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Paper 64
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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 IPR2013-00118
Patent 6,673,381 B2

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

KAMHOLZ, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73(b)

I. INTRODUCTION

A. Background

Petitioner Gnosis S.p.A., Gnosis Bioresearch S.A., and Gnosis U.S.A., Inc. (collectively, "Gnosis") filed a Petition (Paper 2 ("Pet.")) to institute an *inter partes* review of claims 22, 26, and 32-38 ("the challenged claims") of U.S. Patent No. 6,673,381 B2 (Ex. 1002 ("the '381 patent")). The Board instituted trial for the challenged claims on the following grounds of unpatentability asserted by Gnosis:

Reference(s)[1]	**Basis**	**Claims challenged**
Serfontein	§ 102	22, 26, and 33-38
Serfontein and Marazza	§ 103	22, 26, and 32-38

Decision to Institute 2 (Paper 6 ("Dec.")).

After institution of trial, South Alabama Medical Science Foundation ("SAMSF") filed a Patent Owner Response in redacted form (Paper 20) and unredacted form (Paper 21). With our authorization (Paper 26), SAMSF filed a replacement Patent Owner Response in redacted form (Paper 31 ("Resp.")) and unredacted form (Paper 30). Gnosis filed a Reply to the Patent Owner Response in redacted (Paper 38 ("Reply")) and unredacted (Paper 37) forms.

SAMSF also filed a Motion to Amend (Paper 22). In it, SAMSF proposed canceling claims 22, 26, and 33-38, i.e., all challenged claims except claim 32. Paper 22, 1.

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[1] The references are: European Patent Application EP 0 595 005 A1 (Ex. 1009 ("Serfontein")) and U.S. Patent No. 5,194,611 (Ex. 1012 ("Marazza")).

SAMSF also filed a Motion to Exclude certain of Gnosis's evidence (Paper 46 ("PO Motion to Exclude")). Gnosis filed an Opposition (Paper 48), and SAMSF filed a Reply (Paper 55). Gnosis filed a Motion to Exclude certain of SAMSF's evidence (Paper 44 ("Pet. Motion to Exclude")). SAMSF filed an Opposition (Paper 50), and Gnosis filed a Reply (Paper 54).

Gnosis relies upon a declaration of Dr. Joshua W. Miller (Ex. 1005) in support of its Petition. SAMSF relies upon declarations of Dr. Vivian A. Fonseca (Ex. 2013), Dr. Jesse F. Gregory (Ex. 2075), Ivan T. Hofmann (Ex. 2017), Dr. Allen M. Jacobs (Ex. 2008), Dr. Vera A. Katz (Ex. 2016), Dr. Andrew C. Kerr (Ex. 2011), Audy Kent Ladner (Ex. 2022), Dr. Brian C. Reisetter (Ex. 2020), and Dr. Samuel Strada (Ex. 2019) in its Response, along with a deposition of Dr. Miller (Ex. 2064).[2] Gnosis relies upon depositions of Dr. Fonseca (Ex. 1143), Dr. Gregory (Ex. 1142), Mr. Hofmann (Ex. 1146), Dr. Jacobs (Ex. 1144), Dr. Katz (Ex. 1145), and Mr. Ladner (Ex. 1147) in its Reply.

Oral argument was conducted on March 20, 2014. A corrected transcript is entered as Paper 62 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

SAMSF's Motion to Amend is granted. As such, only the obviousness challenge to claim 32 remains at issue in this proceeding.

Gnosis has proved that claim 32 is unpatentable.

SAMSF's Motion to Exclude Evidence is dismissed as moot.

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[2] SAMSF also relies on a deposition of Dr. Miller from ITC Investigation No. 337-TA-857 (Ex. 2063), as well as depositions of several other individuals who were not produced by Gnosis in this proceeding.

Gnosis's Motion to Exclude Evidence is denied.

B. The '381 Patent

The '381 patent is titled "Uses for Food and Vitamin Preparations Containing the Natural Isomer of Reduced Folates," and generally relates to dietary folate supplementation. Ex. 1002, 1:17-19. The patent background explains that folate deficiency has been linked to various birth defects as well as to peripheral vascular disease and other disorders. *Id.* at 1:37-53. The background notes that individuals with peripheral vascular disease often have "abnormal blood levels of homocysteine, a precursor to methionine in the folate dependent step of the S-adenosylmeth[i]onine cycle." *Id.* at 1:47-49. The background explains that folate is added to commercial preparations (sometimes in combination with other vitamins, *id.* at 2:10-11) in the form of folic acid (*id.* at 2:32-33), a form which some individuals reportedly do not absorb readily from the intestine upon oral administration. *Id.* at 4:11-12. The background states that "there is reason to believe" that those with poor oral response to folic acid nevertheless will "possess[] adequate oral response to reduced folates." *Id.* at 4:18-20.

The background section of the '381 patent further explains that "the reduced folates found in nature" include compounds such as tetrahydrofolic acid ("THFA" or "THF"), 5-methyl-tetrahydrofolic acid, 5-formyl-tetrahydrofolic, each "having the same L-configuration at carbon-6." *Id.* at 4:38-41 (referring to compounds (II) – (VIII) shown in col. 3, ll. 1-65). Thus, the '381 patent identifies (6*S*)-THFA, 5-methyl-(6*S*)-THFA, and

5-formyl-(6*S*)-THFA among the "reduced folates found in nature." *Id.*[3] The background notes that recent concerns about adverse effects of the "unnatural isomer component" (i.e., the (6*R*) stereoisomer of 5-formyl-THFA) has led to commercial production of chirally-pure 5-formyl-(6*S*)-THFA for disease therapy. Ex. 1002, 4:43-46. The '381 patent proposes the use of natural isomers of reduced folates in dietary vitamin preparations. *Id.* at 4:59-63.

The detailed description section of the '381 patent specification describes the formulation of dietary vitamin preparations that include natural isomers of reduced folate. It discloses the amounts of one or more natural isomers of reduced folate that are to be included in preparations and expresses those amounts as percentages of the recommended dietary allowance ("RDA") or the reference daily intake ("RDI"). *Id.* at cols. 6-7. Inclusion of other nutrients is discussed, along with relative amounts of such other nutrients compared to the natural isomers of reduced folate. *Id.* at cols. 8-9. Various considerations for the manufacture of preparations are addressed. *Id.* at cols. 10-12. The specification of the '381 patent concludes with a listing of several example preparations. *Id.* at cols. 13-15. Among the other nutrients contemplated for inclusion in reduced folate preparations are pyridoxine hydrochloride (vitamin B_6) (*id.* at 13:52) and cyanocobalamin (vitamin B_{12}) (*id.* at 13:57, 14:58-59).

Claim 32, along with its parent claim 22, are reproduced below:

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[3] The '381 patent refers to these compounds in their acid forms but also refers generally to them as "folates," i.e., in their conjugate base forms. We consider these references synonymous for purposes of this decision. *Accord* Ex. 1012, 1:21-22 ("tetrahydrofolic acid" abbreviated as "THF").

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