

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
U.S. Patent No. 6,673,381

**PATENT OWNER'S NOTICE OF FILING PETITION FOR WRIT OF
CERTIORARI WITHIN THE TIME ALLOWED UNDER SUP. CT. R. 13**

Notice is hereby given that South Alabama Medical Science Foundation (“Patent Owner”) will file a petition for writ of certiorari before the Supreme Court of the United States, appealing from the Court of Appeals for the Federal Circuit’s decision in *S. Ala. Med. Sci. Found. v. Gnosis S.p.A.*, 808 F.3d 823 (Fed. Cir. 2015) (“*SAMSF I*”), affirming the Final Written Decision of the Patent Trial and Appeal Board (“PTAB”) entered on June 20, 2014 (Paper 64). The time for appeal—that is, appeal to the Supreme Court—has not expired. Patent Owner’s petition for writ of certiorari will be filed before July 25, 2016 in accordance with Sup. Ct. R. 13.

Patent Owner’s appeal arose from IPR No. 2013-00118. On December 17, 2015, a divided panel of the Federal Circuit issued a precedential decision upholding the PTAB’s Final Written Decision (Paper 64) finding all claims-at-issue invalid. A 2-1 majority upheld the PTAB’s invalidity rulings on the basis that the factual findings were supported by “substantial evidence.” The dissent indicated that the “clear error” standard should have been applied given the nature of *inter partes* review (“IPR”) proceedings, which were intended to be an alternative for district court proceedings. *SAMSF I*, 808 F.3d at 828 (Newman, J., dissenting) (referring to her dissent in the companion case *Merck & Cie v. Gnosis S.p.A.*, 808 F.3d 829, 839-40 (Fed. Cir. 2015) (“*Merck I*”), where application of the “clear error” standard instead of the “substantial evidence” standard would have changed the outcome of the appeal).

On January 19, 2016, Patent Owner petitioned the Federal Circuit for an *en banc* rehearing arguing, *inter alia*, that the panel majority should have applied a “clear error” standard of review to the PTAB’s factual findings instead of the more deferential “substantial evidence” standard. On April 26, 2016, the Federal Circuit denied Patent Owner’s petition for *en banc* rehearing. *S. Ala. Med. Sci. Found. v. Gnosis S.p.A.*, No. 2014-1778, slip op. at 2 (Fed. Cir. Apr. 26, 2016) (“*SAMSF IP*”) (per curiam).¹ In rejecting Patent Owner’s petition, Judges O’Malley, Wallach, and Stoll concurred while observing that application of the “substantial evidence” standard of review is “seemingly inconsistent with the purpose and content of the [America Invents Act (‘AIA’)]” and that “a substantial evidence standard of review makes little sense in the context of an appeal from an IPR proceeding.” *Id.*, concurrence at 1 (O’Malley, J., *et al.*, concurring) (concurring for the same reasons as stated in the denial of *en banc* rehearing in the companion case *Merck & Cie v. Gnosis S.p.A.*, No. 2014-1779, concurrence at 2 (Fed. Cir. Apr. 26, 2016) (“*Merck IP*”) (O’Malley, J., *et al.*, concurring). However, according to the concurring opinion, the question regarding the appropriate standard of appellate review was more appropriately addressed by Congress or the Supreme Court, given the Supreme Court’s decision in *Dickinson v. Zurko*, 527 U.S. 150 (1999). *Merck II*, concurrence

¹ Slip opinion and mandate included as Attachment 1 and Attachment 2, respectively.

at 2, 6-7 (O'Malley, J., *et al.*, concurring). In a dissenting opinion, Judge Newman likewise recognized the inapplicability of the “substantial evidence” standard of review for appeals from IPR proceedings. *SAMSF II*, dissent at 1-2 (Newman, J., dissenting).

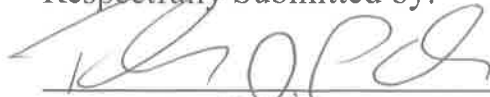
Further, three other judges of the Federal Circuit (Chief Judge Prost and Judges Moore and Reyna) previously have agreed with the premise underlying the issue to be presented by Patent Owner, namely, that IPRs are a surrogate for district court proceedings and should be treated as such. *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1297, 1300 (Fed. Cir. 2015) (Prost, C.J., *et al.*, dissenting), *cert. granted*, *Cuozzo Speed Techs., LLC v. Lee*, 2016 U.S. LEXIS 632 (U.S. Jan. 15, 2016) (No. 15-446).

The issues to be raised by Patent Owner's certiorari petition will include whether the Federal Circuit should apply a “clear error” standard of review to the PTAB's factual findings in IPRs rather than the “substantial evidence” standard given the purpose of the AIA. The petition will present a substantial question that has a reasonable likelihood of being granted because: (1) there is a split within the Federal Circuit over whether the “substantial evidence” standard should apply to IPR reviews given the purpose and content of the AIA; (2) it will address an issue that is predicated on a topic presently before the Supreme Court in *Cuozzo Speed Techs., LLC v. Lee*—namely, whether IPR proceedings were intended to function as

surrogates for district court litigation; and (3) it will have implications for virtually all appeals to the Federal Circuit from IPR final decisions.

Dated: May 9, 2016

Respectfully Submitted by:



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ATTACHMENT 1

**United States Court of Appeals
for the Federal Circuit**

**SOUTH ALABAMA MEDICAL SCIENCE
FOUNDATION,**
Appellant

v.

**GNOSIS S.P.A., GNOSIS BIORESEARCH S.A.,
GNOSIS U.S.A., INC.,**
Appellees

2014-1778, 2014-1780, 2014-1781

Appeals from the United States Patent and Trade-
mark Office, Patent Trial and Appeal Board, in Nos.
IPR2013-00116, IPR2013-00118, IPR2013-00119.

ON PETITION FOR REHEARING EN BANC

THOMAS J. PARKER, Alston & Bird LLP, New York,
NY, for appellant. Also represented by DEEPRO
MUKERJEE, YI WEN WU; JITENDRA MALIK, Durham, NC;
KIRK T. BRADLEY, Charlotte, NC; PETER ROGALSKYJ, Law
Office of Peter Rogalskyj, Livonia, NY.

JOSEPH CWIK, Amin Talati & Upadhye, LLC,
Chicago, IL, for appellees. Also represented by JONATHAN
JACOB KRIT.

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.

O'MALLEY, *Circuit Judge*, with whom WALLACH and STOLL, *Circuit Judges*, join, concur in the denial of the petition for rehearing en banc.

NEWMAN, *Circuit Judge*, dissents from the denial of the petition for rehearing en banc.

PER CURIAM.

ORDER

Appellant South Alabama Medical Science Foundation filed a petition for rehearing en banc. A response to the petition was invited by the court and filed by the appellees Gnosis S.p.A., Gnosis Bioresearch S.A., and Gnosis U.S.A., Inc.

The petition was referred to the panel that heard the appeal, and thereafter the petition and response were referred to the circuit judges who are in regular active service. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for rehearing en banc is denied.

The mandate of the court will issue on May 3, 2016.

FOR THE COURT

April 26, 2016
Date

/s/ Daniel E. O'Toole
Daniel E. O'Toole
Clerk of Court

**United States Court of Appeals
for the Federal Circuit**

**SOUTH ALABAMA MEDICAL SCIENCE
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Appellant

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Appellees

2014-1778, 2014-1780, 2014-1781

Appeals from the United States Patent and Trade-
mark Office, Patent Trial and Appeal Board, in Nos.
IPR2013-00116, IPR2013-00118, IPR2013-00119.

O'MALLEY, *Circuit Judge*, with whom WALLACH and
STOLL, *Circuit Judges*, join, concurring in the denial of the
petition for rehearing en banc.

This is a companion appeal to *Merck & Cie v. Gnosis
S.p.A.*, No. 2014-1779 (Fed. Cir. Dec. 17, 2015). Petitioner
South Alabama Medical Science Foundation “seeks *en
banc* rehearing for the same reasons addressed” by Merck
& Cie in its petition for rehearing. Pet. for Reh’g 3. I
therefore concur in the denial of rehearing en banc for the
same reasons stated in my concurrence in the companion
appeal. See *Merck & Cie v. Gnosis S.p.A.*, No. 2014-1779
(Fed. Cir. 2016 Apr. 26, 2016) (O’Malley, J., concurring in
denial of rehearing en banc).

**United States Court of Appeals
for the Federal Circuit**

**SOUTH ALABAMA MEDICAL SCIENCE
FOUNDATION,**
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v.

**GNOSIS S.P.A., GNOSIS BIORESEARCH S.A.,
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2014-1778, 2014-1780, 2014-1781

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mark Office, Patent Trial and Appeal Board, in Nos.
IPR2013-00116, IPR2013-00118, IPR2013-00119.

NEWMAN, *Circuit Judge*, dissenting from denial of the
petition for rehearing en banc.

This is the companion to *Merck & Cie v. Gnosis S.p.A.*,
No. 14-1777 (*Gnosis I*), decided concurrently. As in *Gno-
sis I*, the panel majority applied the deferential “substan-
tial evidence” standard of review and, in doing so, adopted
the factual findings of the PTAB and affirmed the PTAB’s
cancellation of U.S. Patent Nos. 5,997,915, 6,673,381, and
7,172,778. For the reasons discussed in my dissent to the
denial of *en banc* rehearing in *Gnosis I*, I believe *en banc*
consideration is necessary to realign the appellate stand-
ard of review of these *inter partes* proceedings with the
statutory purpose of the America Invents Act.

This case illustrates the pitfalls of the deferential “substantial evidence” standard. Despite concluding that the PTAB erred in assessing South Alabama Medical Science Foundation’s (SAMSF) licensing evidence, the panel majority affirmed the PTAB’s obviousness determination, on the ground that it was supported by substantial evidence.

There was extensive evidence of licensing, sublicensing, and relicensing of the SASMF patents. More than twelve companies have taken sublicenses to the SAMSF patents, and manufacture or sell products practicing the patents. The royalty stream for the SAMSF patents produces millions of dollars in annual revenue. The PTAB did not mention these as objective indicia of non-obviousness. Instead, the PTAB dismissed all of SAMSF’s objective evidence for lack of “nexus.” This was legal error, as the panel majority held. The majority nonetheless affirmed because “that evidence is not enough to overcome the strong evidence of obviousness . . . relied upon by the Board to reach its conclusion of obviousness.” *Gnosis II* at 8. This too was legal error, for all of the evidence must be considered together in evaluating obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *Leo Pharm. Products, Ltd. v. Rea*, 726 F.3d 1346, 1357 (Fed. Cir. 2013) (“Whether before the Board or a court, this court has emphasized that consideration of the objective indicia is part of the whole obviousness analysis, not just an afterthought.”)

This is a crowded field of science, with conflicting experimental results, from which it was not reasonably predictable that the compositions that were eventually developed would be biologically effective and commercially successful. Objective indicia such as commercial success “may often be the most probative and cogent evidence [of non-obviousness] in the record,” *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 998 (Fed. Cir. 2009) (modification in original) (quoting *Stratoflex, Inc. v.*

Aeroquip Corp., 713 F.2d 1530, 1538 (Fed. Cir. 1983)). Considerations of biological effect and commercial and public response are a balance to judicial hindsight. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 676 F.3d 1063, 1075-76 (Fed. Cir. 2012) (“The objective considerations, when considered with the balance of the obviousness evidence in the record, guard as a check against hindsight bias.”).

Precedent requires that the objective evidence be considered together with the other evidence relating to the question of obviousness. In turn, my colleagues also err in law, for our appellate role includes assuring that the correct law is applied by the PTAB. Although the panel majority finds substantial evidence to support the PTAB’s conclusion, less than all of the evidence was analyzed and weighed by the PTAB. On the entirety of the record, including the objective considerations, the petitioner has not established invalidity by a preponderance of the evidence, as required by statute.

Thus I respectfully dissent from the court’s refusal to reconsider this case *en banc*.

ATTACHMENT 2

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

14-1778, 14-1780, 14-1781

SOUTH ALABAMA MEDICAL SCIENCE FOUNDATION,

Appellant

v.

GNOSIS S.P.A., GNOSIS BIORESEARCH S.A., GNOSIS U.S.A., INC.,

Appellees

Appeals from the United States Patent and Trademark Office in case no. IPR2013-00116, IPR2013-00118, IPR2013-00119

MANDATE

In accordance with the judgment of this Court, entered December 17, 2015, and pursuant to Rule 41(a) of the Federal Rules of Appellate Procedure, the formal mandate is hereby issued.

Costs in the amount of \$265.00 were determined and taxed against the appellant.

FOR THE COURT

/s/ Peter R. Marksteiner

Peter R. Marksteiner
Clerk of Court

CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, in addition to being filed electronically through the Patent Review Processing System, the foregoing Patent Owner's Notice of Filing Petition for Writ of Certiorari Within the Time Allowed Under Sup. Ct. R. 13 was caused to be served by overnight mail to the following recipients:

Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia
22313-1450

Office of the General Counsel
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia
22313-1450

Dated: May 9, 2016



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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, the Patent Owner's Notice of Filing Petition for Writ of Certiorari Within the Time Allowed Under Sup. Ct. R. 13 was served by electronic mail, as consented to by the parties, upon the Petitioners' counsel of record upon the following:

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Dated: May 9, 2016



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