

UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
TYLER DIVISION

PROMOTE INNOVATION LLC,	)	
	)	Case No. 2:10-cv-497
Plaintiff	)	
	)	COMPLAINT FOR FALSE
v.	)	PATENT MARKING
	)	
BRISTOL-MYERS SQUIBB	)	<u>JURY TRIAL DEMANDED</u>
COMPANY,	)	
	)	
Defendant.	)	

Plaintiff PROMOTE INNOVATION LLC alleges as follows:

NATURE OF THE CASE

1. This is an action for false patent marking under Section 292 of the Patent Act (35 U.S.C. § 292), which provides that any person may sue to recover the civil penalty for false patent marking. Plaintiff Promote Innovation brings this *qui tam* action on behalf of the United States of America.

PARTIES

2. Plaintiff PROMOTE INNOVATION LLC is a Texas limited liability company with a principal place of business in Houston, Texas.
3. Defendant BRISTOL-MYERS SQUIBB COMPANY is a Delaware corporation with a principal place of business in New York. Defendant can be served via its registered agent for service of process: CT Corporation System; 350 N. St. Paul St., Suite 2900, Dallas, TX 75201-4234.

JURISDICTION AND VENUE

4. The Court has jurisdiction of this action under 28 U.S.C. §§ 1331 and 1338(a).

5. The Court has personal jurisdiction over defendant. Defendant conducts or has conducted business within the State of Texas. Defendant offers or has offered for sale, sells or has sold, marks or has marked, and/or advertises or has advertised the products that are the subject of this complaint in the United States, the State of Texas, and the Eastern District of Texas.

6. Venue is proper in this district under 28 U.S.C. §§ 1391(b), 1391(c), and 1395(a).

#### FACTS

7. Defendant has marked and/or continues to mark its products, including at least its Cefzil products, its Buspar products, and its Pravachol products (the Falsely Marked Products) with expired or otherwise inapplicable patents, including at least U.S. Patent Nos. 4,520,022; 5,015,646; 5,030,447; and 5,180,589 (the Falsely Marked Patents). Such false marking by defendant includes marking the Falsely Marked Patents upon, affixing the Falsely Marked Patents to, and/or using the Falsely Marked Patents in advertising in connection with the Falsely Marked Products.

8. U.S. Patent No. 4,520,022 was originally set to expire on May 28, 2002.

9. On February 10, 1992, defendant made an application for an extension of the term of U.S. Patent No. 4,520,022. Defendant acknowledged in its application that the expiration date of the patent would be December 23, 2005 if the extension were granted.

10. On May 20, 1993, the Patent Office granted defendant's request for an extension of the term of U.S. Patent No. 4,520,022 to December 23, 2005. Nevertheless, defendant has marked its Cefzil with U.S. Patent No. 4,520,022 after December 23, 2005.

11. Defendant makes a package insert for its Cefzil products available on its website (available at <http://www.bms.com/products/Pages/prescribing.aspx>). The package insert

lists U.S. Patent No. 4,520,022, but bears a revision date of March 2007. Defendant has thus issued, revised, and/or created its package inserts after the expiration of U.S. Patent No. 4,520,022, but nonetheless listed U.S. Patent No. 4,520,022 on the package inserts. Moreover, defendant has continued to include U.S. Patent No. 4,520,022 on its package inserts available on its website to this day.

12. Defendant is the assignee of U.S. Patent No. 4,520,022.

13. The original ribbon copy of U.S. Patent No. 4,520,022 issued by the United States Patent and Trademark Office (“USPTO”) explained that patent’s maximum duration, and the terms of such ribbon copy were reviewed by defendant or its legal representatives. Defendant paid the maintenance fees due approximately four, eight, and twelve years after U.S. Patent No. 4,520,022 issued, and at those times defendant or its legal representatives reviewed U.S. Patent No. 4,520,022 in connection with such payments. Defendant was therefore on repeated notice of the remaining duration and expiration date of U.S. Patent No. 4,520,022.

14. U.S. Patent No. 5,015,646 expired no later than May 14, 2008.

15. On February 14, 2002, Judge Koeltl of the Southern District of New York ruled that U.S. Patent No. 6,150,365 “does not cover the use of buspirone. Moreover, a straightforward application of governing patent law provisions establishes that the '365 Patent would have been invalid if it did.” *See In re Buspirone Patent & Antitrust Litig.*, 185 F. Supp. 2d 363, 376 (S.D.N.Y. 2002).

16. In March 2003, the Federal Trade Commission (FTC) initiated a complaint against defendant alleging that: “BMS willfully maintained its BuSpar monopoly by: (a) entering into an unlawful, anticompetitive agreement with Schein, pursuant to which it

paid Schein millions of dollars to stay off the market with its generic buspirone product; (b) providing false and misleading information to the FDA in order to cause the FDA to list the '365 patent in the Orange Book and withhold approval for generic buspirone products; (c) wrongfully submitting the '365 patent for Orange Book listing without a reasonable good faith belief that the '365 patent met the statutory listing requirements; and (d) initiating and maintaining objectively baseless lawsuits against generic buspirone competitors, without regard to the merits of said lawsuits. By these acts, among others, BMS excluded competition and willfully maintained its BuSpar monopoly based not on the strength and scope of its patents, but rather by abusing competitive and government processes, including by strategically gaming the Hatch-Waxman 30-month provision to block FDA approval for any generic version of BuSpar.”

17. As a result of this complaint, on April 14, 2003, the FTC ordered that “BMS shall not seek, maintain, certify to, or take any other action in furtherance of, the listing or continued listing of any patent in the Orange Book where the listing of such patent in the Orange Book violates Applicable Law.”

18. On June 19, 2003, recognizing that U.S. Patent No. 5,015,646 does not cover its Buspar product, defendant informed that FTC that it had removed U.S. Patent No. 5,015,646 from the Orange Book.

19. Defendant knew that U.S. Patent No. 5,015,646 does not cover its Buspar products.

20. Nevertheless, thereafter defendant continued to mark its Buspar products with U.S. Patent No. 5,015,646 at least on the package insert for its Buspar products (available at <http://www.bms.com/products/Pages/prescribing.aspx>). Moreover, defendant has

continued to include U.S. Patent No. 5,015,646 on its package inserts available on its website to this day.

21. Defendant is the assignee of U.S. Patent No. 5,015,646.

22. The original ribbon copy of U.S. Patent No. 5,015,646 issued by the United States Patent and Trademark Office (“USPTO”) explained that patent’s maximum duration, and the terms of such ribbon copy were reviewed by defendant or its legal representatives. Defendant paid the maintenance fees due approximately four, eight, and twelve years after U.S. Patent No. 5,015,646 issued, and at those times defendant or its legal representatives reviewed U.S. Patent No. 5,015,646 in connection with such payments. Defendant was therefore on repeated notice of the remaining duration and expiration date of U.S. Patent No. 5,015,646.

23. U.S. Patent No. 5,030,447 expired no later than July 9, 2008.

24. The term of U.S. Patent No. 5,180,589 subsequent to July 9, 2008 was disclaimed.

25. Nevertheless, thereafter defendant continued to mark its Pravachol products after July 9, 2008 with U.S. Patent Nos. 5,030,447 and 5,180,589 at least on the package insert for its Pravachol products (available at <http://www.bms.com/products/Pages/prescribing.aspx>). Moreover, defendant has continued to include U.S. Patent Nos. 5,030,447 and 5,180,589 on its package inserts available on its website to this day.

26. Defendant is the assignee of U.S. Patent Nos. 5,030,447 and 5,180,589.

27. The original ribbon copies of U.S. Patent Nos. 5,030,447 and 5,180,589 issued by the United States Patent and Trademark Office (“USPTO”) explained that the patents’ maximum duration, and the terms of such ribbon copy were reviewed by defendant or its

legal representatives. Defendant paid the maintenance fees due approximately four, eight, and twelve years after U.S. Patent Nos. 5,030,447 and 5,180,589 issued, and at those times defendant or its legal representatives reviewed U.S. Patent Nos. 5,030,447 and 5,180,589 in connection with such payments. Defendant was therefore on repeated notice of the remaining duration and expiration date of U.S. Patent Nos. 5,030,447 and 5,180,589.

28. U.S. Patent Nos. 5,030,447 and 5,180,589 were the subject of litigation involving defendant and generic drug manufacturers.

29. Defendant has been previously sued for violating 35 U.S.C. § 292. On April 4, 2010, defendant was sued for false patent marking, but has nonetheless continued to falsely mark many of its products with expired or inapplicable patents.

30. It was a false statement for defendant to mark the Falsely Marked Products with expired or otherwise inapplicable patents.

31. Defendant is a large, sophisticated company. Defendant has, and/or regularly retains, sophisticated legal counsel. Defendant has many years of experience applying for patents, obtaining patents, licensing patents, and/or litigating in patent infringement lawsuits. Defendant's patents, including the Falsely Marked Patents, were prosecuted by sophisticated legal counsel. Defendant maintains, or retains legal counsel that maintains on defendant's behalf, docketing systems that allow determination of patent expiration dates.

32. Defendant knew that a patent that is expired does not cover any product.

33. Defendants knew that the Falsely Marked Patents were expired or otherwise inapplicable to the Falsely Marked Products.

34. Defendant knew that it was a false statement to mark the Falsely Marked Products with an expired or otherwise inapplicable patent.

35. Defendant falsely marked the Falsely Marked Products with the Falsely Marked Patents for the purpose of deceiving the public.

36. Defendant's patent markings for the Falsely Marked Products are made in a manner that can be easily updated to reflect accurate patent information.

37. The competitive advantage gained by marking with expired or inapplicable patents provided a strong motive for defendant to deceive the public about the patented status of the Falsely Marked Products.

INJURY IN FACT TO THE UNITED STATES

38. The false marking alleged above injured the United States.

39. The false marking alleged above caused injuries to the sovereignty of the United States arising from defendant's violations of federal law, specifically, the violation of 35 U.S.C. § 292(a).

40. The false marking alleged above caused proprietary injuries to the United States.

41. The marking and false marking statutes exist to give the public notice of patent rights. Congress intended the public to rely on marking as a ready means of discerning the status of intellectual property embodied in an article of manufacture or design, such as the Falsely Marked Products.

42. Federal patent policy recognizes an important public interest in permitting full and free competition in the use of ideas which are, in reality, a part of the public domain—such as those described in the Falsely Marked Patents.

43. Congress's interest in preventing false marking was so great that it enacted a statute which sought to encourage private parties to enforce the statute. By permitting members of the public to bring *qui tam* suits on behalf of the government, Congress authorized private persons like Promote Innovation to help control false marking.

44. The acts of false marking alleged above deter innovation and stifle competition in the marketplace for at least the following reasons: if an article that is within the public domain is falsely marked, potential competitors may be dissuaded from entering the same market; false marks may also deter scientific research when an inventor sees a mark and decides to forego continued research to avoid possible infringement; and false marking can cause unnecessary investment in design around or costs incurred to analyze the validity or enforceability of a patent whose number has been marked upon a product with which a competitor would like to compete.

45. The false marking alleged above misleads the public into believing that the Falsely Marked Patents give defendant(s) control of the Falsely Marked Products (as well as like products), and places the risk of determining whether the Falsely Marked Products are controlled by such patents on the public, thereby increasing the cost to the public of ascertaining who, if anyone, in fact controls the intellectual property embodied in the Falsely Marked Products.

46. Thus, in each instance where a representation is made that the Falsely Marked Products are protected by the Falsely Marked Patents, a member of the public desiring to participate in the market for products like the Falsely Marked Products must incur the cost of determining whether the involved patents are valid and enforceable. Failure to take on the costs of a reasonably competent search for information necessary to interpret



each patent, investigation into prior art and other information bearing on the quality of the patents, and analysis thereof can result in a finding of willful infringement, which may treble the damages an infringer would otherwise have to pay.

47. The false marking alleged in this case also creates a misleading impression that the Falsely Marked Products are technologically superior to previously available products, as articles bearing the term “patent” may be presumed to be novel, useful, and innovative.

48. Every person or company in the United States is a potential entrepreneur with respect to the process, machine, manufacture, or composition of matter described in the Falsely Marked Patents. Moreover, every person or company in the United States is a potential competitor with respect to the Falsely Marked Products marked with the Falsely Marked Patents.

49. Each Falsely Marked Product or advertisement thereof, because it is marked with or displays the Falsely Marked Patents is likely to, or at least has the potential to, discourage or deter each person or company (itself or by its representatives) which views such marking from commercializing a competing product, even though the Falsely Marked Patents do nothing to prevent any person or company in the United States from competing in commercializing such products.

50. The false marking alleged in this case and/or advertising thereof has quelled competition with respect to similar products to an immeasurable extent, thereby causing harm to the United States in an amount that cannot be readily determined.

51. The false marking alleged in this case constitutes wrongful and illegal advertisement of a patent monopoly that it does not exist and, as a result, and has

resulted in increasing, or at least maintaining, the market power or commercial success with respect to the Falsely Marked Products.

52. Each individual false marking (including each time an advertisement with such marking is accessed on the internet) is likely to harm, or at least potentially harms, the public. Thus, each such false marking is a separate offense under 35 U.S.C. § 292(a).

53. Each offense of false marking creates a proprietary interest of the United States in the penalty that may be recovered under 35 U.S.C. § 292(b).

54. For at least the reasons stated in paragraphs 7 to 53 above, the false marking alleged in this case caused injuries to the sovereignty of the United States arising from violations of federal law, and caused proprietary injuries to the United States.

#### CLAIM

55. For the reasons stated in paragraphs 7 to 54 above, defendant has violated section 292 of the Patent Act by falsely marking the Falsely Marked Products with intent to deceive the public.

#### PRAYER FOR RELIEF

Plaintiff thus requests this Court, pursuant to 35 U.S.C. § 292, to do the following:

A. Enter judgment against defendant and in favor of plaintiff for the violations alleged in this complaint;

B. Order defendant to pay a civil monetary fine of \$500 per false marking offense, or an alternative amount determined by the Court, one-half of which shall be paid to the United States; and

C. Grant plaintiff such other and further relief as it may deem just and equitable.

JURY DEMAND

Plaintiff demands a jury trial on all issues so triable.

Dated: November 18, 2010

Respectfully submitted,

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