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

THOMAS A. SIMONIAN,

Plaintiff,

v.

ALLERGAN, INC.,

Defendant.

Civil Action No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR FALSE PATENT MARKING

Plaintiff THOMAS A. SIMONIAN ("Plaintiff"), by his attorneys, hereby complains against Defendant ALLERGAN, INC. ("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 5,089,509 ("the '509 Patent"), United States Patent No. 4,839,342 ("the '342 Patent"), and United States Patent No. 4,980,470 ("the '470 Patent") (collectively, "the Expired Patents"), even though the '509 Patent has been expired since March 20, 2009, the '342 Patent has been expired since August 2, 2009, and the '470 Patent has been expired since December 25, 2007. 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 ALLERGAN, INC. is a Corporation established under the laws of the State of California with its principal place of business at 2525 Dupont Drive, Irvine, CA 92612.

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) AVAGE®, (2) RESTASIS®, (3) TAZORAC® Cream, (4) TAZORAC® Gel, and (5) ZYMAR®.

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. AVAGE® is currently advertised on Defendant's website (see http://www.allergan.com/products/medical_dermatology/avage.htm, last viewed March 4, 2010). Defendant's website further includes prescribing information for the AVAGE® product (see http://www.allergan.com/assets/pdf/avage_pi.pdf, last viewed March 4, 2010). A copy of the prescribing information is attached hereto as Exhibit A.

11. RESTASIS® is currently advertised on Defendant's website (see http://www.allergan.com/products/eye_care/restasis.htm, last viewed March 4, 2010). Defendant's website further includes prescribing information for the RESTASIS® product (see http://www.allergan.com/assets/pdf/restasis_pi.pdf, last viewed March 4, 2010). A copy of the prescribing information is attached hereto as Exhibit B.

12. TAZORAC® Cream and TAZORAC® Gel are currently advertised on Defendant's website (see http://www.allergan.com/products/medical_dermatology/tazorac_1per.htm, last viewed March 4, 2010). Defendant's website further includes prescribing information for the TAZORAC® Cream product (see http://www.allergan.com/assets/pdf/tazorac_cream_pi.pdf, last viewed March 4, 2010). A copy of the prescribing information for TAZORAC® Cream is attached hereto as Exhibit C. Defendant's website further includes prescribing information for the TAZORAC® Gel product (see http://www.allergan.com/assets/pdf/tazorac_gel_pi.pdf, last viewed March 4, 2010). A copy of the prescribing information for TAZORAC® Gel is attached hereto as Exhibit D.

13. ZYMAR® is currently advertised on Defendant's website (see http://www.allergan.com/products/eye_care/zymar.htm, last viewed March 4, 2010). Defendant's website further includes prescribing information for the ZYMAR® product (see http://www.allergan.com/assets/pdf/zymar_pi.pdf, last viewed March 4, 2010). A copy of the prescribing information is attached hereto as Exhibit E.

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

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

16. 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

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

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

19. This Court has personal jurisdiction over Defendant because it 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 '509 PATENT

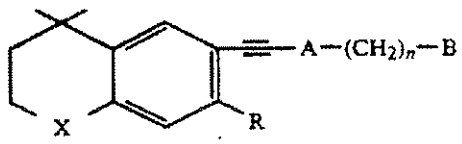
20. Plaintiff incorporates paragraphs 1-19 as if fully set forth herein.

21. 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.

22. 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.

23. The '509 Patent, entitled "Disubstituted Acetylenes bearing Heteroaromatic and Heterobicyclic Groups having Retinoid like Activity," was filed on March 20, 1989, issued on February 18, 1992 and expired on March 20, 2009. A true and correct copy of the '509 Patent is attached hereto as Exhibit F.

24. The Abstract of the '509 Patent states as follows (next page):

> [57] **ABSTRACT**
>
> **Retinoid-like activity is exhibited by compounds of the formula**
>
> 
>
>
> **where X is S, O, or NR' where R' is hydrogen or lower alkyl; R is hydrogen or lower alkyl; A is pyridyl, thienyl, furyl, pyridazinyl, pyrimidinyl or pyrazinyl; n is 0–2; and B is H, —COOH or a pharmaceutically acceptable salt, ester or amide thereof, —CH_2OH or an ether or ester derivative, or —CHO or an acetal derivative, or —COR_1 or a ketal derivative where R_1 is —$(CH_2)_mCH_3$ where m is 0–4, or a pharmaceutically acceptable salt thereof.**

25. 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 AVAGE®, TAZORAC® Cream, and TAZORAC® Gel products with the '509 Patent with the knowledge that the '509 Patent has expired.

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

27. The false patent marking for the TAZORAC® Cream product is found on the product insert. (*See* Exhibit C)

28. The false patent marking for the TAZORAC® Gel product is found on the product insert. (*See* Exhibit D)

29. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '509 Patent marked on the AVAGE®, TAZORAC® Cream, and TAZORAC® Gel products has expired.

30. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the AVAGE®, TAZORAC® Cream, and TAZORAC® Gel products is not covered by the expired '509 Patent marked on such product because an expired patent has no prospective rights.

31. Upon information and belief, Defendant intentionally included the expired '509 Patent in the patent markings of the AVAGE®, TAZORAC® Cream, and TAZORAC® Gel products, in an attempt to deter competitors from using the same or similar pharmaceuticals.

32. Upon information and belief, Defendant marks the AVAGE®, TAZORAC® Cream, and TAZORAC® Gel products with the expired '509 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 '509 patent.

33. Each false marking on the AVAGE®, TAZORAC® Cream, and TAZORAC® Gel products 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 AVAGE®, TAZORAC® Cream, and TAZORAC® Gel products 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 AVAGE®, TAZORAC® Cream, and TAZORAC® Gel products with the expired '509 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 AVAGE®, TAZORAC® Cream, and TAZORAC® Gel products 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 '342 PATENT

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

42. The '342 Patent, entitled "Method of Increasing Tear Production by Topical Administration of Cyclosporin," was filed on September 3, 1987, issued on July 13, 1989 and was set to expire on September 3, 2007. The U.S. Patent & Trademark Office granted a Certificate of Extension of 700 days for the '342 Patent. Therefore, the '342 Patent expired on August 2, 2009. A true and correct copy of the '342 Patent, including the Certificate of Extension, is attached hereto as Exhibit G.

43. The Abstract of the '342 Patent states as follows:

> *"The present invention provides a method of treating an aqueous-deficient dry eye state in a patient suffering therefrom, which method includes the step of administering cyclosporin topically to the patient's eye. The cyclosporin is administered as a solution, suspension or ointment in a pharmaceutically acceptable excipient."*

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 RESTASIS® product with the '342 Patent with the knowledge that the '342 Patent has expired.

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

46. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '342 Patent marked on the RESTASIS® pharmaceutical product has expired.

47. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the RESTASIS® product is not covered by the expired '342 Patent marked on such product because an expired patent has no prospective rights.

48. Upon information and belief, Defendant intentionally included the expired '342 Patent in the patent markings of the RESTASIS® product in an attempt to deter competitors from using the same or similar pharmaceutical products.

49. Upon information and belief, Defendant marks the RESTASIS® product with the expired '342 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 '342 Patent.

50. Each false marking on the RESTASIS® 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 RESTASIS® 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 RESTASIS® product with the expired '342 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 RESTASIS® 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 '470 PATENT

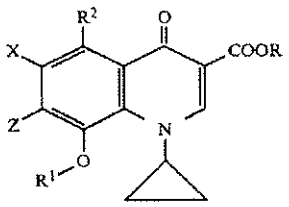
58. Plaintiff incorporates paragraphs 1-57 as if fully set forth herein.

59. The '470 Patent, entitled "8-alkoxyquinolonecarboxylic Acid and Salts Thereof," was filed on January 16, 1987, issued on December 25, 1990, and expired on December 25, 2007. A true and correct copy of the '470 Patent is attached hereto as Exhibit H.

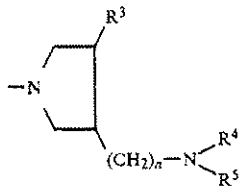
60. The Abstract of the '470 Patent states as follows (next page):

[57] **ABSTRACT**

Quinolonecarboxylic acid derivatives of the following formula:



wherein R indicates a hydrogen atom or lower alkyl group, R^1 indicates a lower alkyl group, R^2 indicates a hydrogen atom, amino group or nitro group, X indicates a halogen atom, and Z indicates a halogen atom, piperazino group, N-methylpiperazino group, 3-methylpiperazino group, 3-hydroxypyrrolidino group, or pyrrolidino group of the following formula,



(here, n is 0 or 1, R^3 indicates a hydrogen atom or lower alkyl group, R^4 indicates a hydrogen atom, lower alkyl group and R^5 indicates a hydrogen atom, lower alkyl group, acyl group or alkoxycarbonyl group), the hydrates and pharmaceutically acceptable salts thereof are useful as antibacterial agents.

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 ZYMAR® product with the '470 Patent with the knowledge that the '470 Patent has expired.

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

63. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '470 Patent marked on the ZYMAR® pharmaceutical product has expired.

64. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the ZYMAR® product is not covered by the expired '470 Patent marked on such product because an expired patent has no prospective rights.

65. Upon information and belief, Defendant intentionally included the expired '470 Patent in the patent markings of the ZYMAR® product in an attempt to deter competitors from using the same or similar pharmaceutical products.

66. Upon information and belief, Defendant marks the ZYMAR® product with the expired '470 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 '470 Patent.

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

68. 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.

69. Upon information and belief, Defendant knows, or reasonably should know, that marking the ZYMAR® 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.

70. Upon information and belief, Defendant's marking of ZYMAR® product with the expired '470 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.

71. 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 ZYMAR® product in the market place.

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

73. 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.

74. 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.
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.

VIII.
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 5, 2010

Respectfully submitted,

/s/ Joseph M. Vanek
Joseph M. Vanek

Attorneys for Plaintiff

Joseph M. Vanek
IL State Bar No. 6197046
David P. Germaine
IL State Bar No. 6274984
Jeffrey R. Moran
IL State Bar No. 6283573
VANEK, VICKERS & MASINI, P.C.
111 S. Wacker Drive, Suite 4050
Chicago, Illinois 60606
(312) 224-1500 Telephone
(312) 224-1510 Facsimile
E-mail: jvanek@vaneklaw.com
E-mail: tvickers@vaneklaw.com
E-mail: dgermaine@vaneklaw.com
E-mail: jmoran@vaneklaw.com

Bruce S. Sperling
IL State Bar No. 2687925
Robert D. Cheifetz
IL State Bar No. 6210105
SPERLING & SLATER, P.C.
55 West Monrie Street
Suite 3200
Chicago, Illinois 60603
(312) 641-3200 Telephone
(312) 641-6492 Facsimile
E-mail: bss@sperling-law.com
E-mail: robc@sperling-law.com

Eugene M. Cummings
IL State Bar No. 556394
David M. Mundt
IL State Bar No. 6243545
David Lesht
IL State Bar No. 6180985
Martin Goering
IL State Bar No. 6286254
Konrad V. Sherinian
IL State Bar No. 6290749
Panasarn Aim Jirut
IL State Bar No. 6281877
Jessica Rissman
IL State Bar No. 6300680
EUGENE M. CUMMINGS, P.C.
One North Wacker Drive, Suite 4130
Chicago, Illinois 60606
(312) 984-0144 Telephone
(312) 984-0146 Facsimile
E-mail: ecummings@emcpc.com
E-mail: dmundt@emcpc.com
E-mail: dlesht@emcpc.com
E-mail: mgoering@emcpc.com
E-mail: ksherinian@emcpc.com
E-mail: ajirut@emcpc.com
E-mail: jrissman@emcpc.com
E-mail: erynne@emcpc.com