

October 19, 2017

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

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

The Honorable Mike Lee
Chairman
Subcommittee on Antitrust, Competition
Policy and Consumer Rights
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Amy Klobuchar
Ranking Member
Subcommittee on Antitrust, Competition
Policy and Consumer Rights
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Chairman Grassley, Ranking Member Feinstein, Chairman Lee, and Ranking Member Klobuchar:

The undersigned organizations, representing healthcare providers, public health experts, people of faith, consumers, businesses, and taxpayers are committed to ensuring that the United States remains a leader in biomedical innovation while also expanding access to affordable medicines. We are deeply concerned by the recent news that Allergan Plc has entered into an anticompetitive agreement with the Saint Regis Mohawk Tribe, under which it is transferring its patents to the drug Restasis to the tribe and then licensing them back from the tribe, in an apparent ploy to prolong its patent exclusivity by inappropriately shielding its potentially weak patent claims for the drug from legitimate challenges through the *inter partes* review (IPR) system.

Seven years ago, bipartisan majorities in Congress passed by overwhelming margins (89-9 in the Senate¹; 304-117 in the House²) and the President signed into law the America Invents Act (AIA). The AIA established the IPR system, in which third parties may challenge patent claims through the Patent Trial Advisory Board (PTAB) at the U.S. Patent and Trademark Office (USPTO).³

Passage of the AIA and affirmation of the IPR system by the Supreme Court⁴ marked important steps towards limiting the harmful impacts of overly broad and dubious, low-quality patents, which inhibit innovation and impede the competition that is vital to a well-functioning marketplace that works for consumers.

Allergan Plc received approval for Restasis in 2002.⁵ But in anticipation of losing its patent exclusivity in May, 2014⁶, Allergan filed six secondary, method-of-treatment patents, in effect extending its monopoly protection until August, 2024, delaying generic competition by an additional 10 years⁷.

In December 2016, the USPTO approved⁸ Mylan's request for review of the six patents under the IPR system, concluding that Mylan's petitions met the threshold⁹ for initiating an IPR review by establishing

that there is a reasonable likelihood that it will prevail with respect to at least one of Allergan's vague and overly-broad patent claims challenged in the petitions.

With its Restasis monopoly profits under threat, Allergan has now moved to circumvent the bipartisan intent of Congress and evade legitimate challenge, with an anticompetitive deal with the Saint Regis Mohawk Tribe that, if it is allowed to stand, could cost U.S. consumers and taxpayers billions of dollars.

In the prescription drug context, low-quality patents not only hinder innovation, but keep prices higher for longer. Generic competition is a well-established, market-based solution to reduce medicine prices, bringing immense savings to consumers and taxpayers, and improving access. Products that attract meaningful generic competition can see prices fall to 20% of the brand-name price or even lower.¹⁰ The huge savings at stake is demonstrated by the numbers: Unbranded generics accounted for 84.6% of prescriptions dispensed in 2016, but only represented 15% of prescription drug spending.¹¹

U.S. sales of Restasis generated \$1.4 billion for Allergan in 2016; and \$645 million in the first two quarters of 2017.¹² One observer estimates that the extended monopoly period for Restasis will cost American consumers and taxpayers \$10.7 billion.¹³ A more conservative estimate suggests American consumers and taxpayers will pay greater than \$7 billion more for Restasis from 2018 through 2024 than under a scenario where Allergan loses its monopoly to a legitimate patent challenge that is allowed to go forward.¹⁴

We recognize that the asserted Restasis patents are also being challenged in court, and, at the district court level, have now been invalidated, subject to appeal.¹⁵ But the IPR process remains an important means of enabling expeditious, expert post-grant review of patents that are overly-broad and keep affordable generics from the marketplace. And we expect this will by no means be the last time that a brand name drug company seeks to use this anticompetitive scheme to block that process.¹⁶ We are concerned that lost competition will force Americans to pay many billions more, many will likely go without needed care, and our health care budgets will face an even heavier burden.

As Judge Bryson, who decided the U.S. District Court case, stated, in a related order joining the Saint Regis Mohawk Tribe as a party¹⁷:

“What Allergan seeks is the right to continue to enjoy the considerable benefits of the U.S. patent system without accepting the limits that Congress has placed on those benefits through the administrative mechanism for canceling invalid patents. If that ploy succeeds, any patentee facing IPR proceedings would presumably be able to defeat those proceedings by employing the same artifice. In short, Allergan's tactic, if successful, could spell the end of the PTO's IPR program, which was a central component of the America Invents Act of 2011.”

We respectfully request the Senate Committee on the Judiciary to investigate the Allergan-Mohawk patent transfer-license-back deal and its implications for U.S. government healthcare budgets, consumers and taxpayers.

Sincerely,

Public Citizen
AFL-CIO
American Antitrust Institute
American Sustainable Business Council
Annie Appleseed Project
Association for Medical Ethics
Breast Cancer Consortium
Congregation of Sisters of St. Agnes
Consumer Action
Consumers Union
Culinary Health Fund
Electronic Frontier Foundation
Families USA
Franciscan Sisters of Allegany, NY
Health GAP
Law Offices of David Balto
MedShadow Foundation
National Center for Health Research
National Women's Health Network
NETWORK Lobby for Catholic Social Justice
Patients for Affordable Drugs
People of Faith for Access to Medicines
Physicians for a National Health Program
Protect All Children's Environment
Public Knowledge
R Street
Social Security Works
The Society for Patient Centered Orthopedics
United Church Funds
US PIRG

¹ "Leahy-Smith America Invents Act: Roll Call Vote 112th Congress No. 129." United States Senate. (September 8, 2011). Retrieved October 5, 2017 from https://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=112&session=1&vote=00129

² "To amend title 35, United States Code, to provide for patent reform: Roll Call Vote 112th Congress No. 491." United States House of Representatives. (June 23, 2011). Retrieved October 5, 2017, from <http://clerk.house.gov/evs/2011/roll491.xml>

³ United States Patent and Trademark Office. Inter Partes Review. Retrieved October 4, 2017, from <https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/inter-partes-review>

⁴ *Cuozzo Speed Technologies, LLC v. Lee* (2016). Retrieved October 4, 2017, from https://www.supremecourt.gov/opinions/15pdf/15-446_ihdk.pdf

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- ⁵ U.S. Food and Drug Administration. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations: Product Details for NDA 050790. Retrieved October 4, 2017, from https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=050790
- ⁶ Ravicher, D. B. (2014, January 14). New Patents Could Sustain Allergan Restasis Franchise Until 2024. Seeking Alpha. Retrieved October 4, 2017, from <https://seekingalpha.com/article/1945551-new-patents-could-sustain-allergan-restasis-franchise-until-2024>
- ⁷ U.S. Food and Drug Administration. Orange Book: Approved Patent and Exclusivity for: N050790. Retrieved October 4, 2017, from https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=050790&Appl_type=N
- ⁸ Tang, W., Ph.D., & Elsevier, J. P., Ph.D. (2016, December 19). PTAB Agrees to Review Patent Claims Covering Dry Eye Ailments. Lexology. Retrieved October 4, 2017, from <https://www.lexology.com/library/detail.aspx?g=d31dd835-947a-466a-80d6-204218a0604b>
- ⁹ 35 U.S.C. § 314 (2011): Institution of inter partes review. *Legal Information Institute*. Retrieved October 4, 2017, from <https://www.law.cornell.edu/uscode/text/35/314>
- ¹⁰ U.S. Food and Drug Administration. Generic Competition and Drug Prices. Retrieved October 4, 2017 from <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm>
- ¹¹ Quintiles IMS Institute. Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021. May, 2017. Retrieved October 4, 2017 from <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021>
- ¹² Allergan Plc. Quarterly Results. Retrieved October 4, 2017, from <https://www.allergan.com/investors/financial-information/quarterly-results>
- ¹³ Silverman, E. (2017, October 2). The U.S. would pay an extra \$10.7 billion without generic Allergan drug. Pharnalot, STAT Plus. Retrieved October 4, 2017, from <https://www.statnews.com/pharmalot/2017/10/02/allergan-restasis-patents-mohawks/>
- ¹⁴ This estimate is based on assumptions that revenue levels remain consistent with the last six quarters and lost savings align with the aforementioned FDA estimate of the effects of generic competition. Average quarterly U.S. Restasis sales from Q1 2016 through Q1 2017 were ~\$344.1 million. Lost savings based on paying 80% less than ~\$344.1 million over the 26 quarters from January, 2018 through June 2024 equal \$7.16 billion.
- ¹⁵ *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc., et. al.* (2017). Retrieved October 17, 2017 from <http://freepdfhosting.com/33aa5f8b16.pdf>
- ¹⁶ Indeed, the anticompetitive impact of this strategy will likely extend beyond the pharmaceutical sector. A company called SRC Labs, LLC recently transferred more than a dozen technology patents to the Saint Regis Mohawk Tribe in what appears to be a similar scheme. See Assignment, U.S. Pat. No. 6,026,459 et al. (Aug. 2, 2017), available at <http://legacy-assignments.uspto.gov/assignments/assignment-pat-43174-318.pdf>
- ¹⁷ *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc., et. al.*, 4-5 (2017). Retrieved October 17, 2017 from <http://freepdfhosting.com/3fa20510ad.pdf>