

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

THOMAS A. SIMONIAN,

Plaintiff,

v.

NOVARTIS CONSUMER HEALTH, 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 NOVARTIS CONSUMER HEALTH, 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 Prevacid® branded products with United States Patent Number 4,628,098 (“the ‘098 Patent”) even though the ‘098 Patent is expired, and has been expired since May 10, 2009. On information and belief, Defendant marks certain of its Prevacid® branded products with the expired ‘098 Patent 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 a person residing in Geneva, Illinois.

5. Defendant NOVARTIS CONSUMER HEALTH, INC. is a Corporation established under the laws of the State of Delaware with its principal place of business at 200 Kimball Drive, Parsippany, New Jersey 07054-0622.

6. Upon information and belief, Defendant is one of the largest pharmaceutical companies in the world.

7. Upon information and belief, Prevacid®24HR was first made available May 14, 2009. Defendant issued a Press Release on May 14, 2009 wherein it announced “today that Prevacid®24HR (lansoprazole delayed-release capsules 15 mg) has been approved by the U.S. Food and Drug Administration (FDA) as the first over-the-counter (OTC) Proton Pump Inhibitor (PPI) for the treatment of frequent heartburn since 2003.” (see <http://www.novartis.com/newsroom/media-releases/en/2009/1314777.shtml>, last visited Feb 24, 2010).

8. Upon information and belief, the FDA approved Prevacid®24HR on May 14, 2009, four days after the ‘098 Patent expired on May 10, 2009.

9. Defendant markets Prevacid®24HR as “the first and only over-the-counter (OTC) Proton Pump Inhibitor (PPI) for the treatment of frequent heartburn in its original formulation.” (see <http://www.novartis.com/newsroom/media-releases/en/2009/1354451.shtml>, last visited Feb 24, 2010). Defendant further states that “Prevacid®24HR works differently from other over-the-counter heartburn treatments.” (see <http://www.prevacid24hr.com/prevacid24hr-difference.jsp>, last visited Feb 24, 2010 and product packaging).

II.
JURISDICTION AND VENUE

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

11. 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.

12. 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.

III.
THE '098 PATENT

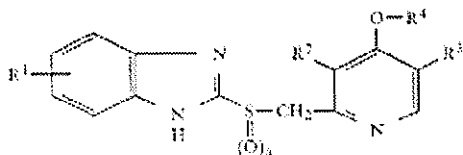
13. The '098 Patent, entitled "2-[2-pyridylmethylthio-(sulfinyl)]benzimidazoles," was filed on July 29, 1985, issued on December 9, 1986 and was originally set to expire on July 29, 2005. The U.S. Patent and Trademark Office extended the patent term under 35 U.S.C. 156 for 1,381 days. Thus, the '098 Patent expired May 10, 2009. A true and correct copy of the '098 Patent is attached hereto as Exhibit A. Additionally, a true and correct copy of the Certificate Extending Patent Term is attached hereto as Exhibit B.

14. Upon information and belief, Prevacid®24HR is comprised of lansopazole delayed-release capsules.

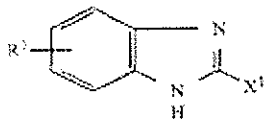
15. Upon information and belief, the '098 Patent relates to pyridine derivatives useful as e.g. anti-ulcer agents and to a method of preparing them. The summary of the invention section of the '520 Patent states in relevant parts as follows:

"It is considered that gastrointestinal ulcer is induced by unbalance between aggressive factors, e.g. hydrochloric acid, pepsin, and defensive factors, e.g. mucus secretion and mucosal blood flow. Therefore, a medicine having both an action of inhibiting gastric acid secretion and an action of enhancing protection of gastric mucosa has been desired.

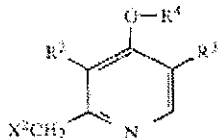
The present inventors diligently studied with the purpose of preparing an anti-ulcer agent having excellent actions of inhibiting gastric acid secretion, of protecting gastric mucosa and of antagonizing ulceration. They found that a certain type of pyridine derivatives meets the said purpose, and they conducted further study to accomplish the present invention.
 (1) pyridine derivatives of the formula (I)



wherein R₁ is hydrogen, methoxy or trifluoromethyl, R₂ and R₃ are independently hydrogen or methyl, R₄ is a C₂₋₅ fluorinated alkyl, and n denotes 0 or 1, or their pharmacologically acceptable salts and (2) a method for preparing a compound (I) or its pharmacologically acceptable salt, which comprises allowing a compound of the formula (II)



wherein R₁ is of the same meaning as defined above, to react with a compound of the formula (III)



wherein R₂, R₃ and R₄ are of the same meaning as defined above, one of X₁ and X₂ is SH and the other is a leaving group and, when necessary, by subjecting the reaction product to oxidation." (col. 1-2, lines 35 – 4)

IV. COUNT I

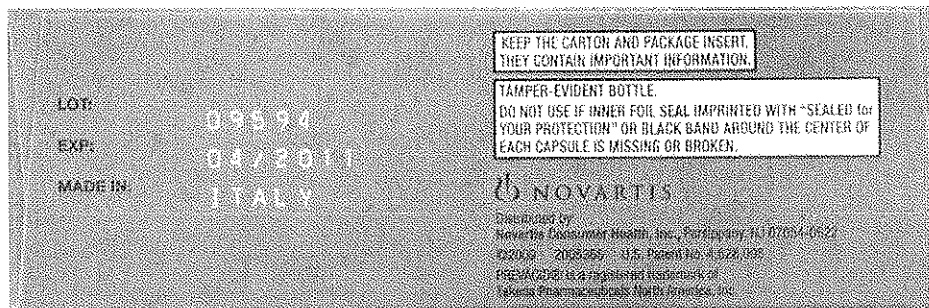
16. Plaintiff incorporates paragraphs 1-15 as if fully set forth herein.
17. Upon information and belief, Defendant has in the past manufactured and marketed, or caused to be manufactured and marketed, and presently manufactures and markets,

or causes to be manufactured or marketed, products for sale to the general consuming public, including, for example, its Prevacid®24HR branded drugs for treating heartburn.

18. The '098 Patent expired on May 10, 2009.

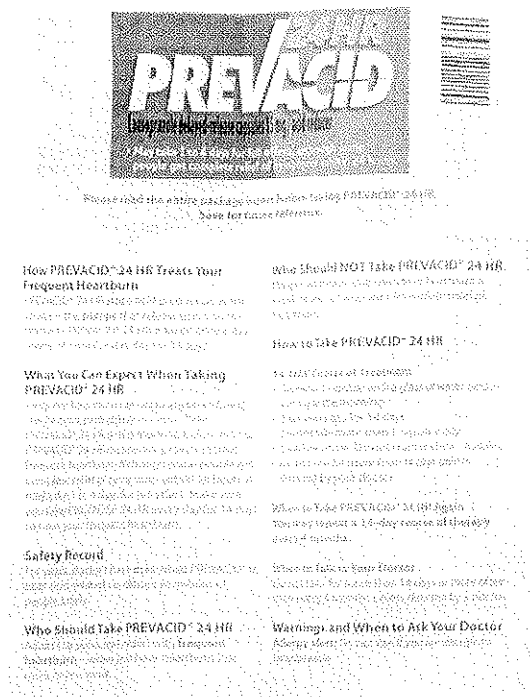
19. Upon information and belief, Defendant has in the past marked, or caused to be marked, and presently marks, or causes to be marked, for example, but not limited to, at least the following products and/or packaging thereof, with the expired '098 patent: Prevacid®24HR.

20. Prevacid®24HR is currently sold in packaging marked as shown below:





21. The “Package Insert” referred to on the Prevacid®24HR packaging includes a marking of the expired ‘098 patent.



Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- liver disease
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if

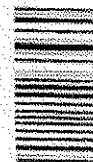
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Tips for Managing Heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
- Eat slowly and do not eat big meals.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.



Clinical studies prove PREVACID® 24 HR effectively treats frequent heartburn
In three clinical studies, PREVACID® 24 HR was shown to be significantly better than placebo in treating frequent heartburn.

How PREVACID® 24 HR is Sold

PREVACID® 24 HR is available in 14 capsule, 28 capsule and 42 capsule sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

For Questions or Comments About PREVACID® 24 HR

Call 1-800-452-0051 or visit us at www.prevacid24hr.com

Distributed by: Novartis Consumer Health, Inc., Parsippany, NJ 07054-0622
©2009 2004864 U.S. Patent No. 4,628,098
PREVACID® is a registered trademark of Takeda Pharmaceuticals North America, Inc.

Distributed by: **Novartis Consumer Health, Inc.**, Parsippany, NJ 07054-0622

©2009 2004864 U.S. Patent No. 4,628,098

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22. Defendant markets Prevacid®24HR with a marking of the expired '098 patent on its website (see <http://www.prevacid24hr.com/pdfs/PackageInsert.pdf>, last viewed Feb 24, 2010), as shown below:



Please read the entire package insert before taking PREVACID[®] 24 HR. Save for future reference.

How PREVACID[®] 24 HR Treats Your Frequent Heartburn

PREVACID[®] 24 HR stops acid production at the source — the pumps that release acid into the stomach. PREVACID[®] 24 HR is taken once a day (every 24 hours), every day for 14 days.

What You Can Expect When Taking PREVACID[®] 24 HR

Frequent heartburn can occur anytime during the 24-hour period (day or night). Take PREVACID[®] 24 HR in the morning before eating. PREVACID[®] 24 HR is clinically proven to treat frequent heartburn. Although some people get complete relief of symptoms within 24 hours, it may take 1 to 4 days for full effect. Make sure you take PREVACID[®] 24 HR every day for 14 days to treat your frequent heartburn.

Safety Record

For years, doctors have prescribed PREVACID[®] to treat acid-related conditions in millions of people safely.

Who Should Take PREVACID[®] 24 HR

Adults (18 years and older) with frequent heartburn — when you have heartburn 2 or more days a week.

Who Should NOT Take PREVACID[®] 24 HR

People who have one episode of heartburn a week or less, or who want immediate relief of heartburn.

How to Take PREVACID[®] 24 HR

14-DAY Course of Treatment

- Swallow 1 capsule with a glass of water before eating in the morning.
- Take every day for 14 days.
- Do not take more than 1 capsule a day.
- Swallow whole. Do not crush or chew capsules.
- Do not use for more than 14 days, unless directed by your doctor.

When to Take PREVACID[®] 24 HR Again

You may repeat a 14-day course of therapy every 4 months.

When to Talk to Your Doctor

Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

Warnings and When to Ask Your Doctor

Allergy alerts: Do not use if you are allergic to lansoprazole.

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- your disease
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine for HIV infection)

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Tips for Managing Heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.

- Eat slowly and do not eat big meals.
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- If you are overweight, lose weight.
- If you smoke, quit smoking.

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For Questions or Comments About PREVACID® 24 HR

Call 1-800-452-0051 or visit us at www.prevacid24hr.com

© 2009, Boehringer-Ingelheim Health, Inc., Division of BMS. 090309

U.S. Patent 4,658,098

PREVACID® is a registered trademark of Takeda Pharmaceutical, Ltd. All other marks

23. The instances of false marking shown in paragraphs 19-22 are representative and not exhaustive.

24. 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.

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

26. Upon information and belief, Defendant has an in-house legal department.

27. Upon information and belief, attorneys in Defendant's in-house legal department are responsible for Defendant's intellectual property and marketing, labeling, and advertising law.

28. 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.

29. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '098 Patent marked on the Prevacid®24HR has expired.

30. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the Prevacid®24HR are not covered by the expired '098 Patent marked on such products because an expired patent has no prospective patent rights.

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

32. As a sophisticated company with, upon information and belief, in-house attorneys who regularly litigate or oversee litigation of patent infringement cases and who regularly prosecute or oversee patent prosecution, Defendant knows, or reasonably should know, of the requirements of 35 U.S.C. §292.

33. The false patent marking for the Prevacid®24HR is found on the product packaging. (*See* paragraphs 19-22 above)

34. Upon information and belief, Defendant intentionally included the expired '098 Patent in the patent markings of the Prevacid®24HR, in an attempt to prevent competitors from using the same or similar heartburn medications.

35. Upon information and belief, Defendant marks the Prevacid®24HR with the expired '098 Patent for the purpose of deceiving the public into believing that something contained in or embodied in the products is covered by or protected by the expired '098 patent.

36. Each false marking on the Prevacid®24HR is likely to, or at least has the potential to, discourage or deter persons and companies from commercializing competing products.

37. Defendant has wrongfully and illegally advertised a patent right which it does not possess and, as a result, has benefitted commercially and financially by maintaining false statements of patent rights.

38. Upon information and belief, Defendant knows, or reasonably should know, that marking the Prevacid®24HR 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.

39. Upon information and belief, Defendant's marking of its Prevacid®24HR with the expired '098 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.

40. 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 Prevacid®24HR in the market place.

41. For at least the reasons provided herein, and/or for reasons which will be later evidenced, each expired patent which is marked on a product contributes to causing harm to the Plaintiff, the United States and the general public.

42. Thus, each expired patent marked on a product, directly or on the packaging 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.
PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment against Defendant as follows:

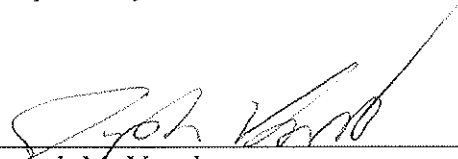
- (a) A decree that Defendant has falsely marked products in violation of 35 U.S.C. §292;
- (b) An award of monetary damages, pursuant to 35 U.S.C. § 292, in the form of a civil monetary fine of \$500 per false marking “offense,” or an alternative amount as determined by the Court, one half of which 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.

VI.
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: February 24, 2010

Respectfully submitted,



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