

David A. Balto
LAW OFFICES

PATIENTS FOR **AFFORDABLE DRUGS™**

ConsumersUnion®

POLICY & ACTION FROM CONSUMER REPORTS

FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS



consumeraction

U.S. PIRG

October 23, 2017

The Honorable Maureen K. Ohlhausen
The Honorable Terrell McSweeny
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580

Dear Chairwoman Ohlhausen and Commissioner McSweeny:

The undersigned groups, Consumer Action, Consumer Federation of America, Consumers Union, Families USA, Patients for Affordable Drugs, Public Citizen, US PIRG, and the Law Offices of David Balto, dedicated to competition, patient and consumer protection and welfare, and access to affordable medicines, are writing to request that the Commission undertake an investigation into the pharmaceutical company Allergan, Plc's recent arrangement with the Saint Regis Mohawk Tribe, regarding its patent claims for the eye drug Restasis, to determine whether the arrangement violates the antitrust laws.

Restasis is used to treat moderate to severe dry eye. It is a very profitable medicine, generating \$1.4 billion in 2016 for Allergan. And the price continues to escalate – it increased by another 9.9% in 2016.¹

In May 2014, Restasis's original patent expired, but Allergan filed six secondary, method-of-treatment patents² to extend its exclusive period until 2024³ – at a potential additional cost to consumers and taxpayers estimated at \$10.7 billion.⁴ These new patent claims are now under challenge – in the courts,⁵ and

¹ Peter Loftus, *Drugmakers Raise Prices Despite Criticisms*, Wall Street Journal, Jan. 10, 2016, <https://www.wsj.com/articles/drugmakers-raise-prices-despite-criticisms-1452474210>.

² FDA Orange Book, Approved Patent and Exclusivity for: N050790, https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=050790&Appl_type=N.

³ Daniel B. Ravicher, *New Patents Could Sustain Allergan Restasis Franchise Until 2024*, Seeking Alpha, Jan. 14, 2014, <https://seekingalpha.com/article/1945551-new-patents-could-sustain-allergan-restasis-franchise-until-2024>.

⁴ Ed Silverman, *The U.S. would pay an extra \$10.7 billion without generic Allergan drug*, STAT NEWS (Oct. 2, 2017),

before the Patent and Trademark Office (PTO)⁶ under the inter partes review (IPR) process established by Congress in the America Invents Act (AIA).⁷

On September 8, 2017, Allergan announced that it had transferred ownership of all its patent claims for Restasis to the Tribe. In exchange, the Tribe granted the company back an exclusive license, for which the Tribe will receive a \$13.75 million payment, plus potentially \$15 million in annual royalties.⁸ The Tribe then filed a motion with the PTO to dismiss review of the claimed Restasis patents, on the grounds of sovereign immunity.⁹ Other than to sell its sovereign immunity, the Tribe has not participated in any way in the funding, development, or marketing of the medicine.

We are deeply concerned that this apparent anti-competitive ploy to shield Allergan's patents from appropriate review will artificially prolong its monopoly profits and unjustifiable price hikes in what patients must pay to obtain this important drug. And we are further concerned that this ploy could become a model for other brand-name drug makers to insulate their patent claims from appropriate review under the law, depriving consumers of the greater competition and affordability that would otherwise result.

The Commission is already familiar with the use of tribal sovereign immunity assertions as a ploy to shield against legal accountability, from the Commission's enforcement against unscrupulous payday lending practices.¹⁰

<https://www.statnews.com/pharmalot/2017/10/02/allergan-restasis-patents-mohawks/>.

⁵ Allergan, Inc. v. Teva Pharmaceuticals USA, Inc., (E.D. Tex. Oct. 16, 2017), <http://freepdfhosting.com/33aa5f8b16.pdf>.

⁶ Tang, W., Ph.D., & Elsevier, J. P., Ph.D, *PTAB Agrees to Review Patent Claims Covering Dry Eye Ailments*, Lexology, Dec. 19, 2016, <https://www.lexology.com/library/detail.aspx?g=d31dd835-947a-466a-80d6-204218a0604b>.

⁷ United States Patent and Trademark Office, Inter Partes Review, <https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/inter-partes-review>.

⁸ Katie Thomas, *How to Protect a Drug Patent? Give It to a Native American Tribe*, NEW YORK TIMES (Sept. 8, 2017), https://www.nytimes.com/2017/09/08/health/allergan-patent-tribe.html?_r=0.

⁹ Jan Wolfe, *Native American Tribe Moves to Dismiss Allergan Patent Case*, Reuters, Sept. 22, 2017, <https://ca.reuters.com/article/businessNews/idCAKCN1BX2MJ-OCABS>.

¹⁰ FTC press release, *AMG Defendants Settle FTC's Debt Collection Charges*, July 22, 2013, <https://www.ftc.gov/news-events/press-releases/2013/07/amg-defendants-settle-ftcs-debt-collection-charges>

These two examples of personal stories from Restasis patients, received by Patients for Affordable Drugs, help demonstrate what is at stake:

Joseph Landi of Boca Raton, FL: "I'm a retired police officer. My doctor prescribed Restasis for chronic dry eye. I expect to spend at least \$1,000 this year for Restasis and there is no cheaper generic. I have had to stop taking other drugs I need to pay for Restasis."¹¹

Ronit Zemel of Washington, DC: "I began having eye pain, blurry vision, and teary eyes early in my 20s. I was prescribed Restasis. Little did I know, that I would need to use half of the recommended amount of medicine each day, as well as borrow money in order to fill the prescription and keep my eyes comfortable, and my cornea from further damage. This ailment does not have a cure yet, so a lifetime of expensive daily medicine is ahead for me. I have to convince myself each month that adding the \$201 to my budget for a medicine that will prevent irreparable eye damage is worth it."¹²

The artificial delay in generic entry that can be expected to result here is akin to what has resulted from pay-for-delay, product hopping, and other schemes that the Commission has challenged as anticompetitive in recent years. We urge you to take a similarly hard and thorough look at this arrangement and, if you conclude that it constitutes an unfair method of competition in violation of section 5 of the FTC Act, to take appropriate enforcement action to stop it and help ensure that competition is permitted to work to bring much-needed savings to patients struggling to afford the medications they need.

Sincerely,

Consumer Action
Consumer Federation of America
Consumers Union
Families USA
Patients for Affordable Drugs
Public Citizen
US PIRG
Law Offices of David Balto

¹¹ <https://www.patientsforaffordabledrugs.org/story/joseph-landi/>.

¹² <https://www.patientsforaffordabledrugs.org/story/ronit-zemel/>.