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

THOMAS A. SIMONIAN,

Plaintiff,

v.

AMGEN, 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 AMGEN, 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 4,810,643 ("the '643 Patent"), and United States Patent No. 4,999,291 ("the '291 Patent") (collectively, "the Expired Patents"), even though the '643 Patent has been expired since March 7, 2006 and the '291 Patent has been expired since March 6, 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 AMGEN, INC. is a Corporation established under the laws of the State of California with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799.

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: NEUPOGEN®.

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. NEUPOGEN® is currently advertised on Defendant's website (see http://wwwext.amgen.com/medpro/products.html, last viewed March 4, 2010). Defendant's website further includes prescribing information for the NEUPOGEN® product (see http://pi.amgen.com/united_states/neupogen/neupogen_pi_hcp_english.pdf, last viewed March 4, 2010). A copy of the prescribing information is attached hereto as Exhibit A.

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

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

13. 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

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

15. 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.

16. 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 '643 PATENT

17. Plaintiff incorporates paragraphs 1-16 as if fully set forth herein.

18. 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.

19. 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.

20. The '643 Patent, entitled "Production of Pluripotent Granulocyte Colony-stimulating Factor," was filed on March 3, 1986, issued on March 7, 1989 and expired on March 7, 2006. A true and correct copy of the '643 Patent is attached hereto as Exhibit B.

21. The Abstract of the '643 Patent states as follows:

> *"Disclosed are novel polypeptides possessing part or all of the primary structural conformation and one or more of the biological properties of a mammalian (e.g., human) pluripotent granulocyte colony-stimulating factor ("hpG-CSF") which are characterized in preferred forms by being the product of procaryotic or eucaryotic host expression of an exogenous DNA sequence. Sequences coding for part or all of the sequence of amino acid residues of hpG-CSF or for analogs thereof may be incorporated into autonomously replicating plasmid or viral vectors employed to transform or transfect suitable procaryotic or eucaryotic host cells such as bacteria, yeast or vertebrate cells in culture. Products of expression of the DNA sequences display, i.e., the physical and immunological properties and in vitro biological activities of isolates of hpG-CSF derived from natural sources. Disclosed also are chemically synthesized polypeptides sharing the biochemical and immunological properties of hpG-CSF."*

22. 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 NEUPOGEN® products with the '643 Patent with the knowledge that the '643 Patent has expired.

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

24. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '643 Patent marked on the NEUPOGEN® product has expired.

25. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the NEUPOGEN® product is not covered by the expired '643 Patent marked on such product because an expired patent has no prospective rights.

26. Upon information and belief, Defendant intentionally included the expired '643 Patent in the patent markings of the NEUPOGEN® product, in an attempt to deter competitors from using the same or similar pharmaceuticals.

27. Upon information and belief, Defendant marks the NEUPOGEN® product with the expired '643 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 '643 patent.

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

29. 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.

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

31. Upon information and belief, Defendant's marking of its NEUPOGEN® product with the expired '643 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.

32. 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 NEUPOGEN® product in the market place.

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

34. 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.

35. 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 '291 PATENT

36. Plaintiff incorporates paragraphs 1-35 as if fully set forth herein.

37. The '291 Patent, entitled "Production of Human Pluripotent Granulocyte Colony-stimulating Factor," was filed on March 6, 1989, issued on March 12, 1991 and expired on March 6, 2009. A true and correct copy of the '291 Patent is attached hereto as Exhibit C.

38. The Abstract of the '291 Patent states as follows:

> *"Disclosed are novel polypeptides possessing part or all of the primary structural conformation and one or more of the biological properties of a mammalian (e.g., human) pluripotent granulocyte colony-stimulating factor ("hpG-CSF") which are characterized in preferred forms by being the product of procaryotic or eucaryotic host expression of an exogenous DNA sequence. Sequences coding for part or all of the sequence of amino acid residues of hpG-CSF or for analogs thereof may be incorporated into autonomously replicating plasmid or viral vectors employed to transform or transfect suitable procaryotic or eucaryotic host cells such as bacteria, yeast or vertebrate cells in culture. Products of expression of the DNA sequences display, e.g., the physical and immunological properties and in vitro biological activities of isolates of hpG-CSF derived from natural sources. Disclosed also are chemically synthesized polypeptides sharing the biochemical and immunological properties of hpG-CSF."*

39. 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 NEUPOGEN® products with the '291 Patent with the knowledge that the '291 Patent has expired.

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

41. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '291 Patent marked on the NEUPOGEN® pharmaceutical product has expired.

42. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the NEUPOGEN® pharmaceutical product is not covered by the expired '291 Patent marked on such product because an expired patent has no prospective rights.

43. Upon information and belief, Defendant intentionally included the expired '291 Patent in the patent markings of the NEUPOGEN® pharmaceutical product in an attempt to deter competitors from using the same or similar pharmaceutical products.

44. Upon information and belief, Defendant marks the NEUPOGEN® pharmaceutical product with the expired '291 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 '291 Patent.

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

46. 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.

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

48. Upon information and belief, Defendant's marking of NEUPOGEN® pharmaceutical product with the expired '291 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.

49. 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 NEUPOGEN® pharmaceutical product in the market place.

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

51. 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.

52. 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 5, 2010

Respectfully submitted,

/s/ Joseph M. Vanek
Joseph M. Vanek

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