PATENT-ASSIGNMENT TRANSACTIONS BETWEEN BRAND-NAME DRUG COMPANIES AND NATIVE AMERICAN TRIBES WILL UNDERMINE A HEALTHY PATENT SYSTEM AND HARM PATIENTS

WILLIAM M. JAY
JAIME A. SANTOS

Goodwin Procter LLP

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I. EXECUTIVE SUMMARY

In September 2017, facing the likely invalidation of the remaining patents shielding a multi-billion-dollar drug from generic competition, Allergan Inc. adopted an unprecedented strategy: it paid millions of dollars to rent the sovereign immunity of an Indian Tribe, and now it claims that its patents are beyond the reach of the U.S. Patent and Trademark Office (USPTO). In effect, Allergan's patents are seeking asylum on tribal lands.

Allergan assigned to the Saint Regis Mohawk Tribe all of its remaining patents covering its multi-billion-dollar drug Restasis® without requiring a dime from the Tribe in return; in fact, it was Allergan that agreed to pay the Tribe—$13.75 million up front and $15 million per year for the life of the patents. And Allergan gave up essentially no rights in the patents, because the Tribe agreed to immediately license those same patents right back to Allergan. What Allergan has attempted to get in exchange for the money was a purported "shield" for its patents. The Tribe agreed that once it acquired the patents, it would seek to invoke its sovereign immunity to attempt to force the dismissal of proceedings to review the patents for invalidity (called *inter partes* review, or IPR). Those proceedings, brought by companies seeking to introduce generic competition to Restasis, had been pending before the Patent and Trademark Office's Patent Trial and Appeal Board (PTAB) for more than a year and were close to final resolution when Allergan unveiled its sovereign-immunity gambit.

Allergan's transaction is the first of its kind. If successful, it will likely not be the last. Allergan and the Tribe have suggested that their business transaction is harmless because potential infringers can simply adjudicate patent disputes in federal court. But these types of transactions pose serious potential risks to the health of our patent system. One key part of that system is review of already-issued patents by the experts in the USPTO, to ensure that they comply with the statutory limitations on patent monopolies. USPTO review of issued patents has existed in various forms for nearly 40 years.

Congress created expert administrative review mechanisms because litigation is too slow and expensive a mechanism to clean up invalid patents. Applicants often seek weak patents—patents that do not actually claim a novel, innovative invention, but that allow the applicant to effectively extend the life of its existing patent monopoly. And while the validity of these patents can be attacked in court, patent litigation in court is expensive (with parties each spending millions of dollars per patent infringement lawsuit) and time-consuming, and generalist judges and juries lack the expertise of patent examiners. USPTO review is more streamlined, because it is focused only on specific reasons why a patent may be invalid; it is strictly time-limited; and it is conducted by expert patent judges. This makes valid patents stronger and helps eliminate the incentives to clog the USPTO with invalid patents that impair competition.

If brand-name drug manufacturers know they can make themselves invulnerable to IPRs simply by paying a tribe a small fraction of the amount they receive in revenues each year, this strategy will proliferate. The result will be harm not only to the integrity of the patent system, but to the patients who lose access to competing products as long as invalid patents remain on the books.

Though Allergan and the Tribe have argued that the PTAB "must" dismiss the pending Restasis IPRs, the PTAB's hands are hardly so tied. Recent Supreme Court decisions support the PTAB's concluding that tribal sovereign immunity does not apply in IPR proceedings, which are fundamentally different from civil litigation between private parties. Moreover, even if tribal immunity applies in IPRs, the PTAB is not forbidden by any statute, regulation, or precedent from continuing to resolve the IPRs that it instituted nearly a year ago when it found that there was a reasonable likelihood that the Restasis patents are invalid. Given Allergan's transparent attempt to avoid the Patent and Trademark Office's review of its patents issuances, the PTAB could readily conclude that fairness and equity warrant in favor of continuing their review of the Restasis patents.

II. ALLERGAN'S EFFORTS TO AVOID *INTER PARTES* REVIEW

For nearly 15 years, Allergan has enjoyed a market monopoly on cyclosporine, a prescription eye-drop medication for chronic dry eye conditions sold under the brand name Restasis®. Restasis is one of Allergan's largest revenue producers (second only to Botox®), bringing in nearly $1.5 billion in 2016 alone—nearly 10% of the company's annual revenue. Patents that prevented generic drug manufacturers from launching a more cost-effective generic version of Restasis were set to expire in 2014—but just before then, Allergan obtained half a dozen *new* Restasis patents, which do not expire until 2024.

Allergan's new patents have been challenged in court and in IPR proceedings before the Patent Trial and Appeal Board (PTAB), an administrative tribunal within the USPTO. In IPRs and similar proceedings (collectively called "post-grant review"), the PTAB decides whether an already-issued patent is invalid. IPR proceedings therefore allow the agency to take a "second look" at its earlier decision to grant a patent, this time aided by an adversarial presentation, which does not occur during the patent-examination process. And while anyone (even non-competitors) can petition the PTAB to take this second look, the PTAB will "institute" an IPR only where it finds a "reasonable likelihood" that the patent is invalid.[1]

The PTAB agreed to review the current set of Restasis patents and granted IPR petitions separately submitted by Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc., and Akorn, Inc. The PTAB consolidated the three instituted IPRs and, after briefing and the submission of evidence by Allergan and the three petitioners, scheduled the final IPR hearing for September 15, 2017, with a final decision expected in early December 2017.

On September 8, 2017, just one week before the scheduled IPR hearing, Allergan entered into an unprecedented transaction: it paid the Saint Regis Mohawk Tribe $13.75 million up front, plus $15 million annually, for the Tribe to take ownership of the Restasis patents, immediately license those same patents back to Allergan, and then move to dismiss the IPRs on the basis of tribal sovereign immunity (which the Tribe did within two hours of signing the assignment and licensing agreements). Allergan and the Tribe were remarkably candid about the reason for the transaction. Allergan's Chief Legal Officer stated that the transaction represented an "opportunity to strengthen the defense of our RESTASIS® intellectual property in the upcoming *inter partes* review proceedings before the Patent Trial and Appeal Board."[2] The Tribe was even more transparent in a "Frequently Asked Questions" document about its newly-established "Office of Technology, Research and Patents." The Tribe stated that it "is not investing any money in this business" and that companies like Allergan will "pay the tribe for

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[1] 35 U.S.C. § 314(a).

[2] Press Release, Allergan, Allergan and Saint Regis Mohawk Tribe Announce Agreements Regarding RESTASIS® Patents (Sept. 8, 2017), https://www.allergan.com/news/news/thomson-reuters/allergan-and-saint-regis-mohawk-tribe-announce-agr.

holding the patents and protecting them" from being invalidated during IPR proceedings, which are "very unfair to companies with valid patents and allow[] . . . infringers to void valid patents."[3]

Within the past several weeks, the Tribe has issued "clarifications" regarding its transaction, arguing in a brief before the PTAB and in a public statement that its patent business utilizes the same business model and legal arguments employed by public universities, which engage in technological innovation and license intellectual property to corporations and start-ups. The Tribe pointed out that such universities enjoy sovereign immunity from patent infringement and from challenges to patent validity and stated that it appears that this strategy "is only a concern when a Tribe decides to enter the same business for the benefit its community."[4] But no state university has accepted a sham patent transfer from a corporate patentee to avoid *inter partes* review, much less one on the eve of the PTAB's IPR hearings. Unlike the Tribe, universities actually engage in research and innovation, for which they seek and obtain their own patents. And if there were any question about whether the Tribe's transaction is unconventional, one need only look at the flow of money—from the assignor (Allergan) to the assignee (the Tribe, which received the patent portfolio covering a multi-billion-dollar product without having to pay a dime).

In short, this case, unlike any other before it, involves a brand-name drug company's attempt to rent tribal immunity for $15 million per year, purely to keep the USPTO from reviewing the patents covering its $1.5 billion-per-year drug.

III. ALLOWING THE RENTAL OF TRIBAL IMMUNITY COULD HAVE SERIOUS REPERCUSSIONS FOR PATIENTS AND DRUG COMPETITION

Allergan and the Tribe have suggested that their transaction poses no serious concerns because generic drug manufacturers can still challenge patents in federal court. But the potential impacts of this scheme on the patent system are profound, for two reasons: (1) USPTO review is a vital component of a healthy patent system in its own right, and (2) tribal immunity threatens to limit judicial proceedings as well.

A. USPTO REVIEW IS A VITAL COMPONENT OF A HEALTHY PATENT SYSTEM

Congress has barred the issuance of patents on purported inventions that are not truly novel, or are just obvious variations on existing knowledge. But the USPTO examination process does not always uncover all the flaws in a patent. And patent owners have incredibly powerful incentives to seek and obtain as many patents as possible, even dubious ones: each new patent can extend the life of an existing monopoly, and even a weak patent can be a powerful deterrent to competition. Indeed, that is exactly what Allergan did here. The patents protecting Allergan's Restasis monopoly expired in May 2014. But in late 2013 and early 2014, Allergan obtained six new patents that provided Allergan with ten more years of patent exclusivity. These patents attempted to claim essentially the same formulation and methods of treatment Allergan had previously claimed, with a bit more detail about the proportions of ingredients.

[3] Frequently Asked Questions About New Research and Technology (Patent) Business, Saint Regis Mohawk Tribe, https://www.srmt-nsn.gov/_uploads/site_files/Office-of-Technology-Research-and-Patents-FAQ.pdf (last accessed Oct. 8, 2017).
[4] Tribe Provides Clarification on Allergan Agreement, Saint Regis Mohawk Tribe, Sept. 14, 2017, https://www.srmt-nsn.gov/news/2017/tribe-provides-clarification-on-allergan-agreement.

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