

United States Senate

WASHINGTON, DC 20510

September 27, 2017

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

The Honorable Dianne Feinstein
Ranking Member
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Chairman Grassley and Ranking Member Feinstein:

In a blatantly anti-competitive attempt to shield its patents from review and keep drug prices high, on September 8, 2017, the Dublin, Ireland-based pharmaceutical company Allergan Plc announced it had transferred the ownership of its patents on the drug Restasis (a cyclosporine ophthalmic emulsion) to the Saint Regis Mohawk Tribe.¹ Allergan will license its patents back from the Tribe and continue to sell Restasis. In conjunction with the business deal, the Saint Regis Mohawk Tribe filed a motion to dismiss the ongoing *inter partes review* (IPR) of the Restasis patents based on the Tribe's sovereign immunity. It appears that Allergan's deal with the Tribe exploits the law to thwart review of the Restasis patents, protecting Allergan's market monopoly – and its profits – at the expense of patients who need the drug.

Allergan's actions directly circumvent the IPR process, established by Congress in the America Invents Act of 2011 (P.L. 112-29). We are deeply concerned with the numerous patent law and anti-competitive implications of Allergan's deal, which harm patients' ability to afford medications, and we write today to urge the Senate Judiciary Committee to immediately investigate this matter.

Restasis is a medication used to treat moderate to severe dry eye, and the drug brought in sales of over \$1.5 billion in 2016 alone.² In line with many other recent, high-profile examples of pharmaceutical companies putting profits before patients, Allergan is doing everything in its power to extend its monopoly on its prescription medication while patients are forced to pay higher and higher prices for their treatments. In 2016, for example, Allergan increased prices for 40 brand drugs, including a 9.9 percent price hike for Restasis.³ And, after its original patent expired in May 2014 – following a market monopoly since the approval of Restasis by the Food and Drug Administration in 2002 – the company filed six additional patents in recent years to extend its market exclusivity until August 2024.⁴

¹ <https://www.allergan.com/News/News/Thomson-Reuters/Allergan-and-Saint-Regis-Mohawk-Tribe-Announce-Agr>

² <https://www.reuters.com/article/us-allergan-patents-mohawk/allergan-pays-mohawk-tribe-to-protect-patents-from-challenges-idUSKCN1BJ2DK>

³ <https://www.wsj.com/articles/drugmakers-raise-prices-despite-criticisms-1452474210>

⁴ https://www.nytimes.com/2017/09/08/health/allergan-patent-tribe.html?_r=0

In order to preserve its profits by avoiding competition on Restasis and preventing patient access to more affordable prescriptions, Allergan made this first-of-its-kind deal with the Saint Regis Mohawk Tribe shortly before the Patent Trial and Appeal Board's IPR review of the six patents on Restasis. Allergan is providing the Saint Regis Mohawk Tribe with a one-time payment of \$13.75 million plus annual payments of up to \$15 million for the company's intellectual property.⁵ In return, Allergan is benefitting from the Tribe's assertion of its sovereign immunity to avoid further legal challenges on the patents for the brand drug. The IPR proceedings on the Restasis patents are expected to conclude in the next several months.

This is not the first time that the Board has considered sovereign immunity as an affirmative defense to IPR review. However, in the previous instances, such as *Covidien LP v. University of Florida Research Foundation Inc.*, those asserting sovereign immunity were the original owners of the patents under review. This case is different in that Allergan, the original owner, paid the Tribe to hold the company's patents and to invoke sovereign immunity. We believe that sovereign immunity is a fundamental precept of our legal structure and that there should be parity among States and Tribes. Companies should not be allowed to pay States and Tribes simply to invoke their sovereign immunity, and companies like Allergan should not be allowed to exploit sovereign immunity at the expense of patients.

Along with numerous legal experts, patient advocates, and health care stakeholders, we are alarmed by Allergan's efforts to circumvent the Congressionally-established IPR process, avoid competition on its top-selling blockbuster treatment, and the potential for other brand pharmaceutical companies to follow suit by making similar business arrangements. We urge the Senate Judiciary Committee to quickly take the lead in investigating the Allergan-Saint Regis Mohawk Tribe deal, examine its implications on pharmaceutical competition and the high cost of prescription drugs, and shine a spotlight to ensure "innovation" in the pharmaceutical industry is not about seeking new legal loopholes but instead about improving the lives of patients.

Sincerely,


Margaret Wood Hassan
UNITED STATES SENATOR


Sherrod Brown
UNITED STATES SENATOR


Robert P. Casey, Jr.
UNITED STATES SENATOR


Richard Blumenthal
UNITED STATES SENATOR

⁵ https://www.nytimes.com/2017/09/08/health/allergan-patent-tribe.html?_r=0