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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEOCHORD, INC., Petitioner,

v.

UNIVERSITY OF MARYLAND, BALTIMORE and HARPOON MEDICAL, INC.,
Patent Owner.

Case IPR2016-00208 Patent 7,635,386 B1

Before SALLY C. MEDLEY, ERICA A. FRANKLIN, and JAMES A. WORTH, *Administrative Patent Judges*.

WORTH, Administrative Patent Judge.

ORDER

Decision Granting Patent Owner's Motion to Dismiss and Terminating *Inter Partes* Review 37 C.F.R. §§ 42.71(a) and 42.72

Patent Owner University of Maryland, Baltimore ("the University") moves to terminate the *inter partes* review proceeding, stating that it possesses Eleventh Amendment immunity. Petitioner NeoChord, Inc. ("NeoChord") opposes. For the reasons set forth below, we grant the University's Motion to Dismiss based on Eleventh Amendment immunity and terminate the *inter partes* review.

I. Procedural History

On November 18, 2015, NeoChord filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 1–23 of U.S. Patent No. 7,635,386 B1 (Ex. 1001, "the '386 patent"). The University did not file a Preliminary Response to the Petition but did file a mandatory notice pursuant to 37 C.F.R. § 42.8, representing that it is the Patent Owner and a real party-in-interest. Paper 5, 2. In the Mandatory Notice, the University explained that Harpoon Medical, Inc. ("Harpoon Medical") is the exclusive licensee of the '386 patent and is also a real party-in-interest. *Id*. ¹

On May 24, 2016, the Board instituted an *inter partes* review on certain of the asserted grounds of unpatentability and issued a Scheduling Order. Paper 6; Paper 7. On September 12, 2016, the University filed a Response to the Petition (Paper 11), and on November 28, 2016, NeoChord filed a Reply. Paper 12.

On January 31, 2017, oral argument was heard on the merits of the instituted grounds pursuant to the Scheduling Order for the proceeding. *See* Paper 27. The day prior to the hearing, the University contacted the Board

¹ Per their respective mandatory notices, the parties indicate that there is no other judicial or administrative matter that would affect, or be affected by, a decision in this proceeding. Pet. 2; Paper 5, 2.

seeking authorization to file a motion to dismiss based on sovereign immunity. Because of the lack of written briefing on this issue, the panel informed the parties that a separate conference call would be held for the University to seek written briefing, pursuant to the Board's requirements for prior authorization for motions. *See* 37 C.F.R. § 42.20(b). On February 7, 2017, a conference call was held between Judges Medley, Franklin, and Worth and counsel for NeoChord and the University. A transcript of the call has been placed in the record as Paper 21. On February 15, 2017, the Board issued an Order authorizing the subject motion and setting a schedule for briefing.

Pursuant to this schedule, on February 23, 2017, the University filed a Motion to Dismiss (Paper 24, "Mot."). On March 2, 2017, NeoChord filed an Opposition to Patent Owner's Motion to Dismiss (Paper 25, "Opp."). On March 9, 2017, the University filed a Reply to Petitioner's Opposition to Patent Owner's Motion to Dismiss (Paper 26, "Mot. Reply").

The University moves to terminate, stating that it possesses Eleventh Amendment immunity pursuant to Maryland State law. Mot. 2–4 (citing MD Code Ann., Educ. §§ 12-102(a)(2)–(a)(4), 12-104(i)(4); *Maryland Stadium Authority v. Ellerbe Becket Inc.*, 407 F.3d 255 (4th Cir. 2005)).² According to the University, it is entitled to assert sovereign immunity as a

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² The University asserts that the only exception to its sovereign immunity under Maryland law is the Maryland Tort Claims Act (MD Code Ann., State Gov't § 12-104), which, according to the University, does not create an exception to sovereign immunity in this proceeding. Mot. 4. NeoChord does not make any arguments with respect to the exception provided by the Maryland Tort Claims Act.

defense because it is an "arm of the State of Maryland," and the '386 patent is "property of the State." Mot. 1.

NeoChord opposes on several grounds. In particular, NeoChord contends that a prior panel of the Board in *Covidien* erred in finding that sovereign immunity was available as a defense before the Board, that the University has waived immunity through its participation in this proceeding, that the University has waived immunity through its licensing activity, and that the Board may proceed without the University. Opp. 2–13 (citing *Covidien LP v. Univ. of Florida Research Foundation Inc.*, Case IPR2016-01274 (PTAB Jan. 25, 2017) (Paper 21)).³

II. Whether a State May Assert Eleventh Amendment Immunity in this *Inter Partes* Review Proceeding

The first issue that we address is whether a State's assertion of sovereign immunity under the Eleventh Amendment is a cognizable defense in this *inter partes* review proceeding. NeoChord argues that a prior panel of the Board in the *Covidien* case erred in concluding that Eleventh Amendment immunity was available as a defense. Opp. 10–12. NeoChord also argues that *Covidien* was decided based on a different procedural posture and is not binding precedent on this panel. Opp. 9 (citing *Chevron N. Am., Inc. v. Milwaukee Electric Tool Corp.*, IPR2015-00595, slip op. at 4 (Paper 35) (Nov. 13, 2015)). We agree with NeoChord that the *Covidien* decision is not binding in this case. Our examination of the availability of Eleventh Amendment immunity is set forth below.

³ NeoChord does not meaningfully contest the University's assertion that it is an "arm of the State of Maryland" (*see* Opp. 1), and we determine that the University has adduced sufficient evidence that it is an arm of the State (*see* Mot. 1–4).

a. Background Law on Agency Proceedings and Application to this *Inter Partes* Review Proceeding

In Federal Maritime Comm'n v. South Carolina State Ports Authority, 535 U.S. 743, 751, 757–59 (2002) (hereinafter, "FMC"), the Supreme Court affirmed a ruling from the U.S. Court of Appeals for the Fourth Circuit, which stated that the agency proceeding "walks, talks, and squawks" like a court proceeding for purposes of the Eleventh Amendment analysis. The Supreme Court analyzed the procedures of the Federal Maritime Commission, and found that they resembled the procedures of a district court, including discovery and application of the Federal Rules of Civil Procedure. *Id*.

In Vas-Cath, Inc. v. Curators of University of Missouri, 473 F.3d 1376, 1382 (Fed. Cir. 2007) (hereinafter, "Vas-Cath"), the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") applied FMC, explaining that agency proceedings may be treated like Court proceedings for Eleventh Amendment purposes, and indicated that interference proceedings before the Board of Patent Appeals and Interferences (our predecessor Board) were similar to district court proceedings in terms of discovery and procedure. See Vas-Cath, 473 F.3d at 1381. In Vas-Cath, the court ultimately found that the Curators of the University of Missouri had waived the Eleventh Amendment defense to an appeal from a district court review proceeding by affirmatively seeking the interference in the first instance. Nevertheless, we understand Vas-Cath's explanation of FMC to provide guidance for the availability of the defense of sovereign immunity, i.e., when the State has not waived its defense by reason of litigation conduct. Indeed, the Vas-Cath court stated that:

Like proceedings in the Federal Maritime Commission, contested interference proceedings in the PTO bear "strong similarities" to civil litigation, id. at 760, 122 S.Ct. 1864, and the administrative proceeding can indeed be characterized as a lawsuit. PTO interferences involve adverse parties, examination and cross-examination by deposition of witnesses, production of documentary evidence, findings by an impartial federal adjudicator, and power to implement the decision. See, e.g., 37 C.F.R. § 1.651(a) (during an interference, "an administrative patent judge shall set a time for filing motions (§ 1.635), for additional discovery under § 1.687(c) and testimony period for taking any necessary testimony."); § 1.671(a) ("Evidence [for an interference] consists of affidavits, transcripts of depositions, documents and things."); § 1.671(b) ("[T]he Federal Rules of Evidence shall apply to interference proceedings" except "[t]hose portions of the Federal Rules of Evidence relating to criminal actions, juries, and other matters not relevant to interferences."). The University invoked and participated in these proceedings with no claim of immunity.

Vas-Cath, 473 F.3d at 1382. Thus, applying *FMC*, the Federal Circuit found that interference procedures of the Board were similar to district court procedures.

The *Vas-Cath* court's reliance on the Board's interference procedures is instructive here as well because the Board's *inter partes* rules bear resemblance to the Board's interference procedures. Similar to an interference, an *inter partes* review typically involves adverse parties, examination of witnesses by motion for observation, cross-examination of witnesses by deposition, findings by an impartial federal adjudicator, and power to implement the decision, e.g., by cancellation of claims (with coordinate agency action). *See, e.g.,* 35 U.S.C. § 6 (composition of the Board), § 311–18 (inter partes review); 37 C.F.R. § 42.51 (discovery), § 42.52 (compelling testimony), § 42.53 (taking testimony). As with an

interference, an administrative patent judge (APJ) in an *inter partes* review can set a time for filing motions and for additional discovery. See 37 C.F.R. § 42.5 (conduct of the proceedings). As with an interference, evidence consists of affidavits (or declarations), transcripts of depositions and documents, and the Federal Rules of Evidence generally apply to *inter* partes review proceedings. 4 See, e.g., id. § 42.62 (applicability of Federal Rules of Evidence). Accordingly, the same factors that led the Vas-Cath court to analogize interference proceedings to district court proceedings also exist when comparing the procedures of *inter partes* review proceedings to those of district court proceedings. Further, the Federal Circuit has held that inter partes review proceedings are subject to the formal procedures of the Administrative Procedure Act. See Dell Inc. v. Acceleron, LLC, 818 F.3d 1293, 1301 (Fed. Cir. 2016) ("For a formal adjudication like the interpartes review considered here, the APA imposes particular requirements on the PTO."). See generally 5 U.S.C. § 554 (impartial federal adjudicator with formal agency procedures).

⁴ Portions of the Federal Rules of Evidence relating to, for example, criminal actions and juries are not relevant to *inter partes* review proceedings. *Id*. § 42.62.

⁵ We note for completeness, the Office has explained that there is not a one to one correspondence between *inter partes* review proceedings and district court litigation inasmuch as *inter partes* review proceedings are designed to allow for a lower cost to parties and a more rapid outcome. *See* Final Rule, Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions, 77 Fed. Reg. 48612, 48636 (Aug. 14, 2012) (Response to Comment 92). Nevertheless, the formal trial-type procedures of the Board, as recognized by the Federal Circuit in *Dell*, retain sufficient formality that renders Board proceedings similar to those of a district court for purposes of the Eleventh Amendment analysis. Significantly, the relevant test is not one of identity, but rather one

b. NeoChord's Arguments Regarding Cuozzo

NeoChord argues that sovereign immunity is unavailable as a defense in *inter partes* review proceedings because, according to NeoChord, the Supreme Court in *Cuozzo* compared *inter partes* review proceedings to reexamination proceedings and distinguished *inter partes* review proceedings from district court proceedings. Opp. 10–12 (citing *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016)). The University replies that the Supreme Court's statements in *Cuozzo* were made in the context of determining the claim construction standard for *inter partes* review proceedings. Mot. Reply 7–9.

We agree with the University that the Supreme Court's statements in *Cuozzo* cannot be taken out of the context of the claim construction standard. In *Cuozzo*, the Supreme Court was reviewing the PTO's standard for claim construction in *inter partes* reviews and found that the Board promulgated its standard for claim construction pursuant to a valid exercise of rulemaking. 136 S. Ct. at 2142. To be sure, the Supreme Court in *Cuozzo* examined arguments that *inter partes* review proceedings are similar to district court proceedings before concluding that *inter partes* review proceedings serve a different purpose than judicial proceedings. *Id.* at 2143–44. We understand this latter point, i.e., that *inter partes* review proceedings serve a different purpose, to be critical to the holding of the Supreme Court in *Cuozzo* in determining that the Board's claim construction standard, which differs from a district court's claim construction standard for

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of similarity, between agency proceedings and district court proceedings, as the Courts have found in *FMC* and *Vas-Cath*. We conclude that the test is met here for similar reasons as in *Vas-Cath*.

unexpired patents, was *reasonable* under the second step of the *Chevron* analysis applied by the Court in *Cuozzo*. *See id.* at 2144 (citing, *inter alia*, *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984) ("The upshot is, whether we look at statutory language alone, or that language in context of the statute's purpose, we find an express delegation of rulemaking authority, a 'gap' that rules might fill, and 'ambiguity' in respect to the boundaries of that gap. We consequently turn to the question whether the Patent Office's regulation is a *reasonable* exercise of its rulemaking authority.") (emphasis added) (citations omitted)).

In other words, the Court in *Cuozzo* held that the different *purpose* of *inter partes* review proceedings made the differing claim construction standard reasonable, but the similarity of procedures is what is relevant for analyzing the applicability of the Eleventh Amendment under *FMC*. Therefore, we conclude that *FMC* remains the primary case law for analyzing the availability of the Eleventh Amendment, e.g., as applied by *Vas-Cath* to the Board, and that the statements in *Cuozzo* relied on by NeoChord were not intended to be taken outside of the context from which they arose.

c. Whether Congress Abrogated Eleventh Amendment Immunity in the Patent Act

Congress may abrogate sovereign immunity when certain conditions are met, when acting under Section 5 of the Fourteenth Amendment, the Spending Clause Power of Article I, or the Compact Clause of Article I. *See College Savings Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 672–87 (1999). When acting under Section 5 of the

Fourteenth Amendment, Congress must be acting to remedy a pervasive pattern of deprivation by the States. *Id.* at 672. When acting pursuant to its Spending Clause Power of Article I, Congress may condition the grant of funds on a waiver and States must clearly waive Eleventh Amendment immunity, e.g., in exchange for a gratuity. *Id.* at 678, 680, 686–87. When acting pursuant to the Compact Clause, Congress may condition approval of an interstate compact on a waiver of sovereign immunity. *Id.*

NeoChord argues that Congress abrogated sovereign immunity in the second sentence of 35 U.S.C. § 271(h) addressing infringement of a patent.⁶ Opp. 13–15. NeoChord contends that the Supreme Court in *Florida Prepaid* only analyzed the first sentence of 271(h) but not the second sentence. Opp. 14 (discussing *Florida Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627 (1999)). We do not agree with this reading of *Florida Prepaid. See* 527 U.S. at 632. In any event, even if this were true, the Supreme Court's reasoning is equally applicable to both sentences of 271(h). In *Florida Prepaid*, the Court understood that Congress intended to abrogate States' Eleventh Amendment immunity but held that Congress lacked the authority to do so under Section 5 of the Fourteenth Amendment,

⁶ Section 271(h) of Title 35 U.S.C. states as follows:

⁽h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

³⁵ U.S.C. § 271(h).

i.e., because there was no pervasive pattern of abuse by the States. As such, NeoChord's argument does not overcome or distinguish *Florida Prepaid*. Indeed, in *Vas-Cath*, the Federal Circuit indicated that participation in the Patent System does not create a waiver for purposes of infringement. *See Vas-Cath*, 473 F.3d at 1381. *See also* Mot. Reply 9–10 (citing *Florida Prepaid*, 527 U.S. at 635–48).

NeoChord does not appear to have argued that the State waived Eleventh Immunity by market participation or by accepting a gratuity. Moreover, we note that in *College Savings*, the Supreme Court overturned *Parden v. Terminal Ry. of Ala. Docks Dept.*, 377 U.S. 184 (1964), and held that market participation does not constitute a constructive waiver. *College Savings*, 527 U.S. at 681, 684. In *College Savings*, the Court held that participation in a federal program does not in itself create a waiver of sovereign immunity, and indicated that a State would typically only waive immunity (by constructive waiver) when accepting a gratuity from Congress such as federal funds or in engaging in interstate compacts under the Compact Clause. 527 U.S. at 687 ("In the present case, however, what Congress threatens if the State refuses to agree to its condition is not the denial of a gift or gratuity, but a sanction: exclusion of the State from otherwise permissible activity.").

Indeed, in *Xechem*, the Federal Circuit explained that the grant of a patent does <u>not</u> constitute a predicate for application of a "gratuity doctrine" waiver because a patent is not a gratuity, i.e., the quid pro quo for receiving a patent is an invention. *See Xechem Int'l., Inc. v. Univ. of Tex. M.D. Anderson Cancer Ctr.*, 382 F.3d 1324, 1331 (2004).

Therefore, following *Florida Prepaid*, *College Savings*, *Vas-Cath*, and *Xechem*, we conclude that Congress has not abrogated Eleventh Amendment immunity with respect to this *inter partes* review proceeding, under Section 5 of the Fourteenth Amendment or under Article I of the Constitution. Nor has the State of Maryland expressed an intent to waive Eleventh Amendment immunity.

d. Whether this Proceeding May Be Likened to a Bankruptcy Proceeding for Which Sovereign Immunity Does Not Apply

NeoChord argues that this proceeding may be likened to a bankruptcy proceeding, which is *in rem*. Opp. at 12–13 (citing *Tennessee Student Assistance Corp. v. Hood*, 541 U.S. 440 (2004); *Central Virginia Cmty*. *College v. Katz*, 546 U.S. 356 (2006)). In *Hood*, the Supreme Court held a bankruptcy court was free to discharge a petition for bankruptcy without a State's participation. *Hood*, 541 U.S. at 448 ("At least when the bankruptcy court's jurisdiction over the res is unquestioned, our cases indicate that the exercise of its *in rem* jurisdiction to discharge the debt does not infringe state sovereignty." (citations omitted)). The Court reasoned, *inter alia*, that bankruptcy proceedings are *in rem*. *See id.* at 450–51.

NeoChord argues that bankruptcy proceedings do not apply sovereign immunity because, in addition to being *in rem*, they rely on rights exclusively granted to the federal government under the Constitution conferred under Article I, Section 4 of the Constitution Opp. at 13 (citing *Katz*, 546 U.S. at 370–71). NeoChord argues that patent law similarly administers powers exclusively granted to the federal government under Article I, Section 8 of the Constitution to create uniform laws and therefore

that the Patent Office does not apply sovereign immunity. *Id.* The University replies that the Federal Circuit has rejected this very argument in *Biomedical Patent Management Corp. v. California, Department of Health Services*, 505 F.3d 1328 (Fed. Cir. 2007), holding that *Katz* had not implicitly overruled *Florida Prepaid*. Mot. Reply 9–10.

We agree with the University that NeoChord's analogy to bankruptcy law is without merit. As the Federal Circuit observed in *Biomedical Patent Management Corp.*, the discussion in *Katz* regarding the constitutional basis for bankruptcy law was provided in the context of a larger historical examination of the bankruptcy laws, in which the Court explained that there is a unique historical tradition of the courts exercising bankruptcy jurisdiction to which the States acquiesced. 505 F.3d at 1343. NeoChord has not presented a similar historical tradition for the patent laws, nor has NeoChord demonstrated that application of Eleventh Amendment immunity, which is also constitutional in origin, would frustrate development of a uniform law for the patent system. Rather, the Supreme Court has merely required, e.g., in *Florida Prepaid*, that the State act as complainant in order to enter the patent system for adjudication.

III. Whether the University Has Waived Its Defense By Reason of Participation in this Proceeding

The next issue that we consider is whether the University has waived its defense of sovereign immunity through participation in this proceeding, as argued by NeoChord. NeoChord argues that the University waived any defense of sovereign immunity by "participating in [the *inter partes* review proceeding] up until the Oral Hearing without a single mention of sovereign

immunity." Opp. 5. In support of its position, NeoChord relies on *Hill v. Blind Industries and Services of Maryland*, 179 F.3d 754 (9th Cir. 1999). Opp. 3–4. In *Hill*, the U.S. Court of Appeals for the Ninth Circuit held that the Blind Industries and Services of Maryland (BISM) had waived its immunity by failing to raise the defense of immunity until the first day of trial. 179 F.3d at 757, 763. The court reasoned, *inter alia*, that the State delayed for tactical purposes such that it had the ability not to pursue the defense if the State liked the direction in which the court would rule on the merits. *Id.* at 757. Further, the *Hill* court amended its opinion, on denial of rehearing, to add a footnote explaining that BISM had failed to argue that State law precluded waiver of sovereign immunity. *Hill v. Blind Industries and Services of Maryland*, 201 F.3d 1186 (9th Cir. 1999) (Order denying reh'g and amending opinion).

The University replies that the Federal Circuit has never followed *Hill*. Mot. Reply 4. The University further cites *Florida Dep't of State v*. *Treasure Salvors, Inc.*, 458 U.S. 670, 683 n.18 (1982), which explains that the Eleventh Amendment defense is in the nature of a jurisdictional bar that may be raised at any time. Mot. Reply 4. Here, we understand the Supreme Court's holding in *Treasure Salvors* to stand for the proposition that there is no time limit on asserting the Eleventh Amendment defense.

In general, mere participation in judicial proceedings does not create a waiver unless the State has taken affirmative steps to invoke federal jurisdiction, such as filing suit as a plaintiff or seeking removal of a proceeding to federal court. *See Lapides v. Bd. of Regents of Univ. Sys. of Ga.*, 535 U.S. 613, 619–20 (2002); *see also Vas-Cath*, 473 F.3d at 1381 (discussing *Lapides*). In other words, when a State serves as a defendant in

federal court, without more, it generally has not waived sovereign immunity and remains free to raise the defense of Eleventh Amendment immunity at any time.

In sum, we have found that the facts of this case differ from those presented in *Hill*, and that our determination is consistent with applicable Federal Circuit and Supreme Court precedent. Nevertheless, there is not necessarily a difference among the circuits, as the University suggests. Rather, the *Hill* opinion, as amended, appears to follow precedent which acknowledges that the law of waiver may vary from State to State, based on an individual State's precedent regarding waiver. See also Opp. 2 (citing Wisconsin Dept. of Corr. v. Schacht, 524 U.S. 381, 389 (1998)). In particular, the Supreme Court has explained that the Eleventh Amendment defense can even be raised for the first time at the Supreme Court unless State law provides for waiver by participation in judicial proceedings. See Sosna v. Iowa, 419 U.S. 393, 396 n.2 (1975) (citing Edelman v. Jordan, 415 U.S. 651 (1974); Ford Motor Co. v. Department of Treasury of Indiana, 323 U.S. 459 (1945)). In Sosna, the Supreme Court examined the precedents of the State of Iowa, and distinguished the law of Iowa from that of Indiana, in determining that Iowa provided for waiver. This may have been the underlying rationale for the *Hill* opinion, as amended. Further, unlike the precedents of Iowa examined by the Court in Sosna v. Iowa, the precedent of Maryland indicates that Maryland does not provide for waiver of State sovereign immunity by reason of delay. See State v. Sharafeldin, 382 Md. 129, 141 (2004). As such, the precedent of Maryland appears to be more like the precedent of Indiana discussed in Sosna, 419 U.S. at 396 n.2 (citing

Ford Motor Co. v. Department of Treasury of Indiana, 323 U.S. 459 (1945)).

Further, unlike in *Hill*, there is no indication that the University has delayed for any tactical reasons. Rather, we take at face value the University's stated reason for not raising the defense sooner, i.e., that before the *Covidien* decision it had not been aware that it could raise the Eleventh Amendment defense before the Board, and that it raised the defense within five business days of the *Covidien* decision. *See* Paper 27, 5:19–6:7.

NeoChord argues that ignorance of the law does not excuse delay. Opp. 4 (citing *Advanced Estimating Systems, Inc. v. Riney*, 130 F.3d 996, 999 (11th Cir. 1997)). Nevertheless, apart from the fact that the University's stated reason for the delay is one that additionally distinguishes the Court's rationale in *Hill*, it is well established that Eleventh Amendment immunity is a defense that may be raised at any time. *See Treasure Salvors, Inc.*, 458 U.S. at 683 n.18 ("the Eleventh Amendment defense sufficiently partakes of the nature of a jurisdictional bar' that it may be raised at any point of the proceedings.") (citations omitted).

IV. Whether the University Waived Its Defense Through Its License Agreement

Next, we address whether the University has waived its defense of sovereign immunity by licensing its patent to Harpoon Medical, as argued by NeoChord. NeoChord argues that the University has waived sovereign immunity in Section 3.7.1 of its Master License Agreement (Ex. 2015, "MLA") with Harpoon Medical. Opp. 6–8. Section 3.7.1. of the MLA states as follows:

3.7 Patent Challenges.

- 3.7.1 (a) Prior to taking or causing the taking of any Patent Challenge, Company agrees to first pursue an appropriate proceeding, filing, or other action in the USPTO in the form of a reexamination pursuant to 35 U.S.C. §302, and all applicable statutes, rules, and regulations.
- (b) If 35 U.S.C. §302 is not applicable, Company agrees to give University the first option, in its sole discretion, to pursue the Patent Challenge under a reissue pursuant to 35 U.S.C. §251.
- (c) Company agrees to await a final determination of any reexamination or reissue pursuant to this <u>Section 3.7.1</u> by the tribunal of last resort having jurisdiction prior to taking or causing the taking of the Patent Challenge in a forum outside of the USPTO.
- (d) Company and University agree that this <u>Section 3.7.1</u> does not prohibit or limit Company's ability to take or cause the taking of any Patent Challenge, but merely dictates procedurally a Patent Challenge falling under the scope and kind that the USPTO is authorized to adjudicate.

Ex. 2015 § 3.7.1. However, the University argues that Section 3.7.1 only waives immunity with respect to challenges by Harpoon Medical, and that Section 14.6 of the MLA expressly reserves the defense of sovereign immunity, as follows:

14.6 <u>State Immunity and Limitations of Liability.</u> No provision of this Agreement shall constitute or be construed as a limitation, abrogation, or waiver of any defense or limitation of liability available to the State of Maryland or its units (including without limitation USM and University), officials, or employees under Maryland or Federal law, including without limitation the defense of sovereign immunity or any other governmental immunity.

Id. § 14.6; see Mot. 6; Mot. Reply 5.

We agree with the University that the waiver of Section 3.7.1 operates as a waiver limited to Harpoon and that Section 14.6 of the license

agreement operates as a savings clause to preserve the defense of sovereign immunity, i.e., with respect to non-parties. States may enter into contracts that effect a limited waiver of sovereign immunity, e.g., as to the parties of the contract, without opening the door to suits from others. *See, e.g., Lizzi v. Alexander*, 255 F.3d 128, 133 (4th Cir. 2001), *overruled on other grounds by Nevada Dep't of Human Res. v. Hibbs*, 123 S. Ct. 1972 (2003); *see also Class Plaintiffs v. City of Seattle*, 955 F.2d 1268 (9th Cir. 1992) (settlement discussions do not waive immunity from suit) ("With these principles in mind, we find no legal impediment to a state's waiver of its Eleventh Amendment immunity for the limited purpose of taking part in the settlement proceedings despite otherwise interposing immunity.").

We recognize that the University's assertion of sovereign immunity creates special treatment for a State entity. Nevertheless, the Supreme Court has explained that any asymmetry is the result of the Eleventh Amendment itself:

In contrast, a suit by an individual against an unconsenting State is the very evil at which the Eleventh Amendment is directed—and it exists whether or not the State is acting for profit, in a traditionally "private" enterprise, and as a "market participant." In the sovereign-immunity context, moreover, "[e]venhandness" between individuals and States is not to be expected: "[T]he constitutional role of the States sets them apart from other employers and defendants."

College Savings, 527 U.S. at 685–86 (citations and footnote omitted).

V. Whether the Board May Proceed Without the University

NeoChord also argues that Harpoon Medical "should be considered the real-party-in-interest and the 'effective patentee' for purposes of this

[proceeding]." Opp. 2. According to NeoChord, the University "should not be considered an indispensible party to this proceeding." *Id.* In other words, NeoChord contends that the Board may conduct its proceeding with NeoChord and Harpoon Medical as the only parties. Opp. 2. The University argues that it has retained rights under the license. See Mot. 5. We agree. For example, in Section 9.5.1 of the MLA, the University retains the right to sue a third party for infringement if Harpoon Medical fails to do so. Ex. 2015 § 9.5.1. In addition, the University has retained other rights. Id. § 3.2.1 (University may practice the '386 patent); § 3.2.2 (University may license the '386 patent to government agencies, universities, educational institutions, and certain non-profit entities); § 5.5 (Harpoon must pay University portion of royalty on any sublicense Harpoon grants); § 9.2.3 (University shares in recovery for patent infringement); § 9.4.2 (University must pre-approve settlement relating to the '386 patent although may not unreasonably withhold approval); §§ 9.5.2, 9.5.3 (University may respond to legal action relating to the '386 patent if Harpoon fails to respond, and reserves the right to intervene in any action relating to the '386 patent). As such, the University has retained rights under the license agreement, and transferred less than "substantially all" rights to Harpoon Medical. Therefore, the University remains a necessary and indispensable party to this proceeding, and we cannot proceed without the University. See A123 Systems, Inc. v. Hydro-Quebec, 626 F.3d 1213, 1217 (Fed. Cir. 2010) (affirming district court dismissal of declaratory judgment suit for noninfringement and invalidity based on findings that patentee had not transferred substantially all rights to patent); see also 37 C.F.R. § 42.9(b) (action by a part interest).

VI. Conclusion

For the foregoing reasons, we conclude that the University has shown sufficiently that it may raise Eleventh Amendment Immunity as a defense in this *inter partes* review proceeding, that the University has not waived its defense through its participation in this proceeding, nor through its licensing agreement, and that the University is a necessary and indispensable party. Accordingly, we grant the University's motion.

Accordingly, it is

ORDERED that the University's Motion is *granted*;

FURTHER ORDERED that we do not proceed to a final written decision under 35 U.S.C. § 318(a); and

FURTHER ORDERED that this proceeding is terminated pursuant to 37 C.F.R. § 42.72.

IPR2016-00208 Patent 7,635,386 B1

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