

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

PROMOTE INNOVATION LLC,	)	
	)	Case No. 2:10-cv-254
Plaintiff	)	
	)	COMPLAINT FOR
v.	)	FALSE PATENT MARKING
	)	
K-V PHARMACEUTICAL CO.,	)	<u>JURY TRIAL DEMANDED</u>
THER-RX CORPORATION,	)	
	)	
Defendants.	)	

Plaintiff PROMOTE INNOVATION LLC alleges as follows:

NATURE OF THE CASE

1. This is an action for false patent marking brought 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 K-V PHARMACEUTICAL CO. is a Delaware corporation.
4. Defendant THER-RX CORPORATION is a Missouri corporation.

JURISDICTION AND VENUE

5. The Court has jurisdiction of this action under 28 U.S.C. §§ 1331 and 1338(a).
6. The Court has personal jurisdiction over defendants. Defendants conduct business within the State of Texas. Defendants offer for sale, sell, mark, and/or advertise

the products that are the subject of this complaint in the United States, the State of Texas, and the Eastern District of Texas.

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

FACTS

8. Defendants have falsely marked and/or continue to falsely mark their Gynazole-1 products (the Falsely Marked Products) with patent(s) that have expired or are otherwise inapplicable, including at least U.S. Patent Nos. 4,078,071, 4,551,148, and 4,636,202 (the Falsely Marked Patents). Such false marking by defendants includes marking the Falsely Marked Patents upon, affixing the Falsely Marked Patents to, or using the Falsely Marked Patents in advertising in connection with the Falsely Marked Products.

9. U.S. Patent No. 4,078,071 expired no later than March 7, 1997.

10. U.S. Patent No. 4,551,148 expired no later than November 5, 2002.

11. U.S. Patent No. 4,636,202 expired no later than July 27, 2004.

12. The label for Gynazole-1 was revised in June 1998, after the expiration date of U.S. Patent No. 4,078,071. The revised label was marked with U.S. Patent Nos. 4,078,071 and 4,636,202.

13. The label for Gynazole-1 was revised again in May 2002, and approved in July 2003. The revised label continued to be marked with U.S. Patent Nos. 4,078,071 and 4,636,202.

14. The May 2002 revised label added U.S. Patent No. 4,551,148, even though it was set to expire only five months later—before the likely date for approval of the revised label.

15. The label for Gynazole-1 is still marked with the Falsely Marked Patents.

16. Defendants have a history of problems with the manufacture and distribution of their products. According to [www.gynazole.com](http://www.gynazole.com), Gynazole-1 is currently unavailable for distribution because it may have been manufactured under conditions that did not comply with current Good Manufacturing Practices. Defendants have entered into a consent decree with the FDA related to these issues, and state that they are working to return Gynazole-1 to the market.

17. It was a false statement for defendants to mark the Falsely Marked Products with an expired or otherwise inapplicable patent.

18. Defendants have many years of experience applying for patents, obtaining patents, licensing patents, and/or litigating in patent infringement lawsuits. Defendants' patents, including the Falsely Marked Patents, were prosecuted by sophisticated legal counsel.

19. Defendants knew that a patent that is expired does not cover any product.

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

#### INJURY IN FACT TO THE UNITED STATES

21. Defendants' false marking injured the United States.

22. Defendants' false marking caused injuries to the sovereignty of the United States arising from defendants' violations of federal law, specifically, defendants' violation of 35 U.S.C. § 292(a).

23. Defendants' false marking caused proprietary injuries to the United States.

24. 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.

25. 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.

26. 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.

27. Defendants' acts of false marking 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.

28. Defendants' false marking misleads the public into believing that the Falsely Marked Patents give Defendants 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 rather than on defendants, thereby increasing the cost to the public of ascertaining whether defendants in fact control the intellectual property embodied in the Falsely Marked Products.

29. Thus, in each instance where defendants represent 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.

30. Defendants' false markings may also create 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.

31. 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 of defendants with respect to the Falsely Marked Products marked with the Falsely Marked Patents.

32. Each Falsely Marked Product or advertisement thereof, because it is marked with or displays the Falsely Marked Patents without identifying them as expired, 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 with defendants in commercializing such products.

33. Defendants' marking of the Falsely Marked Products with expired patents 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.

34. Defendants have wrongfully and illegally advertised a patent monopoly that they do not possess and, as a result, have benefited by increasing, or at least maintaining, their market power or commercial success with respect to the Falsely Marked Products.

35. 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).

36. 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).

37. For at least the reasons stated in paragraphs 8 to 36 above, defendants' false marking caused injuries to the sovereignty of the United States arising from defendants' violations of federal law, and caused proprietary injuries to the United States.

#### CLAIM

38. For the reasons stated in paragraphs 8 to 37 above, defendants have violated section 292 of the Patent Act by falsely marking their 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 defendants and in favor of plaintiff for the violations alleged in this complaint;

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

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: July 20, 2010

Respectfully submitted,

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