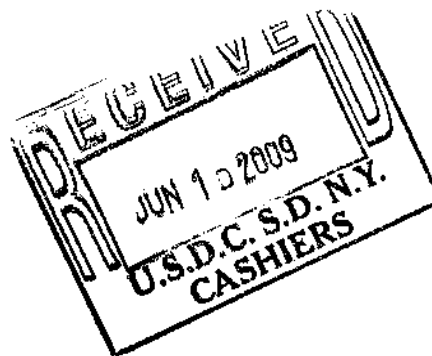


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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Public Patent Foundation, Inc.,
a New York, not-for-profit corporation,

Plaintiff,

v.

McNEIL-PPC, Inc.,
a New Jersey corporation,

Defendant.

Civil Action No. CV _____

**COMPLAINT FOR
FALSE PATENT MARKING**

(Jury Trial Demanded)

Nature of the Action

1. This is an action for false patent marking under Title 35, Section 292, of the United States Code.

2. As set forth in detail below, Defendant has violated 35 U.S.C. §292(a) by marking and advertising certain products with patent numbers of expired

patents and patents that do not – in fact – cover the marked product.

3. Plaintiff seeks the imposition of a fine against Defendant, one-half of which shall be paid to the United States, and the other half of which shall be paid to Plaintiff pursuant to 35 U.S.C. §292(b).

Jurisdiction and Venue

4. This Court has subject matter jurisdiction over Plaintiff's present action for false patent marking pursuant to 28 U.S.C. §1338(a).

5. This Court has personal jurisdiction over Defendant pursuant to Rule 4(K)(1)(a) of the Federal Rules of Civil Procedure and §§ 301 and 302 of the New York Civil Practice Law and Rules because, upon information and belief, Defendant conducts substantial business in the State of New York, including in this Judicial District.

6. Venue in this Judicial District is proper pursuant to 28 U.S.C. §§ 1391 and 1400 because a substantial part of the events giving rise to the claims asserted herein arose/arise in this Judicial District and Defendant, upon information and belief, is and at all times was doing business in this Judicial District.

The Parties

7. The Public Patent Foundation, Inc. ("PUBPAT") is a New York, not-for-profit corporation, with a principal place of business located at Benjamin N. Cardozo School of Law, 55 Fifth Avenue, New York, New York 10003.

8. PUBPAT represents the interests of otherwise unrepresented parties (e.g., consumers) against various misuses of patents and the patent system by commercial entities.

9. Upon information and belief, McNeil-PPC, Inc. ("Defendant") is a corporation formed under the laws of New Jersey, with its principal place of business at 7050 Camp Hill Road, Fort Washington, Pennsylvania 19034.

10. Upon information and belief, Defendant distributes and/or sells TYLENOL® brand acetaminophen pain reliever products to multiple retail stores, including Duane Reade, Walgreens, Rite Aid, CVS and many other retailers. At least some of such activities occur in this Judicial District.

11. Upon information and belief, Defendant also distributes and/or sells and/or uses third parties to distribute and/or sell its TYLENOL® brand acetaminophen pain reliever products on-line. (See <http://www.tylenol.com/page.jhtml?id=tylenol/buy.inc.>) At least some of such activities target and/or involve customers in this Judicial District.

12. Upon information and belief, Defendant promotes its TYLENOL® brand acetaminophen pain reliever products through Internet, radio, and television advertising. At least some of such activities target customers in this Judicial District.

Defendant's Widespread False Patent Marking of TYLENOL® Products

13. Upon information and belief, three TYLENOL® brand acetaminophen pain reliever products distributed and/or sold in retail stores and on-line (in this Judicial District and nationally) by Defendant include products identified as (i) "8 HOUR CAPLETS," (ii) "ARTHRITIS PAIN CAPLETS," and (iii) "ARTHRITIS PAIN GELTABS." Defendant distributes and/or sells these products in various quantities.

14. Upon information and belief, Defendant's 8 HOUR CAPLETS products include labeling on both the outside packaging and the inside container that states, inter alia, "U.S. Pat. Nos. 4,820,522, 4,968,509 and 5,004,613." (See attached Exhibit A.)

15. Upon information and belief, Defendant's ARTHRITIS PAIN CAPLETS products include labeling on both the outside packaging and the inside container that states, inter alia, "U.S. Patent Nos. 4,968,509 and 5,004,613". (See

attached Exhibit B.)

16. Upon information and belief, Defendant's ARTHRITIS PAIN GELTABS products include labeling on both the outside packaging and the inside container that states, inter alia, "U.S. Patent Nos. 5,658,589; 5,436,026; 5,228,916; 5,679,406; 4,968,509 and 5,004,613." (See attached Exhibit C.)

17. U.S. Patent No. 4,820,522 ("the '522 patent"), entitled "ORAL SUSTAINED RELEASE ACETAMINOPHEN FORMULATION AND PROCESS", was issued by the United States Patent and Trademark Office ("PTO") on April 11, 1989, and expired no later than July 27, 2007. (See <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=4,820,522.PN.&OS=PN/4,820,522&RS=PN/4,820,522>.) Because the '522 patent has expired, it no longer can protect or cover anything.

18. U.S. Patent No. 4,968,509 ("the '509 patent"), entitled "ORAL SUSTAINED RELEASE ACETAMINOPHEN FORMULATION AND PROCESS", was issued by the PTO on November 6, 1990, and expired no later than November 6, 2007. (See <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=4,968,509.PN.&OS=PN/4,968,509&RS=>

PN/4,968,509.) Because the '509 patent has expired, it no longer can protect or cover anything.

19. U.S. Patent No. 5,004,613 (“the '613 patent”), entitled “ORAL SUSTAINED RELEASE PHARMACEUTICAL FORMULATION AND PROCESS”, was issued by the PTO on April 2, 1991, and expired no later than April 11, 2006. (See

Because the '613 patent has expired, it no longer can protect or cover anything.

20. U.S. Patent No. 5,436,026 (“the '026 patent”), entitled “DISCHARGE AND TRANSFER SYSTEM FOR APPARATUS FOR GELATIN COATING TABLETS”, was issued by the PTO on July 25, 1995. (See [While the '026 patent](http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnethtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=5,436,026.PN.&OS=PN/5,436,026&RS=PN/5,436,026.)

may not have yet expired, none of its claims can even arguably cover anything embodied or contained in a package of **TYLENOL® ARTHRITIS PAIN GELTABS.**

21. U.S. Patent No. 5,228,916 (“the '916 patent”), entitled “APPARATUS

FOR CREATING A GELATIN COATING”, was issued by the PTO on July 20, 1993. (See <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=5,228,916.PN.&OS=PN/5,228,916&RS=PN/5,228,916>.) While the '916 patent may not have yet expired, none of its claims can even arguably cover anything embodied or contained in a package of TYLENOL® ARTHRITIS PAIN GELTABS.

22. U.S. Patent No. 5,679,406 (“the '406 patent”), entitled “TABLET DIPPING SYSTEMS FOR APPARATUS FOR GELATIN COATING TABLETS”, was issued by the PTO on October 21, 1997. (See <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=5,679,406.PN.&OS=PN/5,679,406&RS=PN/5,679,406>.) While the '406 patent may not have yet expired, its sole claim cannot even arguably cover anything embodied or contained in a package of TYLENOL® ARTHRITIS PAIN GELTABS.

23. U.S. Patent No. 5,658,589 (“the '589 patent”), entitled “SUBCOATED SIMULATED CAPSULE-LIKE MEDICAMENT”, was issued by the PTO on August 19, 1997. (See <http://patft.uspto.gov/netacgi/nph-Parser?>

Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fmetahtml%2FPTO
%2Fsrchnum.htm&r=1&f=G&l=50&s1=5,658,589.PN.&OS=PN/5,658,589&RS=
PN/5,658,589.) While the '589 patent may not have yet expired, each of its independent claims recites, *inter alia*, “a subcoating consisting essentially of a mixture of hydroxypropylmethyl cellulose and castor oil.” Because TYLENOL® ARTHRITIS PAIN GELTABS utilize “hydroxyethyl” cellulose, rather than “hydroxypropylmethyl” cellulose, TYLENOL® ARTHRITIS PAIN GELTABS cannot even arguably fall within the scope of any claim of the '589 patent. (See Exhibit D (showing ingredient list), extracted from http://tylenol.com/product_detail.jhtml?id=tylenol/arth/prod_arth.inc&prod=subparth# .)

24. As a sophisticated company that, upon information and belief, employs multiple in-house patent attorneys and regularly litigates patent-infringement and false advertising cases, Defendant knows, or reasonably should know, of the requirements of 35 U.S.C. §292.

25. Upon information and belief, Defendant marks its TYLENOL® 8 HOUR CAPLETS products with “U.S. Patent Nos. 4,820,522, 4,968,509 and 5,004,613” for the purpose of deceiving the public into believing that something contained or embodied in its TYLENOL® 8 HOUR CAPLETS is covered or

protected by each of the listed patents.

26. Similarly, upon information and belief, Defendant marks its **TYLENOL® ARTHRITIS PAIN CAPLETS** products with “U.S. Patent Nos. 4,968,509 and 5,004,613” for the purpose of deceiving the public into believing that something contained or embodied in its **TYLENOL® ARTHRITIS PAIN CAPLETS** is covered or protected by each of the listed patents.

27. Furthermore, upon information and belief, Defendant marks its **TYLENOL® ARTHRITIS PAIN GELTABS** products with “U.S. Patent Nos. 5,658,589; 5,436,026; 5,228,916; 5,679,406; 4,968,509 and 5,004,613” for the purpose of deceiving the public into believing that something contained or embodied in its **TYLENOL® ARTHRITIS PAIN GELTABS** is covered or protected by each of the listed patents.

28. Upon information and belief, Defendant knows, or reasonably should know, that marking the above-described **TYLENOL®** products with false patent statements was and is illegal under Title 35 of the 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.

29. Each time Defendant makes, has made, uses, offers to sell, or sells within the United States, or imports into the United States, **TYLENOL®** products

containing false patent marking, such as described above, Defendant commits at least one "offense," as defined in 35 U.S.C. §292(a).

30. Each time Defendant uses false patent statements in its advertising or promotion of TYLENOL® products, Defendant commits at least one "offense," as defined in 35 U.S.C. §292(a).

Defendant's TYLENOL® Internet Advertising

31. Since at least 2008, Defendant has promoted its TYLENOL® brand products through an Internet Web Site identified by the URL www.tylenol.com. (See <http://tylenol.com/page.jhtml;jsessionid=AAMNLO5CM5I5ICQPCB3SUYYKB2IIWNSC?id=/tylenol/include/legal.inc&requestid=913608> ("All content of this Internet site is owned or controlled by McNeil Consumer Healthcare Division of McNeil-PPC, Inc. and is protected by worldwide copyright laws.").)

32. Defendant's Web site contains false patent information, including the statements "TYLENOL® Arthritis Pain Caplets or Geltabs use a unique patented bilayer formulation" (see <http://tylenol.com/print.jhtml?id=tylenol/arth/arthlpfaqprint.inc>) and "TYLENOL® has patented technology and clinical trials no store brand can match" (see <http://tylenol.com/different/index.jhtml>).

33. Defendant's Web site even lists multiple reasons why TYLENOL® is

allegedly superior to “store brand” pain relievers, and the first listed reason is the (untrue) fact that “TYLENOL® has patented technology.” (See id.)

34. For at least the reasons detailed above, Defendant knows, or reasonably should know, that the patent-related statements on its Web site are false and violate 35 U.S.C. §292.

35. Upon information and belief, Defendant publishes false patent information on its Web site for the purpose of deceiving the public into believing that unpatented TYLENOL® brand products contain or embody “patented technology.”

36. Each time Defendant transmits, over the Internet, TYLENOL® promotional content containing false patent information or assertions, Defendant commits at least one “offense,” as defined in 35 U.S.C. §292.

Defendant's TYLENOL® Radio Advertising Campaign

37. In or about 2009, Defendant launched a radio advertising campaign that included at least one radio commercial (“the Radio Commercial”) that described TYLENOL® products as having “patented technology ... no store brand can match.”

38. Upon information and belief, Defendant knows, or reasonably should

know, that the Radio Commercial contains at least one false patent assertion that violates 35 U.S.C. §292.

39. Upon information and belief, Defendant has caused the Radio Commercial to be broadcast on stations throughout the United States, including stations in the New York and San Francisco metropolitan areas.

40. Upon information and belief, Defendant has and does cause the Radio Commercial to be broadcast with the intent to deceive the public into believing that unpatented TYLENOL® brand products contain or embody “patented technology.”

41. Each time the Radio Commercial is broadcast that contains false patent information or assertions, Defendant commits at least one “offense,” as defined in 35 U.S.C. §292.

PRAYER FOR RELIEF

WHEREFORE, plaintiff PUBPAT respectfully requests that this Court:

(1) Find that Defendant's manufacture, promotion, advertising, marketing, sale and/or distribution of products with false patent markings or false patent assertions violate 35 U.S.C. §292(a);

(2) Determine an appropriate "fine," not more than \$500 per offense, but sufficient to appropriately penalize Defendant's violations of §292(a), and to deter

Defendant and others similarly situated from violating §292(a) in the future;

(3) Direct that half of the fine be paid to the United States government pursuant to §292(b); and,

(4) Direct that the other half of the fine be paid to PUBPAT pursuant to §292(b).

Request for Jury Trial

Pursuant to Fed. R. Civ. P. 38(b)(1), PUBPAT hereby demands a jury trial on all issues so triable.

Respectfully submitted,

PUBLIC PATENT FOUNDATION, INC.



By: _____

Dated: New York, New York
June 15, 2009

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EXHIBIT A

EXP: 3 0045-0297-242



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RT
15

TYLENOL 8 Hour
24 CAPSULES 650 mg each

Drug Facts (continued)	
Directions (see overdose warning)	
adults and children 12 years and over	<ul style="list-style-type: none"> take 2 capsules every 8 hours with water swallow whole—do not crush, chew or dissolve do not take more than 6 capsules in 24 hours do not use for more than 10 days unless directed by a doctor do not use
children under 12 years	<ul style="list-style-type: none"> do not use
Other information	
<ul style="list-style-type: none"> store at 20° - 25°C (68° - 77°F). Avoid excessive heat 40°C (104°F). do not use if caplet is opened or cracked or if the inner seal is tampered with. "Safety Seal" is broken. see end panel for lot number and expiration date. 	
Inactive ingredients corn starch, D&C yellow #10, FD&C red #40, FD&C yellow #6, hydroxyethyl cellulose.	

Drug Facts (continued)
magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, sucralose, talc, titanium dioxide

Questions or comments?
call 1-877-895-3685 (English) or 1-888-465-6746 (Spanish)

Distributed by:
MCKEL - PPC, INC., FORT WASHINGTON, PA 19034 USA
© MCK-PPC, Inc. 05 www.tylenol.com
U.S. Pat. Nos. 4,826,522, 4,568,508 and 5,094,615



TYLENOL 8 Hour
24 CAPSULES 650 mg each

Drug Facts	
Uses	
<ul style="list-style-type: none"> temporarily relieve minor aches and pains due to: <ul style="list-style-type: none"> muscular aches headache the common cold ear, tooth or arthritis temporarily reduce fever 	

8731940

Drug Facts (continued)

Warnings
Alcohol warnings: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers or fever reducers. Acetaminophen may cause liver damage.

Do not use with any other product containing acetaminophen

Stop use and ask a doctor if:

- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- itching or swelling is present

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

EXHIBIT D

Ingredients

Active Ingredient: Acetaminophen
Purpose: Pain reliever/Fever reducer



* Use only as directed

	Active Ingredients	Inactive Ingredients
Caplet	Acetaminophen 650 mg in each caplet	Carnauba wax, corn starch, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin.
Gelcap	Acetaminophen 650 mg in each gelcap	Butylparaben, castor oil, corn starch, edetate calcium disodium, FD&C Blue #1 aluminum lake, FD&C Blue #2 aluminum lake, gelatin, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, powdered cellulose, pregelatinized starch, shellac, sodium lauryl sulfate, sodium starch glycolate, titanium dioxide.