

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

Case IPR2013-00116
U.S. Patent No. 5,997,915

Case IPR2013-00118
U.S. Patent No. 6,673,381

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

**SUPPLEMENTAL DECLARATION OF SAMUEL STRADA, PH.D.
ADDRESSING CERTAIN EVIDENTIARY ISSUES**

MERCK EXHIBIT 2326 <i>Gnosis v Merck & CIE</i> IPR2013-00117

Supplemental Declaration of Samuel Strada, Ph.D.

1. I understand that Gnosis has raised certain evidentiary objections to my declaration and the exhibits attached thereto. After reviewing Petitioners' Evidentiary Objections Pursuant to 37 C.F.R. § 42.64 (hereafter, "Gnosis's objections"), I have been asked to provide this supplemental declaration addressing Gnosis's objections.

2. I understand Gnosis has objected to ¶¶ 2, 13-16, 18, and 20-30 of my declaration based on the following statement: "This declaration is based on my personal knowledge and/or information provided to me by employees of SAMSF." From this statement, Gnosis concludes that I lack personal knowledge of the facts contained in these paragraphs, or that these paragraphs contain information that represents hearsay. The facts and information set forth in my declaration are based on my personal knowledge.

3. In reference to ¶ 2 of my declaration, as President of SAMSF, I was (and continue to be) involved in managing the organization, which includes, among other things, making all necessary business, management and strategic decisions, which would include furthering and exploiting the development of SAMSF's technological innovations; understanding the finances of the SAMSF; and directing its day-to-day operations. I have been carrying out these duties since 1993. In order to execute my duties as President, I must understand SAMSF's technology and patent portfolio. I

have accumulated extensive, personal knowledge of the organization, its technology and technological assets (*i.e.*, patents and applications), its business and operations, as well as its conduct.

4. I understand that Gnosis has objected to statements in ¶ 13, which is generally directed to “SAMSF Patents.” In my capacity as President of SAMSF, I am fully aware of SAMSF’s patents and their applications; licenses that result from those patents; and I keep track of all royalty payments received by SAMSF from those licenses, as provided under the terms and conditions of those agreements. I perform these tasks to comply with my duties as President. Moreover, Gnosis is well aware that I was a SAMSF executor of the verification of the ITC complaint, and was informed of events relating to the patent portfolio, *e.g.*, Gnosis’s IPR petitions against the SAMSF patents. It is my job to know which patents are being challenged in these IPR proceedings so that I can make decisions on behalf of SAMSF as they relate to these proceedings. Therefore, as President of SAMSF, I have direct and personal knowledge of the facts described in ¶ 13 of my declaration pertaining to U.S. Patent Nos. 5,997,915; 6,673,381; and 7,172,778 (collectively, the “Bailey patents”), the resulting licenses, and royalties that resulted from those licenses.

5. ¶¶ 14-16 are generally directed to the “SAMSF-Merck License.” The SAMSF-Merck license represented a large investment of resources by SAMSF, and provides a significant royalty stream to SAMSF. In executing my duties as President, I am responsible compliances and adherence to the terms of the license (and any amendments thereto). To execute this function, I am personally aware of the facts contained in ¶¶ 14-16. Specifically, I was involved in negotiating these licenses on behalf of SAMSF, including the terms and conditions contained therein. As part of the process, I reviewed these licenses and became intimately familiar with their terms and conditions. This included evaluation of the technology as described in ¶ 14 and how to use the patents to create a source of revenue for SAMSF. As President of SAMSF, I was aware of the companies SAMSF negotiated with, including BASF and Rexall. (See ¶ 15). In fact, I was directly involved in those negotiations. My knowledge of the companies was derived from my having been responsible for licensing the Bailey patents.

6. As to ¶ 16, which pertains to SAMSF’s licensing partner, Merck, I had personal knowledge of the statements contained in ¶ 16.¹ In

¹ As I declare in ¶ 17, “I signed all of the licensing agreements with Merck on behalf of SAMSF.”

fact, I was personally involved in the negotiations with Merck, which led to the license agreements and amendments thereto at the time. I was fully aware of Merck's track record based on my experiences and observations of the folate business, which I acquired in my capacity as President of SAMSF. In reference to ¶ 18, this paragraph generally describes the names of licensees and dates of the license agreements that I signed. *See* ¶ 17. I read and understood the terms and conditions of the agreements when I executed them on behalf of SAMSF.

7. ¶¶ 20-21 relates to other technologies assigned to SAMSF and the revenues generated by the SAMSF-Merck agreement. As President of SAMSF, I am personally aware of SAMSF's licensed technologies and therefore have personal knowledge of the information contained in ¶ 20. During the relevant time period, I personally was aware that the license agreement between SAMSF and Merck was not precipitated under lawsuit or under threat of litigation. (See ¶ 21).

8. ¶¶ 22-30 relate to the "Annual Reports on Licensing" provided by Merck to SAMSF. I regularly review these reports when SAMSF receives them from Merck as required by my duties as President of SAMSF. Therefore, I am intimately familiar with the content of these reports and this is the basis of my knowledge of the statements in ¶¶ 20-30.

9. In providing this supplemental declaration, I have re-reviewed all of the statements and facts contained in ¶¶ 2, 13-16, 18, and 20-30. All of these statements and facts are based on my personal knowledge that I gained and was privy to as the relevant events that took place in my capacity as President of SAMSF.

10. Without providing any details, Gnosis has stated that ¶¶ 20, 25, 27, and 30 contain “improper opinion testimony by a non-expert.” ¶ 20 contains a recitation of the facts and the percentage of licensing royalty generated by the SAMSF-Merck agreement. ¶¶ 25 and 27 are recitations of the statements made to SAMSF in the Annual Reports and how I, as SAMSF’s President, interpreted the statements. The statements contained in ¶¶ 20, 25 and 27 are rationally based on my observations and perception, through the knowledge and experiences I have gained in my capacity as President of SAMSF, of the statements contained in the agreements and the levels of sales of Metafolin®.

11. The statements contained in ¶ 30 are based on my perception of the success of the SAMSF-Merck arrangement, resulting from my observations and experience as President, and having responsibility in managing these license agreements. ¶¶ 22-29 (and the additional facts provided in ¶ 30) contain the bases for my statements in ¶ 30. As President

of SAMSF (*i.e.*, the head of the organization), I am well within my capacity to determine whether an endeavor undertaken by SAMSF is a success, and the reasons for that success. Moreover, ¶ 30 discusses my personal expectations as of the time that SAMSF entered into the agreement (*i.e.*, that Merck as the exclusive licensee would in turn license to other companies). Finally, ¶ 30 makes reference to PamLab's licensed products. My observations were based on the information contained in the Annual Reports, which clearly indicate to me, as President of SAMSF since 1993, together with my experiences and observations in that capacity, that much of Merck's success is driven by PamLab's licensed products.

12. I also understand that Gnosis has objected to ¶¶ 22-30 as being irrelevant. In my view, information concerning the patents at issue and the revenues they have generated are the whole reason for the existence of the SAMSF-Merck license (and any amendments thereto).

13. In terms of Gnosis's objections to ¶ 22 based on lack of foundation, this paragraph provides a description of the Annual Reports Merck provides to SAMSF. The license agreement between SAMSF and Merck obligates Merck to provide these annual reports. The annual reports provide information regarding royalties owed to SAMSF, and information about how SAMSF's technological assets are being used. It is my duty as

President of SAMSF to read and review these reports, and I am therefore intimately familiar with their content.

14. I understand that Gnosis has also objected to certain exhibits attached to my declaration, namely Exhibits 2102, 2106, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2100, and 2252. As part of this supplemental declaration, I have re-reviewed these exhibits and can confirm their authenticity.

15. Exhibit 2102 contains true and accurate copies of the License Agreement between South Alabama Medical Science Foundation and Merck KGaA (1999); Amendment I to the License Agreement (2002); Amendment II to the License Agreement (2004); Amendment III to the License Agreement (2005); and Assignment Agreement (2009) (collectively, the “SAMSF-Merck license agreements”). I executed the SAMSF-Merck license agreements on behalf of SAMSF on the date indicated on each record. Upon execution, these records were kept in the ordinary and regular course of business of the organization in accordance with SAMSF’s retention policy for keeping such business records. Indeed, the regular practice of SAMSF would be that any license agreement (and any amendment thereto) would be written and kept in SAMSF’s files. I would be the custodian of these records.

16. Exhibits 2106, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2100, and 2252 are true and accurate copies of the Annual Reports provided to SAMSF by Merck for the years 2003 to 2012. The Annual Reports were timely provided to SAMSF at the end of their respective years pursuant to the SAMSF-Merck license agreements. I reviewed each Annual Report when each was provided to SAMSF in accordance with my duties. These Annual Reports include, among other things, information on the royalty revenues generated on an annual basis. These Annual Reports were kept by SAMSF in the regular and ordinary course of its business in accordance with SAMSF's retention policy for keeping such business records. I would be the custodian of these records. As discussed above, these written reports were regularly provided by Merck to SAMSF pursuant to the SAMSF-Merck agreement. Indeed, the regular practice was that the Annual Reports were provided in writing and kept in SAMSF's files.

17. Furthermore, I understand that Gnosis has objected to Ex. 2283 and 2284 as being hearsay. Ex. 2283 is entitled "Settlement Agreement and Release." My signature is on page 13 of the document. This document is a settlement agreement with Macoven Pharmaceuticals, LLC. Ex. 2284 is entitled "Settlement Agreement and Release." This document is a settlement agreement with Viva Pharmaceuticals, Inc. My signature is on page 12 of

the document. Collectively, I will refer to Ex. 2283 and 2284 as the “Settlement Agreements.”

18. The Settlement Agreements are true and accurate copies of the agreements that terminated the ITC investigation, In the Matter of Certain Reduced Folate Nutraceutical Products And L-Methylfolate Raw Ingredients Used Therein, Investigation No. 337-TA-857, to which Gnosis was a respondent. The ITC investigation involved the same patents as those involved in these Inter Partes Reviews. I reviewed and executed the Settlement Agreements in accordance with my duties. The Settlement Agreements were kept by SAMSF in the regular and ordinary course of its business in accordance with SAMSF’s retention policy for keeping such business records. I would be the custodian of these Settlement Agreements.

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

Date: October 15, 2013

A handwritten signature in black ink, appearing to read "Samuel J. Strada". The signature is fluid and cursive, with the first name "Samuel" and last name "Strada" being clearly legible.

Samuel J. Strada, Ph.D.

CERTIFICATE OF SERVICE

The undersigned hereby certifies the forgoing Supplemental Declaration of Samuel Strada, Ph.D., was served by email on October 15, 2013 to the Petitioners' counsel of record upon the following:

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Dated: October 15, 2013

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