

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

GNOSIS S.p.A., GNOSIS)	
BIORESEARCH S.A. and GNOSIS)	
U.S.A., INC.,)	Case: IPR2013-00116
Petitioners)	Patent: 5,997,915
)	
v.)	Petition filed:
)	January 23, 2013
)	
SOUTH ALABAMA MEDICAL)	Filed Electronically
SCIENCE FOUNDATION,)	per 37 CFR § 42.6(b)(1)
Patent Owner)	
)	

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**PETITIONERS' REPLY IN SUPPORT OF
MOTION TO EXCLUDE EVIDENCE**

In support of their Motion to Exclude, Petitioners reply as follows:

Compliance With Rule 42.64(c) Exhibit A to Petitioners' Motion to Exclude details its initial objections in table format for each document exhibit and by individual paragraph for each Declaration. (*See*, Paper 49, Ex. A) Rule 42.64(c) does not require page/line number citations. If Patent Owner still could not locate an objection, a page/line number would have been readily provided upon request.

Exhibits 2008, 2013 Jacobs and Fonseca improperly testify as to the intent and belief of other physicians. (Ex. 2008, ¶¶ 42, 44)(Ex. 2013, ¶¶ 46, 48 and 53) This testimony violates established law that an expert cannot testify as to another's intent. *Fleischman v. Albany*, 728 F.Supp.2d 130, 167-68 (NDNY 2010). Because the Supplemental Declarations of Jacobs and Fonseca do not demonstrate the ability to read the minds of others, their testimony on the intent and belief of others should be excluded. (Ex. 2314)(Ex. 2318)

Exhibit 2016, 2022 In ¶¶ 61 and 84 of her declaration, Katz improperly testifies as to the intent and the belief of third-parties without personal knowledge. (Ex. 2016) FRE 602. Katz's Supplemental Declaration does not demonstrate the ability to read the minds of others. (Ex. 2319) The proper foundation for intent should have been through third party IPR discovery which was not pursued via subpoena or otherwise. In ¶¶ 74-79 of her declaration, Katz, a lay witness, provides improper testimony that certain products have certain medical uses. This is expert,

not lay, opinion testimony that requires specialized knowledge. *Daniels v. District of Columbia*, 2014 WL 535213, * 5 (D.D.C. Feb. 11, 2014)(“Testimony as to the diagnosis and treatment of a patient, and the reasons therefore, is beyond the ability of the average lay witness' competency and is necessarily based on “the expert's scientific, technical, or other specialized knowledge,” in the form of doctors' medical training and experience.”); *Granville v. Dart*, 2011 WL 892751, *7 (N.D.Ill. Mar. 11, 2011)(“Opinions or inferences based on medical, scientific, technical, or other specialized knowledge within the scope of Fed.R.Evid. 702 are not admissible as lay testimony.”) Similarly, in ¶¶ 38, 48-50, 56, 60-61, and 64-65 of his declaration, Ladner, a lay witness, provides improper expert opinions concerning the medical effectiveness and medical uses of products. (Ex. 2022) Because neither Katz’s or Ladner’s Supplemental Declaration establish them as experts with specialized medical knowledge, their medical testimony should be excluded. (Ex. 2319, 2323) FRE 701.

Exhibits 2017 and 2020. Hoffman and Reisetter improperly opine on the intent of corporate third-parties. (Hoffman Decl., Ex. 2017, ¶¶ 62-66)(Reisetter Decl., Ex. 2020, ¶¶13, 16-21, 39, 41, 51) Expert witnesses lack the personal knowledge to opine on another company’s intent and internal decisions, and thus any such opinion should be excluded. *Fleischman, supra*. Patent Owner misses the point by arguing that an expert can point to alleged evidence of copying. Here, Petitioners

only seek to exclude the expert statements opining on the intent of others. Also, it is paragraph 36, not paragraph 37, of the Hoffman declaration that improperly seeks to admit the hearsay factual findings from a court. (Ex. 2017, ¶ 36, fn. 11)

Exhibit 2024 Unlike the USPTO reexamination order in *Fresenius*, the hearsay declaration of June Ayling does not comply with FRE 803(8) because it fails to set out the “activities” of a public office, “a matter observed [by the public authority] while under a legal duty to report” or the office’s “factual findings.” FRE 803(8)

Exhibits 2063, 2064 Portions of Dr. Miller’s transcripts are not independently admissible because they exceed scope of his direct testimony in this IPR. Counsel timely objected to the IPR deposition questions with an objection to “form” and explained that the objection related to exceeding the scope. This practice complies with the Board’s commentary stating deposition objections should be made with one word. 48772 Federal Register/Vol. 77, No. 157/August 14, 2012/ Rules and Regulations (“Objections should be limited to a single word or term. Examples of objections that would be properly stated are: “Objection, form”; “Objection, hearsay”;”) Thus, Petitioners timely preserved an objection under Rule 42.53. Patent Owner did not attempt to cure any original question exceeding the direct and does not explain now how any of its questioning would have differed.

Exhibits 2065, 2180, 2183, 2184, 2185, 2229 Because of hearsay, the deposition transcripts from a previous ITC case are not independently admissible. Patent

Owner's argument that the witnesses were "effectively" unavailable is false given that Patent Owner made no attempt to subpoena their depositions here. Thus, the transcripts are not independently admissible even if relied upon by experts.

Exhibit 2074 This list of salts sourced from a 2002 book lacks relevance to a POSA who must view the invention prior to January 31, 1996, and thus, should be excluded as independent evidence. A relevance objection could not be included in the October 1, 2013 original objections because the identity of the 2002 source was withheld until Gregory's October 15, 2013 Supplemental Declaration. (Ex. 2324)

Exhibit 2075 (and his cited Exhibits 2039, 2048, 2049, 2050, 2052, 2055) In ¶¶ 18-25, 32, 43 and 44 of his declaration, Gregory attempts to establish the knowledge of a POSA at the time of the invention by relying upon the above-cited exhibits that post-date the date of invention, and thus are irrelevant. (Ex. 2075) (FRE 401/402, p. 4 of Petitioners' original objections). While the date of invention is January 31, 1996 for the '915 patent, Gregory relies upon the cited references published well after 1996. The MPEP 2124 exception does not apply here because the exhibits are not a post-invention teaching of a "universal fact" or "characteristics and properties of a material or a scientific truism."

Exhibits 2188, 2213, 2214 These loose labels or inserts lack authentication under FRE 902(7) because there is no evidence that they purport "to have been affixed in

the course of business and indicating origin, ownership, or control.” FRE 902(7).

Thus, the exhibits are not independently admissible even if relied upon by experts.

Exhibits 2281, 2296 These ITC discovery answers are not saved from hearsay because of Fed.R.Civ.P. 36. The Fed.R.Civ.P. do not even apply at the ITC which has its own procedural rules. *See*, 19 C.F.R. § 210 *et seq.* FRE 807 also does not apply because the answers are not “more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts” such as subpoenaed testimony in this IPR from Macoven and Viva.

Due to the reply brief page limit, Petitioners stand on their original Motion to Exclude for all other issues not addressed here. To the extent certain objections were not originally asserted, Petitioners rely upon the Board’s inherent power to exclude improper evidence. *Luce v. United States*, 469 U.S. 38, 41 n. 4, 105 S.Ct. 460, 83 L.Ed.2d 443 (1984)(“courts have the power to exclude evidence *in limine* pursuant to their inherent authority to manage trials.”)

March 4, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on March 4, 2014, I served the foregoing REPLY IN SUPPORT OF MOTION TO EXCLUDE in the subject proceeding on the following counsel of record via email (as authorized by South Alabama Medical Science Foundation in its Mandatory Notices, dated February 13, 2013) at the noted email addresses:

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