

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

SUPPLEMENTAL DECLARATION OF AUDY KENT LADNER

MERCK EXHIBIT 2323 <i>Gnosis v Merck & CIE</i> IPR2013-00117

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

1. I submit this Supplemental Declaration to address the evidentiary objections raised by Petitioners regarding my prior declaration (Ex. 2022) in IPRS's 2013-00116; 00117; 00118; and 00119.

I. My Background

2. I have personal knowledge of the facts set forth in my Declaration (Ex. 2022). Such knowledge is based on my personal observations and experiences as a corporate officer of PamLab since joining the company in 2006. At that time, I became Senior Vice President of PamLab LLC. In that capacity, I was in charge of PamLab LLC's Metafolin[®] Business Unit, which is responsible for the marketing, sales and distribution of Metafolin-containing products covered by the Merck licensees. Included in my responsibilities was overseeing the activities of the PamLab sales staff, and directing the promotional strategies and activities for our products.

3. Prior to 2012, I was involved in PamLab's sales activities, including primarily the face-to-face promotion of our products. Eventually, in about 2012 when PamLab Inc. was created, I became President of PamLab LLC and Senior Vice President of PamLab Inc. In that capacity, I was in charge of parts of the organization that are responsible for all of our sales force, the analytics we use to understand the market and forecast

manufacturing, and the strategic aspects of our promotion of products to physicians for our Metafolin-containing products.

4. In my role as a corporate officer of PamLab over the last seven (7) years, I have developed historical corporate knowledge of PamLab's Metafolin[®] business, which includes the development, manufacture, marketing, sales and distribution of PamLab's Metanx[®], Cerefolin[®], CerefolinNAC[®], Deplin[®], Neevo[®] and NeevoDHA[®] (the "PamLab Patented Products"). My current responsibilities include management of all of PamLab's sales force and marketing of these products.

5. At that time when I joined PamLab in 2006, Cerefolin[®] and Metanx[®] were on the market (introduced in 2004 and 2005, respectively), and CerefolinNAC[®] and Deplin[®] 7.5 were either close to launch or newly introduced to the market (each was launched in 2006). I was at PamLab at the time we launched Deplin[®] 15, Neevo[®], and NeevoDHA[®]. As such, my history with PamLab substantially overlaps with the lifespan of the PamLab Patented Products for which I am responsible.

6. Throughout my employment and continuing today, I have become familiar with PamLab as it pertains to its Metafolin[®] business. Moreover, the source of my personal knowledge of the information set forth in my prior declaration resulted from my observations and perceptions in

carrying out my job responsibilities at PamLab over the years, which include, among other things: (i) marketing and sale of the PamLab Patented Products, including tracking the performance of our products using the generally available tools in our industry; (ii) understanding, monitoring and keeping apprised of the uses of our products; (iii) monitoring the activities of PamLab's competitors in the L-methylfolate business, including the presence of competitor products that get substituted for our products; and (iv) knowing how others perceive or have perceived these products in the market, including being aware of awards and other forms of praise by others.

7. Therefore, I am competent to speak about, among other things, the corporate history of PamLab as set forth in paragraphs 10-16 of my prior Declaration.

8. With specific reference to (i) and (iii) in paragraph 6 above, I know of the tools that we use to track the performance of our products and monitor the presence of competitor products on the market. In particular, PamLab uses IMS Health Total Prescription ("TRx") data ("IMS data") to track the sales of the PamLab Patented Products. Based on my years of experience in the field, I know that IMS data is a database of prescription data that is widely used by people in the prescription product industry. On a weekly basis, PamLab receives IMS data from IMS Health. In general, at a

high level, the IMS data shows how many prescriptions were filled with our products. In addition, that data also shows the sales for products that are linked to our products and competing with our products. By way of example, Ex. 2082 is a summary of IMS TRx data from 2010 to 2012 that I and others working at my direction generated for Mr. Hofmann, at his request.

9. In addition to the IMS data, a number of other tools exist in the prescription product industry that are in our business in dealing with the PamLab Patented Products. For example, Analysource is a database that provides information on the pricing and source of products. Exs. 2099 and 2111 are screen shots of Analysource data, captured at the time indicated on those documents. I and others working at my direction routinely generate and rely on Analysource data in the ordinary course of our business. Wolters Kluwer Health/Medispan also provides database information used in our industry. I and others working at my direction routinely generate and use this information in the ordinary course of our business. Exs. 2126 and 2134 are screen shots of Wolters Kluwer/Medispan data. Ex. 2133 are screen shots of Analysource data (MERCK ITC 04 00316329-333) and Wolters Kluwer/Medispan data (MERCK ITC 04 00316334-340).

II. PamLab's Patented Products

10. In paragraphs 37-65 of my prior Declaration, I describe the PamLab Patented Products, which are Metafolin-containing products for which I am responsible in regards to their marketing, sales and distribution. It is my responsibility to know generally how physicians and other prescribing clinicians use these products. .

11. Further, my knowledge of the facts set forth in paragraphs 37-65 is based on the fact that, as the person responsible for the marketing, sales and distribution of PamLab's Patented Products, it was and still is my responsibility to be aware of our products, including what they were used for and what evidence we had to support that they were effective. Also, in my capacity as a corporate officer, I have acquired knowledge about the relevant markets as it concerns PamLab's Patented Products.

12. I have personal knowledge of the facts set forth in paragraph 81. Such knowledge is grounded in my personal observations and experiences from having worked at PamLab as a corporate officer for over seven (7) years, as described above. Throughout that time, it was and still is my responsibility to be made aware of what patients are saying about our Products. PamLab receives testimonials from patients that use its products. PamLab receives this information during its ordinary course of business.

13. I have also personal knowledge of the facts set forth in paragraphs 93-94. Such knowledge is based on my observation and perceptions as a corporate officer of PamLab for over seven years, as described above. As part of my responsibilities, I have become very much aware of the market position of each PamLab Patented Product. Also, throughout my employment with PamLab, my responsibilities and obligations required that I acquire historical knowledge of the market landscape prior to each of the PamLab Patented Products entering the market.

14. Further, I have personal knowledge of the facts set forth in paragraphs 102-103. Such knowledge is based on my observation and perceptions as a corporate officer of PamLab for over seven years, as described above. In carrying out my responsibilities, I have become aware of and witnessed how unauthorized copies of the PamLab Patented Products diminish the sales of our products. Over the years, I have personally observed how third parties copy our products and then try to capitalize on the success of the PamLab Patented Products. As part of my responsibilities, I have acquired knowledge, and witnessed firsthand, how pharmacy databases, such as Medispan, Gold Standard, and Analysource, inform pharmacists of what products can be substituted for certain other products.

15. As Senior Vice President of Sales and Marketing for PamLab, together with my prior and current responsibilities discussed above, I can confirm that the following exhibits submitted in connection with these proceedings are true and accurate copies, and each document is a business record of PamLab made at or near the time by or from an individual with knowledge and each document was generated and kept during the ordinary course of PamLab's business relating to PamLab's Patented Products:

Exs. 2078, 2079, 2080, 2085, 2162, 2251 (Product labels for the PamLab Patented Products.);

Exs. 2146, 2116, 2299, 2300, 2301 (PamLab financial reports from PamLab accounting system/department.);

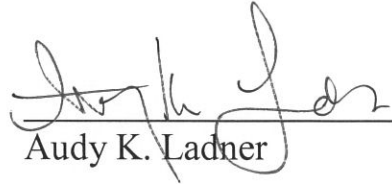
Exs. 2112 (PowerPoint presentation showing historical financial information as well as marketing information.);

Ex. 2117 (Audited consolidated financial statement of PamLab, Inc. and subsidiaries for 2010 and 2011.); and

Ex. 2138 (Audited consolidated financial statement of PamLab, Inc. and subsidiaries for 2011 and 2012.)

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

Dated October 25, 2013.



Audy K. Ladner

CERTIFICATE OF SERVICE

The undersigned hereby certifies the forgoing Supplemental Declaration of Audy Kent Ladner was served by email on October 15, 2013 to the Petitioners' counsel of record upon the following:

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