

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 and MERCK & CIE  
Patent Owners

---

Case IPR2013-00116 (Patent 5,997,915)

Case IPR2013-00117 (Patent 6,011,040)

Case IPR2013-00118 (Patent 6,673,381)

Case IPR2013-00119 (Patent 7,172,778)<sup>1</sup>

Before JACQUELINE WRIGHT BONILLA, SCOTT E. KAMHOLZ, and  
SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

KAMHOLZ, *Administrative Patent Judge*.

ORDER  
Conduct of the Proceeding  
*37 C.F.R. § 42.5*

---

<sup>1</sup> South Alabama Medical Science Foundation (“SAMSF”) is the Patent Owner in cases IPR2013-00116, -00117, and -00119. Merck & Cie (“Merck”) is the Patent Owner in case IPR2013-00117.

IPR2013-00116; IPR2013-00117;  
IPR2013-00118; IPR2013-00119

By email dated May 13, 2014 (copy attached), Gnosis requested correction of several errors in the oral argument transcript. Patent Owners oppose most of the corrections, because they regard the challenged passages as not appearing, on their face, to be transcriptional errors.

Upon review of the proposed corrections, we determine that none of them is sufficiently substantial to warrant formal correction of the oral argument transcript. The parties' positions on the proposed corrections are noted in the record.

Accordingly, it is

ORDERED that Petitioners' request for correction of the oral argument transcript is *denied*.

IPR2013-00116; IPR2013-00117;  
IPR2013-00118; IPR2013-00119

For PETITIONERS:

Jonathan J. Krit  
Janine A. Moderson  
Amin Talati, LLC

Joseph E. Cwik  
Erik B. Flom  
Husch Blackwell LLP

For PATENT OWNERS:

Thomas Parker  
Jitendra Malik  
Alston & Bird, LLP

(SAMSF)  
Peter Rogalskyj  
The Law Office of Peter Rogalskyj

(Merck)  
Anthony J. Zelano  
Brion P. Heaney  
Millen, White, Zelano & Branigan, P.C.

IPR2013-00116; IPR2013-00117;  
IPR2013-00118; IPR2013-00119

---

**From:** Cwik, Joseph [mailto:Joseph.Cwik@huschblackwell.com]  
**Sent:** Tuesday, May 13, 2014 5:31 PM  
**To:** Trials  
**Cc:** thomas.parker@alston.com; Sterling, Andrew (Andrew.Sterling@alston.com); Malik, Jitty (Jitty.Malik@alston.com); Peter Rogalskyj (pr@prpatent.com) (pr@prpatent.com); 'Tony Zelano' (Zelano@mwzb.com); Brion Heaney (heaney@mwzb.com) (heaney@mwzb.com)  
**Subject:** IPR2013-00116, IPR2013-00117, IPR2013-00118, and IPR2013-00119

Dear PTAB:

We are counsel for Petitioners in the above-listed four IPRs.

We write to report several likely transcription errors in the transcript of the Oral Hearing held on March 20, 2014. Case IPR2013-00116, Paper 64; Case IPR2013-00117, Paper 67; Case IPR2013-00118, Paper 60; Case IPR2013-00119, Paper 61.

On May 9, 2014, the Board allowed Patent Owner to correct a similar error in the transcript after the court reporter checked the corresponding audio file. See, Case IPR2013-00116, Paper 65; Case IPR2013-00117, Paper 68; Case IPR2013-00118, Paper 61; Case IPR2013-00119, Paper 61.

Because the Board was willing to correct an error for Patent Owners, Petitioners also request that the audio file be checked for the following additional errors below:

On page 66, ln. 20-23, the transcript states, "Table 4 of Exhibit 1019 contains data that clearly is showing the folate deficiency is created by 5-MTHF, and it's doing this through administration over 60 days, and it's not reporting any of the concerns that Dr. Gregory raised." As is evident from Table 4 of Exhibit 1019 itself, Petitioners request that the incorrect word "created" be replaced by the word "treated."

On page 71, ln. 17 -18, the transcript states "he wrote -- well, the article he wrote was about the potential of a folinic acid for being a successful treatment of DPN." As is evident from the referenced Exhibit 1130, Petitioners request that the incorrect word "folinic" be replaced by the correct word "alpa-lipoic."

IPR2013-00116; IPR2013-00117;  
IPR2013-00118; IPR2013-00119

On page 75, ln. 15, the transcript states "He refers to folic preparations and not folic acid" Petitioners request the incorrect phrase "folic preparations" be replaced with the correct phrase "folate preparations."

On page 139, ln. 19, the transcript states, "discussing -- in its description of the heartbeat reference, but there are." Petitioners request the incorrect word "heartbeat" be replaced with the correct word "Harpey."

On page 141, ln. 17 and 19-20, the transcript states "calcium gluconate." As is evident from the Exhibit 1016, Petitioners request that the incorrect phrase "calcium gluconate" be replaced with correct phrase "calcium leucovorin."

Petitioners seek guidance from the Board regarding how Petitioners may correct these additional transcription errors.

Petitioners raised this matter with Patent Owners, who indicated that "Petitioners' requests refer to changes which, on their face, do not appear to be transcriptional errors, with the exception of replacing the word 'heartbeat' with 'Harpey.' Therefore, Patent Owners have no objection to Petitioners' request to replace 'heartbeat' with 'Harpey.' Patent Owners do, however, object to Petitioners' remaining requested changes to the record."

**Joseph E. Cwik**  
**Partner**

**HUSCH BLACKWELL LLP**  
120 South Riverside Plaza, Suite 2200  
Chicago, IL 60606-3912  
Direct: 312.526.1622  
Fax: 312.655.1501

[Joseph.Cwik@huschblackwell.com](mailto:Joseph.Cwik@huschblackwell.com)  
[huschblackwell.com](http://huschblackwell.com)

[View Bio](#) | [View VCard](#)

***Named a top healthcare law firm by American Health Lawyers Association and Modern Healthcare in 2013.***

Any tax advice contained in or attached to this message or email string is not intended or written to be used, and cannot be used to (i) avoid penalties that may be imposed on any taxpayer under the Internal Revenue Code or (ii) promote, market, or recommend to another any transaction addressed herein.