



Saint Regis Mohawk Tribe

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Kenténha/October 12, 2017

Hon. Charles Grassley
Chairman
Senate Judiciary Committee
Washington, D.C. 20510

Hon. Dianne Feinstein
Ranking Member
Senate Judiciary Committee
Washington, D.C. 20510

Tekwanonhwerá:tons/Greetings Chairman Grassley and Ranking Member Feinstein,

On behalf of the Saint Regis Mohawk Tribe (“SRMT” or “the Tribe”), we are writing to clarify certain claims and misperceptions made in recent media coverage and in a September 27th letter from Senator Maggie Hassan (D-NH), Senator Bob Casey (D-PA), Senator Sherrod Brown (D-OH), and Senator Richard Blumenthal (D-CT) requesting that the Senate Judiciary Committee investigate the Tribe’s purchase of the Orange-Book patents for RESTASIS® (Cyclosporine Ophthalmic Emulsion) from Allergan, Plc.

Background on the Saint Regis Mohawk Tribe

The Saint Regis Mohawk Tribe is a federally recognized tribal government located in our traditional Territory of Akwesasne, an economically depressed region of Northern New York State. The Tribe consists of over 15,600 enrolled tribal members, with approximately 8,000 tribal members living on the Territory. As one of the primary employers in the region, we take pride in our commitment to promoting and strengthening our region’s economy. The Tribe and its tribally owned enterprises—Akwesasne Mohawk Casino Resort, Mohawk Networks, and Akwesasne TV—provide much-needed employment opportunities for more than 1,600 residents of Northern New York and devotes more than \$52 million in salaries annually. Additionally, SRMT provides a number of essential services to tribal members and our neighbors, including public safety, economic development, and broadband. Despite our efforts, critical budget shortfalls remain.

To ensure the strength and vigor of our regional economy and to protect against persistent threats to our tribal general fund and federal funding, we have been forced to diversify our investment strategies. For example, in recent years, our gaming revenue has leveled off. This coupled with inflation, rising costs of living and healthcare, additional pressure of persistent budget cuts, sequestration, elimination of federal programs, increased competition, the Tribe’s inability to tax, and limited economic development opportunities due to our rural location, have further strained our extremely limited budget. While we do the best we can to augment shortfalls in federal funding for the health, public safety, housing, environment, and educational services, we consistently run into roadblocks when attempting to access capital that is essential to promoting the health and wellbeing of our members, employees, and neighboring non-Native communities. This transaction with Allergan is thus, specifically intended to supplement our current funding in order to more adequately exercise and fulfill our essential governmental obligations to our members.

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In addition to financial barriers, our surrounding environment has been polluted in a way that is causing the Tribe's healthcare costs to sky rocket. For the past sixty years, our Territory has been polluted by hazardous polychlorinated biphenyls ("PCBs"), polycyclic aromatic hydrocarbons, aluminum, fluoride, cyanide, and other volatile organic compounds ("VOCs") from (i) the General Motors (Central Foundry Division) Superfund Site, (ii) the Alcoa West – Grasse River Superfund Site, and (iii) Alcoa East (formerly owned by the Reynolds Metals Company) – all of which are located directly upstream and upwind from where our community draws its drinking water and permanently resides. While the industries and associated jobs causing the pollution have come and gone, the pollutants remain and continue to contaminate our water, land, and air. This greatly compromises the health of our tribal members at devastatingly disproportionate rates.

Despite years of SRMT engagement with the EPA, New York, and Congress, mitigation plans that have been put into place are drastically underfunded and insufficient. New research also demonstrates that the EPA's mitigation methods are further exposing our community to additional pollutants. The lack of adequate federal funding to completely mitigate these Superfund Sites is polluting our entire Territory with hazardous PCBs and other VOCs, creating a cycle of pollutant-based health issues, and negatively impacting the traditional practices that are essential to the preservation of our culture.

Preserved as a part of the 1796 Treaty with the Seven Nations of Canada to use the river "unhindered", our Tribe once lived a traditional subsistence lifestyle, relying on many of the natural resources and wildlife along the St. Lawrence and Grasse Rivers. However, 60 years of toxic pollution have forced us to turn away from our subsistent lifestyles. In the 1990s, the New York State Department of Health issued a health advisory warning residents not to consume any fish from the Grasse River. Unfortunately, this advisory warning came decades after our tribal members had been exposed to these contaminants. This has plagued our community with a disproportionately high prevalence of diabetes, thyroid disorders, asthma, arthritis, autoimmune disease, heart disease and cancers. Newly conducted research also suggests that PCBs may be transferred through breast milk and inhibit the ability of our young women to conceive. Thus, even if our children no longer consume wildlife from the St. Lawrence and Grasse Rivers, they consume the milk from their mother who has been exposed to decades of contaminants, passing on a toxic legacy to the next generation of tribal members.

The fact that we are being attacked for diversifying our economy and obtaining a revenue source that could remedy the current environmental disaster that is polluting our community and endangering our well-being, while also offsetting healthcare costs is, at best, another sad example of colonial paternalism. For many of our tribal members, the backlash directed at the Tribe – and not other sovereigns involved in **the very same business** – cannot be reconciled with the government's repeated statements of support for tribal sovereignty and the advancement of true Indian self-determination.

The Tribe is particularly frustrated because we have been working with Congress, EPA, and various Administrations for decades to address the government's failure to warn us of the pollution and to protect us from being poisoned. **We will no longer sit back and wait for the government to figure this out nor will we excuse the government's inability to provide an important remedy that protects our health and well-being.** Our tribal members need adequate healthcare services and we will do everything we can to provide them with those essential services.

On top of this, as members of Congress criticize the Tribe for our actions, each of the individual states own hundreds, if not thousands, of patents. And to be clear, 20-25 percent of these patents were developed by private parties and subsequently transferred to state entities – the exact fact pattern here. The hypocrisy on top of the government's failure to uphold the federal trust responsibility, pass meaningful legislation, maintain important programs, and pay for environmental damages is leaving the Tribe in a perpetual standing of uncertainty regarding our ability to provide desperately needed services for our members. **True fulfillment of the federal trust responsibility to tribal governments should not force Indian Country**

to bear the consequences of partisan disagreements about how to control drug prices and deliver affordable healthcare.

Recommendations as the Committee Moves Forward

As you move forward in your review of our ownership of this patent and the *Inter Partes Review* (“IPR”) proceedings conducted by the Patent Trial and Appeal Board (“PTAB”), we ask that you keep the following considerations in mind:

1. Maintain Parity for Tribal Governments with States and Public Universities.

Tribal governments, like the SRMT, possess the same sovereign authority exercised by state governments and public universities to partner with companies to bring products to the market, while retaining title of intellectual property developed. As you begin your review of the transaction, we encourage you to look at the practices of your own states and the positive impacts of state and public university ownership of Orange Book-listed patents are having on your constituents.

According to the U.S. Patent and Trademark Office (“USPTO”), in 2012, every state had at least one university, foundation, or other institution that owned a patent. In fact, roughly 4,797 Orange Book-listed patents, were acquired by states and their public universities. This is roughly a 1.5 percent increase from 1985, more than 25 years ago, when U.S. colleges and Universities owned less than one percent of all patents. Despite this increase in patent ownership, state and public university patent acquisitions have not been questioned as to whether their sovereign immunity is at fault for rising drug prices and the declining U.S. patent system.

According to USPTO, in 2012 the four states represented by the Senators who objected to the deal owned over 7,000 patents combined. In Senator Hassan’s state, Dartmouth College and the University of New Hampshire owned a total of 257 patents, with 27 acquired in 2012.

In Senator Casey’s state, the University of Pennsylvania, University of Pittsburgh, Penn State Research Foundation, Carnegie Mellon University, Thomas Jefferson University, Temple University, Drexel University, Lehigh University, Duquesne University, Philadelphia Health and Education Corp., Pennsylvania Research Corp., Penn State University, Drexel University College of Medicine, Allegheny University of the Health Sciences, University of Scranton, Villanova University, Bryn Mawr College, University of the Sciences in Philadelphia, Drexel Institute of Technology, Philadelphia College of Osteopathic Medicine, Philadelphia College of Textiles and Science, Philadelphia University, University of Pittsburg Medical Center, Widener College, Franklin and Marshall College, Lehigh University and Northeast Benjamin Franklin, Technology Center of PA, Lock Haven University of Pennsylvania, Philadelphia College of Pharmacy and Science, St. Francis University, Slippery Rock University, University of the Arts, and Widener University owned a total of 3686 patents with 251 acquired in 2012.

In Senator Brown’s state, Ohio State University, Case Western Reserve University, University of Akron, University of Cincinnati, Ohio State University Research Foundation, University of Dayton, University of Toledo, Kent State University, Ohio University, Wright State University, Cleveland State University, the Medical College of Ohio, Bowling Green State University, Miami University, Northeastern Ohio Universities College of Medicine, Ohio University Edison Animal Biotechnology Institute, Ohio Agricultural Research and Development Center, Ohio Northern University, and Antioch College owned a total of 2267 patents, with 149 acquired in 2012.

In Senator Blumenthal’s state, Yale University, the University of Connecticut, University Patents Inc., University of Connecticut Health Center, University of Hartford, Fairfield University, University of Connecticut Research and Development Corp., University of Connecticut – Center for Science and

Technology Commercialization, Connecticut College, and owned a total of 1066 patents, with 51 acquired in 2012.

Your own states, Iowa and California, have also been long-time Orange-book patent owners. In Iowa, the University of Iowa, Iowa State University, Iowa State University Research Foundation Inc., University of Iowa Research Foundation, the University of Iowa Foundation, and Kirkwood Community College owned a total of 1,515 patents, with 46 acquired in 2012.

In California, UC Berkley, Stanford University, Stanford University Medical Center, California Institute of Technology, University of Southern California, Scripps Research Institute, Scripps Clinic and Research Foundation, Loma Linda University Medical Center, University of California Office of Technology Transfer, Alfred E. Mann Institute for Biomedical Engineering at the University of South California, Loma Linda University, San Diego State University, Research and Education Institute – UCLA Medical Center, Los Angeles Biomedical Research Institute at Harbor UCLA Medical Center, California Institute Research Foundation, California Polytechnic State University Foundation, California Polytechnic State University Corporation, Keck Graduate Institute, Cal State Fresno Foundation, Research and Education Institute Inc., Ambassador College, Cal State Fullerton Foundation, Harvey Mudd College, San Diego State University Research Foundation, San Jose State University Foundation, San Jose State University Foundation, University of the Pacific, Western University of Health Sciences, California State University, Humboldt State University Foundation, Loma Linda University Adventist Health Sciences Center, The University Foundation – California State University, USC Stevens Center for Innovation, Art Center College of Design, California Institute of Technology – Jet Propulsion Lab, Chapman College, Charles R. Drew University of Medicine and Science, Jesuit Community at Loyola University, Pepperdine University, San Diego State College Foundation, and USC/Norris Comprehensive Cancer Center.

For more information on other states' rates of Orange Book-listed patents, please the attached documents (U.S. Patent and Trademark Office Data concerning U.S. Colleges and Universities Utility Patent Grants Calendar Years 1969-2012, our analysis of this data by state, and a list of companies who have transferred their patents to state universities in the same manner the Tribe has done).

2. Protect a Revenue Stream that Directly Benefits Tribal Citizens and Augments Lack of Adequate Federal Funding and Limited Economic Development Opportunities

The Tribe's partnership with Allergan opens a new revenue stream that will help offset budget shortfalls for housing, healthcare, eldercare, education and language preservation services due to inadequate annual funding levels, sequestration, the inability to tax, and limited economic development opportunities due to its rural location. The Tribe will receive \$13.75 million upon execution of the agreement and will be eligible to receive \$15 million in annual royalties. The Tribe will use this revenue to address the following shortfalls:

Housing: The Tribe faces a critical housing shortage. As its population expands, its territory has not. Despite nearly 40 years of litigation with respect to returning Mohawk tribal lands, some local communities still have not agreed to the settlement forcing the Tribe to purchase additional lands from willing sellers at a great cost. Additionally, the Tribe's housing program lost a quarter of a million dollars this year forcing a reduction in the workforce by three employees and several key staff transitioned to part-time to maintain operations. Working under these constraints makes it difficult to provide much needed housing for our members.

Healthcare and Environment: The SRMT community is plagued with chronic illness and has disproportionately high rates of diabetes and cancer as a result of the environmental pollutants from three superfund sites located upstream and upwind from the territory. In 2016, SRMT's total healthcare budget was \$18.2 million. Despite receiving health dollars from federal appropriations, and \$1 million in Medicaid, the Tribe had to heavily subsidize the remaining budget shortfall with its already limited resources.

Sequestration and elimination of certain EPA programs have also hindered the Tribes' ability to mitigate the impacts of these environmental health hazards, fully remediate the Superfund sites, and adequately monitor air quality, which further adds costs to the already insufficient healthcare budget.

Eldercare: Like the surrounding non-Indian communities, as the Akwesasne community ages, the need for greater eldercare continues to strain the Tribe's budget. A recent referendum highlighted the community's concern about the need of the Tribal Government to provide more resources and assistance to elders living on fixed incomes.

Language Preservation: Like many indigenous languages, the Mohawk language is endangered and faces the risk of extinction unless the Tribe continues to subsidize and support strong language programs, such as the full language immersion Akwesasne Freedom School and other intensive programs necessary to preserve and pass down the Mohawk language.

3. Understand the Role the Tribe is Playing

A major concern raised is that the Tribe is merely a shell company. This could not be further from the truth. The Tribe has created an Office of Technology Research and Patents that will be an active participant in any proceedings to protect tribal ownership of all its intellectual property. As a sovereign government, the Tribe has a duty to its citizens to protect its investments and cannot responsibly rely on its partners to enforce its sovereign rights.

Finally, in its role as a government, the Tribe has been seeking opportunities that allow it to gain more knowledge on business models and the regulatory framework that protects intellectual property – specifically keeping in mind how the Tribe can use this framework to protect its own traditional ecological knowledge and other innovations.

4. It is Not in the Best Interest of its Tribal Members to Delay Access to Generic Drugs or to Raise Drug Prices

Some commentators fear the patent agreement between Allergan and the Tribe will delay access to generic drugs for the American public, insulate pharmaceutical patents from review, and take advantage of consumers. These concerns reflect a misunderstanding of the federal statutes that govern tribal sovereignty and market entry of generic drugs.

It is the Tribe's job, as a sovereign government, to provide healthcare services to its community members and it is acutely aware of the cost of pharmaceutical drugs and the financial challenges faced by so many families. Currently, 10 percent of the Tribe's overall healthcare budget is dedicated to pharmacy costs. To suggest the Tribe would engage in price-gouging or hinder access to medicine is a complete opposition of the core values of the Tribe and its own financial interest. Furthermore, generic drugs have already saturated the market. In 2016, nearly 90 percent of prescription drugs dispensed were generic drugs. In addition, new research is finding that the cost of generic drugs is rising, not due to state or public university involvement in the sector, but due to below cost pharmacy reimbursements, low maximum allowable cost prices, difficulty sourcing alternative medications to fit patients' budgets, medication non-adherence costs, and inaccurate price forecasts.

5. Like Public Universities Who Own Patents, Tribal Governments Will Not Cause a Rush of Companies Moving their Patents to Tribes Nor will it Result in Patents Evading Review

The accusation that deals between private pharmaceutical companies and tribal governments will cause a rush of companies moving their patents to tribal governments to evade pharmaceutical patents review is factually incorrect. First and foremost, in 2012 states and public universities owned a total of 75,353 patents

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