

UNITED STATES PATENT AND TRADEMARK OFFICE

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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

v.

SOUTH ALABAMA MEDICAL SCIENCE FOUNDATION  
Patent Owner

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

v.

MERCK & CIE  
Patent Owner

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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

**SUPPLEMENTAL DECLARATION OF IVAN T. HOFMANN,  
CPA/CFF, CLP**

<b>MERCK EXHIBIT 2321</b> <i>Gnosis v Merck &amp; CIE</i> IPR2013-00117
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## **I. Response to Gnosis Objections**

1. I understand that Gnosis S.P.A., Gnosis Bioresearch S.A., and Gnosis U.S.A., Inc. (“Petitioners”), have raised certain objections to my September 24, 2013 Declaration in this matter (“Declaration”) and certain of the exhibits cited therein. I submit this declaration to address Gnosis’s objections.

2. I understand that Gnosis has objected to paragraphs 11-13 of my Declaration. In those paragraphs I discuss my understanding of the legal principles, as I understand and believe them to be, applicable to the issue of nonobviousness, particularly, commercial success, licensing, and copying as objective evidence of nonobviousness. My understanding of the legal principles that I discuss in paragraphs 11-13 are based on my prior experience as an expert opining on matters of secondary considerations, for over 10 years, and information learned from discussion with counsel in this case and in ITC Inv. No. 337-TA-857 (the “ITC Investigation”), which involved the parties to these proceedings. I have testified as an expert on these types of matters in Federal District courts in numerous cases. It is customary to include a passage similar to paragraphs 11-13 in my expert reports and declarations such as the one I submitted in this matter. Importantly, paragraphs 11-13 of my Declaration address my understanding

of the relevant legal issues as they apply to my analysis and as such, are not the substantive opinions for which my Declaration was offered in the various Inter Partes Reviews (“IPRs”).

3. Gnosis objects to paragraph 14 of my Declaration. In paragraph 14, I address my understanding of which of the patents in the IPRs cover which of the PamLab Patented Products. My understanding is based on information learned in the ITC Investigation, and in particular, my review of the expert reports of various experts in that case, specifically, the expert reports of Dr. Green and Dr. Reisetter, and from discussions with counsel in this matter. I was also informed that certain of Patent Owners’ experts will opine that Metanx<sup>®</sup>, Cerefolin<sup>®</sup>, CerefolinNAC<sup>®</sup>, Deplin<sup>®</sup>, Neevo<sup>®</sup>, and NeevoDHA<sup>®</sup> are covered by one or more claims of the subject patents.

4. In paragraph 16, I explain my understanding that historically, PamLab has not tracked the profitability of its products on an individual basis. My understanding of this is based on my conversations with professionals at PamLab, namely Kenny Ladner (Senior Vice President of Sales and Marketing for Nestle Health Science-PamLab Inc. (“NHS-PamLab”)) and Julie Hayden (at the time, Vice President, Finance of PamLab). Moreover, I am aware that Mr. Ladner has offered a declaration in

this matter in which he confirms that PamLab historically has not tracked the profitability of its products on an individual basis.

5. Paragraph 20 of my Declaration states my opinions, based on my analyses that I provide in Appendix B, that certain of the PamLab Patented Products have grown increasingly important to PamLab's success, which in my opinion is indicated by the fact that those products represent the majority of PamLab's revenues. In Appendix B, which is referred to in paragraph 20 of my Declaration, I detail on a yearly basis the net revenues for the PamLab Patented Products that I use to arrive at the values stated in paragraph 20 of my Declaration and the opinion that the products are important to PamLab. The documents that I rely on for the product sales information used in Appendix B are Ex. 2112, 2117 and 2138, as well as the royalty reports cited in Appendix A (addressed in detail in ¶¶14-17 herein). As shown in Appendix B, I rely on financial information from Ex. 2112 for years 2005-2009, and Exs. 2117 and 2138 for 2010-2012.

6. Ex. 2112 is a PamLab PowerPoint document that was produced to Gnosis by PamLab in response to discovery in the ITC Investigation. It contains historical financial information for years 2005 to 2009 regarding the performance of the PamLab products sold under the Merck license relative to PamLab's overall performance, at MERCK ITC 02 00122527,

among other information. Based on my independent review and analysis of other financial information produced to Gnosis by PamLab and Merck in response to discovery in the ITC Investigation, I am confident that the information in Ex. 2112 on which I rely is accurate within a reasonable degree of professional certainty. For instance, taking into account minor but acceptable variations due to when sales numbers are recorded, my own analysis of the sales of PamLab's products based on royalty reports discussed above (Exs. 2140, 2107, 2141, 2142, 2143, 2144, 2145, 2147, 2136, and 2139), as shown in Appendix A, show that sales based on the royalty reports and those based on Ex. 2112 are virtually the same. Due in large part to my ability to independently verify the accuracy of the financial information in Ex. 2112, I was confident in the reliability of the information in Ex. 2112 to a level of professional certainty that enabled me to comfortably rely on that information. Based on my experience, the information I relied on in Ex. 2112, specifically, historical financial information that can be independently verified and shown to be accurate within a reasonable degree of professional certainty, is the type reasonably relied upon by experts in my field in forming the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success, and licensing.

7. Ex. 2117 is PamLab's consolidated audited financial statement for 2010 and 2011, and Ex. 2138 is PamLab's consolidated audited financial statement for 2011 and 2012. Ex. 2117 was produced to Gnosis by PamLab in response to discovery in the ITC Investigation and Ex. 2138 was newly produced in this proceeding, as I understand it was not prepared in time to be produced in the ITC Investigation. Based on my experience, a company's audited financial statements are prepared in the ordinary course of business and are generally regarded as highly reliable financial information and are reasonably relied upon by experts in my particular field in forming the types of expert opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success.

8. With respect to the first sentence of Paragraph 33 of my Declaration, I state my understanding that Metafolin<sup>®</sup> is a substantially pure form of L-Methylfolate which is important to each of the U.S. Patents, and is an ingredient in each of the PamLab Patented Products. I base this statement on my conversations with PamLab (Kenny Ladner) and Merck (Dr. Vera Katz). In conversations with the individuals at PamLab and Merck, for example, the importance of Metafolin<sup>®</sup> was emphasized, as it was viewed as a differentiating feature for the PamLab Patented Products. This was further bolstered by the expert report of Dr. Green, issued in the ITC Investigation.

Thus, my opinion is based on discussions with individuals with knowledge and my own review of expert testimony by Dr. Green. This type of information is of the type reasonably relied upon by experts in my field in forming the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success.

9. I understand that Gnosis has objected to paragraph 15 of my Declaration for lack of relevance and because they believe its value is outweighed by its capacity to prejudice/confuse/delay. I believe my opinion that the PamLab Patented Products are a commercial success is a relevant factor to consider as objective evidence of nonobviousness. Further, my opinions and analyses are straightforward, understandable, well-supported by evidence, and comport with the types of analyses typically performed by financial/economic experts on these types of issues.

10. I further understand that Gnosis objects to paragraph 15, along with paragraphs 20, 23-25, of my Declaration alleging lack of personal knowledge and that my opinions are not based on reliable methods or data. Because paragraph 15 is a high level summary of details that are addressed in paragraphs 20, 23-25, among others, of my Declaration, no further specific response is provided with respect this objection to paragraph 15

other than to say that I disagree with Gnosis's objections, as shown below where I address them herein with respect to paragraphs 20 and 23-25.

11. Paragraph 20, and Appendix B to which it cites, are addressed above (¶¶ 5-7). Further, the values I highlight in paragraph 20 and detail in Appendix B to support my opinion that Metanx<sup>®</sup>, Cerefolin<sup>®</sup>, CerefolinNAC<sup>®</sup>, Neevo<sup>®</sup>, and NeevoDHA<sup>®</sup> have grown in importance to PamLab and now represent the majority of PamLab's revenues, were generated by me and/or others working under my direct supervision, as is consistent with my practice in these types of analyses.

12. In paragraph 23 of my Declaration, I summarize my conclusion that Deplin<sup>®</sup> has also grown in importance to PamLab over the years, as evidenced by its increasing percentage of PamLab's overall sales. In paragraph 23 I cite to Appendix B, which details the analysis that I use as a basis for drawing that conclusion. As I discuss above (¶¶ 5-7), the analysis in Appendix B is based on reliable information, was performed by me and/or others working under my direct supervision, and is of the type of information reasonably relied upon by experts in my field in offering the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success and licensing.



13. In paragraph 24 of my Declaration, I discuss the net revenues of all of the PamLab Patented Products, specifically, that they have been successful since launch, demonstrated by sales totaling over \$ million. To support this opinion as stated in paragraph 24, I cite Appendix A of my Declaration.

14. Appendix A of my Declaration shows the net product sales for the PamLab Patented Products from 2004 to the second quarter of 2013. To generate the dollar amounts that are stated in paragraph 24 to support my opinion that the PamLab Patented Products are commercially successful, I use royalty reports that PamLab routinely prepares and provides to Merck to track sales of the licensed PamLab Patented Products. These are identified in Appendix A as Exs. 2140, 2107, 2141, 2142, 2143, 2144, 2145, 2147, 2136 and 2139. Each of Exs. 2140, 2107, 2141, 2142, 2143, 2144, 2145, 2147, and 2136 were produced by PamLab to Gnosis in response to discovery in the ITC Investigation. Exhibit 2139 was not available during the course of discovery in the ITC Investigation, as I understand it was not prepared in time to be produced.

15. I discussed the royalty reports I cite to and rely on in my Declaration, in Appendix A, for example, with professionals at PamLab, namely Julie Hayden and Kenny Ladner, and at Merck, namely Dr. Vera

Katz. Based on the information I learned from speaking with these individuals, and looking at the royalty reports, I understand that PamLab generates the royalty reports based on sales of the PamLab Patented Products in the ordinary course of their business and provides them to Merck on a quarterly basis as a record of the number of royalty bearing sales that PamLab has had for the relevant period. My discussions with the individuals at PamLab and Merck took place during the pendency of the ITC Investigation, and in the specific case of Merck, during the pendency of a prior litigation between Merck and Brookstone/Acella.

16. The royalty reports (identified as Exs. 2140, 2107, 2141, 2142, 2143, 2144, 2145, 2147, 2136 and 2139) detail the net units, net sales and royalty payments due to Merck based on the reported sales for that particular period. This type of financial information and data is of the type that is reasonably relied upon by experts in my field in forming opinions or drawing inferences as to the financial performance of products, relating to objective evidence of nonobviousness, including commercial success and licensing.

17. Paragraph 25 further discusses PamLab's growth in revenues from 2005 to 2012, relying on the analysis detailed in Appendix B. My

discussions above (¶¶ 5-7), addressing PamLab's objection to Appendix B, apply equally to Gnosis's objections to paragraph 25.

18. Gnosis objects to paragraphs 27-32, 36-37, 42 and 43 as not relevant, outweighed by their capacity for prejudice/confusion/delay, and lack of personal knowledge. Paragraphs 27-30 of my Declaration address sales by Macoven, of products that copied Metanx<sup>®</sup>, CerefolinNAC<sup>®</sup> and Deplin<sup>®</sup>, namely Macoven's VitaCirc-B, ALZ-NAC, and L-Methylfolate Calcium. This testimony is relevant to the secondary consideration factor of commercial success. Specifically, the sales of Macoven's products took sales from the PamLab Patented Products, making the sales of the PamLab Patented Products as quantified by PamLab's sales data understated, unless the substituted sales by Macoven's products are specifically addressed. In paragraph 28, I recite Macoven's gross sales from 2011 through early 2013 and cite Ex. 2310 in support. Although not critical to my analysis and conclusion that the PamLab products are commercially successful, the amount of sales of Macoven's products are cited in my report to indicate that even though Macoven sold lower-priced products, the sales were nevertheless significant because they piggy-backed on the success of the PamLab Patented Products. I am aware of Macoven's sales information

because it was filed by Macoven in the ITC Investigation as an exhibit to Macoven's response to the complaint.

19. The larger point of paragraphs 27-32 however, is that sales of the Macoven products, as well as products sold by others, took sales from Pamlab. As stated in paragraph 30, I conclude that Pamlab's sales would have increased by almost \$[REDACTED] million, if Macoven's sales would have gone to Pamlab. With respect to the total impact of sales by Macoven and other companies, namely Brookstone/Acella, Trigen, Virtus, Midlothian and Seton, in paragraph 31, I conclude that Pamlab's sales would have been more than \$[REDACTED] million higher through 2012.

20. I am aware that Macoven and the other companies identified above sold products that were substituted for Pamlab's products. With specific reference to Macoven, I am aware of the products they sold, namely VitaCirc-B, ALZ-NAC, and L-Methylfolate Calcium, as substitutes for Pamlab's products based on information learned from many sources, including the pleadings in the ITC Investigation, (specifically cited in my Declaration), and conversations with Pamlab (Kenny Ladner). Similarly, I am aware that Brookstone/Acella, Trigen, Virtus, Midlothian and Seton sold products that were substitutes for the Pamlab Patented Products based on conversations with Pamlab (Kenny Ladner).

21. Documents I cite in my Declaration further confirm that Macoven, Brookstone/Acella, Trigen, Virtus, Midlothian and Seton sold products that were substituted for the PamLab Patented Products. *See, e.g.*, Ex. 2133 (cited in paragraph 28 with respect to Macoven products); Ex. 2082 (cited in paragraph 8 and Appendix C). Ex. 2133 is a compilation of Analysource screen shots provided by PamLab and produced to Gnosis in response to discovery in the ITC Investigation. Analysource is a database that is used by PamLab and others in the industry to view which products are identified as the innovator product and which products are linked to those products as so-called “generics” so that they can be sold as substitutes for the innovator products. Ex. 2133 shows the PamLab products to which each of the Macoven products were linked. I am personally familiar with the types of screen captures and the information contained therein based on my experience and knowledge in the industry, as detailed below (¶¶ 24, 26).

22. Ex. 2082 is a compilation of sales information that I requested and which PamLab provided to me during the ITC Investigation. It is a summary of data from an IMS database, which is generally used by professionals in the pharmaceutical field to track sales (TRx data) for different products. The TRx data in Ex. 2082 shows the PamLab products, the third party products that are sold as substitutes for those products, and

the quantity of sales of each product (the PamLab innovator product as well as the linked substitutable alternatives) for the relevant time period. Based on this information, I calculated the total number of sales that went to Macoven, Brookstone/Acella, Trigen, Virtus, Midlothian and Seton that should have gone to PamLab. From there, it was a matter of multiplying the quantities by the appropriate price for the PamLab products. This methodology is of the type reasonably relied upon and used by experts in my field to render opinions as to quantifying lost sales.

23. Appendix C further relies on PamLab price lists in determining the amount of sales PamLab lost due to substituted sales by Macoven, Brookstone/Acella, Trigen, Virtus, Midlothian and Seton. These price lists, Exs. 2128, 2129, 2130, 2131, and 2132, were produced by PamLab to Gnosis in response to discovery in the ITC Investigation and in my opinion are the best and most accurate way to determine the appropriate PamLab price for the periods where Macoven and others were profiting from sales due to substitution. The pricing information produced by PamLab is of the type reasonably relied upon by experts in my field in calculating sales information.

24. I am generally aware of the information contained in Exs. 2133 and 2082 based on my extensive experience working in the pharmaceutical

field. *See, e.g.*, Hofmann Dec., ¶ 5; Ex. 2018 (Hofmann CV). Further, in the course of my work in providing consulting and expert services, I regularly analyze and review data for the pharmaceutical industry, including IMS, Wolters Kluwer and Verispan information. I am knowledgeable regarding the role of pharmaceutical databases such as First Databank, Medispan, Gold Standard and the Red Book in the fulfillment of prescriptions. I am also knowledgeable regarding the process of prescription writing, fulfillment and generic substitution in the pharmaceutical industry. I have analyzed data and information and testified as an expert witness in Federal Court numerous times in matters involving the pharmaceutical industry and the role of brand versus generic competition. Further, based on that experience, I am also aware that many in the industry use and rely on the information in the databases identified above in discharging their daily business duties, including to track product sales, market share, and competitors in the market. Based on my conversations with PamLab, they are no different in this regard. Further, the information provided and relied upon in Exs. 2133 and 2082 are of the type reasonably relied upon by experts in my field in forming opinions of the types I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success, licensing, and copying.

25. Gnosis also objects to paragraph 31 and Appendix C of my Declaration, in particular, because the top half of the table in Appendix C allegedly does not contain units and my alleged lack of personal knowledge as to the bottle contents. With respect to the objection that the top half of Appendix C “has no units,” I am unclear as to what Gnosis intends. The quantities on which I base my analysis are indeed provided in the top portion of Appendix C beneath the “2010 Total,” “2011 Total,” and “2012 Total.” Further, those quantities are derived from the quantity information provided in Ex. 2082, which is also addressed herein. By way of example, for the “2010 Total” for Metanx<sup>®</sup>, I show the quantity as 460,745. That quantity, 460,745, represents the total number of non-Pamlab products that were sold as substitutes for Metanx<sup>®</sup> for 2010. I arrived at this value by summing the TRx data in Ex. 2082 for each of the products sold by Macoven, Brookstone/Acella, Virtus, and Seton for each month of 2010. I used the same method to arrive at the non-Pamlab quantities in Appendix C, for each of the other Pamlab Patented Products. The data on which I rely to perform the analysis in Appendix C is of the type reasonably relied upon by experts in my field in forming the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success, licensing, and copying.



26. With respect to the objection that I am not personally knowledgeable as to the bottle contents, my statement that IMS data “converts all prescriptions to 30 count bottles, even if the product is typically dispensed in a 90 count bottle, is a reference to the well-known method of how data is generally kept and tracked by IMS. I know this based on my numerous experiences working on numerous matters where I have analyzed IMS TRx over the past 10 years. In addition, Ex. 2082 specifically provides in its columnar headings that TRx are 30 count.

27. Paragraph 36 addresses sales of the key ingredient in the PamLab Patented Products, Metafolin<sup>®</sup>, and the fact that it commands a price premium over racemic methylfolate products such as Gnosis’s Extrafolate. To support my analysis and opinion, I rely on a District Court’s decision in a case involving the Petitioner (Ex. 2250), in which the Court in that case found, regarding Gnosis’s Extrafolate, that “[b]ecause it is far less costly to produce the mixture product, ... sold for approximately one-third the price of Metafolin.” Ex. 2250 at 6. A District Court’s decision would be of the type of information reasonably relied upon by experts in my field in providing opinions of the types I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success, licensing, and copying.

28. Paragraph 37 addresses sales of the Neevo<sup>®</sup> products, and states my opinion that with respect to NeevoDHA<sup>®</sup>, in particular, it is able to command a price premium over non-prescription prenatal vitamins due to the presence of the Metafolin<sup>®</sup> ingredient. I rely on Ex. 2136 (Pamlab 2012 royalty report, addressed above in ¶¶ 14-16), and Exs. 2148 (Walgreens website) and 2149 (CVS website).

29. Exs. 2148 and 2149 are web pages that show the prices for various non-prescription prenatal products sold by Walgreens (Ex. 2148) and CVS (Ex. 2149). I and others on my team working under my direct supervision, located these web pages by (i) in the case of Ex. 2149, navigating to the “Fertility & Prenatal Care” category and reviewing the prenatal vitamins identified in that category as marketed by CVS; and (ii) in the case of Walgreens (Ex. 2148), navigating to the “Prenatal Support Supplements” category and reviewing the prenatal vitamins identified in that category as marketed by Walgreens. The methodology used to arrive at the particular web pages is discernible from Exs. 2148 and 2149, which each show the path used to arrive at the particular results shown in those exhibits.

30. Walgreens and CVS are two of the country’s largest retailers for healthcare products, including prenatal vitamins. Based on my own review of the materials found at those websites, as shown in Exs. 2148 and

2149, I have no reason to believe that that information is not reliable or what it purports to be. In fact, based on my experience, the information shown in Exs. 2148 and 2149, along with the way that I used that information in my Declaration are consistent with the type of information and methodologies reasonably relied upon by experts in my particular field in forming opinions similar to the ones that I present in my Declaration.

31. In paragraph 37, I also cite to Ex. 2092, which is a web page for NeevoDHA<sup>®</sup>). Ex. 2092 is a website maintained by PamLab which provides information about NeevoDHA<sup>®</sup>, including its ingredients. Ex. 2092 includes a statement that “[t]he ingredient that makes NeevoDHA<sup>®</sup> different from standard prenatal vitamins is the inclusion of L-methylfolate.” Ex. 2092. I further confirmed this information from first hand conversations with PamLab (Kenny Ladner) and Merck (Dr. Vera Katz). Ex. 2092 is of a type reasonably relied upon by experts in my field in forming opinions in the manner detailed in my Declaration, in paragraph 37, in particular.

32. Paragraph 42 sets forth my understanding of the market for the PamLab Patented Products, and is relevant to my detailed discussion of PamLab’s success in the market. The information contained in paragraph 42 is based on my knowledge, observations, and perceptions of the following: medical foods represent a niche market and are a unique form of therapy

compared to traditional pharmaceutical drugs (based on conversations with PamLab and confirmed by my study of the markets for depression, diabetes, and cognitive impairment, as indicated in my Declaration at footnote 20); PamLab had to develop and cultivate a market for its various products, most of which are medical foods that had not been previously utilized by clinicians for applicable indications (conversations with PamLab, including Harold Koch and Kenny Ladner); and a brief explanation of detailing (based on discussions with PamLab, Kenny Ladner, and my own experience in studying and providing expert opinions and analysis in the context of marketing of pharmaceutical and nutraceutical products).

33. Paragraph 43 addresses PamLab's marketing staff and efforts, which are relevant to my analysis of commercial success, and nexus in particular. The information provided in paragraph 43 is based on my conversations with Mr. Kenny Ladner of PamLab, and the specific PamLab document to which I cite. Ex. 2112, cited and relied upon in paragraph 43, is addressed in response to a prior objection by Gnosis above (¶ 6). The information that I rely on to provide the analysis as provided in paragraph 43 (gained from first hand discussions with individuals with knowledge and from documents created, used and maintained in the ordinary course of business) are of the type reasonably relied upon by experts in my field in

forming the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success.

34. With respect to paragraph 38, Gnosis objects to Appendix E to my Declaration. As I state in my Declaration at paragraph 38, in support of my analysis of whether discounts, rebates or other incentives drive the sales of the PamLab Patented Products, I used Appendix E to show the gross and net sales of the PamLab Patented Products. Appendix E explicitly states the documents on which the analysis is based. Specifically, as shown, I rely on Exs. 2146, 2116, 2299, 2300, and 2301. These documents are financial data of PamLab's sales activities for the PamLab Patented Products that were provided by PamLab's accounting/financial system. In fact, Exs. 2146, 2116, and 2299 were produced to Gnosis in response to discovery in the ITC Investigation and I understand Exs. 2300 and 2301 were newly provided pursuant to these proceedings. The information in Exs. 2146, 2116, 2299, 2300, and 2301 are reliable and is what they purport to be. I have personally had conversations with PamLab (Julie Hayden) about these documents to ensure that I understood the information they contained.

35. Based on my extensive experience analyzing financial information in various matters, the sales information provided in Exs. 2146, 2116, 2299, 2300, and 2301 are typical of the type of information that

experts rely upon in forming the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success. Further, as shown in Appendix E and discussed in paragraphs 38-40, I used the information in these exhibits to show that the sales of the PamLab Patented Products are not due to heavy discounting, rebates or other incentives. Based on my extensive experience, sales information as provided in Exs. 2146, 2116, 2299, 2300, and 2301 are generally used to ascertain how much the products being analyzed have been discounted, subject to rebates or other incentives. The information I rely on to generate Appendix E is of the type reasonably relied upon by experts in my field in forming the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success.

36. Gnosis objects to paragraphs 38-40 as outweighed by prejudice/confusion/delay, and alleged lack of personal knowledge. I addressed paragraph 38 above (¶ 34). In paragraphs 39-40 I discuss my analyses as presented in Appendix E and presented in those paragraphs. Thus, my discussions with respect to paragraph 38 are equally applicable to the objections to paragraphs 39-40. I further state in paragraph 40 that based on my experience, discounts and rebates of approximately ■% or less of

gross sales are relatively low and because PamLab's products are in the range of [REDACTED]%, I conclude that they have not been heavily discounted. I base this opinion on my numerous years of experience analyzing products in the pharmaceutical and nutraceutical fields.

37. In paragraphs 45-47, I state my opinions based on my analysis of what the products contain, what I understand to be the marketing message for the PamLab Patented Products and my own observations of the marketplace, in terms of how these products are marketed/advertised, all to establish that marketing is not a main driver of the products' success and also to indicate that to the extent there is a marketing message, that it is consistent with the indications for the products, establishing evidence of nexus. In my discussions in paragraphs 45-47, I identify the bases for my opinions, including conversations with PamLab's Kenny Ladner, an exemplary PamLab document previously addressed (Ex. 2136, addressed in ¶¶ 14-16 herein), and my own observations of information provided to the market at PamLab's web sites (Exs. 2078<sup>1</sup>, 2091, 2085, 2084, 2083, 2162, 2087, 2088). With respect to Exs. 2078, 2091, 2085, 2084, 2083, 2162, 2087, 2088, I know from conversations with PamLab (Kenny Ladner) that

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<sup>1</sup> Note that in footnote 28 of my Declaration I refer to Ex. 2090 in error. This reference should be a reference to Ex. 2078.

Pamlab maintained websites for Metanx<sup>®</sup>, CerefolinNAC<sup>®</sup>, Deplin<sup>®</sup> and NeevoDHA<sup>®</sup>. Further, I reviewed the webpages to determine if the marketing message on those websites were consistent with the indications for each product. Based on that and my understanding of how the patents at issue cover the Pamlab Patented Products gained from experts in the ITC Investigation (namely the expert reports of Drs. Reisetter and Green)<sup>2</sup>, I concluded that the marketing message for the products is consistent with the claims that cover the Pamlab Patented Products. The web page associated with a product is of the type of information reasonably relied upon by experts in my field in forming the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success, and licensing.

38. In paragraphs 48-49, I discuss the license agreements between SAMSF and Merck and highlight particular details from the licensing arrangement between the parties. I cite to the license agreements on which I rely, Ex. 2102. Consideration of licensing activity is relevant to an analysis of secondary considerations. Further, Ex. 2102 was produced to Gnosis in response to discovery in the ITC Investigation. Moreover, I have discussed

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<sup>2</sup> I have also been informed that certain of Patent Owners' experts have opined that the Pamlab Patented Products are covered by one or more claims of the patents under review.



the existence and details of the licensing arrangement between SAMSF and Merck with Dr. Vera Katz of Merck, and have personally reviewed Ex. 2102. The license agreement between SAMSF and Merck (Ex. 2102), which I rely on in my opinions in paragraphs 48-49, is the type of evidence that is reasonably relied upon by experts in my field in forming the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success and licensing.

39. In paragraph 52, I discuss the licensing arrangement between Merck and PamLab. Here again, my analysis is relevant to secondary considerations of non-obviousness. In paragraph 52, I further discuss the numerous agreements between Merck and PamLab and identify those documents, specifically, Exs. 2109<sup>3</sup>, 2110, 2101, 2104, 2103, 2105, 2108, 2125, 2095, and 2094. Each of these documents were produced to Gnosis in response to discovery in the ITC Investigation. Further, I have had conversations with Merck (Dr. Vera Katz) about the licensing arrangement between Merck and PamLab, and have substantiated the licensing arrangement as discussed in my discussions with those individuals by reviewing the agreements themselves.

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<sup>3</sup> In my declaration I refer to Ex. 2019. That reference was in error and should have been to Ex. 2109.

40. Further, in paragraph 52, I discuss the amount of royalties Pamlab has paid to Merck to date. This is based on Ex. 2137 (summary of royalty payments received by Merck); and 2139 (2013 royalty report from Pamlab to Merck). Ex. 2139 is addressed herein in ¶¶ 14-16. Ex. 2137 is a summary of the royalty payments that Merck has received for the patents at issue, including payments received from Merck. Ex. 2137 was produced in the ITC Investigation. Based on my experience, summaries of financial information, of the type I rely on in Exs. 2137 and 2139, is of the type reasonably relied upon by experts in my field in forming opinions of the types I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success and licensing.

41. Further, in paragraph 52, I analyze and calculate how much in royalties Pamlab has paid to Merck over the course of the licensing arrangement between the two companies. My analysis, as shown in Appendix F, is based on the data provided in the royalty reports that Pamlab provides to Merck. I discuss these reports herein in paragraphs 14-16. In addition, I rely on Ex. 2137, discussed above.

42. Paragraph 55 discusses licenses between Merck and other third parties. Paragraph 59 discusses a license between Pamlab and Shionogi. My analysis in paragraph 55 is based on reviewing the executed license

agreements (Exs. 2243, 2254, 2244, 2302, 2098, 2245, 2246, 2297, 2242, 2247, 2248), which were produced to Gnosis in response to discovery in the ITC Investigation, my conversation with Dr. Vera Katz of Merck, and my review of the Merck's annual royalty reports to SAMSF, at Ex. 2106, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2100, 2252. With respect to the reports from Merck to SAMSF, each was produced to Gnosis in the ITC case, with the exception of Ex. 2252 (2012 report). Based on my conversations with Merck (Dr. Vera Katz) during the ITC Investigation and my involvement as an expert in another Merck litigation related to these documents, I am aware that the documents I cited are generated by Merck and provided to SAMSF in the ordinary course of Merck business. These documents, specifically the license agreements and the annual reports, are of the type reasonably relied upon by experts in forming opinions of the types provided in paragraph 55.

43. My analysis in paragraph 59 is based on my review of the license agreement between PamLab and Shionogi (Ex. 2115) and my discussion with PamLab, including Mr. Harold Koch. In addition, in paragraph 59, I address the amount of royalty payments PamLab has provided to Merck based on the Shionogi license agreement, including relying on Ex. 2137, which I address above. I also rely on Ex. 2086, a

webpage that discusses the Shionogi prenatal products that were covered by the PamLab-Shionogi license. The information I rely on for my opinions, as stated in paragraph 59, are of the type reasonably relied upon by experts in my field in forming the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success and licensing.

44. In Paragraphs 62-66 of my Declaration, I discuss the copying activities of certain third parties. In those paragraphs, I rely on documents produced as well as expert reports in the ITC Investigation, discussions with PamLab (Kenny Ladner), and my general understanding of the market of prescription nutraceutical products gained from my prior experiences as an expert, to conclude that the pervasive copying and efforts at copying the PamLab Patented Products by Brookstone/Acella, Trigen, Midlothian, Seton, Macoven and Virtus are further evidence of nonobviousness.

45. With respect to documents, I cite to Exs. 2099, 2134, 2111, 2126, 2127, and 2082. Ex. 2082 is addressed above (¶¶ 21, 22, 24). Each of Exs. 2099, 2134, 2111, 2126, and 2127 were produced by PamLab to Gnosis in response to discovery in the ITC Investigation. Each represents screen shots that depict the PamLab products and the products of third party companies with which they compete.

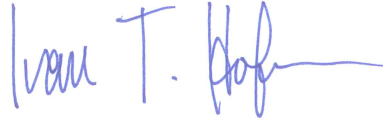
46. Ex. 2134 is a print out of a screen capture of information from the Wolters Kluwer database, showing details about each of Metanx<sup>®</sup> (MERCK ITC 07 00471497-501), Deplin<sup>®</sup> (MERCK ITC 07 00471462-476), CerefolinNAC<sup>®</sup> (MERCK ITC 07 00471457-461), and NeevoDHA<sup>®</sup> (MERCK ITC 07 00471502-506), as well as the products sold by Macoven, Brookstone/Acella, Trigen, Midlothian, Seton and Virtus. Ex. 2134 was generated by PamLab and produced to Gnosis in response to discovery in the ITC Investigation. I am aware of the Wolters Kluwer database from my experience working on various matters that involve pharmaceutical or nutraceutical market information. Based on my experience as an expert in these matters, the Wolters Kluwer database contains information consistent with Ex. 2134. Further, based on my experience in the ITC Investigation, the information related to which particular third party companies have entered the market and taken sales from PamLab via substitution by linking their products to the PamLab Patented Products, was confirmed by other evidence in, including my discussions with PamLab. Ex. 2134 is of the type of information that is reasonably relied upon by experts in my field in forming the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success, licensing, and copying.

47. Exs. 2099 and 2111 are similar to Ex. 2134 in that they were generated and produced by PamLab. Ex. 2099 shows screen captures for Analysource database information for the PamLab products, as well as the content of the Medispan database at the indicated time, showing which products are linked to the PamLab products. Ex. 2111 shows Analysource screen captures for Analysource database information for Deplin<sup>®</sup> in particular, as well as the contents of the Gold Standard database at the indicated time, showing which products are linked to Deplin<sup>®</sup> at the time indicated. Exs. 2099 and 2111 are of the type of information that is reasonably relied upon by experts in my field in forming the types of opinions I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success, licensing, and copying.

48. The evidence of which I am aware, documents produced as well as expert reports in the ITC Investigation, discussions with PamLab, and my general understanding of the market for prescription nutraceutical products gained from my prior experiences as an expert, are of the type reasonably relied upon by experts in my field to render opinions of the types I am offering in these proceedings, relating to objective evidence of nonobviousness, including commercial success, licensing, and copying.

49. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated October 15, 2013.



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Ivan T. Hofmann, CPA/CFF, CLP

## **CERTIFICATE OF SERVICE**

The undersigned hereby certifies the forgoing Supplemental Declaration of Ivan T. Hofmann, CPA/CFF, CLP was served by email on October 15, 2013 to the Petitioners' counsel of record upon the following:

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