

October 10, 2017

The Honorable Paul Ryan
Speaker
United States House of Representatives
H-232, United States Capitol
Washington, D.C. 20515

The Honorable Mitch McConnell
Majority Leader
United States Senate
S-230, United States Capitol
Washington, D.C. 20510

The Honorable Nancy Pelosi
Democratic Leader
United States House of Representatives
H-204, United States Capitol
Washington, D.C. 20515

The Honorable Charles Schumer
Democratic Leader
United States Senate
S-221, United States Capitol
Washington, D.C. 20510

Dear Speaker Ryan, Leaders Pelosi, McConnell and Schumer:

We write today to add our names to the growing list of organizations and individuals who have raised significant concerns with Allergan, Plc's (Allergan) recent decision to transfer the patent rights to its blockbuster drug Restasis® to the St. Regis Mohawk tribe in order to block generic competition. Allergan, a Dublin, Ireland-based drug company, is claiming that placing its U.S. patents with a Native American tribe will shield these patents from review by the U.S. Patent and Trademark Office (PTO) as Congress authorized in the America Invents Act. Indeed, Allergan's scheme may be the first ever "IP Inversion."

According to a recent poll by the Kaiser Family Foundation, 77 percent of Americans believe the cost of prescription medicines is "unreasonable." Allergan's move to protect profits at the expense of patients confirms why. Congress should take steps to stop this behavior and eliminate barriers to the timely entry of U.S Food and Drug Administration (FDA) approved generic versions of these expensive treatments. As brand name drug companies continue to increase their prices year-over-year, lawmakers should also be aware of the unprecedented price deflation in the market for generic medicines. If transactions like those devised by Allergan are allowed to continue unchecked, brand name drug prices will continue to rise and hurt patients. And generic drug companies will be squeezed from the market, keeping affordable medicines from patients. Congress cannot allow this to stand.

I. Allergan's Patent Transfer Scheme

Allergan's questionable business practice threatens patient access to needed health treatments, threatens the underpinnings of the U.S. patent system and runs afoul of congressional intent in enacting a legal pathway for generic competition. Allergan's transfer of patent ownership rights to the St. Regis tribe is a brazen attempt to circumvent U.S. law and engineer a mechanism to maintain monopolistic high drug prices. We encourage Congress to vigorously exercise its oversight authority over drug

companies operating in U.S. commerce, the PTO and the FDA's drug approval process to provide transparency to the public about the effects of this transaction in order to determine whether this latest scheme to protect drug industry profits at the expense of patients and taxpayers will stand.

On September 8, 2017 Allergan announced it had transferred all Orange Book-listed patents for Restasis (Cyclosporine Ophthalmic Emulsion) 0.05 percent to the St. Regis Mohawk Tribe. Allergan was then granted an exclusive license by the Tribe to the Restasis patents by the new patent "holder," allowing Allergan to maintain its U.S. monopoly over the drug and control over its ever-increasing cost. In January 2016 the price of Restasis increased 9.9 percent.¹ As part of this arrangement, the St. Regis tribe announced the same day that it would move to dismiss an ongoing inter partes review (IPR) challenge of the Restasis patents based on the tribe's sovereign immunity. Cyclosporine, the active ingredient in Restasis was first approved by the FDA in 1983. Allergan developed Restasis as an ophthalmic solution and received U.S. approval for the drug in December 2002. The drug's initial patents expired in 2014, but Allergan filed four additional patents in late 2013 and early 2014 that, if left unchallenged, would expire in 2024 – well beyond the monopoly period that Congress intended or the public should support.

For Allergan, the deal with the St. Regis Mohawk Tribe, if allowed to proceed, would be a profitable one. Restasis generated \$1.4 billion in 2016 sales.² For less than 0.01 percent of the drug's annual sales, Allergan's deal could delay competition (by protecting its new patents from review) for at least six additional years. According to press reports, Allergan provided an initial payment of \$15 million to the St. Regis tribe and \$13.75 million in annual licensing fees. Every day Allergan delays competition, the company takes in over \$4 million in revenue due to the lack of generic competition. According to our calculations, Allergan will recoup this licensing fee in around four days.

II. Allergan's Attempt to Circumvent Review of its New Patents Under America Invents Act

In 2011 the America Invents Act (P.L. 112-29) created the IPR process within the Patent Trial and Appeal Board (PTAB). Its intent was to create an administrative process to consider the validity of patents, quickly and cost-effectively. AIA is closely aligned with the legislative intent of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman), and the Biologic Price Competition and Innovation Act (BPCIA): the need to increase competition in pharmaceutical markets by encouraging challenges to weak patents to expedite generic and biosimilar market entry.

IPR is an important option for the pharmaceutical industry when adjudicating patent disputes. In 2015, the brand name drug industry was unsuccessful in its efforts to invalidate the AIA for drug patents, when the industry failed to secure a pharmaceutical carve-out in the IPR process. The same year, using the law as Congress intended, several generic developers filed an IPR challenge to Allergan's four late-filed Restasis patents. Successfully challenging these patents would clear the way for the timely entry of safe, effective and more affordable generic competitors to Restasis and would thus save patients, taxpayers and health care payors billions of dollars. After two years of litigation, PTAB heard

¹ "Drugmakers Raise Prices Despite Criticisms," Wall Street Journal, January 2016. ([link](#))

² Allergan plc, Annual Report (Form 10-K), at 59 (February 2017) ([link](#))

the challenge between August 28 and September 1, 2017. A decision was expected later this year; the PTAB's decision may be postponed due to the Allergan/St. Regis tribe's claim of sovereign immunity.

Allergan's decision to transfer patents to the St. Regis Mohawk Tribe and rely on the tribe's claim of sovereign immunity to remove its patents from IPR proceedings is an end-run around the AIA's IPR process that Congress established specifically to challenge questionable patents. Allergan's actions threaten to upend the very foundation of the nation's intellectual property framework. We are concerned that, if left unchallenged, this scheme sets a dangerous precedent and other brand drug companies could quickly follow suit – protecting and extending their monopolies at all costs – keeping drug prices high for patients and payors.

The actions taken by Allergan and the St. Regis tribe to ensure that patients and payors do not benefit from timely generic competition to Restasis is an alarming new example of the steps that brand name drug companies will take to put profits above the public interest. Over the last two years there has been a great deal of congressional, media and public focus and scrutiny paid to branded products like Daraprim and EpiPen. Given the ongoing concern about drug costs, it warrants mention that Restasis generates more in annual revenue than both of those products combined.

We call on Congress to fully examine the impact that this questionable business tactic would have on our current and future drug supply and, most importantly, the economic impact it would have on patients. If left unchallenged, this potentially precedent-setting transfer of patents to Native American tribes to avoid lawful review of these government-granted monopolies may represent the beginning of a lucrative business strategy at the expense of the public interest, thus jeopardizing timely access to lower-cost generic and biosimilar medicines. This issue deserves the prompt attention of Congress, and we encourage you to vigorously apply your oversight authority to shine a light on the possible effects of this transaction between Allergan and the St. Regis Mohawk Tribe and its implications for U.S. health care spending, intellectual property law, and access to affordable medicines.

Sincerely,

Alliance of Community Health Plans (ACHP)
America's Health Insurance Plans (AHIP)
American Academy of Family Physicians
American College of Physicians
American Hospital Association
Association for Accessible Medicines (AAM)
BlueCross BlueShield Association (BCBSA)
Federation of American Hospitals
Pharmaceutical Care Management Association (PCMA)
Public Sector HealthCare Roundtable

cc: House and Senate Judiciary Committees, Senate Health, Education, Labor, and Pensions Committee, House Energy and Commerce Committee, Senate Indian Affairs Committee, House Committee on Natural Resources, Senate Aging Committee, and the House and Senate Committees on Oversight and Government Reform