***Merck & Cie v. Gnosis*: "Substantial Evidence" Rule at the PTAB**

Today in *Merck & Cie v. Gnosis S.P.A.,* __ F.3d __ (Fed. Cir. 2016)(den. reh'g en banc)(Newman, J., dissenting) and *South Alabama Medical Science Foundation v. Gnosis S.P.A.,* __ F.3d __ (Fed. Cir. 2016)(den. reh'g en banc)(Newman, J., dissenting), the Great Dissenter once again set a new cumulative record for patent law dissents:

She unsuccessfully argued that the "substantial evidence" test should not be applied in post-grant proceedings at the PTAB under the new post grant review proceedings of the *Leahy Smith America Invents Act*.

It's Up to Congress to Act: In each case a concurring opinion was filed by O'Malley, J., joined by Wallach, Stoll JJ., concurring in the denial of the petition for rehearing en banc). She argued that the "substantial evidence" test may well be bad policy but it is up to Congress to rectify the situation.

Copies of the opinions in both cases are attached.

Regards,

Hal

United States Court of Appeals for the Federal Circuit

MERCK & CIE,
Appellant

v.

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

2014-1779

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in No. IPR2013-00117.

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

The panel majority considered whether the Patent Trial and Appeal Board's conclusion that the contested claims of the patent-in-suit are invalid as obvious was supported by substantial evidence. *Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 833 (Fed. Cir. 2015). Merck now urges this court to sit en banc to decide whether application of a more searching standard of review—clear error—is required for appeals from *inter partes* review proceedings ("IPR") under the America Invents Act ("AIA"). While I understand Merck's concerns, and those of the dissent, I do not believe we can alter our standard of

review for Board decisions, even via en banc consideration.

I agree that application of the substantial evidence standard of review is seemingly inconsistent with the purpose and content of the AIA. This court is bound by binding Supreme Court precedent—*Dickinson v. Zurko*, 527 U.S. 150 (1999)—and this court's own—*In re Gartside*, 203 F.3d 1305 (Fed. Cir. 2000)—to apply the substantial evidence standard of review to factual findings by the Board, however. Because Congress failed to expressly change the standard of review employed by this court in reviewing Board decisions when it created IPR proceedings via the AIA, we are not free to do so now. I, thus, concur in the denial of en banc rehearing in this case because there is nothing that could come of our en banc consideration of the question posed. I write separately, however, because I agree with the dissent to the extent it argues that a substantial evidence standard of review makes little sense in the context of an appeal from an IPR proceeding. But the question is one for Congress.

DISCUSSION

Before *Dickinson v. Zurko*, this court had a "settled practice of reviewing factual findings of the board's patentability determinations for clear error." *In re Zurko*, 142 F.3d 1447, 1458 (Fed. Cir. 1998) (en banc). In *Dickinson*, the Supreme Court disagreed, "conclud[ing] that [5 U.S.C. § 706 of the APA] does apply [to Board findings], and the Federal Circuit must use the framework set forth in that section." *Zurko*, 527 U.S. at 152.

In *In re Gartside*, we followed *Zurko*, concluding "that we must apply one of the standards set forth in the [APA]." 203 F.3d at 1311. Section 706 lays out two such standards: "arbitrary[and] capricious" and "substantial evidence." 5 U.S.C. § 706(2)(A), (E). Between these, we concluded that the relatively more searching "substantial evidence" standard is appropriate for review of factual

findings by the Board. We came to this conclusion based on the language of both the APA and Title 35.

The APA provides that "substantial evidence" review is afforded to agency factfinding "reviewed on the record of an agency hearing provided by statute." 5 U.S.C. § 706(2)(E). Title 35 gives the Federal Circuit the authority to review Board decisions:

> Section 144 explicitly provides that we must review Board decisions "on the record" developed by the PTO, *see* 35 U.S.C. § 144 (1994) ("The United States Court of Appeals for the Federal Circuit shall *review* the decision from which an appeal is taken *on the record* before the Patent and Trademark Office.") (emphasis added), and it is for this reason that the Commissioner is required to convey the record to us in the event of an appeal, *see id.* § 143. Moreover, the "hearing" upon which the "record" is based is "provided by" 35 U.S.C. § 7(b) . . . .

In re Gartside, 203 F.3d at 1313. In light of §§ 7 and 144 of Title 35, we concluded that "we review Board decisions 'on the record of an agency hearing provided by statute,' and that we should therefore review Board factfinding for 'substantial evidence.'" *Id.*

In light of *In re Gartside*, this court consistently has reviewed all of the Board's factual findings, including those in IPRs, for substantial evidence. *See* Pet. for Reh'g 5 ("[E]very Federal Circuit decision stemming from an IPR has applied the 'substantial evidence' standard . . . ."). I continue to believe that *In re Gartside* controls our standard of review for all Board proceedings, including those under the AIA.

It is true that, when authorizing IPR proceedings under the AIA, Congress created an adjudicative process involving a petitioner, a respondent, and a merits pro-

ceeding culminating in a deliberative resolution by administrative judges. It is also true that Congress viewed IPR proceedings as cost-efficient substitutes for litigation in federal district courts. The AIA's legislative history reflects this fact:

> The overarching purpose and effect of the present bill is to create a patent system that is clearer, fairer, more transparent, and more objective. It is a system that will ultimately reduce litigation costs and reduce the need to hire patent lawyers. . . . .
>
> By allowing post-grant review of patents, especially low quality, business method patents, *the bill creates an inexpensive substitute for district court litigation* and allows key issues to be addressed by experts in the field.

157 Cong. Rec. S5319 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl) (emphasis added). *See also*, 157 Cong. Rec. S1053 (daily ed. Mar. 1, 2011) (statement of Sen. Whitehouse) ("[T]he bill will improve administrative processes so that disputes over patents can be resolved quickly and cheaply without patents being tied up for years in expensive litigation."); 157 Cong. Rec. S1326 (daily ed. March 7, 2011) (statement of Sen. Sessions) ("This will allow invalid patents that were mistakenly issued by the PTO to be fixed early in their life, before they disrupt an entire industry or result in expensive litigation.").

To the extent IPR proceedings were intended to replace district court litigation, it would make sense for this court to review factual findings by the Board *in these new IPR proceedings* under the same standard we employ when reviewing factual findings of district judges—for clear error.

Indeed, throughout *Zurko*, the Supreme Court refers to clear error review as "court/court" review and to other standards of review contemplated by the APA as "court/agency" review. If Congress meant to create an adversary, party-instituted proceeding to consider what would otherwise be considered by district courts, it follows that review of a decision regarding patentability issued in an IPR could be viewed more like "court/court" review.

While we have always reviewed decisions in *inter partes* reexaminations for substantial evidence, those proceedings are different in character. *Inter partes* reexamination requests were assigned to a patent examiner in the Central Reexamination Unit trained in the same field of art in the initial prosecution, MPEP § 2636 (Eighth Edition, Revision 9, August 2012), and were decided initially by those examiners. IPRs, instead, are reviewed in the first instance by three technically-trained Administrative Patent Judges from the Board. 37 C.F.R. § 42.108. Once IPR is instituted, unlike in *inter partes* reexaminations, the Board applies the Federal Rules of Evidence, 37 C.F.R. § 42.62(a), it oversees various discovery obligations, 37 C.F.R. § 42.51, and it hears oral argument, 37 C.F.R. § 42.70. And where appeals from *inter partes* reexaminations were first made to the Board of Patent Appeals and Interferences, 35 U.S.C. § 134 (pre-AIA), appeals from IPRs are made directly to the Federal Circuit, 35 U.S.C. § 141. Congress did not merely state in legislative hearings that IPRs were meant to substitute for district court proceedings, it enacted substantive and procedural changes that brought IPR proceedings in line with district court proceedings in meaningful ways.

The AIA directs the Board to determine whether a petitioner in an IPR proceeding has met its "burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. § 316(e). It did not provide any such directive to this court, however. Merck argues that, "[b]ecause Congress intended PTAB rulings

to be reviewed for correct application of the standard of proof established by the AIA—preponderance of the evidence—this court must review the rulings for 'clear error,' not substantial evidence." Pet. for Reh'g 10. The fact that it might have made sense for Congress to change our standard of review for IPRs does not mean it did so.

While the failure to change our standard of review is seemingly inconsistent with what Congress sought to accomplish by creating IPR proceedings and may have been an oversight, it is not an inconsistency or oversight I believe we can correct. I believe we continue to be bound by the Supreme Court's decision in *Zurko* absent an express directive to the contrary. *See Zurko*, 527 U.S. at 155 (relying on the "congressional specification in the APA that '[n]o subsequent legislation shall be held to supersede or modify the provisions of this Act except to the extent that such legislation shall do so *expressly*.'" (emphasis added)). I also believe that IPRs are "agency hearing[s] provided by statute" within the meaning of *In re Gartside*.

As the dissent to the panel opinion points out, Congress knows well how to expressly address the level of review by an Article III court of a determination by an administrative agency, such as the Board. *See Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 841 (Fed. Cir. 2015) (Newman, J., dissenting) (noting that Congress has "adopted [the preponderance of the evidence standard] in other special situations. For example, Under the Service Contract Act, '[i]f supported by a preponderance of the evidence, the [agency's] findings are conclusive in any court of the United States.' 41 U.S.C. § 6507(e) (formerly 41 U.S.C. § 39)."). Though it may someday do so, Congress did not make such a clear statement in the AIA.

Unless and until Congress or the Supreme Court sees fit to change our standard of review expressly, we must

continue to review factual findings of the Board for substantial evidence.

United States Court of Appeals for the Federal Circuit

MERCK & CIE,
Appellant

v.

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

2014-1779

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in No. IPR2013-00117.

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

The America Invents Act created a new tribunal in the Patent and Trademark Office. This tribunal, called the Patent Trial and Appeal Board (PTAB), has several assignments including conduct of the post-grant proceedings authorized by the America Invents Act of 2012. Pub. L. No. 112-29, 125 Stat. 284 (2011) (effective September 16, 2012). In an *inter partes* review, a petitioner's allegations of invalidity on grounds of sections 102 and 103 of Title 35 can lead to PTAB proceedings similar to trial in the district courts, with discovery, evidence, testimony, briefs, hearings, and written decision. The PTAB decision may be appealed to the Federal Circuit, but cannot be

taken to remedy by civil action in the district court. *Compare* 35 U.S.C. § 319 *with* 35 U.S.C. § 145.

When the final decision is adverse to the patent owner, the PTAB cancels the affected patent or claims. An important aspect of the America Invents Act is that the final decision produces an estoppel against the petitioner in any ensuing litigation. Thus these PTAB proceedings carry a heavy load, for they affect not only the property rights of the patent owner, but also the potential liability and opportunity of the petitioner.

My concern relates to the Federal Circuit's implementation of its appellate role, for the court has adopted a highly deferential standard of review of these PTAB decisions, instead of the full and fair review that is appropriate to the America Invents Act. The entire thrust of the America Invents Act is that these PTAB proceedings would be an alternative to district court proceedings on these issues, and would receive the same level of appellate review. The highly deferential review standard of "support by substantial evidence" does not assure the intended identity of result for these PTAB and district court determinations.

En banc action is needed to realign the Federal Circuit's standard of review with the legislative purpose. Thus I respectfully dissent from my colleagues' denial of this request for *en banc* consideration.

DISCUSSION

To fulfill the Act's purpose that these PTAB proceedings will be a just substitute for district court proceedings on the designated issues, and will provide confidence and finality for the patent-based innovation communities, the PTAB decision must be subject to full and fair appellate review.

Precedent does not prohibit objective review of PTAB decisions

Although the concurring opinion states that the Court's decision in *Dickinson v. Zurko*, 527 U.S. 150 (1999), leaves no choice but to apply the substantial evidence standard, that view is an unwarranted enlargement. In *Zurko,* the Court held that the PTO is subject to the judicial review framework of the Administrative Procedure Act. *Id.* at 152 (citing 5 U.S.C. § 706). However, *Zurko* did not prohibit future legislation such as here enacted, where Congress created a new tribunal with authority to substitute for district court actions and results, and for these proceedings eliminated *de novo* review that is otherwise available for PTO decisions.

Statutes must be implemented to conform to "the design of the statute as a whole and to its object and policy." *Crandon v. United States*, 494 U.S. 152, 158 (1990). The design of the America Invents Act is not only to provide an efficient and economical surrogate for district court determinations of patent validity, but also to bind and estop the petitioner in any infringement proceeding. It is noteworthy that the PTAB is reviewing past PTO actions for error, without the deference that those actions receive in district court.

Viewing the America Invents Act in its entirety, the conclusion is compelled that Congress expected that these PTAB decisions would be reviewed on the same judicial standard as applies to the district court proceedings that are replaced. Our responsibility is to assure that the legislative purpose is implemented in accordance with the design, object, and policy of the statute. *Id.*

The "substantial evidence" standard does not conform to the statutory plan

The record shows a decade of study and evolution, as Congress and the technology-concerned public collaborated to provide an improved system for litigation resolution of the major patent validity issues. *See* H.R. Rep. No. 112-98, pt. 1, at 48 (2011) (*Inter partes* review will provide

"quick and cost effective alternatives to litigation"). Nowhere in the record is there a hint of intent to diminish the appellate responsibility of review of validity on the grounds of correctness in law and clear error of fact.

"Substantial evidence" is defined as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Consol. Edison Co. v. N.L.R.B.*, 305 U.S. 197, 229 (1938). "It must be enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury." *N.L.R.B. v. Columbian Enameling & Stamping Co.*, 306 U.S. 292, 300 (1939). As the Court stated in *Consolo v. Maritime Commission*, 383 U.S. 607, 620 (1966), "the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." This is the distinction here of concern, for application of the substantial evidence standard can lead to affirmance of a ruling that is not in accordance with the weight of the evidence. It is unlikely that Congress intended to place PTAB decisions in that "rubber-stamp" category—for in PTAB proceedings, with documentary and testamentary evidence presented by both sides, substantial evidence is usually present on both sides.

If on appeal the Federal Circuit simply looks for substantial evidence on the side of the PTAB decision, then the purpose of the America Invents Act to provide a surrogate for district court proceedings is thwarted. The decade of legislative hearings shows that the AIA-provided path of appellate review was intended and expected to be conducted on judicial standards, not on administrative standards. The America Invents Act rests on the foundation that PTAB proceedings will substitute for district court proceedings, and that the Federal Circuit will provide full appellate review. Note the elimination of access to district court review under 35 U.S.C. § 145 for post-grant proceedings, unlike the statute that existed at

the time of *Zurko*. 527 U.S. at 164 (1999) (highlighting the availability of 5 U.S.C. § 145 and the review of agency action under a clear error standard of review on appeal from a § 145 action).

There is no hint that Congress and the concerned communities contemplated omitting full appellate review by the Federal Circuit, while eliminating district court review and imposing an estoppel against the petitioner, who may not assert in defense to a charge of infringement any ground of invalidity "that the petitioner raised or reasonably could have raised" in the PTAB. 35 U.S.C. § 315(e)(2). With these substantive consequences, it is not reasonable to infer the legislative intent to apply highly deferential review to issues traditionally subjected to appellate review for correctness and clear error.

The standard by which the new PTO tribunal would determine validity was the subject of controversy in the Congress. The American Intellectual Property Law Association testified that: "The proposed second window, where the burden of proof is a 'preponderance of the evidence' instead of 'clear and convincing evidence,' will increase the risks faced by patent holders and dampen their enthusiasm for investing in the development and commercialization of their patented technologies." *Patent Act of 2005: Hearing on H.R. 2795 Before the House Subcomm. on Courts, the Internet, and Intell. Prop.*, 109th Cong. 15 (2005). Eventually the preponderance standard was adopted, but with balancing provisions including the estoppel provision and the review path to the Federal Circuit. It is not tenable to assume silent legislative intent to accompany this lightened burden of proving invalidity in the PTAB and restricted path of appeal, with a highly deferential standard of appellate review.

The PTAB proceeding is a trial between private parties, and requires commensurate review

This new proceeding is not an agency grant, but adjudication in accordance with the law of statute and precedent. At issue are property rights that were previously granted, vesting the patent right to exclude. *See James v. Campbell*, 104 U.S. 356, 358 (1881) ("When [the government] grants a patent the grantee is entitled to it as a matter of right, and does not receive it . . . as a matter of grace and favor."). This too weighs against deferential review of PTAB decision, for cancellation of property rights that the agency previously granted weighs against deferential review, lest any further error be ratified.

The legislative record shows the evolution of the America Invents Act from a simple "opposition"-like proposal, to a full trial proceeding whose result produces an estoppel. *Compare* H.R. Rep. No. 112-98, pt. 1, at 8 as enacted (describing the PTAB as a "court-like proceeding") *with* Patent Quality Assistance Act of 2004, H.R. 5299, 108th Cong. § 336(a)(2) (2d Sess. 2004) (permitting "opposer in an opposition proceeding" to avoid any estoppel in court proceedings). If the PTAB decision must be sustained if it is supported only by substantial evidence—even if the weight of the evidence would produce a contrary result—then the ambitious design of the America Invents Act collapses. Such an intent cannot be presumed.

Rather, the legislative record provides the expectation that the Federal Circuit will apply the standard judicial criteria for review. These criteria conform to the legislative purpose of providing an efficient and economical surrogate for district court trial, as well as authorizing challenges to patents not yet in litigation. The purpose is to reinforce reliability of the patent-based incentive to technological innovation, whereby valid patents are recognized and invalid patents are eliminated. *See* 157 Cong. Rec. S5327 (Sept. 6, 2011) (statement of Sen. Leahy) ("This bill will establish a more efficient and streamlined patent system that will improve patent

quality and limit unnecessary and counterproductive litigation costs, while making sure no party's access to court is denied.").

Post-grant proceedings are not simple administrative actions. The America Invents Act departs from the Administrative Procedure Act in its provisions for appeal directly to the Federal Circuit, eliminates district court review, and imposes estoppel against the petitioner. The substantial evidence standard of review distorts the legislative balance. *En banc* consideration is necessary to realign the appellate standard with the statutory purpose.

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 Trademark 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,
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 Trademark 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 *Gnosis I*, the panel majority applied the deferential "substantial 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 standard 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*.