United States Senate
WASHINGTON, DC 20510

November 7, 2017

Mr. Brenton L. Saunders
Chairman, President and Chief Executive Officer
Allergan plc
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054

Dear Mr. Saunders:

We write regarding Allergan's recent sale of patents to the Saint Regis Mohawk Tribe (St. Regis Mohawk) in a blatant effort to further Allergan's market monopoly on Restasis beyond the original patent term and exclusivity period by shielding the company from legal patent challenges through the inter partes review (IPR) process. This action is a clear attempt to circumvent the carefully crafted U.S. drug market, which was designed to balance the competing interests of brand and generic companies to both fuel innovation and reduce costs for patients and families. Despite the fact that a federal district court has already acted to invalidate several of these patents, we remain concerned by the intent behind these actions designed to stifle competition and perpetuate higher drug prices for consumers, and request that Allergan expeditiously provide lawmakers with additional information relevant to its recent sale of patents to the St. Regis Mohawk.

The Food and Drug Administration (FDA) approved Restasis, Allergan's second-highest selling product worth nearly $1.5 billion in sales last year alone, on December 23, 2002. At the time, the intellectual property behind Restasis was protected by one patent, which expired on May 17, 2014. However, in late 2013 and early 2014, six new patents were filed on and approved for Restasis. Absent any efforts to challenge these patents, these would expire on August 27, 2024, resulting in a 22-year market monopoly for this product.

A number of generic drug manufacturers have challenged the validity of these six Restasis patents in order to pave the way for competition under two Congressionally-designed and widely-utilized processes: inter partes review (IPR) through the Patent Trial and Appeal Board (PTAB) at the U.S. Patent and Trademark Office's (USPTO), and the Hatch-Waxman process through the federal district courts. A number of generic competitors have filed challenges before the PTAB, and the PTAB granted the companies' petitions, agreeing to institute IPR of the Restasis patents. A hearing before the PTAB on this issue was initially scheduled for September 15, 2017.

Shockingly, on September 8, 2017, Allergan announced that it had sold all six disputed patents for Restasis to the St. Regis Mohawk. Allergan paid the St. Regis Mohawk $13.75 million up front, and the St. Regis Mohawk was contractually eligible to receive $15 million in annual royalties for as long as the patents remain valid. Immediately subsequent to this transfer, the St.

Regis Mohawk granted Allergan exclusive licenses on the patents. The St. Regis Mohawk quickly filed a motion with the PTAB to dismiss the ongoing IPR proceedings over the Restasis patents, claiming sovereign immunity from IPR challenges. While the federal district court ruling on October 16, 2017 invalidating four of the six patents has created uncertainty about the next steps for these patents in the PTAB process, we expect that additional actions will take place in the coming months, given that Allergan has already signaled an intent to appeal the ruling.

We fully support the fundamental protections that sovereign immunity grants tribes and states to protect their own rights and property. However, it is difficult to conceive of Allergan's transaction as anything other than a sham to subvert the existing intellectual property system, which Congress established to set forth clear rules and expectations for the ownership and use of intellectual property. Put simply, Allergan paid another entity to take possession of its property, and then guaranteed annual payments for doing no more than holding the property and asserting a special legal standing to quash all disputes related to said property. By doing so, Allergan acted deliberately to shield its second round of Restasis patents from IPR in order to continue gouging consumers, who will continue to face high costs for Restasis for the foreseeable future.

Allergan's actions, which raise real questions about the rights transferred, are an abuse of the intellectual property system crafted to protect pharmaceutical developers while enabling robust generic competition. The Hatch-Waxman Act was a compromise between brand-name pharmaceutical companies and their generic competitors. Brand-name companies received a set period of data exclusivity from the FDA for their products, while generic companies received a clear path to market. The Pharmaceutical Research and Manufactures of America (PhRMA) recently referred to the Hatch-Waxman balance of rewarding innovation and generic competition as "built-in cost containment."

Likewise, when Congress passed the America Invents Act in 2011, it specifically intended to provide a process for evaluating post-grant opposition procedures, continuing to strengthen the balance created by Hatch-Waxman. Despite arguments to the contrary, there is no indication that Congress intended the pharmaceutical industry be exempt from the IPR process. While it is clear that members of the pharmaceutical industry oppose this process, and though IPR is currently under consideration by the Supreme Court, it remains the law of the land that all entities must respect.

In the Hatch-Waxman litigation over the patents in federal district court, the judge recently handed down a decision invalidating the Restasis patents. The court held that Allergan "is not entitled to renewed patent rights for Restasis in the form of a second wave of patent protection."

We agree with Judge Bryson and his holding: in attempting to shield itself from litigation, Allergan seeks to fundamentally undermine the carefully constructed balance of innovation and competition in several ways – and it calls into question not only the commitment to "built-in cost containment," but also that of the branded pharmaceutical industry, which has remained silent with regard to these tactics.

In addition to this general concern, Allergan's action also raise the following concerns:

- The Restasis patents were set to expire in 2014, which could have spurred competition from generic manufacturers three years ago. Yet, in filing new patents and extending Restasis's exclusive status, consumers have not yet benefited from generic competition. It is a matter of public record that the patents being challenged protect material discovered during the initial development of Restasis and not new innovation by Allergan over the life of the product – which a federal district court confirmed in declaring the patents invalid. There are a number of generic competitors prepared to enter the market that have been thwarted by Allergan's decision to register these new patents just before the previous one expired, thereby extending Allergan's monopoly.

- Not only has Allergan sought to extend its monopoly by additional patent protection, the company has attempted to fundamentally undermine the IPR process, which was designed by Congress as a mechanism for patent challenges to be assessed quickly and efficiently. The IPR process is the product of current law, and generic companies have the right to challenge patents through it. Actions to shelter patents in this way are an attempt to destroy this entire process to keep competition off the market.

- Several legal scholars have called into question the implications of sovereign immunity in Hatch-Waxman litigation. While the company stated publically that St. Regis Mohawk would not use sovereign immunity in federal district court litigation, Allergan's actions have raised a number of questions about whether sovereign immunity can be used as a defense by drug makers, both brand and generic, in Hatch-Waxman litigation. This uncertainty on its own may upset the balance that has successfully brought competition to the market for over three decades.

Further, Allergan's recent actions call into question the company's commitment to its "social contract," which debuted just last year. On its website, Allergan introduces the second principle of its social contract – Access and Pricing – with the following statement: **"We commit to making these branded therapeutic treatments accessible and affordable to patients."** Allergan goes on to make the following commitments:

1. "We will price our products in a way that is commensurate with, or lower than, the value they create"
2. "We will enhance access to patients"
3. "We will work with policy makers and payers to facilitate better access to our medicines"
4. "We will not engage in price gouging actions or predatory pricing"
5. **"We will limit price increases"**
6. "We will not engage in the practice of taking major price increases without corresponding cost increases as our products near patent expiration"
7. **"We commit to providing an aggregate view of the net impact of price on our business"**

In taking unprecedented action to shield its patents from legal challenges, Allergan reveals its commitment, or lack thereof, to its "social contract." It is unclear how this behavior will increase access to Allergan's medicines, help patients, or limit prices. It is also unclear how this behavior supports true innovation – another one of Allergan's principles in its "social contract." If anything, Allergan's actions will have the opposite effect. The hypocrisy of promising to increase access and to not substantially raise drug prices while creating and exploiting loopholes to thwart competition renders meaningless the entire "social contract." And doing so under the guise of innovation, despite four of these patents being invalidated by a federal district court, takes the hypocrisy to another level entirely.

To help us better understand Allergan's actions, please respond to the following questions and document requests no later than December 1, 2017:

1. In addition to transferring ownership of the six Restasis patents to the St. Regis Mohawk, Allergan also paid the St. Regis Mohawk $13.75 million, and the St. Regis Mohawk will receive $15 million in annual royalties for as long as the patents remain valid.
    a. Please provide the terms of the agreement reached between Allergan and St. Regis Mohawk.
    b. Please explain what benefit Allergan is receiving from this transaction.
    c. Please state who will be paying the St. Regis Mohawk's legal fees in the IPR proceedings and include any terms or limitations on the payment of said fees.

2. Does Allergan have plans to transfer patents associated with any of its other pharmaceutical products to the St. Regis Mohawk or any other sovereign, such as state universities? If so, please list such patents under consideration and provide the details of those plans or arrangements.

3. Before the district court decision, Allergan stated that it does not plan to introduce sovereign immunity into Hatch-Waxman litigation, which would seem to be a decision left to the discretion of Allergan and the St. Regis Mohawk. Allergan has already stated that it plans to appeal the district court decision invalidating the Restasis patents.
    a. Please provide any legal briefs or memos prepared by Allergan regarding sovereign immunity, particularly as it applies in context of the IPR process and Hatch-Waxman litigation.
    b. Does Allergan continue to maintain that it will not introduce or instruct the St. Regis Mohawk to introduce the sovereign immunity argument in its Hatch-Waxman litigation?
    c. Does Allergan have information to dispute the theories of legal scholars that sovereign immunity could be applied in Hatch-Waxman litigation?
    d. Does Allergan have, or is Allergan aware of, any legal theory that would serve as a limiting construct for assertion of sovereign immunity in non-IPR situations?

4. The press release from Allergan defends that these actions are not discordant with the social contract: "One of the main tenets of the social contract is a focus on innovation and research to help patients… We're not trying to artificially extend these patents, we're just trying to protect our property against a system that exposes us to double jeopardy." Yet, four of the six patents Allergan was "protecting" from a challenge were invalidated by a federal district court. Please provide a detailed accounting of how revenue accruing from Restasis from September 8, 2017, forward will be reinvested in innovation and to help patients, including a detailed comparison to how this revenue plan differs from the plan in each of the four quarters leading up to the date of the sale.

Thank you in advance for your prompt attention to this critical matter. If you have any questions, or would like to further discuss compliance with this request, please contact Abigail Duggan in Senator Brown's office (Abigail_Duggan@brown.senate.gov).

Sincerely,

Sherrod Brown
United States Senator

Margaret Wood Hassan
United States Senator

Amy Klobuchar
United States Senator

Al Franken
United States Senator

Patty Murray
United States Senator