Pharmaceutical Patent Transfer as a Strategy for Tribal Economic Self Sufficiency: A Case Study Among the Saint Regis Mohawk Community

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I. Abstract

In September of 2017 the Allergan pharmaceutical company transferred their patent for Restasis eye drops to the St. Regis Mohawk Tribe. Their intention was to protect their lucrative patent through utilization of the tribe's sovereign immunity, preventing generic versions of Restasis from being produced. In exchange they were to pay the tribe $13.75 million dollars upfront as well as $15 million in royalties annually to lease the patent back to Allergan. This business deal ignited a legal controversy on the international stage, and in February of 2018 the United States Supreme Court rejected this transaction, claiming that the St. Regis Mohawk's may not use their sovereign immunity status to protect a patent. Drawing on extensive research that includes a content analysis of St. Regis Mohawk social media sites, newspaper and scholarly articles, and legal briefs about the Supreme Court, this paper explores the way Tribal leaders and community members presented this deal and understood the opportunity for their community. The Mohawk tribe articulated an intention to help alleviate poverty and economic despair with the funds. This research offers an interesting paradigm on the usage of sovereign immunity and speaks to the broader issues of self-determination in light of corporate influence.

II. Introduction

How did Saint Regis Tribal members react online to the 2017 public announcement of their budding partnership with Allergan pharmaceutical company and accusation that the patent transfer was an egregious ploy to steal from consumers and investors? My qualitative research suggests that Tribal members' expressed pride in the entrepreneurial strategy of their Tribal

government. They projected this pride onto the Tribe's search for self-reliance and additional income by utilizing their sovereign immunity to address Akwesasne Reservation issues. "Sovereign immunity" is legal status granted by the United States Federal Government in 1787 (Understanding Tribal 2013) that extended to Native Americans the status of sovereignty as an independent nation and allow them the right to self-governing. They also expressed a combination of frustration and dismay with the federal government's decision to reject the patent agreement, therefore denying the sovereign immunity status of the tribe in the name of individual consumer ethics while simultaneously contradicting its original purpose.

III. Background

The St. Regis Mohawk tribe is a community of 13,000 people residing on the Akwesasne Reservation. This reservation borders New York and Ontario Canada and is located approximately 8 miles West of the Grasse River Superfund site which traditionally has strong ties to SRMT culture and was a historical location of natural medicine, hunting, fishing, and transport for the tribe (Arconic Grasse River). This same river now possesses a sustained threat due to environmental toxins from pollution from an aluminum production site (Arconic Grasse River). Further, nearly 20% of Mohawk families on the Akwesasne reservation are living below the poverty line (National Communications). Prior to the COVID-19 pandemic, the SRMT and the Akwesasne Mohawk Casino on the reservation provide jobs for 1,900 members of the Mohawk community (Economic Impact). The Akwesasne Mohawk Casino also accounts for the tribe's main income; however, they have made attempts to diversify their income through engagements with various industries.

They have established a reputation for being an entrepreneurial tribe by becoming involved in the cannabis, research, and pharmaceutical industries among others (Gallo 2020) (Allergan 2017) (Mohawk Tribe Establishing 2009). Throughout various business ventures the St. Regis Mohawk tribe has utilized their sovereign immunity, as a federally recognized Native America tribe, to amalgamate efforts with pharmaceutical companies to protect lucrative patents. Sovereign immunity is a judicial doctrine that provides immunity to Native American tribes from legal suits by stating it is a separate entity and maintains the right to self-govern (Burns 2012) (Richards 2019). However, the title of sovereign immunity for Native American tribes is deceiving as their "sovereignty" only extends to what is allowed to them by the United States government in light of federal interests and agenda. As a result, we see a quasi-sovereign immunity status where the federal government is legally entitled to revoke this status at their discrepancy (Burns 2012).

The result of their entrepreneurial history and success directed the SRMT towards Allergan pharmaceutical company, whose patent for Restasis eyedrops (which has an annual revenue of $1.5 billion) was about to expire (Indian Tribe Joins 2019). In the summer of 2017 Allergan attempted to transfer their billion-dollar patent for Restasis eyedrops to the St. Regis Mohawk tribe (Allergan 2017) (Indian Tribe Joins 2019). The patent was set to cease in 2024 and was facing many legal challenges in the renewal process (Dyer 2017). By transferring the patent to the tribe, the patent would be protected by sovereign immunity. This would have allowed Allergan to not only avoid the legal issues surrounding the patent but prevent generic versions of Restasis eye drops from being created, therefore preserving their income from the drug (Hurley 2019). In exchange, the St. Regis Mohawk tribe would receive $13.75 million upfront from the

pharmaceutical company, as well as $15 million in royalties annually to lease the patent back to Allergan (Indian Tribe Joins 2019).

However, almost immediately controversy surrounding the Restasis patent transfer ensued. After Allergan and Saint Regis Mohawk Tribe announced this partnership Mylan NV, a competing pharmaceutical company that intended on selling a more affordable version of Restasis, brought this to the attention of the Patent Trial and Appeal Board with the hopes of having the transfer denied (Hurley 2019). Mylan NV was successful, and the deal was officially rejected in February of 2018 with the claim that "tribal sovereign immunity does not apply to its patent review proceedings" (Hurley 2019). Allergan and the SRMT appealed this ruling and the case was eventually taken to the United States Supreme Court. The Supreme Court affirmed the initial ruling and also rejected the patent transfer claiming that "By transferring the patents to a tribe that had no part in the development of the drug, Allergan attempted to purchase sovereign immunity to rip off consumers" (Indian Tribe Joins 2019). While further appeals occurred after, the final decision was no different than the initial ruling. This resulted in an international controversy surrounding the sovereign immunity of federally recognized Native American Tribes and the extent to which it reaches. It also introduced the question of whether preservation of federal funds, consumer interest, or the Native American tribe should be of primary concern when considering the boundaries of sovereign immunity.

IV. Case Evaluation

Throughout the process of Allergan's attempt to transfer their Restasis patent to the St. Regis Mohawk tribe a significant amount of legal research ensued and continued over the last four years. A majority of this surrounding the lawfulness of the Patent Trial and Appeal Board and Supreme Court's official ruling, as well as the bounds of Native American tribes' sovereign

immunity (Orzo 2019) (Burns 2012) (Brickey 2018) (McDonagh 2020). However, less studied is the way the St. Regis Tribe articulated the benefits of this potential deal to their community and how the community interpreted those benefits. Therefore, I chose to focus on this aspect of the case, with research evaluating the St. Regis Tribes interpretation of what could have been gained and what was ultimately lost. I maintained a focus in the diction used by Tribal leaders to relay the opportunity at hand, the SRMT community's response, and the Tribal response to negative evaluation of their utilization of sovereign immunity from those outside of the Tribal community.

V. Methodology

In order to glean St. Regis Mohawk tribe understanding I conducted a content analysis of predominantly non-academic papers. This included an examination into various newspapers featuring SRMT leaders, posts by Tribal council and leaders on the Saint Regis Mohawk Facebook page, comments by Tribal members on the Saint Regis Mohawk Facebook page, and attempts to contact members of the Tribal council for firsthand account of this articulation. While academic papers were beneficial in gaining an understanding of the SRMT, non-academic accounts provided a greater insight to the presentation of Allergan's patent transfer from Tribal leaders to community and Tribal members. Facebook was utilized to gain insight to how the SRMT interacted and continued communication with their community about the deal and how the community responded. This was analyzed by comparing the number of positive and negative comments on the SRMT Facebook posts regarding their deal with Allergan, as well as how many of these posts came from within the Tribal community compared to outside of it. The number of comments from the SRMT Facebook page in response to those on their post was also measured to provide insight to continued communication about the subject (reference Table 1c). The

amount of interaction for each post was measured by number of comments, number of "reactions", and number of shares to indicate the level of community engagement (reference Table 1a). Finally, the type of "reaction" to the posts was compiled to help further indicate positive or negative emotion (reference Table 1b). A Facebook "reaction" is a relatively new feature that allows number of emoticons to be placed where a "like" traditionally would be. The "reactions" available on Facebook are "Like", "Love", "Wow", "Sad", "Angry", and "Funny".

In addition, I am aware of the growing body of research of annotative content and quantitative research on social media articles. Social media gives the impression for how events unfolded for the tribe and most importantly the communication between Tribal leaders and members during the progression of said events. The content analysis of social media posts, comments, and responses has strength in that it is raw and unfiltered. It often shows a real time response to the situation rather than a retrospective one. However, there are weaknesses with this type of an analysis as well. It only provides a perception of that particular snapshot of time and can make it difficult to see the development of responses as time and immediate emotion passes. It also only shows the perspicacity of those using social media which leaves out those not using social media, including older generations and elders of the SRMT.

VI. Results

Economic Self-Sufficiency

From the content analysis of non-academic literature and social media interaction on the Saint Regis Mohawk Tribe official Facebook page, it was apparent that not only was there an initial articulation of the situation from the SRMT to their community, but further dialogue surrounding the patent, Allergan, and Tribal benefits occurred as well (reference Table 1c). The

delineation of this budding partnership with Allergan pharmaceuticals by Tribal leaders was outlined in the benefit to the SRMT community. In an initial post regarding the deal the Saint Regis Mohawk Tribal Council stated;

"We realize that we cannot depend solely on casino revenues and, in order for us to be self-reliant, we must enter into diverse business sectors to address the chronically unmet needs of the Akwesasne community; such as housing, employment, education, healthcare, cultural and language preservation" (SRMT Facebook 2017).

This initial articulation placed recognition on the fact that the SRMT needed to establish self-reliance within their economics and emphasized the continuously unfulfilled needs of the community. They communicated to the community that while the casino acted as their largest source of income, it was unrealistic to depend on that alone to support them. Little did they know how valid this statement would be only three years later during the COVID-19 pandemic when the casino would be forced to close resulting in loss of Tribal income and employment for hundreds of Tribal members (O'Brein 2020).

The Tribal Council continued the dialogue surrounding this deal by answering questions asked, disputing inaccurate information presented, and promoting further interest by elaborating on community benefits. Further support for "another revenue stream to address unmet community needs" (SRMT Facebook 2017) was shown with positive responses by members of the SRMT community (reference Table 1b). Although a small number of SRMT members voiced concern at this business preposition (reference Table 1c), they were met by SRM Tribal Council response that "prior to the adoption of any Tribal ordinance, law or procedure there is an opportunity for membership to provide input on its development…. This is to ensure that any resulting regulation and policy are reflections of our own community's interests" (SRMT

Facebook, 2017). This further speaks to the fact that the articulation of this deal was done through a lens of community benefit and increased economic self-reliance.

Furthermore, increased income would allow the SRMT increased opportunity for cultural preservation by purchasing back more of their ancestral land that was lost during the 1824 treaty (Alfred 2014) (Gawronski 2020). The tribe had lost nearly 12,000 acres during the 1824 treaty and had been fighting the United States Government since 1982 with that claim that "subject lands were taken under color of law, depriving them of the rights, privileges and immunities secured by the United States Constitution and the various treaties" (Canadian 2001).

Overall, this opportunity was perceived by Tribal leaders as a solution to economic struggle and therefore elucidated to the community as a means to gain economic self-sufficiency, alleviate poverty, improve education, allocate funds towards pollution relief, and help families afford everyday costs associated with lack of access to the Grasse River. Ultimately the SRMT and their communities perceived this as a strategic move to diversify their economy and address necessary improvements on the reservation.

Pride

Another aspect that became apparent through SRMT articulation of their attempted deal with Allergan and the community responses, was the sense of Tribal pride at their ability to engage in an unfamiliar industry to procure a lucrative deal for their benefit. Comments of pride, endearment, and support varied from "Woohooo! Proud of our Tribe!!!" (Wahiahawi Fitch Facebook) to "Amazing! Love seeing my Tribe make progress my Grandma would have been so happy about this" (Frankie Panipinto Facebook). Pride surrounding the Tribes engagement in this new industry was also shown in the 117 Facebook shares on the 4 posts occurring on September 8th, 2017 that officially announced the deal with Allergan and addressed various

aspects of it. This sense of pride was affirmed publicly through recognition by Allergan pharmaceuticals in their announcement of the deal. They commented on the tribes "thoughtful and enterprising approach, which will allow them to achieve their goals of self-reliance and help them address the most urgent needs in their community" (Allergan 2017). The SRMT went on to share this article on their own Facebook page to further to show their community the immense progress that was being made in the pursuit of economic self-sufficiency and self-reliance.

Public Response to Sovereign Immunity

While the Tribe maintained a strong sense of pride surrounding the deal with Allergan, responses were less enthusiastic and supportive in the Facebook comments of those outside of the Tribe. Comments from non-Tribal members extended from "B.S. You are helping big pharma screw the American People" (Dennis Adams Facebook) to simply "Then you are not sovereign" (Roxene Jones Facebook). In comparison to the 11 positive comments coming from outside of the Tribe, there were 21 negative ones (reference Table 1c). Non-Tribal members adopted the perspective that if the Tribe wanted to economically engage in industries outside of their reservation then they could no longer be sovereign. Those who were not a part of the SRMT community felt that because the tribe resides in the United States and is granted the same luxuries as a United States citizen, they should have to pay taxes and engage in legal processing the same way US citizens must if they wanted to partake in the lucrative industries of the US. The SRMT defended their sovereignty and intention stating

"The Tribe is committed to defending, preserving and strengthening the sovereignty of Akwesasne in its dealings with outside governments and other entities. Skennen." (SRMT Facebook 2017)

The word Skennen in Kanien'Keha, the traditional language of the Akwesasne SRMT, means great peace (Dolittle). Despite accusations of taking advantage of a system that was in place to protect them, the Tribe defended their decision with the position that as a sovereign government they were acting well within their status of sovereign immunity (SRMT Facebook 2017).

The scrutiny surrounding the SRMT use of their sovereign immunity extended beyond individual Facebook comments, into news outlets and media. Articles with titles such as *Sovereign Immunity for Rent*... (Geddes 2021), *Rent-A-Tribe*… (Brickey 2018), *Patently Absurd*… (Ginga 2018), *The Dark Side of Tribal Sovereign Immunity* (Orozco 2019), and *How to Protect a Drug Patent? Give it to a Native American Tribe* (Thomas 2017) began to immerge, criticizing the SRMT and Allergan for their partnership. The legal system, pharmaceutical industry, and news industry all continued to voice strong opinions on the Restasis patent transfer even after the deal was denied (Orozco 2019) (Hurley 2019) (Kennedy 2021). Even large news outlets such as the Wall Street Journal released articles with titles that focused on the pharmaceutical aspect of this deal, rather than benefit to the tribe. For example, *Allergan Partners with Indian Tribe to Protect Drug Patents* (Rockoff 2017) identifies the specific pharmaceutical company and the benefit to them, but deidentifies the SRMT by only referring to them as "Indian Tribe". It also fails to note that this is a mutual benefit situation and that Allergan was approached by the SRMT seeking self-reliance. Many of these articles focused their conversation around the Tribe "commodifying their sovereign immunity" (Geddes 2021) and lack of help developing Restasis, rather than around the Tribes continued articulation of gaining financial and economic self-reliance and addressing the immense unmet needs of their people.

Summary

To recapitulate, the St. Regis Mohawk Tribal Council initially approached Allergen pharmaceutical company with this mutually beneficial business proposal. Tribal leaders presented it to Tribal and community members similarly as they had to Allergan; in terms of self-reliance and communal improvement through diversifying their economy and creating a source of supplemental income (Allergan 2017) (SRMT Facebook 2017). The articulation of this business proposition was done as the beginning of a solution to help alleviate poverty and provide funding to help address necessary issues on the reservation was well received by the Mohawk community. Results from this analysis of Facebook comments and responses found on the Saint Regis Mohawk Tribe Facebook page confirmed the overwhelmingly positive response by Tribal members and a strong sense of pride at their Tribes resilience in pursuit of economic self-sufficiency. However, the remainder of the pharmaceutical industry and portions of the legal system saw this as a sordid abuse of their sovereign immunity and criticized them for commodifying the very thing that is in place to shield them from exploitation. Their perspective is rooted in the ideology that sovereignty is simply to protect Native American tribes but cannot be used outside of that for economic gain.

1a. Total Post Engagement- Saint Regis Mohawk Tribe				
Post Content	Date	Total Number Comments	Total Number "Reactions"	Total Number "Shares"
SRMT Clarifies Misperceptions to Senate Judiciary Committee	13 October, 2017	2	20	6
Frequently asked questions about patent business	11 September, 2017	5	36	23

Akwesasne TV community benefit	8 September, 2017	3	34	0
Slamming the unfair playing field of IPRs at PTAB	15 October, 2017	23	44	25
Forget Casinos: This Native American tribe is…	8 September, 2017	22	65	36
Deal offers the promise of a new revenue stream	8 September, 2017	61	116	23
NY tribe's attorney defends Allergan Patent Deal	18 September, 2017	2	15	3
Tribe provides clarification on Allergan agreement	14 September, 2017	31	58	24
Allergan and Saint Regis Mohawk Tribe Announce Agreement	8 September, 2017	28	55	35

1b. "Reaction" Compilation- Saint Regis Mohawk Tribe Posts						
Post Content	Number of "Likes"	Number of "Love"	Number of "Wow"	Number of "Sad"	Number of "Angry"	Number of "Funny"
SRMT Clarifies Misperceptions to Senate Judiciary Committee	20	0	0	0	0	0
Frequently asked questions about patent business	36	0	0	0	0	0
Akwesasne TV community benefit	24	4	6	0	0	0

Slamming the unfair playing field of IPRs at PTAB	37	5	0	2	0	0
Forget Casinos: This Native American tribe is…	53	2	6	1	3	0
Deal offers the promise of a new revenue stream	99	2	7	4	3	1
NY tribe's attorney defends Allergan Patent Deal	13	1	0	0	1	0
Tribe provides clarification on Allergan agreement	52	6	0	0	0	0
Allergan and Saint Regis Mohawk Tribe Announce Agreement	49	1	5	0	0	0

1c. Comment Compilation- Saint Regis Mohawk Tribe's Facebook Post			
	Internal to the SRMT	External to the SRMT	SRMT Page Replies
Total Number Supporting Comments	33	11	35
Total Number Opposing Comments	10	21	0

VII. Discussion

The strategy of buying patents allows for self-determination by permitting the Tribe to engage in the economic industries of the Euro-American world rather than relying solely on their expected casino income. It created a foot in the door for tribes to be involved in some of the

more lucrative industries in the United States. This content analysis of non-academic literature and social media interaction points to several distinct conclusions. It speaks to the Saint Regis Mohawk Tribes strive for economic self- sufficiency and self-reliance. It is important to note that even though the Mohawk had no ties to the modified extracts in Restasis (Brennan) (Churchill 2003) (Cultural Appropriation 2020) (ETC Staff 2012) (Glycerin Topical) (Herrygyers 2005) (Polysorbate 80 2021), they were willing to enter into this agreement with Allergan to secure the benefits to their tribe and people. They have recognized their need for supplemental income to support that of the Akwesasne Mohawk Casino and the ways that additional income would benefit their tribe. The Akwesasne Mohawk Casino constituted a majority of the St. Regis Mohawk tribe's income and was immensely impacted by the COVID-19 pandemic. They reported losing millions of dollars and having to let go of 700 employees. Prior they were one of the main employers on the Akwesasne Reservation. This immense loss of income could have been lessened by the multimillion-dollar Allergan deal. The benefits highlight a necessity for increased funds to address issues on the reservation. Also included, are relief programs for the large percentage of Mohawk families living below the poverty line, support for the education system, language preservation efforts, buying back more ancestral land lost in the 1796 treaty, higher education scholarships, and stressors of living next to a superfund site (SRMT Facebook) (Alfred 2014) (Tribe Reacquires 2018).

In particular, the Grasse River superfund site has had severe cultural and financial implications on the community. It was created by the release of polychlorinated biphenyls (PCBs) from the Alcoa West Facility (which produces and fabricates aluminum) into the Grasse River (Arconic 2021) (Grasse River Superfund 2019) (Hoover 2017). While superfund pollution sites are managed using government funding, this often takes an extensive amount of time.

Investigation began into this site in 1989, yet clean up didn't begin until 1995, and it wasn't declared a superfund site until 2012. Prior to the pollution, the Grasse River was a site of fishing, hunting, transportation, and medicinal plants for the SRMT (Arconic 2021). The loss of this resource was not only impactful on the current generation of SRMT living on the Akwesasne Reservation as a loss of freely accessible natural resources and access to continue teaching culture, but also because of the negative health consequences of living near this site (Grasse River Superfund 2019). PCBs are known human carcinogens that have devastating impacts on the immune system, nervous system, reproductive system, and endocrine system, and also causes dermal and ocular effects, liver disease, and increased blood pressure (Carpenter). The SRMT has had to live through the effects of this extreme pollution and cope with its impact on their culture. They recognize that diversifying their economy and gaining self-reliance through more Tribal income would grant them the funds to address these issues.

VIII. Conclusion

In conclusion, this agreement with Allergan was presented by Tribal leaders to the St. Regis Mohawk tribe as a mutually beneficial deal that would have provided the tribe with much needed immediate and long-term financial relief. While I understand that the federal government felt obligated to shut it down to protect investors and sanctity of the market, the verbal attacks on the SRMT and labeling of abusing their sovereignty and taking advantage is unwarranted. This strategy for economic development by the tribe went sorely underappreciated. As a federally recognized tribe, the SRMT received sovereign immunity because colonialism interfered with the Native American way of life. Sovereign immunity is in place to allow the Mohawk tribe the right to self-govern and forces the United States government to view these tribes as distinct

governments that manage their own internal and external affairs. This is important for “the protection of Tribal resources and protection of Tribal economic and social interests” (Tribal Sovereign Immunity), but also speaks to the quasi nature of the sovereign immunity the US government offers Native American Tribes. The SRMT attorney Dale White emphasized this in their appeal to the United States Supreme Court saying;

"Moreover, the harm to the Tribe’s sovereignty is separate from the scope or outcome of the IPR proceeding. The Tribe suffers irreparable harm from being subject to the PTAB’s jurisdiction, whatever its decision. As this Court has recognized, the purpose of sovereign immunity is to safeguard “the dignity” of “sovereign entities” which is lost regardless of the outcome of administrative adjudications brought by private parties. FMC, 535 U.S. at 760."

The SRMT was clear in articulating their utilization of their sovereign immunity to gain economic self-sufficiency and provide necessary financial assuagement to their community. The Saint Regis Mohawk Tribe was aware that their sovereign immunity did not allot self-determination but recognized it as an opportunity to get there.

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