Filed: November 30, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., and AKORN INC.,

Petitioners,

v.

SAINT REGIS MOHAWK TRIBE,

Patent Owner.

Case IPR2016-01127 (US 8,685,930 B2)
Case IPR2016-01128 (US 8,629,111 B2)
Case IPR2016-01129 (US 8,642,556 B2)
Case IPR2016-01130 (US 8,633,162 B2)
Case IPR2016-01131 (US 8,648,048 B2)
Case IPR2016-01132 (US 9,248,191 B2)[1]

BRIEF OF PUBLIC KNOWLEDGE AND THE ELECTRONIC FRONTIER FOUNDATION AS *AMICI COLLEGII* IN OPPOSITION TO THE MOTION TO TERMINATE

[1]Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601, have respectively been joined with the captioned proceedings. The word-for-word identical paper is filed in each proceeding identified in the caption.

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INTEREST OF *AMICI COLLEGII*

Amici Public Knowledge and the Electronic Frontier Foundation are nonprofit organizations that promote consumer interests with regard to intellectual property law. They and their members have a strong interest in promoting balanced intellectual property policy that serves both public and private interests.

Authorization for this brief is based on the order of the Board dated November 3, 2017. No one other than counsel for *amici* authored this brief in whole or in part, or made a monetary contribution to the preparation or submission of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

In *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, the Supreme Court explained that a patent wrongly deemed valid "does not concern only private parties. There are issues of great moment to the public." 322 U.S. 238, 246 (1944). "The public welfare demands that the agencies of public justice be not so impotent that they must always be mute and helpless victims of deception and fraud." *Id.*

The Patent Trial and Appeal Board is an agency of public justice, and need not be the helpless victim of the sovereign immunity scheme at play here. Because its mandate is to determine the validity of patents—a matter of great moment to the public, not just a concern of private parties—the Board's powers are distinct from the limited ambit of courts, which only determine relative rights of individuals.

The Board's public interest mandate renders sovereign immunity inapplicable before the Board, for at least three reasons. First, it causes *inter partes* review to be more like a public agency determination than private dispute resolution. Second, the Board's jurisdiction is solely directed to patents and not parties, and sovereign immunity does not apply to *in rem* proceedings. Third, the nature and result of the proceeding is distinct from judicial procedure in ways that have been held to render sovereign immunity inapplicable.

In any event, the Board should certify the question of sovereign immunity for guidance from the Director of the Patent and Trademark Office after public notice and comment. That procedure would enable participation by members of the public with key knowledge or interests, would guarantee consistency across Board decisions, and would work to avoid conflicts with other policy decisions and positions of the Office.

ARGUMENT

I. *Inter Partes* Review Is a Public-Interest Administrative Proceeding, Not Private Litigation

Applicability of sovereign immunity to an agency proceeding depends in part on the character of the proceeding and its similarity to traditional litigation. *See Fed. Mar. Comm'n v. S.C. State Ports Auth.* ("*FMC*"), 535 U.S. 743, 756–60 (2002). *But see Tenn. Student Assistance Corp. v. Hood* ("*TSAC*"), 541 U.S. 440,

452 (2004) (questioning *FMC*'s reliance on procedural similarities) (discussed *infra* p. 12). *Inter partes* review is not similar to litigation because it is not simply dispute resolution between two parties. A patent affects the entire public, and cancellation of improperly granted patents is a matter of the public interest as a whole. As a result, assessment of patent validity before the Board is more akin to an agency administrative proceeding, with effect on the public at large rather than merely the private parties before the agency.

1. "A patent by its very nature is affected with a public interest." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). Specifically, patents are a statutory instrument for promoting the public good: "The sole reason and purpose of the constitutional grant to Congress to enact patent laws is to promote the progress of science and useful arts." *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 35 (1923) (quoting U.S. Const. art. I, § 8, cl. 8); *see also Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917); *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 666 (1944) (patent is "conditioned by a public purpose"). The exclusive rights of a patent are not granted merely as a windfall or reward to inventors; the rights are part of a "carefully crafted bargain" between inventors and the public, where "the benefit to the public or community at large was . . . doubtless the primary object." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989); *Kendall v.*

Winsor, 62 U.S. (21 How.) 322, 328 (1859); *accord Motion Picture Patents*, 243 U.S. at 511; *see also J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) (describing "quid pro quo" of patent bargain) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 470 (1974)); *Universal Oil Co. v. Globe Co.*, 322 U.S. 471, 484 (1944) (same). "[T]he public interest in granting patent monopolies exists only to the extent that the public is given a novel and useful invention in consideration for its grant." *Fed. Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 2223, 2232 (2013) (quoting *United States v. Singer Mfg. Co.*, 374 U.S. 174, 199 (1963) (White, J., concurring)) (internal quotations omitted).

Fundamental to this bargain is that "the federal patent laws must determine not only what is protected, but also what is free for all to use." *Bonito Boats*, 489 U.S. at 151. Ensuring that "ideas in the public domain remain there for the use of the public" is the basic purpose behind the novelty and obviousness requirements of patentability. *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). The patent system thus "has a paramount interest in seeing that patent monopolies are kept within their legitimate scope." *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 851 (2014) (quoting *Precision Instrument*, 324 U.S. at 816) (internal quotes and alterations omitted); *see also United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 232 (1942); *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998); *Bilski v. Kappos*, 561 U.S. 593, 606 (2010).

2. Patents on anticipated or obvious ideas fail the patent bargain and injure the interests of the entire public, by preventing "the use of ideas that are in reality a part of the public domain." *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). A wrongly granted patent discourages innovation, diverts funds from research and development to litigation, increases consumer prices, delays competition, and ultimately "reduces the overall value of patent protection and undermines the public's confidence in the patent system at large." Megan M. La Belle, *Patent Litigation, Personal Jurisdiction, and the Public Good*, 18 Geo. Mason L. Rev. 43, 51 (2010). Thus, it is "important to the public that competition should not be repressed by worthless patents." *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892).

Two examples among many illustrate these harms. The first relates to erroneous pharmaceutical patents that block generic entry. Generic drugs create market competition that saves consumers money; "broad generic substitution of outpatient prescription drugs could save approximately $8.8 billion . . . in the United States each year." Jennifer S. Haas, *Potential Savings from Substituting Generic Drugs for Brand-Name Drugs*, 142 Annals Internal Med. 891, 894 (2005). An invalid patent that blocks generic entry thus denies the public those cost savings—perhaps the difference between life and death for some.

A study on HIV treatments identified two drugs for which the patents on the compounds were expired but for which generics were unavailable due to "sec-

ondary patenting" of minor variations and methods of manufacturing and treatment. Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals*, 31 Health Aff. 2286, 2288–89 (2012). The researchers found 108 secondary patents that could potentially delay generic entry by 12 years after the expiration of the base-compound patents; they also found in the patents "signs of quality concerns" that "may serve as a basis for challenging their validity." *Id.* at 2290–91. This is no outlier: A Federal Trade Commission study found that drug patents were invalidated at least 28% of the time in litigation. Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration* 20 (July 2002).

Another example of public harm from invalid patents comes from a firm, MPHJ, who held a patent on obvious methods of using document scanners. *See In re MPHJ Tech. Invs., LLC*, 159 F.T.C. 1004, 1006 (Mar. 13, 2015). This patent on everyday technology enabled MPHJ to scam large swaths of the public. The firm reportedly sent over 16,000 letters to small businesses, demanding payment of $1,000 or $1,200 per employee. *See id.* at 1010–11. Broad public nuisance was possible only because MPHJ's patent purported to take away a right to use technology in the public domain.

3. If wrongly granted patents are a public harm, then revocation of wrongly granted patents is "a public good to be shared . . . by society as a whole." La Belle, *supra*, at 97. The case of MPHJ exemplifies this: Its invalid patents and associated

scam were finally put to rest through *inter partes* review. *See MPHJ Tech. Invs., LLC v. Ricoh Americas Corp.*, 847 F.3d 1363 (Fed. Cir. 2017).

This public benefit of invalidation of erroneous patents has led the Supreme Court repeatedly to reject limitations on parties' ability to challenge patent validity. *See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 342 (1971) (expanding collateral estoppel effect of patent invalidity holding); *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007) (removing requirement that a licensee breach its license before seeking declaratory judgment of invalidity); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 102–03 (1993) (rejecting Federal Circuit practice of automatically vacating certain invalidity determinations); *Lear*, 395 U.S. at 670–71 (public interest in patent validity determinations overrides private interest in contract enforcement).

Inter partes review also ensures that patents "are kept within their legitimate scope" by enabling the Office "to reexamine an earlier agency decision" in view of new information. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016). This public purpose demonstrates, as *Cuozzo* concluded, that in "significant respects, inter partes review is less like a judicial proceeding and more like a specialized agency proceeding." *Id.* at 2143. Here, too, the public interest objective of *inter partes* review renders it more like a specialized agency proceeding, distinguishing *FMC* and rendering sovereign immunity inapplicable.

II. Sovereign Immunity Does Not Apply to *Inter Partes* Review Based on Judicial Precedent

In view of the unique public-interest purpose of *inter partes* review, case law dictates that sovereign immunity does not apply to preclude the proceeding. Cases on sovereign immunity have focused on the jurisdictional reach of the agency adjudicator and the nature and effect of the proceeding. All the factors under these considerations weigh against applicability of sovereign immunity.

A. The Board Has Jurisdiction Only over Patents, and Exercises No Jurisdiction over the Patent Owner or Other Parties

Sovereign immunity does not require dismissal of an *inter partes* review proceeding because the Board's jurisdiction over the proceeding is over the patents, and not the patent owner or any other party.

Where an adjudicator's jurisdictional power is over a thing rather than a party, sovereign immunity does not apply. In *TSAC*, an individual opened a bankruptcy proceeding to discharge her student loans, some of which were owed to a state agency, and the agency moved to dismiss based on sovereign immunity under the Eleventh Amendment. *See* 541 U.S. at 444–45. The Supreme Court held that sovereign immunity did not apply because the bankruptcy court's jurisdiction was *in rem*, "premised on the debtor and his estate, and not on the creditors." *Id.* at 447. The Court reviewed extensive precedent that had "drawn a distinction between *in rem* and *in personam* jurisdiction, even when the underlying proceedings are, for

the most part, identical." *Id.* at 453 (citing *California v. Deep Sea Research, Inc.*, 523 U.S. 491 (1998); *Van Huffel v. Harkelrode*, 284 U.S. 225 (1931); *New York v. Irving Trust Co.*, 288 U.S. 329 (1933)). In particular, the state was not a necessary party to the proceeding: "the Bankruptcy Court's *in rem* jurisdiction allows it to adjudicate the debtor's discharge claim without *in personam* jurisdiction over the State." *Id.* Because the bankruptcy court adjudicated only the debt and not the creditors, the Court distinguished *FMC* and held that no sovereign dignity was injured contrary to the Eleventh Amendment. *See TSAC*, 541 U.S. at 450.

In *Tennessee v. United States Department of Transportation*, a federal agency instituted a proceeding based on the complaint of a private party, to determine a state's compliance with federal waste management standards; the state contended that sovereign immunity precluded the agency proceeding. 326 F.3d 729, 732–33 (6th Cir. 2003), *cert. denied*, 540 U.S. 981. The Sixth Circuit held that sovereign immunity did not apply and *FMC* was "clearly distinguish[ed]" because the proceeding "approximates other administrative procedures already given approval." *Tennessee*, 326 F.3d at 734. In particular, the court relied on the fact that the proceeding "does not result in an order of enforcement against a state." *Id.* at 736.

Inter partes review is akin to the above two cases. As with *TSAC*, the sovereign is not a necessary party to the proceeding, and the Board exercises no *in personam* jurisdiction. The Board's sole power is over the patent—the *res*. And as in

Tennessee, *inter partes* review "does not result in an order of enforcement" against any party. Indeed, the Board "is without authority to issue an order against" any party, sovereign or not. 326 F.3d at 736. Certainly a sovereign's interests can be affected by the proceeding (either by cancellation of the patent or by estoppel under 37 C.F.R. § 42.73(d)(3)), but mere effect on interests is insufficient: Even "individualized determinations of [sovereigns'] interests" are permitted so long as no jurisdiction is exercised over the sovereign. *TSAC*, 541 U.S. at 450.

The unique nature of the Board's jurisdiction results in a unique remedy distinct from any judicial action. Courts in patent cases exercise *in personam* jurisdiction so invalidity determinations are personal to the parties; it is only because of modern collateral estoppel doctrine that judicial invalidity findings have broader effect. *See Blonder-Tongue*, 402 U.S. at 350 (overruling *Triplett v. Lowell*, 297 U.S. 638, 642–43 (1936)). The power to attach a certificate of cancellation to a patent is reserved to the Board, because its jurisdiction is *in rem*. *See* 35 U.S.C. § 318(b).

The Board's jurisdiction is over patents, not parties. Accordingly, a sovereign cannot assert immunity to prevent the Board from deciding the validity of patents.

B. The Character and Effect of *Inter Partes* Review Is Closer to Generalized Agency Action than Private Dispute Resolution

Several other features of *inter partes* review further demonstrate that, under judicial precedent, sovereign immunity does not apply.

Where the presence of affected parties in a proceeding is optional and the proceeding is "one against the world," sovereign immunity will not bar the proceeding. *TSAC*, 541 U.S. at 448. In *inter partes* review, the patent owner is not required to file any response, *see, e.g.,* 35 U.S.C. § 314(a)(2), and the Board has an independent power to determine patent validity even if the parties all withdraw from the proceeding, § 317(a). Furthermore, cancellation of a patent affects all people, so the proceeding is "one against the world." *See Lear*, 395 U.S. at 670.

Applicability of sovereign immunity also depends on "whether the adjudicator acts as the functional equivalent of an Article III judge" or rather "as an administrator of a federal agency." *Tennessee*, 326 F.3d at 735. Although administrative patent judges certainly enjoy a great degree of independence, the *inter partes* review process remains statutorily bound to the policy of the agency. The Director prescribes the rules for the proceeding, 35 U.S.C. § 316(a), makes the decision to institute review, § 314(b), and decides which opinions of the Board are to be precedential, PTAB Standard Operating Procedure 2, § III.D (rev. 9).

Sovereign immunity also will not bar a proceeding where the complainant "seeks relief properly characterized as prospective." *Verizon Md. Inc. v. Pub. Serv. Comm'n*, 535 U.S. 635, 645 (2002) (quoting *Idaho v. Coeur d'Alene Tribe*, 521 U.S. 261, 296, 298–99 (1997)); *accord Va. Office for Prot. & Advocacy v. Stewart*, 131 S. Ct. 1632, 1639 (2011); *Ex parte Young*, 209 U.S. 123 (1908). In *inter partes*

review, the only relief available is prospective. Patent cancellation does not result in damages against the patent owner or affect prior final infringement decisions.

Finally, *FMC* observed that while sovereign immunity is implicated when an agency resolves private disputes, the agency "remains free" to take action "either upon its own initiative or upon information supplied by a private party." 535 U.S. at 768. Determination of patent validity in *inter partes* review is much closer to this permissible form of administrative proceeding. As noted above, the parties need not be present in the proceeding, and the Board can conduct an independent analysis of patent validity even if the parties are in agreement. *Inter partes* review is best characterized as agency action "upon information supplied by" petitioners and patent owners, such that sovereign immunity is inapplicable.

It is irrelevant that, superficially, *inter partes* review resembles court litigation in certain procedures including discovery and motion practice. *Cf. Covidien LP v. Univ. of Fla. Research Found. Inc.*, IPR2016-01274 to -01276, at 22–23 (PTAB Jan. 25, 2017) (paper no. 21). In *TSAC*, the Court recognized that the bankruptcy proceeding at issue there "has some similarities to a traditional civil trial" in its procedural rules, such as a summons procedure. 541 U.S. at 452. Nevertheless, the Court found the rules insufficient to render the bankruptcy proceeding sufficiently court-like for sovereign immunity to apply; to do otherwise, said the Court, "would give the Rules an impermissible effect." *Id.* at 454.

The result for *inter partes* review is the same: To hold that procedural rules render sovereign immunity applicable would give those rules "an impermissible effect." The correct analysis focuses on whether jurisdiction is *in rem*, whether the parties are optional to the proceeding, whether the proceeding is subject to agency policy, whether the relief is prospective, and whether the agency exercises power to act independent of the parties' positions. On all of these counts, sovereign immunity does not apply to *inter partes* review.

III. The Board Should Certify This Question to the Director

While *amici* appreciate the opportunity to submit a brief in this matter, the decision on sovereign immunity question should ultimately be submitted to the Director, who should solicit broader public comment and issue agency-wide guidance, akin to the process that the Office has used in issuing guidance on subject matter eligibility for example. Notice and comment would be more proper than resolution by a panel of the Board, for at least three reasons.

First, a notice and comment proceeding would enable all interested parties to participate and provide useful information to the Office and the Board, and to do so without expensive and onerous requirements of retaining registered counsel. The question of applicability of sovereign immunity is one of tribal and constitutional law, and a notice and comment proceeding is the established mechanism to obtain diverse and useful public input from relevant experts and interested parties.

Second, certification to the Director will avoid inconsistent policy across panels of the Board. A decision by a panel of the Board is not necessarily precedential for other panels, whereas guidance from the Director will have immediate effect.

Third, and perhaps most importantly, the Director is best positioned to assess any consequences for the Office as a whole. The determination of this sovereign immunity question could affect a variety of administrative and policy issues, potentially even impacting legal positions that the Office has taken in other contexts. *Compare* Brief for the Federal Respondent at 24, *Oil States Energy Servs., LLC v. Greene's Energy Group, LLC*, No. 16-712 (U.S. Oct. 23, 2017) (*inter partes* review determines "rights as against the world"), *and id.* at 25 ("Board's role is . . . not to determine the respective rights of the patentee and challenger vis-à-vis each other"), *with Covidien*, IPR2016-01274 to -01276, at 15 ("*inter partes* review is not a proceeding 'against the world'"), *and id.* at 19 ("*inter partes* review is an action against the patent owner").

Cognizance of the ripple effects of any action on this issue is of the utmost importance here. Indeed, the disposition of the subsidiary question of how court-like *inter partes* review appears is arguably already affected by the *amicus curiae* brief solicitation itself. Besides peculiarly styling the Board as a "*curiae*" (something that the caption to this brief seeks to correct), the choice of a judicial practice for public input rather than the ordinary agency practice of notice and comment could

potentially, if unintentionally, tilt the substantive outcome.

The Board's work is exceptionally important, in view of the national interest in a balanced and properly functioning patent system not flooded with invalid patents. But the Board is not a freestanding entity; it is a part of the United States Patent and Trademark Office. To ensure that a correct, consistent decision without unintended consequences is reached on a momentous issue such as sovereign immunity, the Board should defer the question to the agency as a whole.

CONCLUSION

For the foregoing reasons, the Board should deny the Patent Owner's motion to terminate these proceedings.

Respectfully submitted,

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/Charles Duan/

Charles Duan
USPTO Reg. No. 65,114
Public Knowledge
1818 N Street NW, Suite 410
Washington, DC 20036
(202) 861-0020
cduan@publicknowledge.org
Counsel for Public Knowledge and the Electronic Frontier Foundation

CERTIFICATE OF SERVICE

I hereby certify that on November 30, 2017, I caused the foregoing **Brief of Public Knowledge and the Electronic Frontier Foundation as *Amici Collegii* in Opposition to the Motion to Terminate** to be served by email on the following counsel of record:

PETITIONER MYLAN:

Steven W. Parmelee
Michael T. Rosato
Jad A. Mills
Richard Torczon
WILSON SONSINI GOODRICH & ROSATI
sparmelee@wsgr.com
mrosato@wsgr.com
jmills@wsgr.com
rtorczon@wsgr.com

PETITIONER TEVA:

Gary Speier
Mark Schuman
CARLSON, CASPERS, VANDENBURH, LINDQUIST & SCHUMAN, P.A.
gspeier@carlsoncaspers.com
mschuman@carlsoncaspers.com

PETITIONER AKORN:

Michael Dzwonczyk
Azadeh Kokabi
Travis Ribar
SUGHRUE MION, PLLC
mdzwonczyk@sughrue.com
akokabi@sughrue.com

PATENT OWNER:

Dorothy P. Whelan
Michael Kane
Susan Coletti
Robert Oakes
FISH & RICHARDSON P.C.
whelan@fr.com
PTABInbound@fr.com
coletti@fr.com
oakes@fr.com
singer@fr.com

Alfonso Chan
Joseph DePumpo
Michael Shore
Christopher Evans
SHORE CHAN DEPUMPO LLP
achan@shorechan.com
jdepumpo@shorechan.com
mshore@shorechan.com
cevans@shorechan.com

Marsha Schmidt
marsha@mkschmidtlaw.com

Dated: November 30, 2017

/Charles Duan/
Charles Duan
Counsel for Public Knowledge and the Electronic Frontier Foundation