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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GNOSIS S.P.A., GNOSIS BIORESEARCH S.A., AND
GNOSIS U.S.A., INC.
Petitioners

v.

SOUTH ALABAMA MEDICAL SCIENCE FOUNDATION
Patent Owner

GNOSIS S.P.A., GNOSIS BIORESEARCH S.A., AND
GNOSIS U.S.A., INC.
Petitioners

v.

MERCK & CIE
Patent Owner

Case IPR 2013-00116
U.S. Patent No. 5,997,915

Case IPR 2013-00118
U.S. Patent No. 6,673, 381

Case IPR 2013-00119
U.S. Patent No. 7,172,778

Case IPR 2013-00117
U.S. Patent 6,011,040

REPLACEMENT DECLARATION OF AUDY KENT LADNER

<p>MERCK EXHIBIT REPLACEMENT 2022 <i>Gnosis v Merck & Cie</i> IPR2013-00117</p>

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I, Audy Kent Ladner, pursuant to 37 C.F.R. § 42.53, declare as follows:

I. Introduction

1. I am the Senior Vice President of Sales and Marketing for Nestle Health Science-Pamlab Inc. (“NHS-Pamlab”), a licensee of Merck & Cie (“Merck”) for U.S. Patent Nos. 5,997,915 (“915 patent”); 6,671,381 (“381 patent”); 7,172,778 (“778 patent”) (collectively the “Bailey patents”); and 6,011,040 (“’040 patent”).

2. My testimony here is based on my review of documents and material during the ordinary course of business as well as firsthand knowledge or information learned from other managers and/or employees of NHS-Pamlab in my capacity as an officer of the company.

3. I became an employee of NHS-Pamlab as of April 2013, when NHS-Pamlab purchased the operating assets of Pamlab Inc. and all of Pamlab Inc.’s subsidiaries, including Pamlab L.L.C., Red River Pharmaceuticals L.L.C. (“Red River”), and Pan American LLC (“Pan American”). Prior to April 2013, I was an employee of Pamlab Inc. and Pamlab L.L.C.

4. Pamlab LLC was the original licensee of the Bailey patents and the ’040 patent. Following the asset purchase, [REDACTED] became the

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licensee under the license agreement(s) between Merck & Cie and PamLab LLC.

5. For purposes of this document, I will use “PamLab” to refer to the activities of PamLab LLC and NHS-PamLab under the license with Merck.

II. Background and Experience

6. I received a Bachelor of Science Degree in Business Administration, with an emphasis in pharmaceutical sales from Southern Mississippi in Hattiesburg in 1990.

7. I have worked in the field of pharmaceutical sales and marketing for about 23 years. I began at Eli Lilly and Company in 1990 and held various positions regarding sales management, sales, sales training, and operations.

8. I joined PamLab LLC in 2006 as the Vice President of the Metafolin® Business Unit, which is responsible for Metafolin-containing products covered by the Merck license. Prior to the NHS-PamLab asset purchase in April 2013, I was President of PamLab LLC and Senior Vice President of PamLab Inc.

9. My current responsibilities include management of all of PamLab’s sales force and marketing. My prior responsibilities as of office of

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Pamlab LLC and Pamlab Inc. included the analytics we use to understand the market and forecast manufacturing, and the strategic aspects of our communication of our products to physicians. Based on my experience in my previous and current positions at Pamlab, I am aware of the market for our products and the products from third party companies that compete with our products.

III. Pamlab Background

10. Pamlab's primary business today is making and selling specialized medical food products that are prescribed for managing certain medical conditions.

11. We began as a small cough and cold medicine company, then grew to the company it is today, which generates over \$[REDACTED] million in revenues, primarily based on sales of products that are licensed under the Bailey patents and the '040 patent.

12. We employ more than 140 people who work in Louisiana at our facilities in Covington and Shreveport. We do our R&D and product development in the U.S., and we manufacture most of our products ourselves, here in the U.S. We are proud of the products we offer and the standard we maintain in developing, testing and manufacturing those products.

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13. PamLab is unique in the market because it offers health care providers high quality prescription medical foods to safely address the distinct nutritional requirements of patients suffering from various medical conditions. Whereas, in general, traditional drugs are usually a "one molecule fits all" approach. We use current breakthroughs in genetics to create science-based personalized nutritional solutions available to the market.

14. One particular differentiator that makes our product unique is our use of Merck's Metafolin® as our L-methylfolate ingredient. I understand Metafolin® is a synthetic form of 5-methyl-(6S)-tetrahydrofolic acid calcium salt. Metafolin® is considered substantially chirally pure because it consists of more than 99% of the active "L" isomer and less than 1% of the inactive "D" isomer. The term "L-methylfolate" refers to the natural isomer of reduced folate, 5-methyl-(6S)-tetrahydrofolic acid. This ingredient significantly increases the quality of our products.

15. PamLab was founded as Pan American Laboratories, Inc. in 1957. There was a change in ownership in 1987 that was really the beginning of the company that existed up until April 2013.

16. PamLab started out as a cough and cold company with product lines that focused on antihistamines, decongestants, cough medicines,

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expectorants, and muscle relaxers. Over time, however, PamLab transitioned itself into a provider of prescription medical food products. In particular, after we entered into the Merck license, we went in the direction of selling a line of products that are in the category of medical foods and foods for special dietary use (NeevoDHA®), which is a classification defined by the U.S. Food and Drug Administration.

IV. Merck-PamLab License

17. PamLab entered into a license with Merck in 2002. The latest agreement between Merck and PamLab was signed in 2013.

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19. Over the course of the life of the licensing relationship between Merck and PamLab, the parties signed a number of Amendments and extensions to the original April 2002 License Agreement, with the most recent amendment occurring in 2013.

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22. PamLab was willing to enter into a license with Merck because it also desired to avoid infringement and obtain strong patent protection for the significant investment it would make in developing its new line of

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products utilizing the Merck Metafolin ingredient. At the time, we believed in the validity of the Bailey and '040 patents.

23. Further, the Merck-Pamlab license has been amended numerous times. These amendments generally have expanded the scope and duration of the license to include additional products, additional dosages and additional fields of use. Our decision to extend the license is premised on our belief in the strength and validity of the patents, as reflected in the significant investments made in developing, manufacturing, and commercializing the Pamlab Patented Products for over 10 years as well as our enforcing the patents against multiple third party infringers.

24. Pamlab has viewed and still views its license agreements with Merck and the intellectual property licensed under them as valuable assets that allowed Pamlab to develop, manufacture, and sell commercially successful products, namely the Pamlab Patented Products. Pamlab believed there was a great deal of value in the inventions covered by the license agreements. Also, Pamlab considered the patents covering those inventions as important for its continued goals in bringing worthwhile products to certain populations and thus, sought ways to expand the scope of the agreements to capture more of the value of the intellectual property covered by those agreements.

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25. Accordingly, PamLab desired the license expansions and extensions because it recognized the opportunities the licensed patents provided. After an initial period of study and development, since entering into the license with Merck, PamLab has sold products under the license continuously. As a result, PamLab has experienced tremendous growth based on the success of the licensed products that it sells. PamLab views these license agreements and the patents licensed under them as valuable assets that spurred that growth by allowing PamLab to manufacture and sell successful medical food products with the security of patents we believe were strong.

26. Over the years, PamLab sought ways to expand the scope of the agreements to capture more of the value of the intellectual property covered by those agreements. In particular, the scope of the agreements became broader to allow PamLab to purchase more Metafolin® from Merck, to market more products, and to market products which cover more indications under the licensed patents. PamLab believes there is a great deal of value in the inventions covered by the license agreements.

27. The Merck license agreement was not precipitated by any litigation or threat of litigation between PamLab and Merck.

V. PamLab's Products

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28. Prior to the first licensing agreement between PamLab and Merck, PamLab was basically a cough and cold company with product lines that focused on antihistamines, decongestants, cough medicines, expectorants, and muscle relaxers.

29. The license agreement with Merck changed PamLab's business drastically.

30. Entering into the licensing agreement with Merck allowed PamLab to develop a new class of products protected by the licensed patents. After several years of research and development, PamLab launched several products that were sold under the license: Cerefolin® (introduced March 2004), Metanx® (introduced April 2005), CerefolinNAC® (introduced March 2006), Deplin® (introduced July 2006), Neevo® (introduced January 2007), and NeevoDHA® (introduced March 2009) (collectively, the "PamLab Patented Products"). Without the license from Merck, PamLab would not have moved forward with the development of Metanx®, CerefolinNAC®, Deplin®, Cerefolin®, Neevo®, or NeevoDHA®.

31. Each of the PamLab Patented Products is depicted below.

Pamlab Domestic Industry Products



CDX-0294

Other Pamlab Products



CDX-0295

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32. In general, the PamLab Patented Products each have labels that provide information about the products. But, the most significant source of information for the products is the package insert for each product. The package insert is how we provide information to clinicians in particular, and to the market in general. It discloses the ingredients in the products, and identifies the conditions and illnesses the products can be used for.

33. In developing the PamLab Patented Products, PamLab invested and continues to invest heavily in research and development efforts.

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A. Metanx®

37. Metanx® is a medical food dispensed by prescription for the clinical dietary management of endothelial dysfunction in patients with diabetic peripheral neuropathy. Metanx® is also indicated for the distinct nutritional requirements of individuals with endothelial dysfunction who present with loss of protective sensation and neuropathic pain associated with diabetic peripheral neuropathy. It is further indicated for the distinct nutritional requirements of patients with endothelial dysfunction and/or

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hyperhomocysteinemia who present with lower extremity ulcerations. Ex. 2078 (package insert for the Metanx®; MERCK ITC 16 00474393-94) at MERCK ITC 16 00474393. This information provided at the “Indication and Usage” section of the product insert.

38. My understanding is Metanx® is effective because of the unique combination of three ingredients: 3 mg of L-methylfolate; 35 mg of pyridoxal-5'-Phosphate, and 2 mg methylcobalamin.

39. PamLab sponsored several studies that investigated the effectiveness of Metanx® and, in particular, the effectiveness of Metanx® in patients with diabetic neuropathy. Over the years, PamLab has already invested over █ million dollars in clinical trials involving Metanx® and anticipates spending █ million more in conducting future clinical trials.

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B. CerefolinNAC® and Cerefolin®

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46. Cerefolin® is used for hyperhomocysteinemia, with particular emphasis for individuals diagnosed with or at risk for mild to moderate cognitive impairment, and vascular dementia. Ex. 2251 (package insert for the Cerefolin®; MERCK ITC 02 00105198-99) at MERCK ITC 02 00105198.

47. CerefolinNAC® is a medical food indicated for treatment of early memory loss with particular emphasis for those individuals diagnosed with or at risk for neurovascular oxidative stress and/or hyperhomocysteinemia, mild to moderate cognitive impairment with or without vitamin B12 deficiency, or vascular dementia. Ex. 2085 (CerefolinNAC 04/10 Package Insert; MERCK ITC 04 00315371). This information provided at the “Indication and Usage” section of the product insert.

48. My understanding is CerefolinNAC® is effective because of the unique combination of three ingredients: 6 mg of L-methylfolate, 2 mg methylcobalamin, and 600 mg N-Acetylcysteine.

49. We have received feedback regarding the effectiveness of CerefolinNAC®. For example, there was a collection of case studies involving CerefolinNAC® that was published in a special report put out by the American Psychiatry News and Primary Care Quarterly. The special

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report showed how effective CerefolinNAC® was in slowing the progressive cognitive decline in patients with age-associated memory problems.

50. PamLab sponsored several studies that investigated the effectiveness of CerefolinNAC® and, in particular, the effectiveness of CerefolinNAC® in patients with mild to moderate cognitive impairment. Over the years, PamLab has already invested over [REDACTED] million dollars in clinical trials involving CerefolinNAC®.

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C. Deplin 7.5 mg and 15 mg

55. Deplin® is a medical food indicated for adjunctive use in major depressive disorder (in combination with other approved psychotropics) for adjunctive use in schizophrenia. Ex. 2162 (Deplin® 7.5 mg and 15 mg package inserts). This information provided at the “Indication and Usage” section of the product insert.

56. My understanding is Deplin® is effective because of its unique formulation, in particular the inclusion of the L-methylfolate, the natural

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form of folate. Over the years, PamLab has already invested approximately [REDACTED] million dollars in clinical trials involving Deplin®.

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D. Neevo® and NeevoDHA®

60. Neevo® is used for women with distinct nutritional requirements for any of the following conditions: hyperhomocysteinemia during pregnancy; high risk recurrent pregnancy loss; impaired folic acid absorption impaired metabolism due to 677C-T mutations in the methylenetetrahydrofolate reductase gene; and dysfunctional folic acid metabolism. Ex. 2079 (Neevo® package insert; MERCK ITC 04 00356204). This information provided at the “Indication and Usage” section of the product insert.

61. NeevoDHA® is used for women with distinct nutritional requirements for any of the following conditions: hyperhomocysteinemia during pregnancy; high risk recurrent pregnancy loss; risk of anemia due to impaired folic acid absorption and impaired metabolism due to 677C-T mutations in the methylenetetrahydrofolate reductase gene. Ex. 2080 (NeevoDHA® package insert; MERCK ITC 02 00115896). This

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information provided at the “Indication and Usage” section of the product insert.

62. Neevo® and NeevoDHA® (collectively “Neevo Products”) are prescription prenatal vitamins. They are formulated to help mothers-to-be who are higher risk pregnancies or who have experienced multiple miscarriages. The Neevo® Products were launched beginning in 2007 and many obstetricians prescribe these products to their patients.

63. Specifically, the Neevo Products are indicated for nutritional supplementation during pregnancy, prenatal, and postnatal periods in women with or at risk for folate 667C>T polymorphism and/or women who are associated with immediate to higher risk pregnancies. It is also administered to mothers-to-be or to women already pregnant to reduce the female’s risk of having a fetus with a neural tube defect.

64. The Neevo® Products are different from other prescription prenatal vitamins on the market. Some women have difficulty absorbing folate or folic acid. The Neevo® Products deliver folate in a different form, namely L-5-MTHF, a form which many women who may be prone to non-absorption, can indeed absorb.

65. In addition to supplying folate to a pregnant woman in a different form, the Neevo® Products also supply vitamin B12. The Neevo®

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Products provide B12 to aid in the production of red blood cells and to help metabolize homocysteine into methionine. Both low levels of folate and high levels of homocysteine have been linked to early pregnancy loss and higher than normal incidence of fetuses born with neural tube defect. An effective amount of L-5-MTHF is provided by the Neevo® Products to reduce the risk of these serious medical conditions. The Neevo® Products also contain other essential vitamins and minerals for a healthy pregnancy.

66. [INTENTIONALLY LEFT BLANK]

VI. Success of the PamLab Patented Products

67. Since their introduction to the market, the PamLab Patented Products have experienced tremendous success and generated [REDACTED] billion dollars in revenues.

68. Although PamLab historically has not tracked the profitability of its products on an individual product basis, the significant growth in sales and revenues year over year shows the PamLab Patented Products are commercially successful.

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79. The substantial sales of the PamLab Patented Products are particularly remarkable because PamLab had to cultivate a niche market for prescription-only medical foods, where traditional drug products approved by the FDA were the norm.

80. Sales of the PamLab Patented Products have grown to the point where they now make up a majority of PamLab's revenues. PamLab in effect built the company around the PamLab Patented Products, thus, PamLab's success is driven by the success of these products.

81. PamLab often hears testimonials from patients that use its products. In several instances, patients inform PamLab of the successful experiences they have using the PamLab Patented Products, Metanx® and Deplin® in particular. Oftentimes, patients find success with the PamLab Patented Products after having used a number of other products without

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success and we hear from them because they are so pleased with their experience with the PamLab Patented Products.

82. [INTENTIONALLY LEFT BLANK]

83. We believe in our products and believe that they can be an effective form of treatment for the conditions they treat. So, we are looking to grow the number of clinicians that prescribe our products so that we may grow the number of patients that get access to our products. In order to do that, we are generally looking for sales increases year over year based on our internal metrics for the kinds of increases we want to see.

VII. Marketing of PamLab Patented Products

84. PamLab markets its products through various outreach programs aimed at informing prescribing clinicians about the product, and how the PamLab Patented Products can be used as an option for them and their patients.

85. The marketing approach PamLab employs entails some of its sales staff calling on clinicians throughout the country in person. This practice is referred to as “detailing,” and the sales people that do this work are sometimes referred to as “detailers.” Notably, although we refer to our detailers as “sales staff,” they do not actually sell our products to clinicians in the traditional sense. Instead, what we do is inform the clinicians of our

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unique blend of ingredients and the types of successful outcomes that they have achieved based on clinical trials or patient case studies. Basically, we inform the clinicians of what is borne out in the data from our clinical studies. Our outside sales staff call on approximately 32,000 medical professionals throughout the U.S.

86. Because the reach of our sales staff is geographically limited, we have an inside sales staff that provides coverage for the locations that are not covered by our sales people out in the field. The inside sales staff primarily works by phone. The inside sales staff call on approximately 56,000 medical professionals.

87. PamLab's sales staff informs clinicians of the unique blend of ingredients in the PamLab Patented Products, and of the successful clinical outcomes that they have achieved based on clinical trials or patient case studies. Basically, PamLab informs the clinicians of what is borne out in the data from clinical studies.

88. PamLab's sales staff consists of approximately [REDACTED] outside sales representatives and approximately [REDACTED] inside sales representatives. The outside sales representatives are responsible for Metanx® and Deplin®, and generally target general practice physicians, podiatrists, psychiatrists and other clinicians who prescribe those products. The inside sales

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representatives cover Metanx®, CerefolinNAC® and Deplin®. Cerefolin®, Neevo® and NeevoDHA® are not detailed.

89. We do not promote all of our products with an outside sales staff because we have limited time and access with the clinicians we see face to face. We have to maximize our time and product mix. Currently, Metanx® and Deplin® are the two products we promote in face to face time with clinicians.

90. In general, our marketing efforts are focused on informing clinicians about the outcomes our products achieve. In other words, that our particular blend of ingredients, including the use of METAFOLIN®, provides successful outcomes that can help their patients. Metanx® and Deplin® are the two products for which we have the most clinical outcome data, so those are the two products that we have the most positive patient outcome data. Now, of course, that is not to say that the other products, for example, CerefolinNAC® is not ineffective. To the contrary, CerefolinNAC® is very effective in treating moderate cognitive impairment with, and vascular dementia.

91. Based on my experience working in the pharmaceutical industry, the size of PamLab's sales force are in line with what you would ordinarily see for a company of our size. Based on my experience,

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compared to the approach of large pharmaceutical companies like Eli Lilly, for example, our numbers are actually very conservative.

92. In addition to the “detailing” discussed above, we also have speaker programs in which individuals with experience with the clinical use of our products, we call them Key Opinion Leaders or Thought Leaders, will give a peer-to-peer presentation to other clinicians. In conducting these programs, we follow the FDA’s guidelines, per Pharmaceutical Research and Manufacturers of America (“PhRMA”), a trade organization for pharmaceutical companies.

93. Pamlab’s practice of using peer-to-peer presentations are not unusual in the industry; they are commonly done in the industry.

94. Pamlab’s success is particularly remarkable given the products we sell and our scale. I said earlier, we sell a unique blend of ingredients to treat certain conditions. In the case of Metanx®, Deplin®, CerefolinNAC®, and Cerefolin®, prior to those particular products entering the market, the conditions those products address were primarily treated with traditional drugs, not medical foods. We have had to inform clinicians of the availability of our products in markets that were traditionally dominated by big pharmaceutical companies. In that sense, our success has been

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remarkable, given the level of sales we have achieved since the launch of the first products in the mid-2000s time frame.

VIII. Royalties

95. Pamlab has also paid significant royalties pursuant to its license with Merck.

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100. [INTENTIONALLY LEFT BLANK]

IX. Pamlab Sublicensees

101. Pamlab has also sublicensed the Bailey and '040 patents to three companies: (i) [REDACTED]. (now [REDACTED]); (ii) [REDACTED]; and (iii) [REDACTED].

X. Third Party Imposter Products

102. The presence of products that are presented to the market as whole sale copies of our products diminish sales of the Pamlab Patented Products. In effect, companies copy the Pamlab Patented Products, and then position their products as substitutes for Pamlab's products to wholesalers and pharmacies, among others. We refer to them as "imposter" products in the market.

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103. In my experience, the companies that make these “imposter” products intentionally create a perception in the market that their products are substitutable for the PamLab Patented Products. They simply try to achieve sales on the backs of the commercial success of our products by copying our products. By copy, I mean same active ingredients, in the same amount, same dosage form, and same route of administration.

104. In my general experience, those companies manufacture their product to be copies, or at least promote them to be copies, of PamLab Patented Products. They then use that similarity or appearance of similarity to convince the pharmaceutical databases and pharmacies that are in the marketplace to link their products to the PamLab Patented Products as so called “generics” so that they can be sold in place of our products.

105. The pharmaceutical databases I am aware of, based on my experience, are Medispan, Gold Standard, and First DataBank, which is now Analysource. These companies provide information that inform pharmacists of what products can be substituted for certain other products.

106. Based on my experience, the databases generally list branded products in their databases, as well as generics for those products. So in this instance, the PamLab product would be the branded product. If there are so-

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called “generic alternatives” to that branded product, those generic alternatives are listed in the databases alongside the branded products.

107. I am aware of several manufacturers of imposter products that have marketed products that competed with the PamLab Patented Products at one time or another, as explained above. For example, Macoven Pharmaceuticals LLC (“Macoven”) has manufactured and sold products that were marketed as substitutes for Metanx®, Deplin®, and CerefolinNAC®, namely VitaCircB, L-Methylfolate Calcium, and ALZ-NAC, respectively. Macoven promoted these imposter products as wholesale copies of our products in terms of having the same active ingredients, in the same strengths, in the same dosage form, and for the same route of administration.

108. Macoven’s objective was to have their products be prescribed for the same uses as our products, as specified in the PamLab Patented Products’ package inserts. Macoven accomplished this goal, and consequently unlawfully took a significant amount of sales away from PamLab.

109. In addition to Macoven, I am also aware of several other companies that have copied the PamLab Patented Products, namely, Brookstone/Acella, Trigen, Virtus, Midlothian and Seton.

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110. Brookstone/Acella marketed products named: (i) Neurpath-B and Folast, which were copies of Metanx®; (ii) Enfolast-N, which was a copy of CerefolinNAC®; (iii) L-Methylfolate Calcium, which was a copy of Deplin®; (iv) Enfolast, which was a copy of Cerefolin®; (v) PNV-Iron, which was a copy of Neevo®; and (vi) PNV-DHA Plus, which was a copy of NeevoDHA®.

111. Trigen marketed products named: (i) Triveen-CF NAC, which was a copy of CerefolinNAC®; (ii) Rovin-CF OF, which was a copy of Cerefolin®; (iii) Rovin-NV DHA, which was a copy of NeevoDHA®; and (iv) Rovin-NV, which was a copy of Neevo®.

112. Seton marketed products named: (i) Duleek-Met New, which was a copy of Metanx®; and (ii) Duleek-DP, which was a copy of Deplin®.

113. Midlothian marketed a product named L-Methylfolate Calcium, which was a copy of Deplin®.

114. Virtus marketed products named: (i) L-Methyl-B6-B12, which was a copy of Metanx®; (ii) L-Methylfolate Calcium, which was a copy of Deplin®; and (iii) L-Methyl-MC, which was a copy of Cerefolin®.

115. A summary of the different imposter products is provided below to show the extensive nature and the all-out effort by third parties to copy the PamLab Patented Products in order to capitalize on the commercial

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success. Such success is based on the effectiveness of our products in providing nutritional support for individuals with serious and debilitating diseases such as diabetic peripheral neuropathy, mild cognitive impairment, major depressive disorder, and consequences of countering the ill effects of unhealthy pregnancies due to folate deficiencies.

Imposter products						
Pamlab's Product	Macoven's Imposters	Acella Pharm. Imposters	Trigen Labs Imposters	Seton Pharm. Imposters	Midlothian Labs Imposters	Virtus Pharm. Imposters
Metanx®	VitaCiro-B	Neurpath-B and Folate		DuLeek-Met New		L-Methylfolate-B6-B12
Cerefolin NAC®	ALZ-NAC	Enfolast-N	Triven-Cf NAC			
Depilin®	L-Methylfolate	L-Methylfolate Calcium		DuLeek-DP	L-Methylfolate Calcium	L-Methylfolate Calcium
Cerefolin®		Enfolast	Rovin-CF OF			L-Methyl-MC
NeevoDHA®	L-Met Fol DHA PNV	PNV-DHA Plus	Rovin-NV DHA			
Neevo®		PNV-Iron	Rovin-NV			

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116. PamLab would not have taken a license under the Bailey and '040 patents if they did not believe in the validity of these patents. PamLab built a successful business around these patents by investing millions of dollars in research and development to bring the PamLab Patented Products to market. These efforts, among others, clearly reflect PamLab's belief in the strength of these patents. PamLab's belief in the strength of the patents is further evidenced by PamLab's decision to bring suits for patent infringement against multiple defendants in the International Trade Commission, *In the Matter of Reduced Folate Nutraceutical Products and L-Methylfolate Raw Ingredients Used There*, ITC Inv. No. 337-TA-857, and the Eastern District of Texas, *Merck & Cie, et al. v. Macoven Pharmaceuticals, LLC et al.*, Civil Action No. 6:12-cv-00027 (E.D. Texas).

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117. I declare under penalty of perjury that the foregoing is true and correct.

Dated October 5, 2013.

A handwritten signature in black ink, appearing to read "Andy Kent Ladner", written in a cursive style.

Andy Kent Ladner

CERTIFICATE OF SERVICE

The undersigned hereby certifies the forgoing , was served by email
on October 16, 2013 to the Petitioners' counsel of record upon the
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