

THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION

No. 5:10-cv-449:

BIOGAIA AB,

Plaintiff

v.

NATURE'S WAY PRODUCTS, INC.,

Defendant

COMPLAINT

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**INTRODUCTION**

1. This is a complaint for patent infringement and associated unfair competition involving probiotic dietary supplements advertised as containing *Lactobacillus reuteri*. Many if not all of these supplements contain *Lactobacillus reuteri* and are being sold and marketed in violation of patents owned and licensed by plaintiff. Some of these supplements, however, do not contain strains of *Lactobacillus reuteri* that have been proven effective as advertised by the defendant, and the advertising and sale of these supplements constitutes unfair competition. The defendant, a former licensee of plaintiff Biogaia AB, has willfully engaged in its infringing and unfairly competitive activities in order to reap the benefits of the inventions owned and licensed by plaintiff while avoiding payment therefor.

**PARTIES**

2. Plaintiff BIOGAIA AB (formerly named BIOGAIA BIOLOGICS AB and hereafter referred to as "Biogaia") is a corporation incorporated under the laws of Sweden, having its principal office or a place of business in Stockholm, Sweden and is the assignee and owner of the patents in suit, more fully described hereafter.

3. Biogaia sells and/or authorizes the sale of products covered by the patents in suit and its interests are harmed by the sale of Defendant's infringing and falsely advertised products.

4. Defendant NATURE'S WAY PRODUCTS, INC. ("Nature's Way") is a corporation incorporated under the laws of Utah. In May of 2001, Defendant applied to the Secretary of State of North Carolina for a Certificate of Authority to do business in North Carolina, received that Certificate, and has been continuously registered as a foreign corporation authorized to do business in North Carolina since that time. Defendant currently actively conducts business within the State of North Carolina and has a registered agent and registered office within North Carolina, each located in Raleigh, North Carolina.

5. Defendant's infringing and unfairly competitive products that are the subject of this litigation, as more fully described hereafter, are sold within the State of North Carolina, including in Raleigh and in Cary, North Carolina, and many of the acts of infringement and unfair competition hereafter described have occurred within the State of North Carolina.

#### **JURISDICTION AND VENUE**

6. This Court has jurisdiction over patent and unfair competition claims pursuant to 28 U.S.C. §1338, and supplemental jurisdiction, to the extent required, pursuant to 28 U.S.C. §1367. Venue is proper under 28 U.S.C. §§ 1391(b) and 1400(b).

#### **FACTS UNDERLYING ALL CLAIMS**

7. Biogaia is the owner of numerous inventions relating to the use of *Lactobacillus reuteri* which have been made the subject of legally and duly issued United States patents, referred to collectively hereafter as the Biogaia Patents. These patents include but are not limited to United States Patents 5,439,678 and 5,849,289, each of which is currently in full force and effect and

assigned to Biogaia, which has been and still is the owner of all rights in each patent assigned to it, including the right to sue for infringement:

8. In 1999, after Biogaia already had obtained a first patent pertaining to *Lactobacillus reuteri*, Nature's Way entered into an agreement licensing Nature's Way to use *Lactobacillus reuteri* in certain probiotic products. Pursuant to the license agreement, Biogaia was obligated to, and did, supply Nature's Way with documentation, technical information, and other information regarding *Lactobacillus reuteri* for the manufacture, distribution, marketing and sale of the licensed products; and Biogaia agreed to and did supply Nature's Way's approved manufacturers with supplies of *Lactobacillus reuteri* as needed to create the licensed products. Nature's Way agreed, in an amendment entered in 2006, that in order to maintain product quality, all products manufactured under the agreement would contain *Lactobacillus reuteri* in a minimum concentration of  $1 \times 10^8$  CFU per serving throughout the shelf life of the product.
9. On August 2, 2007, the license agreement between the parties expired and Nature's Way no longer has any right or license to manufacture or authorize the manufacture of product covered by any of Biogaia's patents.
10. On February 15, 2008, Biogaia gave express notice to Nature's Way of nine of Biogaia's United States Patents that already had issued, including but not limited to United States Patents 5,439,678 and 5,849,289, and also notified Nature's Way of the serial number of additional ones of Biogaia's United States Patents that had been published but had not yet issued.
11. Subsequent to termination of the license agreement and receipt of Biogaia's letter of February 15, 2008, Nature's Way continued to manufacture products that are or appear to be identical to or substantially similar to those manufactured under the license with Biogaia and covered by claims of the Biogaia Patents.

12. Nature's Way procures the manufacture of certain dietary supplement products that it sells and offers for sale under the following brand names (collectively referred to hereafter as the "Primadophilus Reuteri" products):

- *Primadophilus Reuteri* (currently sold under product numbers 14240, 14241, and 15024);  
and
- *Primadophilus Reuteri Pearls* (currently sold under product numbers 15770 and 15752).

13. Nature's Way asserts in advertising of the Primadophilus Reuteri products that they are helpful for digestion and immunity.

14. Nature's Way asserts in advertising of the Primadophilus Reuteri products that they are patented.

15. Packaging of the Primadophilus Reuteri products touts the beneficial role of *Lactobacillus reuteri* and includes claims of the efficacy of *Lactobacillus reuteri* in the Primadophilus Reuteri products, including the following:




**DIGESTION & IMMUNITY**

**WHY TAKE PRIMADOPHILUS® REUTERI?**  
Maintaining a proper level of *L. reuteri*, *L. rhamnosus* and *L. acidophilus* in the intestinal tract can help:

- Support healthy immune function\*
- Promote healthy digestion and nutrient uptake\*

Taking this product may also be helpful during episodes of digestive distress.

**What is Reuteri?**  
Pronounced roy'-tur-eye, this unique lactobacillus is naturally found in human breast milk, and is one of the first defenses a nursing mother passes to her child. When taken as a supplement, reuteri colonizes in the intestine and provides healthy benefits.



**SUPERIOR PROBIOTIC**

**PRIMADOPHILUS® REUTERI** fortifies the intestinal tract with a high potency of active lactobacillus cultures.

- **OVER 5 BILLION CFU** per serving
- **MULTI-STRAIN FORMULA** with *reuteri*, *rhamnosus* and *acidophilus*
- **ENTERIC-COATED** to survive stomach acid and deliver to the intestines
- **PLUS PREBIOTIC SUPPORT** with *NutraFlora®* scFOS (short-chain fructooligosaccharides) to optimally feed probiotics in the intestinal tract

**True Potency™ Guarantee**  
Primadophilus® Reuteri contains at least 5 billion CFU through to the date of expiration on this box. Most other probiotic brands claim their potency as of time of manufacture.



16. Nature's Way's advertising of the Primadophilus Reuteri products includes the following additional claims:

**Overview**

- 5 billion CFUs
- Enteric-coated Vcaps®
- Patented Probiotic
- Full Clinical Dose
- *L. Reuteri* plus *Acidophilus* & *Rhamnosus*

**Superior Colonization**

Reuteri uniquely contains the "AGGH" protein that encourages colonization in the digestive tract. In clinical use, reuteri supplements effectively colonize in over 90% of patients.

**Digestive Health**

Reuteri promotes healthy digestion and intestinal integrity.<sup>†</sup> It improves intestinal cell structures (longer villi and deeper crypts) for more efficient nutrient uptake and better health.<sup>†</sup>

**True Potency™** ensures 5 billion CFUs per capsule for the entire shelf life

**True Identity™** ensures only the strains listed on the label are found in the product

**True Release™** enteric-coating ensures stomach acid survival and intestinal delivery

17. Each of the Primadophilus Reuteri products is sold and advertised by Nature's Way in a manner designed to induce the purchaser to select the Primadophilus Reuteri product containing one or more strains of *Lactobacillus reuteri* in an amount effective to produce the results associated with such strains, and to feed it to a mammal, namely a human, as a probiotic in an amount sufficient to colonize the gastrointestinal tract of the human and achieve healthy digestion, healthy immune function including improved immunity to disease, reduction in digestive distress, improvements in nutrient uptake, and better health for the human taking it.

18. On information and belief, despite the claims made in its advertising, Nature's Way has not conducted clinical tests of its Primadophilus Reuteri products in order to determine the "full clinical dose" thereof, has not undertaken testing to determine whether "clinical use" of the Primadophilus Reuteri products supports its advertising claims, and has not undertaken testing of the particular strains of *Lactobacillus reuteri* used in its Primadophilus Reuteri products to determine whether those strains, in the amounts contained in the Primadophilus Reuteri products, fortify the intestinal tract at a significant level or produce the beneficial effects (for example, longer villi and deeper crypts) that Nature's Way claims.

19. At least some of the Primadophilus Reuteri products that contain *Lactobacillus reuteri* contain one or more of the following biologically pure strains that have been formulated into a product: DSM 17938, ATCC 55730, DSM20016, ATCC PTA 6475, ATCC PTA 5289 or ATCC PTA 4659; and in one at least case a so-far unidentified strain of *Lactobacillus reuteri*.

20. At least some of the Primadophilus Reuteri products contain strains of *Lactobacillus reuteri* that are capable of producing the antibiotic reuterin or a derivative thereof, under conditions for production of the antibiotic and is capable of producing  $\beta$ -hydroxypropionaldehyde.

21. The Primadophilus Reuteri products that do not contain strains of *Lactobacillus reuteri* that have been proven to provide useful benefits from the presence of such *Lactobacillus reuteri* strains, in amounts known to be sufficient to provide such benefits, nonetheless contain claims as to the efficacy of *Lactobacillus reuteri* on their packaging.

22. The sale by Nature's Way of Primadophilus Reuteri products without having a license to use the patents of BioGaia and in competition with the sales of probiotic *Lactobacillus reuteri* dietary supplements by Biogaia's authorized licensees, is damaging Biogaia both directly and by harming the relationships Biogaia enjoys with its licensees throughout the world, particularly those in the United States and Canada.

#### **COUNT I. WILLFUL PATENT INFRINGEMENT**

23. Notwithstanding its knowledge of Biogaia's patent rights, Nature's Way has for a long time past been, and still is, infringing the Biogaia Patents and inducing the infringement thereof, directly and contributorily, by procuring the manufacture of, importing into the United States, using and procuring the use of, and selling and offering for sale, *Lactobacillus reuteri* and probiotic dietary supplements containing *Lactobacillus reuteri* especially adapted for and/or embodying all or a material part of the inventive products covered by the Biogaia Patents, and sold for use in practicing the inventive methods of the Biogaia Patents, and will continue to do so unless enjoined by this Court.

24. The infringing products sold by Nature's Way include those Primadophilus Reuteri products containing *Lactobacillus reuteri* and the infringing material components imported by Nature's Way include *Lactobacillus reuteri* imported for use in Primadophilus Reuteri products, as well as various Primadophilus Reuteri products.

25. Nature's Way's infringements were and are willful and are causing damage to Biogaia, and will continue unless enjoined by this Court.

## **COUNT II. UNFAIR COMPETITION**

26. Nature's Way directly and by implication claims in its advertising that its Primadophilus Reuteri products contain *Lactobacillus reuteri* in a "full clinical dose" sufficient to "effectively colonize in over 90% of patients" and sufficient to favorably affect human health, and makes other claims as heretofore set out, despite the fact that not all of the products so advertised actually contain *Lactobacillus reuteri* in quantities, or effectiveness, sufficient to effectively colonize and to favorably affect human health and to meet the other claims made by Nature's Way.

27. Nature's Way directly and by implication claims in its advertising that its Primadophilus Reuteri products contain a patented probiotic, despite the fact that not all of the products so advertised contain a patented probiotic.

28. Nature's Way's advertising is false and misleading.

29. The false and misleading claims made by Nature's Way in its advertising are material and likely to influence the purchasing decisions of consumers.

30. Nature's Way's false and misleading advertising has the capacity to deceive a substantial segment of the intended audience including purchasers and prospective purchasers, and has actually deceived such persons.

31. Nature's Way has caused the Primadophilus Reuteri products that are the subject of its false and misleading advertising to enter interstate commerce and has sold those goods in interstate commerce and caused those goods to be sold into and within North Carolina and elsewhere within the United States, wrongfully enriching itself and damaging Biogaia.



### **COUNT III. FALSE PATENT MARKING**

32. Nature's Way advertised its Primadophilus Reuteri products claiming them to be patented with the intent of counterfeiting or imitating the mark of the patentee, of deceiving the public and inducing them to believe that the allegedly patented Primadophilus Reuteri products continued to be sold by or with the consent of Biogaia as they had been when Nature's Way was a licensee of Biogaia.

33. Nature's Way advertised its Primadophilus Reuteri products as patented for the purpose of deceiving the public.

34. Nature's Way's claims that its Primadophilus Reuteri products are patented constitute false marking of the products so advertised.

### **COUNT IV. UNFAIR AND DECEPTIVE ACTS IN NORTH CAROLINA COMMERCE**

35. A substantial part of Nature's Way's aforesaid wrongful acts have been directed towards the State of North Carolina and have been committed in commerce in the State of North Carolina; a substantial part of Nature's Way's aforesaid wrongful acts have been committed with respect to customers and prospective customers located in the State of North Carolina; and such acts have affected commerce in the State of North Carolina and have injured Biogaia, which does business in the State of North Carolina.

36. Nature's Way has willfully engaged in the aforesaid wrongful acts and has without warrant refused fully to resolve the matter constituting the basis of this action.

37. Biogaia has been damaged by the unfair and deceptive acts of Nature's Way.

### **DAMAGE**

38. The aforesaid wrongful acts of Nature's Way have damaged and are likely to damage the goodwill associated with Biogaia's products and the value of those products to Biogaia and its

licensees; have resulted in the accumulation of savings and profits to Nature's Way to which Nature's Way was not entitled; and have resulted in lost profits and/or other damage to Biogaia, the extent of which is not yet fully known.

39. There is no adequate remedy at law for said damages, and Biogaia is entitled to equitable relief in the form of an injunction against continued infringements and unfair competition by Nature's Way; the officers, agents, and employees of Nature's Way; and all others acting in association or concert with Nature's Way.

### **PRAYER FOR RELIEF**

WHEREFORE, Biogaia demands trial by jury as to all claims, and judgment against Nature's Way and in its favor on each count hereof, and:

1. An Order enjoining Defendant, its officers, agents, and affiliates from:
  - a. providing or selling products containing *Lactobacillus reuteri* in combination with advertisements or instructions of any nature suggesting that the products be consumed by, or fed to, humans or other animals;
  - b. otherwise infringing or contributing to infringement of the patents in suit;
  - c. advertising that their products contain any patented probiotic unless in fact the product does contain a patented probiotic in an effective amount;
  - d. continuing their unfair and deceptive trade practices, including but not limited to stating or implying in any way, whether through advertising, use of marks or patent claims, or otherwise, that Nature's Way or its products are associated with, endorsed by, or affiliated with Biogaia;
2. Requiring Nature's Way to pay the cost of remedial advertising directed to all persons who may have been misled by their false and misleading advertising;

3. Requiring Nature's Way to, for a time, post remedial advertising on any and all of their websites notifying all consumers who visit said websites of the false and misleading statements previously made and correcting those mis-statements;
4. Requiring Nature's Way to account for all monies that they have received on account of the wrongful conduct in which they have engaged;
5. Awarding to Biogaia its damages, including all monies received by Nature's Way on account of its wrongful acts, in excess of \$10,000;
6. Trebling all damages awarded to Biogaia as provided by law on account of the willful nature of Defendant's conduct;
7. Assessing against Nature's Way the penalties provided by 35 U.S.C. §292(a), in the amount of \$500 for each product sold during the time that Nature's Way falsely advertised its products as patented, with one-half of such penalties going to Biogaia and one-half going to the United States;
8. Awarding to Biogaia its attorneys' fees as well as the costs and other expenses of this litigation; and
9. Awarding to Biogaia such other and further relief as to the Court may seem just.

Respectfully submitted this the 20<sup>th</sup> day of October, 2010.

/s/Susan Freya Olive  
N.C. Bar No. 7252  
OLIVE & OLIVE, P.A.  
Attorneys for Plaintiff

500 Memorial Street  
P.O. Box 2049  
Durham, NC 27702  
(919) 683-5514  
Fax: (919) 683-5514  
Email: [emailboxEDNC@oliveandolive.com](mailto:emailboxEDNC@oliveandolive.com)