserts and website, Defendant has wrongfully and illegally advertised patent rights which it does not possess and, as a result, has benefited commercially and financially by maintaining false statements of patent rights.

52. Upon information and belief, Defendant knows, or reasonably should know, that marking the ADVATE® product with false patent statements was and is illegal under Title 35 of the United States Code. At a minimum, Defendant had no reasonable basis to believe that its use of the false markings was or is proper or otherwise permitted under federal law.

53. Upon information and belief, Defendant's marking of ADVATE® product with the expired '319 Patent, as described above and/or as will be further later evidenced, has wrongfully quelled competition with respect to such products to an immeasurable extent thereby causing harm to the United States in an amount which cannot be readily determined.

54. Upon information and belief, for at least the reasons set for the herein, Defendant has wrongfully and illegally advertised patent rights which it does not possess, and, as a result, has likely benefited in at least maintaining its market share with respect to the herein described ADVATE® product in the market place.

55. The instances of false marking alleged in Count II of this Complaint are representative and not meant to be exhaustive.

56. For at least the reasons provided herein, and/or for reasons which will later be evidenced, each instance of false marking contributes to causing harm to the Plaintiff, the United States and the general public.

57. Thus, each expired patent marked on a product, directly or in connection with the packaging or advertising thereof, multiplied by the number of products and/or packaging materials on which it appears is a separate "offense" pursuant to 35 U.S.C. §292(a).

VI.
COUNT III- False Marking of the '834 Patent

58. Plaintiff incorporates paragraphs 1-57 as if fully set forth herein.

59. The '834 Patent, entitled "Method of inactivating reproducible filterable pathogens in blood products as well as a method of producing blood products," was filed on February 26, 1985, issued on February 3, 1987, and expired on February 26, 2005. A true and correct copy of the '834 Patent is attached hereto as Exhibit I.

60. The Abstract of the '834 Patent states as follows:

[57] **ABSTRACT**

A method of inactivating viruses in blood products is described, wherein the blood products are heat-treated in a humid or in a solid state in the presence of inorganic or organic hydroxyl group-containing compounds having an H^+-dissociation constant of $< 10^{-11}$ in a concentration of more than 0.05 (5% by weight) and less than 0.70 (70% by weight). The hydroxyl group-containing compounds may be water, methanol, ethanol or mannitol. The temperature may amount up to 121° C., the heat treatment may last from 1 s to 100 h. The inactivation method may be applied for producing blood products selected from enzymes, proenzymes including coagulation factors, enzyme inhibitors, immunoglobulins, albumin, plasminogen, fibrinogen, fibronectin or plasma, the inactivation destroying any reproducible filterable pathogens that might be present.

61. Upon information and belief, Defendant has in the past or currently is responsible for marking the product packaging or product inserts of, at least, its ARTISS®, BEBULIN VH®, FEIBA®, FLOSEAL®, and TISSEEL® products with the '834 Patent with the knowledge that the '834 Patent has expired.

62. The false patent marking for the ARTISS® pharmaceutical product is found on the product insert. (*See* Exhibit B)

63. The false patent marking for the BEBULIN VH® pharmaceutical product is found on the product insert. (*See* Exhibit C)

64. The false patent marking for the FEIBA® pharmaceutical product is found on the product insert. (*See* Exhibit D)

65. The false patent marking for the FLOSEAL® pharmaceutical product is found on the product insert. (*See* Exhibit E)

66. The false patent marking for the TISSEEL® pharmaceutical product is found on the product insert. (*See* Exhibit F)

67. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '834 Patent marked on the ARTISS®, BEBULIN VH®, FEIBA VH®, FLOSEAL®, and TISSEEL® products has expired.

68. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the ARTISS®, BEBULIN VH®, FEIBA VH®, FLOSEAL®, and TISSEEL® products is not covered by the expired '834 Patent marked on such product because an expired patent has no prospective rights.

69. Upon information and belief, Defendant intentionally included the expired '834 Patent in the patent markings of the ARTISS®, BEBULIN VH®, FEIBA VH®, FLOSEAL®, and TISSEEL® products in an attempt to deter competitors from using the same or similar pharmaceutical products.

70. Upon information and belief, Defendant marks the ARTISS®, BEBULIN VH®, FEIBA VH®, FLOSEAL®, and TISSEEL® products with the expired '834 Patent for the purpose of deceiving the public into believing that something contained in or embodied in the product is covered by or protected by the expired '834 Patent.

71. Each false marking on the ARTISS®, BEBULIN VH®, FEIBA VH®, FLOSEAL®, and TISSEEL® products is likely to, or at least has the potential to, discourage or deter persons and companies from commercializing competing products.

72. Through its product packaging inserts and website, Defendant has wrongfully and illegally advertised patent rights which it does not possess and, as a result, has benefited commercially and financially by maintaining false statements of patent rights.

73. Upon information and belief, Defendant knows, or reasonably should know, that marking the ARTISS®, BEBULIN VH®, FEIBA VH®, FLOSEAL®, and TISSEEL® products

with false patent statements was and is illegal under Title 35 of the United States Code. At a minimum, Defendant had no reasonable basis to believe that its use of the false markings was or is proper or otherwise permitted under federal law.

74. Upon information and belief, Defendant's marking of ARTISS®, BEBULIN VH®, FEIBA VH®, FLOSEAL®, and TISSEEL® products with the expired '834 Patent, as described above and/or as will be further later evidenced, has wrongfully quelled competition with respect to such products to an immeasurable extent thereby causing harm to the United States in an amount which cannot be readily determined.

75. Upon information and belief, for at least the reasons set for the herein, Defendant has wrongfully and illegally advertised patent rights which it does not possess, and, as a result, has likely benefited in at least maintaining its market share with respect to the herein described ARTISS®, BEBULIN VH®, FEIBA VH®, FLOSEAL®, and TISSEEL® products in the market place.

76. The instances of false marking alleged in Count III of this Complaint are representative and not meant to be exhaustive.

77. For at least the reasons provided herein, and/or for reasons which will later be evidenced, each instance of false marking contributes to causing harm to the Plaintiff, the United States and the general public.

78. Thus, each expired patent marked on a product, directly or in connection with the packaging or advertising thereof, multiplied by the number of products and/or packaging materials on which it appears is a separate "offense" pursuant to 35 U.S.C. §292(a).

VII.
COUNT IV- False Marking of the '232 Patent

79. Plaintiff incorporates paragraphs 1-78 as if fully set forth herein.

80. The '232 Patent, entitled "Method of Producing Plasma Fractions Free of Side-effects using Fast-reacting Antithrombin," was filed on May 5, 1982, issued on June 14, 1983 and expired on May 5, 2002. A true and correct copy of the '232 Patent, including the Certificate of Extension, is attached hereto as Exhibit J.

81. The Abstract of the '232 Patent states as follows:

> *"In a method of producing plasma fractions free of side-effects by purification and step-wise enrichment of plasma proteins in the presence of calcium-binding anticoagulants, also fast reactive (avid) antithrombin is present, wherein a concentration of the fast reacting (avid) antithrombin of 0.05 to 50 units per ml of the respective solution is maintained during all fractionation process steps."*

82. Upon information and belief, Defendant has in the past or currently is responsible for marking the product packaging or product inserts of, at least, its BEBULIN VH® product with the '232 Patent with the knowledge that the '232 Patent has expired.

83. The false patent marking for the BEBULIN VH® pharmaceutical product is found on the product insert. (*See* Exhibit C)

84. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '232 Patent marked on the BEBULIN VH® pharmaceutical product has expired.

85. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the BEBULIN VH® product is not covered by the expired '232 Patent marked on such product because an expired patent has no prospective rights.

86. Upon information and belief, Defendant intentionally included the expired '232 Patent in the patent markings of the BEBULIN VH® product in an attempt to deter competitors from using the same or similar pharmaceutical products.

87. Upon information and belief, Defendant marks the BEBULIN VH® product with the expired '232 Patent for the purpose of deceiving the public into believing that something contained in or embodied in the product is covered by or protected by the expired '232 Patent.

88. Each false marking on the BEBULIN VH® product is likely to, or at least has the potential to, discourage or deter persons and companies from commercializing competing products.

89. Through its product packaging inserts and website, Defendant has wrongfully and illegally advertised patent rights which it does not possess and, as a result, has benefited commercially and financially by maintaining false statements of patent rights.

90. Upon information and belief, Defendant knows, or reasonably should know, that marking the BEBULIN VH® product with false patent statements was and is illegal under Title 35 of the United States Code. At a minimum, Defendant had no reasonable basis to believe that its use of the false markings was or is proper or otherwise permitted under federal law.

91. Upon information and belief, Defendant's marking of BEBULIN VH® product with the expired '232 Patent, as described above and/or as will be further later evidenced, has wrongfully quelled competition with respect to such products to an immeasurable extent thereby causing harm to the United States in an amount which cannot be readily determined.

92. Upon information and belief, for at least the reasons set for the herein, Defendant has wrongfully and illegally advertised patent rights which it does not possess, and, as a result,

has likely benefited in at least maintaining its market share with respect to the herein described BEBULIN VH® product in the market place.

93. The instances of false marking alleged in Count IV of this Complaint are representative and not meant to be exhaustive.

94. For at least the reasons provided herein, and/or for reasons which will later be evidenced, each instance of false marking contributes to causing harm to the Plaintiff, the United States and the general public.

95. Thus, each expired patent marked on a product, directly or in connection with the packaging or advertising thereof, multiplied by the number of products and/or packaging materials on which it appears is a separate "offense" pursuant to 35 U.S.C. §292(a).

VIII.
PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment against Defendant as follows:

(a) A decree that Defendant has falsely marked products in violation of 35 U.S.C. §292;

(b) An award of monetary damages, pursuant to 35 U.S.C. § 292, in the form of a civil monetary fine of $500 per false marking "offense," or an alternative amount as determined by the Court, one half of which should be paid to the United States of America;

(c) An accounting for any falsely marked products not presented at trial and an award by the Court of additional damages for any such falsely marked products;

(d) All costs and fees incurred as a result of the prosecution of this action; and

(e) Such other and further relief, at law or in equity, to which Plaintiff is justly entitled.

IX.
DEMAND FOR JURY TRIAL

Pursuant to Federal Rules of Civil Procedure Rule 38, Plaintiff hereby demands a jury trial on all issues triable by jury.

Dated: March 8, 2010

Respectfully submitted,

s/ Joseph M. Vanek

Joseph M. Vanek

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