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

THOMAS A. SIMONIAN,

Plaintiff,

v.

ABBOTT LABORATORIES,

Defendant.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR FALSE PATENT MARKING

Plaintiff THOMAS A. SIMONIAN ("Plaintiff"), by his attorneys, hereby complains against Defendant ABBOTT LABORATORIES ("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 4,340,582 ("the '582 Patent"), and United States Patent No. 4,874,614 ("the '614 Patent") (collectively, "the Expired Patents"), even though the '582 Patent has been expired since January 15, 2001 and the '614 Patent has been expired since January 30, 2009. 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 ABBOTT LABORATORIES is a Corporation established under the laws of the State of Illinois with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

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) Ery-Tab® (erythromycin delayed-release tablets) and (2) PCE® (erythromycin particles in tablets).

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 product

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 under 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. Ery-Tab® is currently advertised on Defendant's website (see http://www.abbott.com/content/en_US/20.10.1035:1035/product/Product_Master_0352.htm, last viewed March 3, 2010). Defendant's website further includes prescribing information for the Ery-Tab® product (see http://www.rxabbott.com/pdf/erytab.pdf, last viewed March 3, 2010). A copy of the prescribing information is attached hereto as Exhibit A.

11. PCE® is currently advertised on Defendant's website (see http://www.abbott.com/content/en_US/20.10.1095:1095/product/Product_Master_0363.htm, last viewed March 3, 2010). Defendant's website further includes prescribing information for the PCE® product (see http://www.rxabbott.com/pdf/pce.pdf, last viewed March 3, 2010). A copy of the prescribing information is attached hereto as Exhibit B.

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

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

14. 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

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

16. 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.

17. 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 '582 PATENT

18. Plaintiff incorporates paragraphs 1-17 as if fully set forth herein.

19. 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.

20. 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.

21. The '582 Patent, entitled "Erythromycin Base Tablets," was filed on January 15, 1981, issued on July 20, 1982 and expired on January 15, 2001. A true and correct copy of the '582 Patent is attached hereto as Exhibit C.

22. The Abstract of the '582 Patent states as follows:

> *"An enteric coated erythromycin tablet is provided that produces essentially the same blood levels in fasting and nonfasting subjects. The tablet contains erythromycin base dihydrate and a highly water-soluble nontoxic salt in the core and the coating polymer is a hydroxypropyl methylcellulose phthalate."*

23. 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 Ery-Tab® product with the '582 Patent with the knowledge that the '582 Patent is expired.

24. The false patent marking for the Ery-Tab® product is found on the product insert. (*See* Exhibit A)

25. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '582 Patent marked on the Ery-Tab® product has expired.

26. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the Ery-Tab® product is not covered by the expired '582 Patent marked on such product because an expired patent has no prospective rights.

27. Upon information and belief, Defendant intentionally included the expired '582 Patent in the patent markings of the Ery-Tab® product, in an attempt to detert competitors from using the same or similar pharmaceuticals.

28. Upon information and belief, Defendant marks the Ery-Tab® product with the expired '582 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 '582 patent.

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

30. 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.

31. Upon information and belief, Defendant knows, or reasonably should know, that marking the Ery-Tab® 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.

32. Upon information and belief, Defendant's marking of its Ery-Tab® product with the expired '582 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.

33. 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 Ery-Tab® product in the market place.

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

35. 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.

36. 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 '614 Patent

37. Plaintiff incorporates paragraphs 1-36 as if fully set forth herein.

38. The '614 Patent, entitled "Pharmaceutical Tableting Method," was filed on January 31, 1989, issued on October 17, 1989 and expired on January 31, 2009. A true and correct copy of the '614 Patent is attached hereto as Exhibit D.

39. The Abstract of the '614 Patent states as follows:

> *"A method of preventing the fracture of coated drug granules during the compression of the granules into a commercially acceptable tablet matrix is disclosed. The method involves incorporating into the matrix, along with the granules, from about 10% to about 50% by weight microcrystalline cellulose."*

40. 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 PCE® product with the '614 Patent with the knowledge that the '614 Patent is expired.

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

42. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '614 Patent marked on the PCE® pharmaceutical product has expired.

43. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the PCE® pharmaceutical product is not covered by the expired '614 Patent marked on such product because an expired patent has no prospective rights.

44. Upon information and belief, Defendant intentionally included the expired '614 Patent in the patent markings of the PCE® pharmaceutical product in an attempt to deter competitors from using the same or similar pharmaceutical products.

45. Upon information and belief, Defendant marks the PCE® pharmaceutical product with the expired '614 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 '614 Patent.

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

47. 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.

48. Upon information and belief, Defendant knows, or reasonably should know, that marking the PCE® pharmaceutical 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.

49. Upon information and belief, Defendant's marking of PCE® pharmaceutical product with the expired '614 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.

50. 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 PCE® pharmaceutical product in the market place.

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

52. 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.

53. 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.

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.

VII.

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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