

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

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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).

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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*.