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



Case IPR2013-00118 U.S. Patent 6,673,381

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 P"), 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 II") (per curiam). 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 II") (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.

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