

Memorandum

Transferring Patents to Sovereign Entities to Avoid *Inter Partes* Review

September 20, 2017

On September 8th, drug maker Allergan announced that it had transferred six patents for its blockbuster drug RESTASIS®, approved for treating chronic dry eye, to the Saint Regis Mohawk Tribe in upstate New York.¹ The transfer was part of Allergan’s defense of the RESTASIS® patents, which are currently being challenged in both the U.S. District Court for the Eastern District of Texas and in *inter partes* reviews (IPRs) currently pending before the Patent Trial and Appeal Board (PTAB).

As a part of the transaction, the Tribe received six U.S. Patents and a payment of \$13.75 million. Going forward, the Tribe will be eligible to receive up to \$15 million in royalties annually so long as the patents remain valid, potentially through August 27, 2024. As a result of the transaction, the Tribe will attempt to have the IPRs dismissed, on the basis of sovereign immunity. The IPR challenges to the RESTASIS® patents were filed by would-be generic competitors, Mylan Pharmaceuticals, Teva Pharmaceutical Industries, and Akorn.

The novel transaction was reportedly a way to help protect the patents covering RESTASIS®, which generates about 10% of Allergan’s current annual revenues. The move comes in the wake of dismissals in two recent IPRs on the basis of sovereign immunity:

In January of 2017, the University of Florida Research Foundation (UFRF) succeeded on a motion to dismiss pending IPRs filed by Covidien LP on the basis of UFRF’s sovereign immunity under the Eleventh Amendment as an arm of the State of Florida. *See IPR2016-1274, Covidien LP v. Univ. of Fla. Research Found. Inc.*, Patent No. 7,062,251 B2. Under the Eleventh Amendment to the U.S. Constitution, “[t]he

¹ See Press Release, Allergan plc, Allergan and Saint Regis Mohawk Tribe Announce Agreements Regarding RESTASIS® Patents (September 8, 2017) (available at <http://www.prnewswire.com/news-releases/allergan-and-saint-regis-mohawk-tribe-announce-agreements-regarding-restasis-patents-300516422.html>).

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.” While immunity under the Eleventh Amendment has been applied by patent owners in district court litigation in the past, UFRF’s assertion of the immunity was a first in an IPR.

In dismissing the *Covidien* IPR under the Eleventh Amendment, the PTAB was “cognizant of the fact that applying an Eleventh Amendment immunity to *inter partes* review . . . precludes the institution of *inter partes* review against a state entity entitled to Eleventh Amendment immunity,” but found that such a result was “precisely the point of the Eleventh Amendment, which is the preservation of the dignity afforded to sovereign states.” IPR2016-1274, decision of the Patent Trial and Appeal Board, Patent No. 7,062,251 B2, paper no. 21, at 26 (Jan. 25, 2017).

In May of 2017, the PTAB granted a second, similar motion to dismiss on the basis of sovereign immunity under the Eleventh Amendment, filed by the University of Maryland, Baltimore (UMDB). *See* IPR2016-208, *NeoChord, Inc. v. Univ. of Md., Baltimore*, Patent No. 7,635,386 B1. The *NeoChord* IPR addressed a situation where a non-sovereign entity, Harpoon Medical, Inc., was the licensee of a patent and was *also* a real party-in-interest. In opposing UMDB’s motion to dismiss, NeoChord argued that even if UMDB were to receive sovereign immunity the IPR could proceed as between NeoChord and licensee Harpoon Medical. The PTAB disagreed, finding that, although UMDB had licensed its patent to a non-sovereign entity, the license agreement from UMDB to Harpoon specifically preserved UMDB’s sovereign immunity. *See id.*, decision of the Patent Trial and Appeal Board, Patent No. 7,635,386 B1, paper no. 28, at 17-18 (May 23, 2017). Critically, the PTAB found that UMDB had transferred less than “substantially all” rights in the subject patent to Harpoon Medical because UMDB had retained significant rights in the patent, including rights to practice the patent, to license the patent to certain government, educational, and non-profit entities, to royalties on any sublicense granted by Harpoon, to a portion of any recovery for patent infringement, and to pre-approval rights for any settlements. *Id.* at 19. The PTAB found that the fact that UMDB had transferred less than “substantially all” rights to Harpoon Medical made UMDB a necessary and indispensable party to the proceedings, and granted the motion to dismiss based on UMDB’s sovereign immunity. *Id.* at 19-20.

While the Saint Regis Mohawk Tribe has not yet briefed its motion to dismiss, there are a number of factors that should be considered by any patent owner contemplating a similar assignment, license-back transaction with a sovereign entity.

Limitations on Sovereign Immunity to IPR

Based on the dismissals in *Covidien* and *NeoChord*, it may be tempting to conclude that a patent owned by a sovereign entity, such as the Saint Regis Mohawk Tribe, is always immune from review in IPR—but that is not yet settled. The PTAB recently *declined* to dismiss an IPR where the patent was owned by the Regents of

the University of Minnesota, a sovereign entity, because it was *also* owned by Toyota Motor Corp. See IPR2016-1914, *Reactive Surfaces Ltd., LLP v. Toyota Motor Corp.*, decision of the Patent Trial and Appeal Board, Patent No. 8,394,618 B2, paper no. 39 (July 13, 2017). In its decision, the PTAB found *Covidien* and *NeoChord* persuasive, and dismissed the Regents from the IPR proceeding, but declined to dismiss Toyota. See *id.* at 10. In doing so, the PTAB rejected Toyota’s argument, “that the only way to prevent ‘injury to the interests of the absent sovereign’ is to dismiss the action entirely,” *id.* at 13, finding that there was no “bright-line rule that requires dismissal of any action after a finding that one defendant has sovereign immunity.” *Id.* Ultimately, the PTAB held that “when the absent sovereign party and a remaining party have identical ‘interests in the asserted patents,’ the remaining party adequately represents the interests of the absent sovereign party” and allowed the IPR to proceed with Toyota, which shared the same counsel as the Regents, representing the interests of both patent owners. *Id.* at 15 (citing *A123 Sys., Inc. v. Hydro-Quebec*, 626 F.3d 1213, 1221 (Fed. Cir. 2010)).

As a result of the PTAB’s decision in *Reactive Surfaces*, it is clear that, while a sovereign-entity *itself* may be immune from an IPR proceeding, the result may not always be the same for a *patent* owned by that same sovereign entity.

Exclusive License vs. Assignment

The Federal Circuit has repeatedly held that if a license conveys all substantial rights to a patent, it is tantamount to an assignment.² Parties that enter into an assignment, license-back transaction with a sovereign entity, therefore, should take care that an exclusive license-back to the assignor does not itself present as an assignment, effectively negating the prior assignment to the sovereign entity.

The PTAB’s decision in *NeoChord* makes clear that the details of the license matter. UMDB was able to assert its sovereign immunity in order to protect its patent from IPR, even though it had granted a broad license to Harpoon, precisely because it retained significant rights in its patent. Any transaction made with the intent of taking advantage of an apparent sovereign immunity to IPRs should be carefully structured to ensure that the sovereign entity retains substantial rights in the patent. Doing so may also prevent the license from being viewed as an effective assignment, precluding the PTAB from treating the exclusive-licensee as a co-owner under *Reactive Surfaces* for the purposes of an IPR.

² See, e.g., *Pac. Coast Marine Windshields Ltd. v. Malibu Boats, LLC*, 739 F.3d 694, 699 at n.1 (Fed. Cir. 2014) (“Whether a transfer of a particular right or interest under a patent is an assignment or a license does not depend upon the name by which it calls itself, but upon the legal effect of its provisions.”) (quoting *Waterman v. Mackenzie*, 138 U.S. 252, 256 (1891)); *Keranos, LLC v. Silicon Storage Tech., Inc.*, 797 F.3d 1025 (Fed. Cir. 2015); cf. *Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336, 1342 (Fed. Cir. 2006) (finding exclusive licensee was not the owner of the patent because licensee’s grant of all substantial rights would terminate at a date certain, with all rights reverting to the licensor-owner).

Sham Transactions

Patent owners contemplating entering into an assignment, license-back transaction with a sovereign entity should also be careful not to do so as a part of what may be seen as a “sham transaction.” In both *Covidien* and *NeoChord*, the university entity asserting sovereign immunity was the original assignee of the patents because the inventions had been made (at least in part) by university faculty. However in the RESTASIS® transaction, the Saint Regis Mohawk Tribe had no connection to the patents prior to the assignment, and was paid \$13.75 million by Allergan to receive the assignment, a move that will certainly attract the attention of the PTAB and any reviewing courts. The details of this transaction, and any transaction where a patent is transferred to a third-party sovereign entity without payment by the sovereign entity, are likely to be scrutinized for any sign of a sham transaction, for example, one that is for no or insufficient legal consideration or that is entered into solely with the purpose of avoiding judgment. Indeed, the petitioners in the IPR challenges to the RESTASIS® patent have already raised this issue, arguing that the Tribe was paid to take the RESTASIS® patents, and that the Tribe was “offering this protective service . . . explicit[ly] selling immunity.” IPR2016-01127, Transcript of Telephonic Hearing at 17:23-24, Patent No. 8,685,930 B2 (Sept. 11, 2017).

Regulatory Scrutiny

Although different in many ways from the ‘pay-for-delay’ deals that have drawn the attention of the Federal Trade Commission and were addressed by the Supreme Court in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), the substance of assignment, license-back transactions of this type has certain parallels. It is certainly possible to view a transaction of this type as a substantial payment to the sovereign for the sole purpose of postponing possible patent invalidation by avoiding the relatively expeditious proceedings of an IPR. The likelihood that regulators (or enterprising counsel) will seize on this in light of *Actavis* and its progeny should certainly be considered.

Public Perception

The largest unknown for assignment, license-back transactions with sovereign entities may be how the transaction will be viewed in the court of public opinion. It remains to be seen whether or not companies that enter into such transactions will face a reputational hit for what may be perceived as an unfair end-run around PTAB procedures, or whether the public will adopt the stance that it is merely a clever defensive maneuver to avoid unfair ‘double jeopardy’ in front of both the PTAB and a district court. In the short term, it appears that additional patent holders, including those outside the pharmaceutical industry, are actively investigating similar transactions—SRC Labs recently assigned approximately 40 patents and patent applications to the Saint Regis Mohawk Tribe, *see* USPTO, Aug. 2, 2017 Assignment of Assignor’s Interest by

SRC Labs, LLC, reel/frame 043174/0318 (recorded Aug. 2, 2017), for which the Tribe is currently preparing an enforcement campaign. See Saint Regis Mohawk Tribe, Frequently Asked Questions About New Research and Technology (Patent) Business, https://www.srmt-nsn.gov/uploads/site_files/Office-of-Technology-Research-and-Patents-FAQs.pdf.

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