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DEFENSE ONLY: ENFORCING BOUNDARIES ON THE USE OF SOVEREIGN IMMUNITY

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In *Board of Regents of the University of Texas System v. Boston Scientific Corporation*,[1] a panel for the Federal Circuit, again, addressed the question of sovereign immunity in the context of patent cases. By affirming the lower court's decision that sovereign immunity is limited to use as a defensive litigation strategy, the Federal Circuit continued its recent trend of refusing to expand the reach of sovereign immunity.[2] The court asserted that a plaintiff could not contravene the federal venue statute[3] by using sovereign immunity,[4] in line with its previous decisions regarding sovereign immunity and patent cases.

In the Western District of Texas, the Board of Regents of the University of Texas ("UT") and TissueGen Inc. brought a patent infringement suit against Boston Scientific Corporation ("BSC") for alleged infringement of multiple patents directed to drug-eluting biodegradable fibers, designed for use in implantable devices.[5] Dr. Kevin Nelson, a co-inventor of these patents, developed this technology in conjunction with the University of Texas at Arlington.[6] As "UT is the assignee and exclusive owner of patents resulting from research conducted" at its campuses, UT has ownership of the patents in question.[7] UT exclusively licensed these patents to Dr. Nelson's TissueGen Inc.[8] The specific technology at hand is intended for use in implantable medical devices to dispense "therapeutic agents directly to the site of implantation."[9] The technology was commercialized by TissueGen Inc. as ELUTE® fiber products.[10] These fiber products have the ability to deliver a wide variety of drugs and can provide a sustained release of a therapeutic agent.[11] An example of the application of these fibers is a stent that could deliver therapeutic agents directly when placed in a vessel. The technology is thought to have broad applications in advanced drug delivery, nerve regeneration, and tissue engineering.[12]

[1] 936 F.3d 1365 (Fed. Cir. 2019).
[2] *Id*. at 1369.
[3] 28 U.S.C. § 1400(b) (2018).
[4] *Bd. of Regents*, 936 F.3d at 1380.
[5] The patents in question are U.S. Patent Nos. 6,596,296 ("the '296 patent") and 7,033,603 ("the '603 patent"). *Id.* at 1379. The technology in both patents was developed at the University of Texas at Arlington and was licensed to TissueGen Inc. *Id.* The '296 patent is directed to three-dimensional matrices for cell growth; the matrices contain therapeutic agents. The '603 patent relates to fiber compositions in gels or hydrogels, which can be used in changing the rate of therapeutic agent release.
[6] *Id.* at 1369.
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] *Id*.
[11] Sarah Faulkner, *Tackling drug delivery challenges with TissueGen's implantable fibers*, DRUG DELIVERY BUSINESS NEWS (Aug. 2, 2018), https://www.drugdeliverybusiness.com/tackling-the-challenges-of-drug-delivery-with-tissuegens-implantable-fibers/.
[12] *Id.*; TISSUEGEN, https://www.tissuegen.com/ (last visited Nov. 23, 2019).

UT alleged that multiple BSC stent products infringed these patents relating to these fiber products.[13] As BSC is a Delaware corporation with a principal place of business in Massachusetts, the court found that venue was improper for BSC in the Western District of Texas.[14] The district court transferred the case to the District of Delaware under the federal venue statute.[15] UT appealed the transfer order at the Federal Circuit under the theory of sovereign immunity, asserting that principles of sovereignty prevent it from being hailed into another court, specifically the District of Delaware.[16]

Sovereign immunity stands for the principle that a sovereign state and its arms are immune from being brought into court for civil suits or criminal prosecution; this doctrine extends to states.[17] As UT, a state school and an institution of the State of Texas, is clearly "an arm of the State of Texas,"[18] principles of state sovereign immunity, if properly applied, would be in effect. UT argued that sovereign immunity prevented the movement of its suit to another court, that the Eleventh Amendment[19] allowed UT to choose where it litigates, and that its lack of consent to litigate in Delaware trumped the federal venue statute.[20] However, the court did not find these arguments, which push the outer boundaries of sovereign immunity, to be persuasive.

The Western District of Texas determined that state sovereignty principles did not apply, and thus the transfer of venue was permissible.[21] The court's rationale stated: first, although the sovereignty issues raised were important, their resolution was not relevant to the merits of the underlying patent suit; and, second, because UT was acting as the plaintiff, it could not use the theory of sovereign immunity to challenge the transfer of venue.[22] In short, UT's attempted application of the Eleventh Amendment to prevent a venue transfer was not permitted by the district court. Relying on the holding from *Eli Lilly & Co.*,[23] the district court found that the role of sovereign immunity is to function as a defensive "shield," not as an offensive "sword" in litigation.[24] UT appealed this decision to the

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[13] Bd. of Regents v. Boston Sci. Corp., 2018 U.S. Dist. LEXIS 22707, at *2 (W.D. Tex. Mar. 12, 2018).
[14] *Id.* at *3-*5.
[15] *Id.* at *2-*3.
[16] Bd. of Regents v. Boston Sci. Corp., 936 F.3d 1365, 1369 (Fed. Cir. 2019).
[17] *See* U.S. CONST. amend. XI.
[18] *Bd. of Regents*, 936 F.3d at 1369.
[19] "The judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by citizens of another state, or by citizens or subjects of any foreign state." U.S. CONST. amend. XI.
[20] *Bd. of Regents*, 936 F.3d at 1372.
[21] 2018 U.S. Dist. LEXIS 22707, at *5.
[22] *Id.* at *3-*5.
[23] Regents of the Univ. of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).
[24] Bd. of Regents v. Boston Sci. Corp., 2018 U.S. Dist. LEXIS 22707, at *4 (referencing *Eli Lilly & Co.*).

Federal Circuit, seeking a reversal of the transfer to the District of Delaware.[25]

Judge Stoll, writing for a panel of the Federal Circuit, affirmed the Western District of Texas's decision, holding that "sovereign immunity cannot be asserted to challenge a venue transfer in a patent infringement case where a State acts solely as a plaintiff."[26] The court found the controlling standard to be the federal patent venue statute. UT's claims of state sovereign immunity via the Eleventh Amendment did not apply, as this doctrine "applies only in situations where a State is a defendant."[27] The court also found that the Original Jurisdiction Clause,[28] which prevents states from being forced to litigate in other state courts, does not permit UT to bring suit in any forum as long as personal jurisdiction for the defendant exists.[29] The court found that even if the doctrine of sovereign immunity had applied, UT "waive[d] sovereign immunity" when it appeared in court, and therefore "must accept the federal statutory provisions that govern the allocation of cases among the courts."[30] UT was unable to use sovereign immunity to avoid adherence to the federal venue statute, as UT acted only as a plaintiff in the suit.

The use of sovereign immunity in patent cases occurs with some regularity, especially as state schools hold many patents. Recently, the Federal Circuit addressed the question of sovereign immunity in the context of an *inter partes* review ("IPR"). In *Regents of the University of Minnesota v. LSI Corporation*,[31] the Federal Circuit declined to allow principles of sovereign immunity to bar a private defendant's request for an IPR against the plaintiff, a state institution. Specifically, the University of Minnesota moved to dismiss the defendant's petitions for IPR proceedings, which were a response to the original litigation, under sovereign immunity.[32] However, the Patent Trial and Appeal Board ("PTAB") found that the University of Minnesota waived its sovereign immunity privileges by initiating the lawsuit,[33] similar to the logic in *Board of Regents of the University of Texas System v. Boston Scientific Corporation*. In *LSI Corporation*, the Federal Circuit affirmed the PTAB's decision, but with a different rationale. It found that because an IPR was akin to a federal agency adjudication, state sovereign immunity

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[25] Bd. of Regents v. Boston Sci. Corp., 936 F.3d 1365, 1369 (Fed. Cir. 2019).
[26] *Id*. at 1377.
[27] *Id.* at 1376 (referencing *Eli Lilly & Co.* and *United States v. Peters*, 9 U.S. 115 (1809)).
[28] The Original Jurisdiction Clause states that in all suits in which a State is a part, the Supreme Court has original jurisdiction over the case. U.S. CONST. art. III, § 2 , cl. 2.
[29] *Id.* at 1375-76 (analyzing *Ames v. Kansas*, 111 U.S. 449 (1884), *Georgia v. Pennsylvania Railroad Co.*, 324 U.S. 439 (1945), and *Ohio v. Wyandotte Chemicals Corp.*, 401 U.S. 493 (1971)). Even though UT did not present this argument at the district court level, the Federal Circuit used its discretion to address this issue. 936 F.3d at 1377 n.2.
[30] *Id.* at 1380.
[31] 926 F.3d 1327 (Fed. Cir. 2019).
[32] *Id*. at 1330.
[33] *Id.* at 1342.

was not applicable.[34] This relied on the holding of *St. Regis Mohawk Tribe v. Mylan Pharmaceuticals, Inc.*,[35] which arrived at an identical conclusion, but for tribal sovereign immunity instead of state sovereign immunity. Although the IPRs in *LSI Corporation* and *St. Regis* differ greatly in nature from the patent infringement suit in *Board of Regents of the University of Texas System v. Boston Scientific Corporation*, the Federal Circuit seems averse to expanding the use of sovereign immunity in the patent realm. The Federal Circuit, in adopting reasoning that it originally rejected in *LSI Corporation*, emphasized that the role of sovereign immunity is primarily defensive.

This case also touches upon the role of venue in patent suits by following the standard set forth by the Supreme Court in *TC Heartland*.[36] *TC Heartland* changed the distribution of patent infringement cases across the nation through the imposition of specific venue requirements.[37] Venue must be tied to either the defendant corporation's state of incorporation or where the act of infringement occurred, as long as the defendant has an established place of business in that jurisdiction.[38] Prior, patent suits could be brought in any jurisdiction where a defendant was subject to personal jurisdiction. This is still the controlling standard for venue in patent cases, as this case indicates that the federal statute takes precedence over the application of sovereign immunity.

In summary, the Federal Circuit affirmed the defensive nature of sovereign immunity and the importance of the federal venue statutes in *Board of Regents of the University of Texas System v. Boston Scientific Corporation*. First, offensive use of state sovereign immunity is not permitted, meaning that a state or a state agent cannot use this doctrine when assuming the role of a plaintiff. Second, the act of bringing a suit in a federal court waives a state's claim to sovereign immunity. Third, this case affirms that states and their agencies, when acting as plaintiffs, are subject to the federal venue statute and cannot contravene these requirements through sovereign immunity. The Federal Circuit, through declining to expand the role of sovereign immunity in patent cases, emphasized the existing boundaries of this defenses's use in patent litigation.

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[34] *Id.* at 1337.
[35] 896 F.3d 1322 (Fed. Cir. 2018).
[36] TC Heartland LLC v. Kraft Foods Group Brands LLC, 137 S. Ct. 1514 (2017).
[37] *See generally* Shawn P. Miller, *Venue One Year After* TC Heartland*: An Early Empirical Assessment of the Major Changes in Patent Filing*, 52 AKRON L. REV. 3, 763 (2019).
[38] *TC Heartland*, 137 S. Ct. at 1516.