

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 IVAN T. HOFMANN,
CPA/CFF, CLP**

**MERCK EXHIBIT
REPLACEMENT 2017
Gnosis v Merck & Cie
IPR2013-00117**

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I. Introduction

1. I have been retained in this matter by Counsel for Patent Owner to provide an expert opinion related to the commercial success and nexus of that success for certain products. I am a Managing Director at Gleason IP, a division of Gleason & Associates, P.C. (“Gleason”). Gleason is an accounting, financial and economic consulting firm which provides services primarily in the areas of Valuation, Litigation Support, Intellectual Property, Forensic Accounting and Financial Reorganization. I am the leader of the Intellectual Property Practice and also specialize in Litigation Support and Forensic Accounting. In addition to client service, I have responsibility for quality review and practice management functions at Gleason. Prior to joining Gleason, I worked for the global accounting and consulting firm of Deloitte & Touche, LLP as a senior manager in the Forensic & Dispute Services and Assurance & Advisory departments.

II. Qualifications and Experience

2. I graduated magna cum laude from the University of Notre Dame in 1994 with a Bachelor of Business Administration degree and a double major in Accounting and Economics. I am a Certified Public Accountant (“CPA”) and Certified in Financial Forensics (“CFF”). I am a member of the Licensing Executives Society (“LES”) and have been

actively involved in establishing the Pittsburgh chapter of LES. I am also a Certified Licensing Professional (“CLP”), which is a designation granted by the LES to professionals with demonstrated knowledge and experience in the area of intellectual property and licensing. I have attended and instructed over 1,200 hours of various continuing education seminars since the completion of my formal education and have been a speaker on numerous occasions on a variety of financial, economic, accounting and valuation topics. I have presented to various bar associations and organizations on the issues of financial damages, valuation, financial statement analysis, intellectual property matters, and other topics.

3. My intellectual property experience includes valuation of intellectual property, analysis of objective indicia of nonobviousness, market analysis involving success drivers, the determination of damages associated with patent infringement and other intellectual property (including lost profits, disgorgement, and reasonable royalty), consideration of irreparable harm, analysis of Panduit Factors related to demand for patented features, and market analysis of non-infringing alternatives. I have experience in a broad range of industries including pharmaceuticals, manufacturing, technology, healthcare, communications, construction, extractive, and other industries.

4. Among the numerous projects on which I have worked involving objective indicia of nonobviousness, I have been engaged by the United States Patent and Trademark Office (“USPTO”) and Office of the Solicitor as an expert to analyze and testify on issues involving commercial success and nexus related to proceedings in which the Honorable David Kappos, former Under Secretary of Commerce for Intellectual Property and Director of the USPTO, was defending the USPTO’s denial of a patent application.

5. My work experience also includes litigation support and consulting engagements with a variety of pharmaceutical and biologic companies, including predominantly generic companies such as Mylan Pharmaceuticals, Inc., Glenmark Pharmaceuticals, Inc., Actavis Pharmaceuticals, Inc., Zydus Pharmaceuticals, Inc., and Lupin Pharmaceuticals, Inc. and predominantly branded drug companies such as ImClone Systems, Inc. (a subsidiary of Eli Lilly & Company), Merck KGaA, Middlebrook Pharmaceuticals, Inc., Dey Pharmaceuticals, Inc., and Laboratorios del Dr. Esteve, S.A. I have performed numerous financial analyses for products designed to treat a variety of indications. These analyses include evaluations of objective indicia of nonobviousness

(including commercial success and nexus), consideration of irreparable harm, determination of damages, and licensing and settlement negotiations.

6. In addition, with respect to the current proceeding, because I was also an expert in the prior investigation before the International Trade Commission, Inv. No. 337-TA-857, (“ITC action”) involving these parties, my understanding and opinions are influenced by the materials I reviewed in that action. It is my understanding that Gnosis already has my report, addressing similar subject-matter from the corresponding ITC action. In addition, various documents cited in my declaration were produced by parties to the ITC action. Based on my experience, the documents produced in the ITC action and cited in my declaration are the types of documents typically used and relied upon by experts in my field in forming the types of opinions that I have set forth in my declaration. My curriculum vitae is attached hereto as **Appendix G**.

III. Objectives

7. I have been retained by the law firm of Alston & Bird LLP on behalf of the Patent Owner to analyze certain objective indicia of nonobviousness related to U.S. Patent Nos. 5,997,915 (the “915 Patent”), 6,673,381 (the “381 Patent”), 7,172,778 (the “778 Patent”), and 6,011,040 (the “040 Patent”) (collectively, the “U.S. Patents”). Specifically, I analyze

whether products covered by the U.S. Patents, including Metanx®, CerefolinNAC®, Deplin®, Cerefolin®, Neevo® and NeevoDHA®, (collectively, the “Pamlab Patented Products”) are a commercial success. In addition, I also analyze the licensing activities of South Alabama Medical Science Foundation (“SAMSF”), Merck & Cie (“Merck”) and Pamlab, LLC (“Pamlab”) with respect to the U.S. Patents, as well as evidence of copying of the Pamlab Patented Products.

8. Based upon my analysis, the commercial success of the Pamlab Patented Products constitutes an objective indicator of the nonobviousness of the U.S. Patents.

9. In addition, based on my analysis, the extensive licensing of the U.S. Patents, and significant royalties paid by various parties for rights to the U.S. Patents also constitutes an objective indicator of nonobviousness of the U.S. Patents.

10. Further, based on my analysis, attempts at copying the Pamlab Patented Products and the subject patents, by numerous others, and their extensive efforts in doing so, also constitute an objective indicator of nonobviousness of the U.S. Patents.

IV. Applicable Legal Principles

11. It is my understanding that objective evidence of nonobviousness is an important component in determining whether a patent is obvious. I understand that so called secondary considerations may often be the most probative evidence in the obviousness inquiry and must be considered as part of all of the evidence related to obviousness, not just when the trier of fact remains in doubt after reviewing the prior art.

12. It is my understanding that objective evidence of nonobviousness includes evidence of “commercial success.” My understanding is that “commercial success” is a legal construct that has been established through case law. Under this construct, I understand that courts consider a number of factors, including sales and profitability, in determining whether a product is “commercially successful.” I also understand that the commercial success of the product must be tied to the claimed invention. In other words, there must be “nexus” between the core feature(s) or unique merits of the claimed invention and the success of the product.

13. I also understand that evidence of copying in the marketplace and licensing by others are further objective evidence of nonobviousness.

V. Commercial Success

14. I understand that the PamLab Patented Products practice certain of the claims of the '778, '381, '915 and '040 Patents that are being reviewed in this proceeding, as shown in the following table:

	Metanx®	Cerefolin® / CerefolinNAC®	Deplin®	Neevo® / NeevoDHA®
'915 Patent	X	X		X
'381 Patent	X	X		
'778 Patent	X	X		X
'040 Patent	X	X	X	X

15. Based on my analysis, Metanx®, CerefolinNAC®, Deplin®, Cerefolin®, Neevo® and NeevoDHA® are a commercial success. The significant sales in terms of dollars and prescription growth of these products are demonstrative of their commercial success. Furthermore, the sales of products substituted for the PamLab Patented Products provide additional evidence of the commercial success of the PamLab Patented Products. Moreover, based on my analysis, the commercial success of Metanx®, CerefolinNAC®, Deplin®, Cerefolin®, Neevo® and NeevoDHA® is not due to excessive marketing or discounting.

A. Sales of PamLab Patented Products

16. PamLab tracks sales by product which I discuss more fully below. However, it is my understanding that PamLab does not maintain

historic records which track the profitability of its products on an individual basis. Based on my analysis, the commercial success of the PamLab Patented Products is apparent from a number of perspectives.

1. Sales of Metanx®, Cerefolin®, CerefolinNAC®, Neevo®, and NeevoDHA®

17. Beginning with the initial launch of Cerefolin® in 2004, Metanx®, Cerefolin®, CerefolinNAC®, Neevo®, and NeevoDHA® have generated [REDACTED] billion dollars in net sales. See **Appendix A**. These sales are representative of significant growth year over year and clearly demonstrate the commercial success of Metanx®, Cerefolin®, CerefolinNAC®, Neevo®, and NeevoDHA®.

18. For example, in 2005, sales of Metanx® and Cerefolin®¹ were over \$[REDACTED] million. By 2010, sales of Metanx®, Cerefolin®, CerefolinNAC®, Neevo®, and NeevoDHA® had grown to over \$[REDACTED] million. Sales of these products continued to grow in 2011, increasing to almost \$[REDACTED] million, and by 2012 increased to over \$[REDACTED] million. See **Appendix A**.

¹ In 2005, the only PamLab Patented Products that had launched were Metanx® and Cerefolin®.

19. The following table summarizes the significant sales that Metanx®, Cerefolin®, CerefolinNAC®, Neevo®, and NeevoDHA® have generated since their respective launches:²

<u>Net Sales</u>					
	Launch Date	2012		Cumulative Total For Period 2004-2013*	
Metanx®	04/01/05	\$		\$	
CerefolinNAC®	04/01/06				
Cerefolin®	04/01/04				
Neevo® and NeevoDHA®	01/01/07 and 03/01/07				
Total		\$		\$	

* 2013 data is through the second quarter of 2013.

20. Metanx®, Cerefolin®, CerefolinNAC®, Neevo®, and NeevoDHA® have become increasingly important to PamLab's success. In 2005, sales of these products represented approximately █ percent of PamLab's total revenues. See **Appendix B**. In 2010 these products had grown to represent approximately █ percent of PamLab's sales. Metanx®, Cerefolin®, CerefolinNAC®, Neevo®, and NeevoDHA® continued to grow in importance over time, generating █ percent of PamLab's sales in 2011 and █ percent by 2012. See **Appendix B**. As shown by these figures, Metanx®, Cerefolin®, CerefolinNAC®, Neevo®, and NeevoDHA®

² See **Appendix A**.

represent the majority of PamLab's revenues, and are critical to PamLab's success.

2. Sales of Deplin®

21. Since launching in 2006, Deplin® has generated sales of approximately \$[REDACTED] million. See **Appendix A**. The following table summarizes the significant sales that Deplin® has generated since its launch:³

<u>Net Sales</u>			
	<u>Launch Date</u>	<u>2012</u>	<u>Cumulative Total For Period 2006-2013*</u>
Deplin® [A]	07/01/06	[REDACTED]	[REDACTED]
[A]: Includes both Deplin® 7.5mg and Deplin® 15mg. Deplin® 15mg launched on October 1, 2009.			
* 2013 data is through the second quarter of 2013.			

These sales clearly demonstrate the commercial success of Deplin®.

22. For example, in 2007, sales of Deplin® were approximately \$[REDACTED] million. By 2010, sales of Deplin® had grown to over \$[REDACTED] million. Sales of these products continued to grow, increasing to approximately \$[REDACTED] million in each of 2011 and 2012. See **Appendix A**.

23. Deplin® has also become increasingly important to PamLab's success. In 2007, sales of Deplin® represented approximately [REDACTED] percent of

³ See **Appendix A**.

Pamlab's total revenues. See **Appendix B**. In 2010 Deplin® had grown to represent approximately █ percent of Pamlab's sales. In 2011 and 2012, Deplin® represented █ percent and █ percent of Pamlab's sales, respectively. See **Appendix B**. As shown by these figures, Deplin® is a significant portion of Pamlab's revenues, and is critical to Pamlab's success.

24. The sales of Metanx®, Cerefolin®, CerefolinNAC®, Deplin®, Neevo® and NeevoDHA®, account for the vast majority of Pamlab's net revenues. Since 2004, total sales of the Pamlab Patented Products have been over █ million. For 2005, net sales of the Pamlab Patented Products amounted to over \$█ million, whereas net sales for the Pamlab Patented Products for 2010 were approximately \$█ million, for 2011 were approximately \$█ million, and for 2012 were approximately \$█ million. See **Appendix A**. Pamlab is essentially a company built entirely around these products. The significant sales of the Pamlab Patented Products, and the profits generated by Pamlab (discussed more fully below), demonstrate the commercial success of Metanx®, Cerefolin®, CerefolinNAC®, Deplin®, Neevo®, and NeevoDHA®.

3. Pamlab Success and Profitability

25. As detailed in **Appendix B**, Pamlab has experienced significant growth in revenue, driven by products which are covered by the U.S.

Patents. Pamlab's overall revenues increased [REDACTED] percent from approximately \$[REDACTED] million in 2005 to approximately \$[REDACTED] million in 2012.⁴

26. Pamlab has continued to grow its revenue, as well as its operating profit and net income. Pamlab has generated strong financial results largely based on sales of the Pamlab Patented Products as discussed above, as shown in its audited financial results for the years ended 2010, 2011, and 2012:

Pamlab Financial Results			
	2010	2011	2012
Net Revenues	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Cost of Revenues	[REDACTED]	[REDACTED]	[REDACTED]
Gross Profit	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Operating Expenses	[REDACTED]	[REDACTED]	[REDACTED]
Operating Income Before Research & Development	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Research and Development Expense	[REDACTED]	[REDACTED]	[REDACTED]
Operating Income	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Other Income (Expense)	[REDACTED]	[REDACTED]	[REDACTED]
Pre-tax Income	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Income Taxes	[REDACTED]	[REDACTED]	[REDACTED]
Net Income	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]

⁴ See **Appendix B.**

B. Sales of Products by Other Companies

1. Macoven's Sales of VitaCirc-B®, ALZ-NAC®, and L-Methylfolate Calcium®

27. It is my understanding that several companies, including Macoven Pharmaceuticals, LLC (“Macoven”), Brookstone Pharmaceuticals, LLC (“Brookstone”), now known as Acella Pharmaceuticals, LLC (“Acella”), Trigen Laboratories, Inc. (“Trigen”), Virtus Pharmaceuticals (“Virtus”), Midlothian Pharmaceuticals (“Midlothian”), and Seton Pharmaceuticals (“Seton”), sell or have sold unauthorized products that take sales from the PamLab Patented Products.

28. For example, I understand that Macoven has historically marketed and sold VitaCirc-B, ALZ-NAC, and L-Methylfolate Calcium as generic versions of Metanx®, CerefolinNAC®, and Deplin respectively. Cumulatively from launch in late 2011 through early 2013, Macoven's VitaCirc-B, ALZ-NAC, and L-Methylfolate Calcium have generated millions of dollars in sales.

29. Since VitaCirc-B, ALZ-NAC, and L-Methylfolate Calcium are marketed by Macoven as generic substitutes for Metanx®, CerefolinNAC®, and Deplin®, I understand the market for these Macoven products is the same as the market for PamLab's products and sales of the Macoven products

reduced PamLab's sales. I understand that Macoven's marketing activities concerning these products are directed to, *inter alia*, pharmacies, wholesalers, and pharmaceutical databases in which Macoven deliberately promotes its products as copies of PamLab's products. If PamLab had not been successful in establishing a market for these products, no incentive would exist for Macoven to develop and sell generic products that are substituted for PamLab's products.

30. As a result, Macoven's sales of VitaCirc-B, ALZ-NAC, and L-Methylfolate Calcium provide further indication of the commercial success of Metanx®, CerefolinNAC®, and Deplin®. Assuming Macoven's sales of these products would have been sales of PamLab, PamLab would have sold an additional 340,000 units.⁵

2. Sales of Other Products that Compete with the PamLab Patented Products

31. In addition to Macoven, others have sold unauthorized copies of PamLab's products that have taken sales from Metanx®, Cerefolin®, CerefolinNAC®, Neevo®, NeevoDHA®, and Deplin® including Brookstone/Acella, Trigen, Virtus, Midlothian and Seton. Assuming the sales of these companies' products and Macoven's products would have

⁵ Amount calculated using Ex. 2082 (HOF-000047-56).

been sales of the PamLab Patented Products, PamLab would have sold an additional 1.8 million units. See **Appendix C**. The sales volume and number of entities willing to sell competing, low cost imitations of the PamLab Patented Products provide further evidence of the commercial success of the PamLab Patented Products.

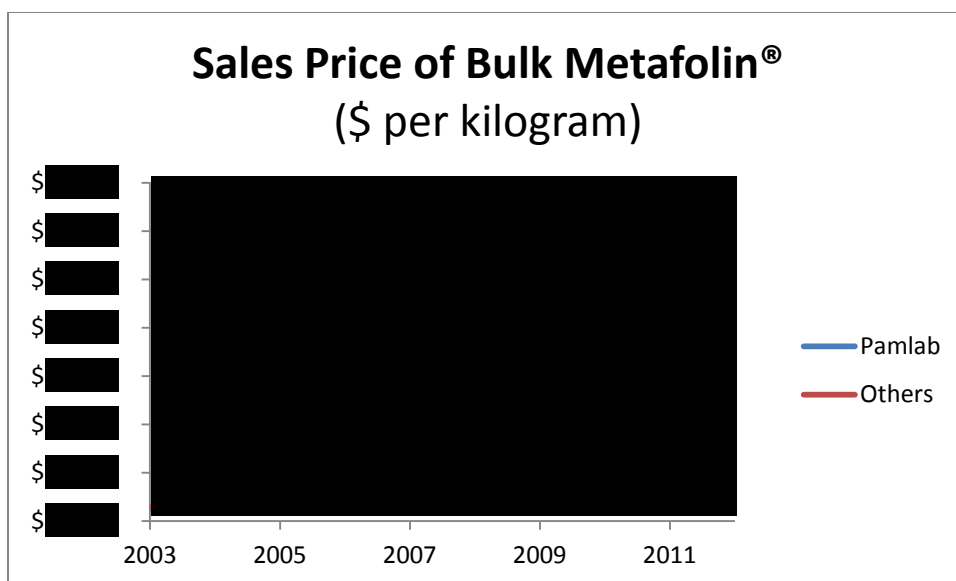
32. Furthermore, PamLab's ability to maintain strong sales levels, despite lower cost copies being on the market is a further indicator of the commercial success of Metanx®, Cerefolin®, CerefolinNAC®, Neevo®, NeevoDHA®, and Deplin®.

C. Ability to Command a Price Premium

33. I understand that METAFOLIN® 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 PamLab's Metanx®, CerefolinNAC®, Deplin®, Cerefolin®, Neevo® and NeevoDHA®. Since the first sales of bulk METAFOLIN® by Merck in 2003, the price of METAFOLIN® has consistently increased. During the period from 2003 to 2012, the largest purchaser of METAFOLIN® [REDACTED] has cumulative purchases of [REDACTED] kilograms of bulk METAFOLIN® at an average price of over \$[REDACTED] per

kilogram.⁶ Sales to other purchasers of METAFOLIN® have an average price of over \$[REDACTED] per kilogram.⁷

34. The average price per kilogram for METAFOLIN® for PamLab has increased approximately [REDACTED] percent from \$[REDACTED] to \$[REDACTED] from 2003 to 2012.⁸ The average price per kilogram paid by companies other than PamLab reflects an even more dramatic increase from an average of \$[REDACTED] in 2003 to an average of \$[REDACTED] in 2012, a [REDACTED] percent increase.⁹



35. The increase in average price per kilogram for METAFOLIN® has occurred despite competition from significantly lower priced folates.

⁶ See **Appendix D.**

⁷ See **Appendix D.**

⁸ See **Appendix D.**

⁹ See **Appendix D.**

For example, the average price a non-Pamlab customer paid for METAFOLIN® in 2012 was \$ [REDACTED] per kilogram. This is more than [REDACTED] *percent* higher than the price of bulk folic acid (approximately \$ [REDACTED] per kilogram).¹⁰

36. Furthermore, METAFOLIN® has been able to command a price premium compared to racemic methylfolate products such as Extrafolate. In fact, METAFOLIN® is priced at a level 300 percent above Gnosis' Extrafolate product.¹¹

37. Further, Pamlab products such as NeevoDHA® are able to command a price premium. For example, in 2012, NeevoDHA® had a net price of almost \$47 per bottle.¹² Non-prescription prenatal vitamins sell for a fraction of that price (on average around \$10 to \$20 per bottle), and often contain substantially more pills per bottle.¹³ I have analyzed the market for prenatal vitamins, including both prescription and over the counter prenatal

¹⁰ See, for example, Ex. 2090 (<http://purebulk.com/folic-acid-vitamin-b9-pure.html> (HOF-000015)).

¹¹ See (*Merck Eprova AG v. Gnosis SpA and Gnosis Bioresearch S.A.* Case 1:07-cv-05898-RJS –JCF, at 6 (S.D. N.Y.)).

¹² Based on net sales of \$ [REDACTED] on [REDACTED] units. Stipulation, ¶ 78.

¹³ For example, see Ex. 2148 (<http://www.walgreens.com/store/store/category/productlist.jsp?Erp=96&N=361277&Eon=361277>, (accessed September 21, 2013)); *see also* Ex. 2149 (http://www.cvs.com/shop/Vitamins/Health-Goals/Fertility-&-Prenatal-Care/_/N-3uZe84cZ2k?pt=SUBCATEGORY&pageNum=1&sortBy=&navNum=20, (accessed September 21, 2013)).

vitamins. In general, one of the primary distinguishing features between prescription and over the counter prenatal vitamins is the level of folate in the vitamin. From an economic perspective, many of the ingredients in prenatal vitamins are widely and cheaply available. It is the use of METAFOLIN® that is the primary feature for which PamLab is able to charge a price premium compared to over the counter prenatal vitamins.¹⁴ I also understand that NeevoDHA® is one of the most expensive prescription prenatal vitamins. The price premium commanded by products such as NeevoDHA® is another indicator of its commercial success.

D. Reasons for the Commercial Success

1. Sales are not driven by Discounting of Metanx®, Cerefolin®, CerefolinNAC®, Deplin®, Neevo®, and NeevoDHA®

38. In my experience, heavy discounting, rebates, and other incentives can have an effect on the sales of pharmaceutical products. However, some level of discounting with wholesalers, distributors, and formularies is expected and standard in the pharmaceutical industry.¹⁵ I

¹⁴ For example, see Ex. 2092 (<http://www.neevodha.com/> (HOF-000016-18) (“The ingredient that makes NeevoDHA® different from standard prenatal vitamins is the inclusion of L-methylfolate.”).

¹⁵ I have analyzed hundreds of product profit and loss statements during my professional career as both a consultant and as an expert witness. Each of these profit and loss statements contained some level of discounts, rebates, and other incentives. In

analyzed whether discounts, rebates, and other incentives drive the sales of the PamLab Patented Products. I have summarized gross and net sales of the PamLab Patented Products in the following table.¹⁶

PamLab Sales Information						
<u>Metanx®</u>		2010		2011		2012
Metanx® Gross Sales	\$		\$		\$	
Sales Returns	\$		\$		\$	
Metanx® Adjusted Gross Sales	\$		\$		\$	
Rebates/Discounts	\$		\$		\$	
Drug Rebate Fee	\$		\$		\$	
Metanx® Net Sales	\$		\$		\$	
Net Sales as % of Gross Sales		%		%		%
<u>Cerefolin®</u>		2010		2011		2012
Cerefolin® Gross Sales	\$		\$		\$	
Sales Returns	\$		\$		\$	
Cerefolin® Adjusted Gross Sales	\$		\$		\$	
Rebates/Discounts	\$		\$		\$	
Drug Rebate Fee	\$		\$		\$	
Cerefolin® Net Sales	\$		\$		\$	
Net Sales as % of Gross Sales		%		%		%
<u>CerefolinNAC®</u>		2010		2011		2012
CerefolinNAC® Gross Sales	\$		\$		\$	
Sales Returns	\$		\$		\$	
CerefolinNAC® Adjusted Gross Sales	\$		\$		\$	
Rebates/Discounts	\$		\$		\$	
Drug Rebate Fee	\$		\$		\$	
CerefolinNAC® Net Sales	\$		\$		\$	
Net as % of Gross		%		%		%

particular, the distribution, reimbursement and role of pharmacies and third party payers in the pharmaceutical industry typically involve discounts and rebates at various levels.

¹⁶ See **Appendix E**.

[REDACTED]

<u>Neevo® and NeevoDHA®</u>				
	2010		2011	2012
Neevo® and NeevoDHA® Gross Sales	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
Sales Returns	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
<hr/>				
<u>Neevo® and NeevoDHA®</u>				
Adjusted Gross Sales	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
Rebates/Discounts	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
Drug Rebate Fee	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
Neevo® and NeevoDHA® Net Sales	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
Net as % of Gross	[REDACTED] %		[REDACTED] %	[REDACTED] %
<hr/>				
<u>Deplin®</u>				
	2010		2011	2012
Deplin® Gross Sales	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
Sales Returns	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
<hr/>				
Deplin® Adjusted Gross Sales	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
Rebates/Discounts	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
Drug Rebate Fee	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
Deplin® Net Sales	\$ [REDACTED]	\$	[REDACTED]	\$ [REDACTED]
Net as % of Gross	[REDACTED] %		[REDACTED] %	[REDACTED] %

39. Excluding sales returns (which are unrelated to discounts and rebates), the PamLab Patented Products each have net sales that are above approximately [REDACTED] percent of gross sales, with most products only having discounts and rebates of [REDACTED] to [REDACTED] percent. Based upon my knowledge and experience in the pharmaceutical industry, this represents a relatively low level of discounts, rebates, and other incentives. In my experience, some level of discounts and rebates are the normal course of contracts with distributors of pharmaceutical products. Additionally, it is not uncommon to provide some level of discounts and rebates to formularies.

40. The limited level of discounts from 2010 to 2012 is particularly noteworthy, given that PamLab faced competition from lower cost alternatives such as Brookstone, Trigen, and Macoven in that timeframe. That PamLab has been able to maintain pricing with limited rebates and discounts is indicative of the commercial success of the PamLab Patented Products and that discounts are not driving the sales of the PamLab Patented Products. In my experience, discounts and rebates of approximately 20 percent or less of gross sales are relatively low. Based upon my analysis, PamLab has not heavily discounted its products to achieve its sales levels. Therefore, discounts and rebates have not been the driver of the commercial success of the PamLab Patented Products.

2. Marketing of Metanx®, Cerefolin®, CerefolinNAC®, Deplin®, Neevo®, and NeevoDHA® is Not Excessive

41. In my experience, marketing efforts can also sometimes be a driver of demand in the pharmaceutical industry. In general, pharmaceutical companies spend a substantial amount of money and resources on marketing products. Some level of marketing is necessary to disseminate information regarding prescription pharmaceutical and medical food products. This is particularly true when new products and/or new indications for prescription pharmaceutical products and/or medical foods are identified.

42. I understand that medical foods represent a niche market and are a unique form of therapy compared to traditional pharmaceutical drugs. I further understand that 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 the applicable indications.¹⁷ One of the most common forms of marketing spending by pharmaceutical companies is referred to as detailing. Detailing represents the process by which sales representatives call on physicians to provide information regarding products to encourage physicians to write prescriptions for the particular products.

43. PamLab has approximately [REDACTED] outside sales representatives that call on various types of physicians.¹⁸ I understand that the outside sales representatives are responsible for targeting potential writers of prescriptions, including general practice physicians, mental health practitioners, and podiatrists by visiting offices and directly promoting Deplin® and Metanx®.¹⁹ I further understand that each outside sales representative has between [REDACTED] and [REDACTED] potential prescribers to which they

¹⁷ I have studied the markets for depression, diabetes, and cognitive impairment and am familiar with the traditional treatments for these indications using drugs. PamLab is a leader in the sales and distribution of medical foods for treating these indications.

¹⁸ Based upon discussions with Mr. Kenny Ladner, Senior VP of Nestle Health Science – PamLab Inc.

¹⁹ *Id.*

are responsible for detailing Deplin® and Metanx®. In addition, PamLab has approximately [REDACTED] inside sales representatives who are responsible for promoting the outcome of clinical trials of Metanx®, CerefolinNAC®, and Deplin® through phone calls and other marketing techniques.²⁰ I understand that Cerefolin®, Neevo®, and NeevoDHA® are not currently actively promoted.²¹

44. I understand that the outside sales force calls on approximately 32,000 medical professionals, while the inside sales force calls on approximately 56,000 medical professionals to disseminate information regarding Metanx®, CerefolinNAC®, and Deplin®. Based upon my experience, the size of PamLab's sales force is reasonable considering the number and various types of physicians to which PamLab disseminates information.²²

²⁰ Based upon discussions with Mr. Kenny Ladner.

²¹ I understand that NeevoDHA® is no longer actively promoted (based upon discussions with Mr. Kenny Ladner). However, PamLab does field sample requests for NeevoDHA® and maintains a website for NeevoDHA®. See id.; see also Ex. 2092 (<http://www.neevodha.com/> (HOF-000016-18)).

²² Over the course of my career, I have studied product profit and loss statements, analyzed the size of a company's sales force for numerous prescription products and have studied industry and product data and articles regarding marketing resources deployed by pharmaceutical companies in my role as a testifying expert and/or as a consultant. Based upon my experience, PamLab's marketing efforts and resources are reasonable and not excessive.

45. The PamLab Patented Products have only been on the market since the mid to late 2000s. I understand that these products represent new and alternative methods for treating various conditions identified in the product inserts, such as, for example, peripheral neuropathy, mild to moderate cognitive impairment, and depression. In order to create awareness among prescribers of these products for treating these indications, some level of detailing and marketing is expected and necessary. The marketing by PamLab is commensurate with the level I would expect for disseminating information regarding the use of the products for their respective indications. Based upon my analysis, PamLab has not excessively marketed its products and marketing has not been the driver of the commercial success of the PamLab Patented Products.²³

46. In any event, the marketing messages for Metanx®, CerefolinNAC® and Deplin® are directed to what I understand are the claimed inventions. For example, I understand from discussions with Mr. Kenny Ladner, Senior VP of Nestle Health Science – PamLab Inc., that PamLab informs clinicians that prescribe its products of clinical data that

²³ As discussed earlier, PamLab's sales have increased significantly over time. If the PamLab Patented Products were not effective, and marketing was the primary driver of sales, I would not expect the continued growth in PamLab's sales.

demonstrate the effectiveness of its products, including the key L-Methylfolate ingredient, for the particular uses for which they are indicated.

47. My observation of the marketing message and differentiation of Metanx®, CerefolinNAC® and Deplin® relative to other products confirms this to be the case. PamLab’s marketing materials discuss the effectiveness of the different PamLab Patented Products for their particular indications, including highlighting the particular ingredients, most notably L-Methylfolate, that lead to the successful outcomes.²⁴

VI. Licensing

A. Licensing by SAMSF, Merck, and PamLab

48. SAMSF’s License Agreement with Merck (the “SAMSF License Agreement”), which covers the ‘915 Patent, the ‘381 Patent, and the ‘778 Patent (collectively, the “SAMSF Patents”), entitles Merck to, the practice of the Licensed Patent Rights for the manufacture, use, offer to sell, sale, or importation of Licensed Product that are [REDACTED]

[REDACTED]

²⁴ For example, see Ex. 2078 (MERCK ITC 16 00474393-94); Ex. 2091 (<http://www.metanx.com/learn-about-metanx/> (HOF-000034-38)); Ex. 2085 (MERCK ITC 04 00315371); Ex. 2084 (<http://cerefolinnac.com/mild-cognitive-impairment/learn> (HOF-000032-33)) and Ex. 2083 (<http://cerefolinnac.com/memory-loss-and-alzheimers-information/dosage-hyperhomocysteinemia-and-folate-deficiency> (HOF-000030-31)); Ex. 2162 (http://www.deplin.com/wp-content/uploads/Deplin_PI.pdf (MERCK ITC 03 00237040)); Ex. 2087 (<http://www.deplin.com/> (HOF-000028)); and Ex. 2088 (<http://www.deplin.com/folate-for-depression/> (HOF-000026-27)).

████████████████████. Under the license, Merck has undertaken research and development, product development, clinical trials, marketing risks, market development, manufacturing risks, and production volume.

49. Merck's willingness to enter into the SAMSF License Agreement represents an additional objective indicator of the nonobviousness of the SAMSF Patents. In exchange for the granting of rights to the SAMSF Patents, Merck paid \$████ million to SAMSF in issue and benchmark royalties. These issue and benchmark royalties included \$████ paid ten days after the effective date of the SAMSF License Agreement and several benchmark royalties of \$████ each after various production and sales milestones.

50. The SAMSF License Agreement also requires Merck to pay SAMSF █████ percent of royalties received by Merck related to the patents sublicensed by Merck to other parties. The significant portion of sublicense royalties agreed to be paid to SAMSF by Merck provides further objective indicia of nonobviousness of the SAMSF Patents.

51. The ongoing desire of Merck to continue to operate under the SAMSF License Agreement and the ability of Merck to generate significant sales of bulk METAFOLIN® as a result of the SAMSF License Agreement

provide further indications of the nonobviousness of the SAMSF Patents. As part of the SAMSF License Agreement, Merck agreed to pay SAMSF royalties earned on [REDACTED] of bulk METAFOLIN® for use in products covered by the SAMSF License Agreement.

52. Since 2002, PamLab has entered into numerous agreements with Merck to market and sell certain products covered by the U.S. Patents (the “Merck Agreements”). The terms of the Merck Agreements range from 2002 through 2020 and, at times, were for periods shorter than the lives of the U.S. Patents. Merck and PamLab had the option to renew at the end of each term if they desired to continue the licensing relationship. In fact, Merck and PamLab have both continued to renew their agreements even when either party could have terminated the agreements, providing further evidence of the nonobviousness of the U.S. Patents. The most recent agreements extend the term through 2020. To date, PamLab has paid Merck approximately \$[REDACTED] million in royalties based on the license agreements for the U.S. Patents, approximately \$[REDACTED] million of which are based on sales of the PamLab Patented Products. See **Appendix F**. Royalties based on Metanx®, CerefolinNAC®, Cerefolin®, Neevo®, and NeevoDHA® amount to approximately \$[REDACTED] million, and royalties based on Deplin® amount to approximately \$[REDACTED] million. See **Appendix F**.

53. As between PamLab and Merck, within the 2007 Patent, Know-How and Trademark License Agreement, among others, the parties agreed to apportion royalties based on [REDACTED] of PamLab licensed products [REDACTED] among the [REDACTED], [REDACTED], and [REDACTED] at a rate of [REDACTED] of the royalty rate each. These terms and apportionment were agreed to by profit motivated third parties in an arms-length transaction outside of litigation and is not an unreasonable method of apportionment for the licenses conveyed.

54. In addition, I understand the SAMSF License Agreements and the Merck Agreements with PamLab resulted from the desire and willingness of each entity to enter into the licenses and were not the result of litigation. The willingness of the parties to enter into the license agreements outside of litigation and the commercial success of the products sold as a result of the agreements provides further objective indicia of nonobviousness.

B. Licensing by Merck to Others

55. In addition to the license agreement between Merck and PamLab, Merck has licensed the U.S. Patents to numerous other entities throughout the world. Through 2012, Merck has collected \$[REDACTED] million in royalties from its licensing of the U.S. Patents. SAMSF has received a total

of approximately \$[REDACTED] million (including Pamlab) in royalties from Merck for licenses to the SAMSF Patents. The number of licenses as well as the significant royalty stream are strong indications of the commercial success of Pamlab's licensed products and the nonobviousness of the U.S. Patents. Merck's Licensees of the U.S. Patents other than Pamlab include the following entities:

- [REDACTED];
- [REDACTED];
- [REDACTED];
- [REDACTED];
- [REDACTED];
- [REDACTED];
- [REDACTED];
- [REDACTED];
- [REDACTED]; and
- [REDACTED].

56. With the exception of [REDACTED]²⁵, I understand that the license agreements between Merck and the licensees identified above resulted from

²⁵ Based upon discussions with Dr. Vera Katz, Merck's head of API global marketing, I understand that Merck entered into litigation with [REDACTED].

the independent desire and willingness of each entity to enter into the licenses and were not the result of or induced by litigation. In general, I understand that the parties to which Merck has granted licenses to the U.S. Patents have sought out Merck based on interest in purchasing METAFOLIN® and obtaining a license to the U.S. Patents.

57. I also understand that numerous companies seek to obtain a licensing relationship with Merck for the U.S. Patents and to purchase METAFOLIN® on a regular basis. It is my understanding that when considering a potential licensee, Merck generally looks for a partner that has a strong vision for product development; has the potential to make annual purchases of approximately ■ kg or more of METAFOLIN®; has an acceptable manufacturing facility; and that such an arrangement is not inconsistent with any of Merck's pre-existing licensing relationships. Further, it is my understanding that Merck declines potential customers a licensing arrangement for the U.S. Patents more than once a week because of their failure to meet Merck's business criteria.²⁶

58. It is apparent that the value of Merck's METAFOLIN® and products containing METAFOLIN® is well recognized by parties, who

²⁶ Based on discussions with Dr. Vera Katz, Merck's head of API global marketing.

reach out to Merck, without the need for Merck to engage in significant marketing.

C. Licensing by PamLab to Others

59. PamLab has also sublicensed the U.S. Patents to [REDACTED] Inc. which was acquired by [REDACTED] (“[REDACTED]”). [REDACTED] sold a [REDACTED] family of prenatal vitamins which I understand were covered by certain of the U.S. Patents and incorporated METAFOLIN® for many years. Merck received approximately \$[REDACTED] million in royalty payments from PamLab (related to [REDACTED] sales) between 2004 and 2011. See **Appendix F**.

60. In addition, [REDACTED] (“[REDACTED]”) and [REDACTED] (“[REDACTED]”) have also entered into sublicense agreements with PamLab at various times, for rights to the U.S. Patents.

61. It is my understanding that in the case of each of the above licenses, the license agreements between PamLab and its licensees resulted

from each entity's independent desire and willingness to enter into the licenses and did not result from litigation.²⁷

VII. Copying

62. The commercial manufacture and sale of products which are marketed as substitutable for the PamLab Patented Products provide further objective indicia of nonobviousness. Indeed, I understand that entities have endeavored to have pharmacies and national databases link their products to the PamLab Patented Products in an effort to have their lower priced alternative products substituted for prescriptions written for PamLab's products.²⁸

63. The selection of Metanx®, CerefolinNAC®, and Deplin® by Macoven for their competing copies is further objective evidence of nonobviousness. It is my understanding that Macoven set out to copy Metanx®, CerefolinNAC®, and Deplin® by directing a contract manufacturer to study those products and formulate its products to be generic copies. Moreover, I understand that in marketing and linking their

²⁷ I understand that [REDACTED] and PamLab had previously been involved in a litigation related to Foltx® which settled several years before [REDACTED] became the authorized generic for any PamLab products containing METAFOLIN®.

²⁸ For example, see Ex. 2099 (MERCK ITC 01 00056685 to MERCK ITC 01 00056701) at MERCK ITC 01 00056688, 697; Ex. 2134 (MERCK ITC 07 00471452 to MERCK ITC 07 00471515) at MERCK ITC 07 00471461, 466, 471, 501, 506. See, e.g., Ex. 2082 (HOF-000047-56).

products to the PamLab Patented Products, Macoven sought to copy the novel aspects of the claimed inventions because they copied Metanx®, CerefolinNAC®, and Deplin® for the purpose of marketing and selling these products as substitutable alternatives to the PamLab Patented Products, containing the same unique blend of ingredients, including the critical reduced folate ingredient, to treat the particular indications for which the PamLab Patented Products are used.

64. In addition to Macoven, many other entities have copied the PamLab Patented Products and/or have attempted to pass off their products as copies of the PamLab Patented Products. In each case, I understand that these entities endeavored to have pharmacies and national databases link their products to the PamLab Patented Products, in an effort to have their lower priced imitations substituted for the PamLab Patented Products, including: Brookstone/Acella, Trigen, Midlothian, Seton, and Virtus.

65. Each of the above-identified entities has attempted to copy the PamLab Patented Products, including linking their respective products to the PamLab Patented Products.²⁹ In doing so, I understand that each sought to copy the novel aspects of the claimed inventions because each sought to

²⁹ For example, see Ex. 2099 (MERCK ITC 01 00056685 to MERCK ITC 01 00056701); Ex. 2134 (MERCK ITC 07 00471452 to MERCK ITC 07 00471515).

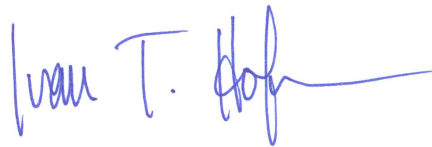
PUBLIC VERSION

copy the PamLab Patented Products for the purpose of marketing and selling these products as generic copies of the PamLab Patented Products, containing the same unique blend of ingredients, including the critical reduced folate ingredient, to treat the particular indications for which the PamLab Patented Products are used.

66. The number of entities attempting to copy the PamLab Patented Products is further objective evidence of nonobviousness of the U.S. Patents.

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

Dated October 16, 2013.

A handwritten signature in blue ink, appearing to read "Ivan T. Hofmann", with a long horizontal flourish extending to the right.

Ivan T. Hofmann, CPA/CFF, CLP

APPENDICES



	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013 [A]	Total
Metanx®	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
CerefolinNAC®	-	-	-	-	-	-	-	-	-	-	-
Cerefolin®	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Deplin® 7.5 mg	-	-	-	-	-	-	-	-	-	-	-
Deplin® 15 mg	-	-	-	-	-	-	-	-	-	-	-
Neevo® and NeevoDHA®	-	-	-	-	-	-	-	-	-	-	-

Sources: Information obtained from Royalty Reports, which may differ from other sales information spreadsheets due to timing and basis of accounting.

[A]: 2013 sales are through the second quarter of 2013.

Gnosis S.P.A., et al v. SAMSF and Gnosis S.P.A, et al. v. Merck & Cie
Pamlab Product Revenues as a Percentage of Sales

Appendix B

	[A] 2005	[A] 2006	[A] 2007	[A] 2008	[A] 2009	[A] 2010	[A] 2011	[A] 2012
Net Revenues (\$ in millions)	\$█	\$█	\$█	\$█	\$█	\$█	\$█	\$█
Metanx®	█%	█%	█%	█%	█%	█%	█%	█%
CerefolinNAC®	0%	█%	█%	█%	█%	█%	█%	█%
Cerefolin®	█%	█%	█%	█%	█%	█%	█%	█%
Deplin® 7.5 mg	0%	█%	█%	█%	█%	█%	█%	█%
Deplin® 15 mg	0%	0%	0%	0%	█%	█%	█%	█%
Neevo® and NeevoDHA®	0%	0%	█%	█%	█%	█%	█%	█%
Total	█%	█%	█%	█%	█%	█%	█%	█%

Sources: Note that information obtained from sales spreadsheets may differ from other sales information such as royalty reports due to timing and basis of accounting.

[A]: Percentages based upon sales from royalty reports as shown on **Appendix A**.

Gnosis S.P.A., et al v. SAMSF and Gnosis S.P.A, et al. v. Merck & Cie
Pamlab's Potential Lost TRx (IMS)

Appendix C

TRx Sales of Pamlab Products by Macoven and Other Entities

[A]	2010 Total	2011 Total	2012 Total	Total
Metanx®	460,745	341,580	219,646	1,021,971
CerefolinNAC®	62,958	80,307	47,738	191,003
Deplin® 7.5mg	49,042	64,624	42,146	155,812
Deplin® 15mg	3,444	4,665	105,353	113,462
Cerefolin®	26,550	45,550	15,312	87,413
Neevo®	16,204	26,060	1,704	43,969
NeevoDHA®	45,724	99,337	15,997	161,058
Total	664,667	662,122	447,897	1,774,686

Note:

[A]: Information for TRx from Macoven and other entities was obtained from IMS data at Ex. 2082 (HOF-000047-56). The IMS data at Ex. 2082 (HOF-000047-56) provided converts all prescriptions to 30 count bottles, even if the product is typically dispensed in a 90 count bottle. "Other entities" includes IMS data from Acella, Trigen, Virtus, Midlothian, and Seton.

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	Total
Net Sales (\$)											
Pamlab [A]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Others	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Kilograms Sold											
Pamlab [A]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Others	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Total	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Average Price per Kilogram											
Pamlab [A]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Others	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Overall Average	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]

Note:
[A]: Sales of bulk Metafolin® to Pamlab were for Pamlab's use of Metafolin® in products produced by Pamlab that contain Metafolin® (including sublicenses).

	2010	2011	2012
	Total	Total	Total
Metanx®			
Metanx® Gross Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Sales Returns	[REDACTED]	[REDACTED]	[REDACTED]
Metanx® Adjusted Gross Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Rebates/Discounts	[REDACTED]	[REDACTED]	[REDACTED]
Drug Rebate Fee	[REDACTED]	[REDACTED]	[REDACTED]
Metanx® Net Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Net Sales as % of Gross Sales	[REDACTED] %	[REDACTED] %	[REDACTED] %
CerefolinNAC®			
CerefolinNAC® Gross Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Sales Returns	[REDACTED]	[REDACTED]	[REDACTED]
CerefolinNAC® Adjusted Gross Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Rebates/Discounts	[REDACTED]	[REDACTED]	[REDACTED]
Drug Rebate Fee	[REDACTED]	[REDACTED]	[REDACTED]
CerefolinNAC® Net Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Net as % of Gross	[REDACTED] %	[REDACTED] %	[REDACTED] %
Deplin®			
Deplin® Gross Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Sales Returns	[REDACTED]	[REDACTED]	[REDACTED]
Deplin® Adjusted Gross Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Rebates/Discounts	[REDACTED]	[REDACTED]	[REDACTED]
Drug Rebate Fee	[REDACTED]	[REDACTED]	[REDACTED]
Deplin® Net Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Net as % of Gross	[REDACTED] %	[REDACTED] %	[REDACTED] %
Cerefolin®			
Cerefolin® Gross Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Sales Returns	[REDACTED]	[REDACTED]	[REDACTED]
Cerefolin® Adjusted Gross Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Rebates/Discounts	[REDACTED]	[REDACTED]	[REDACTED]
Drug Rebate Fee	[REDACTED]	[REDACTED]	[REDACTED]
Cerefolin® Net Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Net Sales as % of Gross Sales	[REDACTED] %	[REDACTED] %	[REDACTED] %
Neevo® and NeevoDHA®			
Neevo® and NeevoDHA® Gross Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Sales Returns	[REDACTED]	[REDACTED]	[REDACTED]
Neevo® and NeevoDHA® Adjusted Gross Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Rebates/Discounts	[REDACTED]	[REDACTED]	[REDACTED]
Drug Rebate Fee	[REDACTED]	[REDACTED]	[REDACTED]
Neevo® and NeevoDHA® Net Sales	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Net as % of Gross	[REDACTED] %	[REDACTED] %	[REDACTED] %

Product	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013 [A]	Total	% Total Pamlab
Cerefolin	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	%
CerefolinNAC	-	-	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	%
Metanx	-	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	%
Deplin	-	-	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	%
Neevo	-	-	-	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	%
NeevoDHA	-	-	-	-	-	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	%
Zervalx	-	-	-	-	-	[REDACTED]	[REDACTED]	[REDACTED]	-	[REDACTED]	[REDACTED]	%
Foltx	-	-	-	-	-	-	-	-	-	[REDACTED]	[REDACTED]	%
Total Pamlab	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	100%
Total [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	-	-	[REDACTED]	
Total	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	

[A] 2013 information is through the second quarter of 2013 only.

Ivan T. Hofmann, C.P.A., C.F.F., C.L.P.

Curriculum Vitae

Professional History

Gleason IP, a division of Gleason & Associates, P.C. – Managing Director/Shareholder

2006 to Present

Ivan Hofmann is a managing director and shareholder at Gleason IP. He has years of professional experience with a deep specialization in complex intellectual property matters. Mr. Hofmann's IP expertise includes extensive litigation support and testifying experience in quantifying financial damages related to patent infringement and other intellectual property issues, as well as breach of contract claims, warranty issues, class action law suits and other litigation-related matters. His experience includes using statistical, financial, and economic analysis and models related to various technical issues. He provides value-added services in all phases of litigation in various capacities, including assistance with discovery, depositions, expert opinions, and testimony during trial.

Mr. Hofmann's experience with intellectual property matters includes false advertising cases, theft of trade secrets, and trademark infringement matters. He has performed analysis of irreparable harm in preliminary injunction hearings and regularly performs analysis of commercial success in connection with secondary considerations of nonobviousness. Mr. Hofmann has experience with intellectual property issues in numerous industries, including extensive experience in the pharmaceutical industry.

As a Certified Licensing Professional (CLP), Mr. Hofmann has demonstrated knowledge and experience in analyzing license agreements and royalty terms. He assists companies in licensing negotiations with economic analysis in licensing agreements. He also has performed royalty audits on behalf of universities and corporations. Mr. Hofmann's extensive knowledge of licensing is useful in his analysis of reasonable royalties in patent infringement cases.

Also, Mr. Hofmann has experience in the areas of accounting, auditing, forensic accounting, fraud investigations and due diligence work. He has been involved in matters in state and federal civil and criminal courts, as well as domestic and international arbitration and other forums for dispute resolution. His experience includes matters with public and private companies in a broad range of industries including pharmaceuticals, telecommunications, broadband, health care, manufacturing, oil and gas, coal, utilities, land development, hospitality, and others.

Deloitte & Touche LLP – Senior Manager

1994 -2006

Mr. Hofmann was a senior manager with the public accounting firm of Deloitte & Touche LLP in the Forensic and Dispute Services and Assurance and Advisory services departments. He served numerous clients in various industries ranging in size from small, privately held companies to large, multi-national Fortune 500 companies.

Education and Certification

Bachelor of Business Administration, double major in Accounting and Economics, *Magna Cum Laude*,
University of Notre Dame, 1994
Certified Public Accountant, Pennsylvania 1996
Certified in Financial Forensics, 2008
Certified Licensing Professional 2010

Professional and Business Affiliations

American Institute of Certified Public Accountants, Member
Pennsylvania Institute of Certified Public Accountants, Member
Licensing Executives Society, Member

Civic Affiliations

Notre Dame Club of Pittsburgh