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

THOMAS A. SIMONIAN,

Plaintiff,

v.

NOVARTIS ANIMAL HEALTH US, 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 ANIMAL HEALTH US, 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 Interceptor® branded products with United States Patent Number 4,547,520 ("the '520 Patent") even though the '520 Patent is expired, and has been expired since July 25, 2005. On information and belief, Defendant marks certain of its Interceptor® branded products with the expired '520 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 ANIMAL HEALTH US, INC. is a Corporation established under the laws of the State of Delaware with its principal place of business at 3200 Northline Avenue, Suite 300, Greensboro, North Carolina 27408.

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

7. Defendant markets Interceptor® Flavor Tabs® as "the only oral monthly preventive that protects against four parasites all at once." Defendant further states that "Nothing else can protect your dog from parasites like INTERCEPTOR Flavor Tabs can." (see http://www.interceptor.novartis.us/dog/en/about.shtml, last visited on Feb 24, 2009). Defendant further states that "Nothing else can protect your cat from heartworms and remove adult hookworms and roundworms, as effectively as INTERCEPTOR Flavor Tabs for cats can." (see http://www.interceptor.novartis.us/cat/en/about.shtml, last visited Feb 24, 2010).

II.
JURISDICTION AND VENUE

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

9. 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.

10. 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 '520 PATENT

11. The '520 Patent, entitled "5-Oxime Derivatives of Milbemycins and Veterinary and Agricultural Use Thereof," was filed on November 25, 1983, issued on October 15, 1985 and was originally set to expire on November 25, 2003. The U.S. Patent and Trademark Office extended the patent term under 35 U.S.C. 156 for 608 days. Thus, the '520 Patent expired July 25, 2005. A true and correct copy of the '520 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.

12. Upon information and belief, Inceptor® Flavor Tabs® are comprised of tablets formulated to provide a minimum of 0.9 mg/lb body weight of milbemycin oxime, which consists of oxime derivatives of 5-didehydromilbemycins in the ration of approximately 80% A_4 ($C_{32}H_{45}NO_7$, MW 555.71) and 20% A_3 ($C_{31}H_{43}NO_7$, MW 541.68).

13. Upon information and belief, the '520 Patent discloses a series of derivatives of the compounds known as "milbemycins," particularly of milbemycin A_3, milbemycin A_4 and milbemycin D. The summary of the invention section of the '520 Patent states in relevant parts as follows:

> *"The compounds of the invention are 5-oxime derivatives of 5-didehydromilbemycins, and may be represented by the formula (II)[...]*
>
> *The invention also provides an anthelmintic, acaricidal and insecticidal composition comprising an anthelmintic, acaricidal and insecticidal compound in admixture with a pharmaceutically, agriculturally or horticulturally acceptable carrier or diluent, wherein the compound is selected from compounds of formula (II), their salts, their esters and mixtures thereof.*

The invention still further provides a method of treating an animal, which may be human or non-human, parasitized by a parasite selected from helminths, acarids and insects, which comprises applying to or administering to said animal an active compound, wherein said active compound is selected from compounds of formula (II), their salts, their esters and mixtures thereof." (col. 1-2, lines 65 – 43)

IV.
COUNT I

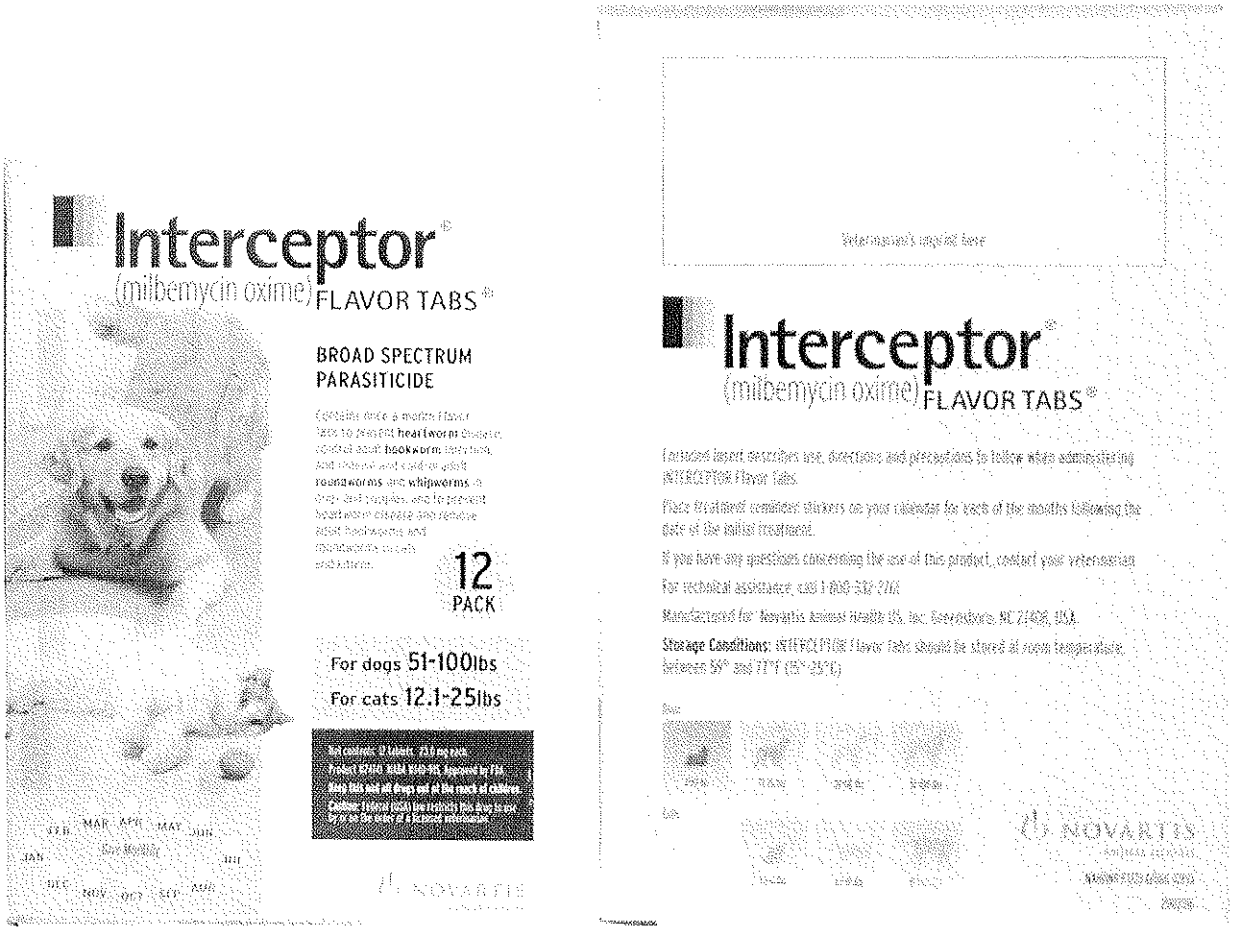
14. Plaintiff incorporates paragraphs 1-14 as if fully set forth herein.

15. 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 Interceptor® branded drugs for preventing heartworm, controlling/removing roundworms and hookworm in pets, specifically cats and dogs.

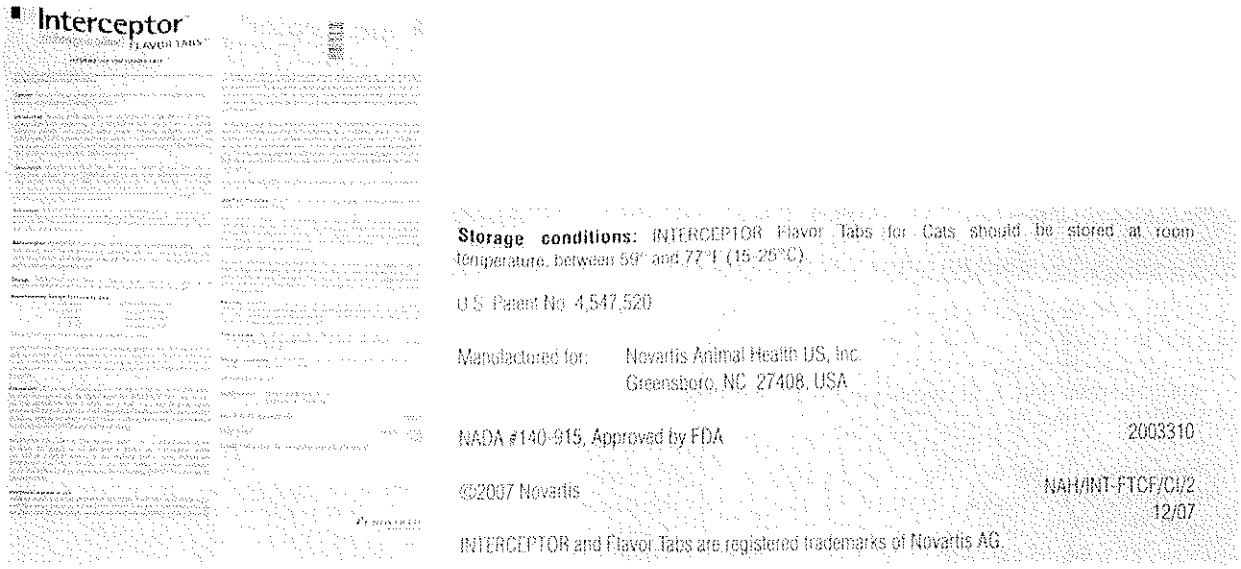
16. The '520 Patent expired on July 25, 2005.

17. 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 '520 patent: Interceptor® Flavor Tabs®.

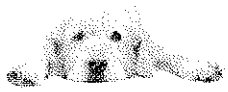
18. Interceptor® Flavor Tabs® are currently sold in packaging marked as shown below (next page):



19. The "Enclosed insert" referred to on the Interceptor® Flavor Tabs® packaging includes a marking of the expired '520 patent, as shown below:



20. Defendant markets Interceptor® Flavor Tabs® with a marking of the expired '520 patent on its website (see http://www.interceptor.novartis.us/cat/en/label.shtml, last visited Feb 24, 2010). The website is marked as shown below (next page):



Home > Dogs > Product Information

INTERCEPTOR® Flavor Tabs® for Dogs Product Information

Information for dosing dogs

The palatable anthelmintic tablet that prevents heartworm disease, controls adult hookworm and removes and controls adult roundworm and whipworm infections in dogs and puppies.

Caution

U.S. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description

INTERCEPTOR (milbemycin oxime) Flavor Tabs are available in four tablet sizes in color-coded packages for oral administration to dogs and puppies. Each tablet is formulated to provide a minimum of (0.23 mg/lb (0.5 mg/kg) body weight of milbemycin oxime. Milbemycin oxime consists of the oxime derivatives of 5-didehydronarbomycins in the ratio of approximately 80% A_4 ($C_{32}H_{45}NO_7$, MW 555.71) and 20% A_3 ($C_{31}H_{43}NO_7$, MW 541.68).

Package color	Milbemycin oxime tablet
Brown	2.3 mg
Green	5.75 mg
Yellow	11.5 mg
White	23.0 mg

Indications

INTERCEPTOR Flavor Tabs are indicated for use in the prevention of heartworm disease caused by *Dirofilaria immitis*, the control of adult *Ancylostoma caninum* (hookworm), and the removal and control of adult *Toxocara canis* and *Toxascaris leonina* (roundworms) and *Trichuris vulpis* (whipworm) infections in dogs and in puppies four weeks of age or greater, and two pounds body weight or greater.

Dosage

INTERCEPTOR Flavor Tabs are given orally, once a month, at the recommended minimum dosage rate of 0.23 mg milbemycin oxime per pound of body weight (0.5 mg/kg).

Recommended Dosage Schedule for Dogs

Body Weight	INTERCEPTOR Flavor Tabs
2-10 lbs.	One tablet (2.3 mg)
11-25 lbs.	One tablet (5.75 mg)
26-50 lbs.	One tablet (11.5 mg)
51-100 lbs.	One tablet (23.0 mg)

Dogs over 100 lbs. are provided the appropriate combination of tablets.

Administration

INTERCEPTOR Flavor Tabs are palatable and most dogs will consume the tablet willingly when offered by the owner. As an alternative, the dual-purpose tablet may be offered in food or administered as other tablet medications. Watch the dog closely following dosing to be sure the entire dose has been consumed. If it is not entirely consumed, redose once with the full recommended dose as soon as possible.

INTERCEPTOR Flavor Tabs must be administered monthly, preferably on the same date each month. The first dose should be administered within one month of the dog's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. If a dose is missed and a 30-day interval between dosing is exceeded, administer INTERCEPTOR Flavor Tabs immediately and resume the monthly dosing schedule.

If INTERCEPTOR Flavor Tabs replaces diethylcarbamazine (DEC) for heartworm prevention, the first dose must be given within 30 days after the last dose of DEC.

Palatability

Palatability trials conducted in 244 dogs from 10 different U.S. veterinary practices demonstrated that INTERCEPTOR Flavor Tabs were willingly accepted from the owner by over 95% of dogs. The trial was comprised of dogs representing 60 different breeds and both sexes.

with weights ranging from 2.1 lbs. to 140.3 lbs., and ages ranging from 8 weeks to 15 years.

Precautions

Do not use in puppies less than four weeks of age and less than two pounds of body weight. Prior to initiation of the INTERCEPTOR Flavor Tabs treatment program, dogs should be tested for existing heartworm infections. Infected dogs should be treated to remove adult heartworms and microfilariae prior to initiating treatment with INTERCEPTOR Flavor Tabs. Mild, transient hypersensitivity reactions manifested as labored respiration, vomiting, salivation and lethargy, have been noted in some treated dogs carrying a high number of circulating microfilariae. These reactions are presumably caused by release of protein from dead or dying microfilariae.

Adverse Reactions

The following adverse reactions have been reported following the use of INTERCEPTOR:

Depression/lethargy, vomiting, ataxia, anorexia, diarrhea, convulsions, weakness and hyperactivation.

Efficacy

INTERCEPTOR Flavor Tabs eliminate the tissue stage of heartworm larvae and the adult stage of hookworm (*Ancylostoma caninum*), roundworms (*Toxocara canis*, *Toxascaris leonina*) and whipworm (*Trichuris vulpis*) infestations when administered orally according to the recommended dosage schedule. The anthelmintic activity of milbemycin oxime is believed to be a result of interference with invertebrate neurotransmission.

Safety

INTERCEPTOR has been tested safely in over 75 different breeds of dogs, including collies, pregnant females, breeding males and females, and puppies over two weeks of age. In well-controlled clinical field studies, 786 dogs completed treatment with milbemycin oxime. Milbemycin oxime was used safely in animals receiving frequently used veterinary products such as vaccines, anthelmintics, antibiotics, steroids, flea collars, shampoos and dips.

Two studies in heartworm-infected dogs were conducted which demonstrated mild, transient hypersensitivity reactions in treated dogs with high microfilaremia counts (see Precautions for reactions observed). Safety studies in pregnant dogs demonstrated that high doses (3.5 mg/kg = 3X) of milbemycin oxime given in an exaggerated dosing regimen (daily from mating through weaning), resulted in measurable concentrations of the drug in milk. Puppies nursing these females which received exaggerated dosing regimens demonstrated milbemycin-related effects.These effects were directly attributable to the exaggerated experimental dosing regimen. The product is normally intended for once-a-month administration only. Subsequent studies included dosing 3X daily from mating to one week before weaning and demonstrated no effects on the pregnant females or their litters. A second study where pregnant females were dosed once at 3X the monthly use rate either before, on the day of or shortly after whelping resulted in no effects on the puppies.

Some nursing puppies, at 2, 4, and 6 weeks of age, given greatly exaggerated oral INTERCEPTOR doses (9.8 mg/kg = 19X) exhibited signs typified by tremors, vocalization and ataxia. These effects were all transient and puppies returned to normal within 24 to 48 hours. No effects were observed in puppies given the recommended dose of INTERCEPTOR (0.5 mg/kg). This product has not been tested in dogs less than 1 kg weight.

A range-dose safety study conducted in rough-coated collies manifested a clinical reaction consisting of ataxia, pyrexia and periodic recumbency in one of fourteen dogs treated with milbemycin oxime at 12.5 mg/kg (25X monthly use rate). Prior to receiving the 12.5 mg/kg dose (25X monthly use rate) on day 56 of the study, all animals had undergone an exaggerated dosing regimen consisting of 2.5 mg/kg milbemycin oxime (5X monthly use rate) on day 0, followed by 5.0 mg/kg (10X monthly use rate) on day 14 and 10.0 mg/kg (20X monthly use rate) on day 28. No adverse reactions were observed in any of the collies treated with this regimen up through the 10.0 mg/kg (20X monthly use rate) dose.

How Supplied

INTERCEPTOR Flavor Tabs are available in four tablet sizes (see Dosage section), formulated according to the weight of the dog. Each tablet size is available in color-coded packages of 6 or 12 tablets each, which are packaged 36 per display carton.

Storage Conditions

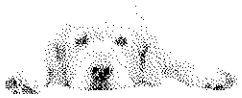
INTERCEPTOR Flavor Tabs should be stored at room temperature, between 59° and 86°F (15-30°C).

Keep this and all drugs out of the reach of children.

U.S. Patent No. 4,547,520

Manufactured for:
Novartis Animal Health US, Inc.
Greensboro, NC 27408, USA

NADA #140-915, Approved by FDA.



INTERCEPTOR® Flavor Tabs® for Cats Product Information

Information for dosing cats

The palatable once-a-month tablet that prevents heartworm disease and removes adult roundworms (*Toxocara cati*) and hookworms (*Ancylostoma tubaeforme*) in cats and kittens

Caution

U.S. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description

INTERCEPTOR Flavor Tabs for Cats are available in three tablet sizes in color-coded packages for oral administration to cats and kittens. Each tablet is formulated to provide a minimum of 0.6 mg/lb (2.0 mg/kg) body weight of milbemycin oxime. Milbemycin oxime consists of the oxime derivatives of 5-didehydroron lbemycins in the ratio of approximately 80% A_4 ($C_{31}H_{44}NO_7$; MW 543.68) and 20% A_3 ($C_{30}H_{42}NO_7$; MW 541.68).

Indications

INTERCEPTOR Flavor Tabs for Cats are indicated for use in the prevention of heartworm disease caused by *Dirofilaria immitis*, and the removal of adult *Ancylostoma tubaeforme* (hookworm) and *Toxocara cati* (roundworm) in cats and kittens six weeks of age or greater and 1.5 lbs. body weight or greater.

Dosage

INTERCEPTOR Flavor Tabs for Cats are given orally, once a month, at the recommended minimum dosage rate of 0.6 mg milbemycin oxime per pound of body weight (2.0 mg/kg).

Recommended Dosage Schedule for Cats

Body Weight	INTERCEPTOR Flavor Tabs
1.5 - 6 lbs.	One tablet (5.75 mg)
6.1 - 12 lbs.	One tablet (11.5 mg)
12.1 - 25 lbs.	One tablet (23.0 mg)

Cats over 25 lbs. are provided the appropriate combination of tablets.

Administration

INTERCEPTOR Flavor Tabs for Cats are palatable and may be offered by the owner as a treat. As an alternative, the tablet may be offered in food or administered as other tablet medications. The tablets can be broken for ease of administration. Watch the cat closely following dosing to be sure the entire dose has been consumed. If it is not entirely consumed, redose once with the full recommended dose as soon as possible.

INTERCEPTOR Flavor Tabs for Cats must be administered monthly, preferably on the same date each month. The first dose should be administered within one month of the cat's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. If a dose is missed and a 30-day interval between dosing is exceeded, administer INTERCEPTOR Flavor Tabs for Cats immediately and resume the monthly dosing schedule. It is recommended that cats be tested for existing heartworm infection prior to starting treatment with INTERCEPTOR Flavor Tabs for Cats. (See Precautions.)

Palatability

Palatability trials conducted in 72 cats demonstrated that INTERCEPTOR Flavor Tabs for Cats were successfully dosed by the owner when they either offered the tablet as a treat, placed the tablet in the cat's mouth or placed the tablet in the cat's food in 72% of cats. About 16% of the cats were manually dosed and 13% of the cats were not successfully dosed according to the protocol.

Precautions

Do not use in kittens less than six weeks of age or less than 1.5 lbs. body weight. Safety in heartworm-positive cats has not been established. Safety in breeding, pregnant and lactating queens, and breeding toms has not been established.

Efficacy

INTERCEPTOR Flavor Tabs for Cats eliminate the tissue stage of heartworm larvae and hookworm

(*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections when administered orally according to the recommended dosage schedule. The antiheartworm activity of milbemycin oxime is believed to be a result of interference with invertebrate neurotransmission.

Safety
INTERCEPTOR Flavor Tabs for Cats has been tested safely in over 8 different breeds of cats. In well-controlled clinical field studies 141 cats completed treatment with milbemycin oxime. Milbemycin oxime was used safely in animals receiving frequently used veterinary products such as vaccines, anthelmintics, anesthetics, antibiotics, steroids, flea collars, shampoos and dips.

Safety studies were conducted in young cats and kittens and doses of 1X, 3X and 5X the minimum recommended dose of 2.0 mg/kg demonstrated no drug-related effects. Tolerability studies at exaggerated doses of 10X also demonstrated no drug-related adverse effects in kittens and young adult cats.

How Supplied
INTERCEPTOR Flavor Tabs for Cats are available in three tablet sizes (see Dosage section), formulated according to the weight of the cat. Each tablet size is available in color-coded packages of 6 or 12 tablets each, which are packaged 10 per display carton.

Storage Conditions
INTERCEPTOR Flavor Tabs for Cats should be stored at room temperature, between 59° and 86°F (15-30°C).

Keep this and all drugs out of the reach of children.

U.S. Patent No. 4,547,520

Manufactured for:
Novartis Animal Health US, Inc.
Greensboro, NC 27408, USA

NADA #140-915, Approved by FDA.

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21. The instances of false marking shown in paragraphs 18-20 above are representative and not exhaustive.

22. 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.

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

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

25. 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.

26. 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.

27. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the '520 Patent marked on the Interceptor® Flavor Tabs® has expired.

28. Upon information and belief, Defendant knows, or should know (by itself or by its representatives), that the Interceptor® Flavor Tabs® are not covered by the expired '520 Patent marked on such products because an expired patent has no prospective patent rights.

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

30. 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.

31. The false patent markings for the Interceptor® Flavor Tabs® are found in the "Enclosed inserts" accompanying the product packaging. (*See* paragraph 19 above)

32. Upon information and belief, Defendant intentionally included the expired '520 Patent in the patent markings of the Interceptor® Flavor Tabs® Products, in an attempt to prevent competitors from using the same or similar oxime derivatives for veterinary use.

33. Upon information and belief, Defendant marks the Interceptor® Flavor Tabs® Products with the expired '520 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 '520 patent.

34. Each false marking on the Interceptor® Flavor Tabs® Products is likely to, or at least has the potential to, discourage or deter persons and companies from commercializing competing products.

35. 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.

36. Upon information and belief, Defendant knows, or reasonably should know, that marking the Interceptor® Flavor Tabs® 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.

37. Upon information and belief, Defendant's marking of its Interceptor® Flavor Tabs® with the expired '520 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.

38. 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 Interceptor® Flavor Tabs® in the market place.

39. 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.

40. 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

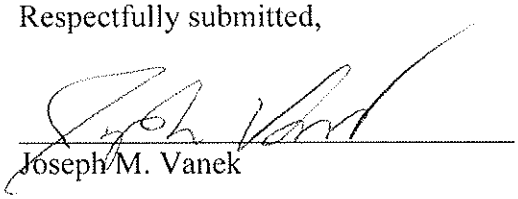
(e) Such other and further relief, at law or in equity, to which Plaintiff is justly entitled.

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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