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Sovereign Immunity, Intellectual Property, and the Life Sciences:

Investigation and Analysis of the Preserving Access to Cost Effective Drugs Act

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A Thesis in the Field of Biology

for the Degree of Master of Liberal Arts in Extension Studies

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Chapter I
Introduction

Patent filings in the life sciences are one of the most significant influencers of modern technology as well as the most significant contributor to the advancement and availability of scientific knowledge for use of public benefit. However, over the past twenty-five years, changes have been made to patent law that have complicated an already competitive and at times cutthroat area of law, and as a result this valued intersection of science and law has been further muddled with discourse, patent challenges, and industry leaders seeking every legal avenue or “loophole” to improve their position in the patenting arena. Most recently, this has included the attempt of pharmaceutical company Allergan to circumvent a patent challenge through capitalizing on the sovereign immunity of a Native American Tribe. (Allergan, Inc. and the Saint Regis Mohawk Tribe v. Teva Pharmaceuticals USA, Inc., No. 2:15-cv-1455-WCB (Fed. Cir. Oct. 16, 2017). In July of 2018, a three-justice panel of the U.S. Court of Appeals for the Federal circuit (“CAFC”) issued a scathing decision against Allergan, though Allergan and the Saint Regis Mohawk Tribe have since filed for an en banc rehearing before the CAFC, a rarely granted review in which the full CAFC would preside over the rehearing, but which has yet to be granted. Presuming that the decision of the CAFC is affirmed, sovereign immunity would be rendered be inapplicable to patent law proceedings and, sovereign entities actually participating in invention and development within biotechnology and the life sciences may be penalized for the bad acts of Allergan and the tribe in their attempt to “rent out” sovereign status. The hypervigilant response to the
Allergan case is likely to provide unwarranted deprivation of sovereign rights to deserving entities.

Throughout its lengthy history, sovereign immunity (“SI”) has been valiantly upheld and rarely restricted by the federal courts of the United States. The origin of SI includes its granting to the states in exchange for their agreement to join the union and establish the entity of the United States in itself. SI has faced significant legal challenges; however, the vast majority of cases have upheld this immunity with very little exception. When SI was limited in its scope or application, foregoing rulings were not necessarily consistent, with justices overturning or ruling contrary to precedent case law decisions.

In the history of lawsuits involving a question of sovereign immunity, no such area of law has faced the volume, or the intensity of challenges then patent law and licensing. Within the last 20 years alone, patent law and its sovereign actors have been affected by the America Invents Act (2012), the Bayh Dole Act (1980), the Patent and Plant Variety Protection Remedy Clarification Act (“PRCA”, 1992), the Copyright Remedy Clarification Act (“CRCA”, 1990), the Trademark Remedy Clarification Act (“TRCA”, 1992), and the Intellectual Property Jurisdiction Clarification Act (2011). These changes to patent law still respected the boundaries of sovereign status for state-entity patent actors, though, and include carved out provisions dictating how such should be applied to non-profit academics and state actors.

In the life science patent area, a valuable and mutually beneficial relationship exists between private and public entities. Information and inventions flow from academic partnerships (often public actors) to the private sector by way of Sponsored Research Agreements and Licenses, through which a private corporation financially supports the
research of an academic with the anticipatory return of a license offer to practice any inventions or innovations that may result from the researcher’s work. This benefits the academic not only financially, but in furthering their objective to disseminate information and foster more innovation, benefitting the greater public good and contributing to society in the process. The private entity is able to access and collaborate with the research that a faculty member has invested years or even decades of work to, without which the company would likely not be able to establish on its own.

As these business relationships have been further solidified over years with impressive success rates, industry partners further explored the beneficial relationships and business partnerships to be made with public entities, particularly due to their tax-exempt status, established, innovative faculty, pursuit of research endeavors, and, more recently, their sovereign status.

In recent years, landmark challenges were brought to the Patent Trial and Appeals Board (“PTAB”) in the course of its Inter Partes Review process (“IPR”). In 2018, Oil States Energy Services v Greene’s Energy (584 U.S.) (“Oil States”), was heard before the Supreme Court of the United States. Oil States Energy Services, the moving party, alleged that in 2012, when the Leahy-Smith America Invents Act (“AIA”) expanded the power of the USPTO, through its Patent Trial and Appeal Board (“PTAB”) to review and issue decisions on challenges to patent validity within an inter partes review (“IPR”), the AIA violated Article III of the Constitution as well as the Seventh Amendment, and, according to the claims of Oil States Energy Services, was unconstitutional. Oil States’ argument was based on Constitutional provisions that establish the powers and authority of the judicial branch as well as the right to a jury trial under the Seventh Amendment. However, on April 24, 2018,
the United States Supreme Court ("USSC") ruled against Oil States’ argument, finding that the process of inter partes review was not unconstitutional. The USSC’s finding struck down Oil State’s claim on the basis that patents are not personal property but instead are considered a public right, therefore eliminating any applicability to the Constitution’s Article III or Seventh Amendment. If Oil States’ argument had prevailed before the USSC, the problem that inter partes review was designed to address (increased rate of patent validity challenges) may have been even further complicated. As demonstrated by the statistical sources and figures provided below, PTAB challenges and IPR have steadily risen in the field of life sciences.

Figure 1: U.S. Court of Appeals Filings in Various Categories

Source: cafc.uscourts.gov
On May 3, 2018, Lex Machina announced the release of its annual Hatch-Waxman/ANDA (Abbreviated New Drug Applications) Litigation report which notes that pharmaceutical patent litigation increased approximately 30% in 2017 over the previous year (Lex Machina Fourth Annual Hatch-Waxman/ANDA Litigation Report, 2018). In addition, complaints and challenges have been filed outside of the IPR AND PTAB authority and instead within the jurisdiction of the Federal Courts. This has led to inconsistencies in rulings and in the application of Sovereign Immunity. In April of 2018, the aforementioned Allergan case pushed the proverbial envelope of sovereign immunity’s boundaries,
projecting life science patent law into the limelight, subjecting the field to an onslaught of both public and government criticism.

i. The Case At Hand: St. Regis Mohawk Tribe, Allergan v. Mylan Pharmaceuticals Inc., Teva, Akorn, 18-1638, U.S. Court of Appeals for the Federal Circuit (Washington);

In the case of the St. Regis Mohawk Tribe v. Mylan Pharmaceuticals Inc., the pharmaceutical Restasis, owned by Allergan, was facing IPR challenges by several other large pharmaceutical companies including Teva Pharmaceuticals, Mylan NV, and Akorn, Inc. In response to Allergan suing these pharmaceutical companies for infringement on the Restasis patents, Mylan, Teva, and Akorn successfully sought to initiate inter partes review against Allergan’s patents. Prior to the inter partes review taking place, Allergan contacted the St. Regis Mohawk Native American tribe and the pair collaborated to construct what the U.S. Court of Appeals for the Federal Circuit has since called a “renting of sovereign immunity”. Allergan agreed to pay the tribe fifteen million dollars per year to accept assignment and ownership of the Restasis patents, so long as a licensing agreement was entered into containing a stipulation that licensed the exclusive ownership of all rights in the patents back to Allergan. Then, Allergan and the St. Regis Mohawk Tribe asserted within the inter partes review that the challenges posed to the Restasis patents by other pharmaceutical companies should be immediately dismissed as they were barred due to the tribal sovereign immunity of the (new) patent owner, the St. Regis Mohawk Tribe. The Patent Trial and Appeal Board (“PTAB”) did not agree, and found in favor of Teva, Mylan,
and Akorn. Allergan and the St. Regis Mohawk Tribe then appealed PTAB’s decision within the U.S. Court of Appeals for the Federal Circuit.

In their appeal, Allergan and the St. Regis Mohawk Tribe argued that since inter partes review is an established method of judicial review for the purposes of extending the arm of the U.S. Courts, the inter partes review was inappropriately conducted and PTAB’s decision should be vacated in place of an immunity from inter partes review for the Restasis patents, as owned by the St. Regis Mohawk Tribe with applicable tribal sovereign immunity status.

The ruling of the U.S. Court of Appeals for the Federal Circuit struck down this argument and further condemned the St. Regis Mohawk Tribe and Allergan’s attempt to appeal. In its decision, the Court of Appeals for the Federal Circuit stated that the inter partes review process “is more like an agency enforcement action than a civil suit brought by a private party, and we conclude that tribal immunity is not implicated,” continuing that The patent office “is acting as the United States in its role as a superior sovereign to reconsider a prior administrative grant and protect the public interest in keeping patent monopolies within their legitimate scope.” It is further explained in the ruling that, “IPR is neither clearly a judicial proceeding instituted by a private party nor clearly an enforcement action brought by the federal government. It is a “hybrid proceeding” with “adjudicatory characteristics” similar to court proceedings, but in other respects it “is less like a judicial proceeding and more like a specialized agency proceeding” (Saint Regis Mohawk Tribe, Allergan, Inc. v. Mylan Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., Akorn, Inc., U.S. Court of Appeals for the Federal Circuit, decided 7/20/2018).
The U.S. Court of Appeals for the Federal Circuit also addressed the prior decision in Oil States, writing that it was “held that IPR is a matter which arises between the Government and persons subject to its authority in connection with the performance of constitutional functions of the executive or legislative departments” and that inter partes review serves to protect “the public’s paramount interest in seeing that patent monopolies are kept within their legitimate scope” (Saint Regis Mohawk Tribe, Allergan, Inc. v. Mylan Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., Akorn, Inc., U.S. Court of Appeals for the Federal Circuit, decided 7/20/2018).

Additional support relied upon by the U.S. Court of Appeals for the Federal Circuit is mentioned pertaining to the role of inter partes review (“IPR”) in general, and the scope of authority of the Patent Trial and Appeals Board (“PTAB” or the “Board”), “the role of the parties in IPR suggests immunity does not apply in these proceedings. Once IPR has been initiated, the Board may choose to continue review even if the petitioner chooses not to participate. 35 U.S.C. § 317(a). The Director has also been granted the right to participate in appeals “even if the private challengers drop out.” Cuozzo, 136 S. Ct. at 2144; see also 35 U.S.C. § 143… This reinforces the view that IPR is an act by the agency in reconsidering its own grant of a public franchise” (Saint Regis Mohawk Tribe, Allergan, Inc. v. Mylan Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., Akorn, Inc., U.S. Court of Appeals for the Federal Circuit, decided 7/20/2018).

Lastly, the U.S. Court of Appeals for the Federal Circuit included in their decision the elements of IPR that differ from the Federal Rules of Civil Procedure, “While the Federal Rules of Civil Procedure provide opportunities for a plaintiff to make significant amendments to its complaint, [see Fed. R. Civ. P. 15], the Board has determined that in IPR a
petitioner may only make clerical or typographical corrections to its petition... At the same time, a patent owner in IPR may seek to amend its patent claims during the proceedings, an option not available in civil litigation. [35 U.S.C. § 316(d).] IPR also lacks many of the preliminary proceedings that exist in civil litigation” (Saint Regis Mohawk Tribe, Allergan, Inc. v. Mylan Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., Akorn, Inc., U.S. Court of Appeals for the Federal Circuit, decided 7/20/2018 “Allergan” case).

Regardless of any arguable merits to Allergan’s attempt to evade the review of the IPR, the U.S. Court of Appeals for the Federal Circuit disagreed and ruled against Allergan. In fact, Allergan’s actions led to scrutiny from the general public and from entities outside of the legal system. The Association for Accessible Medicines issued a statement that “Allergan’s immunity-renting transaction with the tribe is the first of its kind, but if the gambit succeeds, it is sure not to be the last”, and furthered that “it would harm not only the patent system but the health care system as well”. Several large technology and financial companies also expressed their disapproval of Allergan’s actions, even filing legal arguments in the case (Bloomberg, 2018). This began a campaign undertaken by private companies, seeking confirmation that the ruling in Allergan case was intended for all sovereign actors, regardless of whether tribal sovereign immunity or state sovereignty was in question.

i. The Preserving Access to Cost Effective Drugs Act

In its decision, the U.S. Court of Appeals for the Federal Circuit specifically “left undecided “for another day” whether state institutions can continue to claim immunity from the reviews” (Bloomberg, 2018). Despite the silence on state institutions within the decision in the Allergan case, technology companies were quick to express their opinions that the
decision should be applied across all types of sovereign actors within patent law. “The reasoning should compel a similar result for state sovereign immunity,” said John Thorne, general counsel for the ‘High-Tech Inventors Alliance’ (Bloomberg, 2018).

As a result of the Allergan case and the U.S. Court of Appeals for the Federal Circuit’s silence regarding state institutions, a bill was introduced which has not yet been voted on by the U.S. Senate. Bill S.2514, referred to as the “Preserving Access to Cost Effective Drugs” or “PACED” Act, calls for the elimination of sovereign immunity protection from both state actors (public academics) and tribal immunity, for the purposes of patenting, licensing, and subjectivity to federal jurisdiction within PTAB reviews. PACED was claimed to be a direct response to the actions of Allergan and the St. Regis Mohawk Tribe, as stated by United States Senator Claire McCaskill of Missouri in a letter written by McCaskill to the Pharmaceutical Research Manufacturers of America (“PhRMA”). McCaskill wrote that Allergan was merely attempting to use a “loophole” that “should be illegal” and called on PhRMA to condemn this action and uphold “corporate responsibility” and efforts to “promote innovation and discourage predatory pricing practices and anticompetitive conduct” (Biospace, 2017). Then, outlining the purpose for the PACED Act, Senator McCaskill wrote that “Congress never imagined tribes would allow themselves to be used by pharmaceutical companies to avoid challenges to patents, and this bill would shut the practice down before others follow suit” (Biospace, 2017).

The ripeness of the problem examined within this study was escalated upon the introduction of the PACED Act on March 7, 2018. In direct response to the Saint Regis and Allergan case, the bill aims to completely eliminate sovereign immunity for both states and tribes, instituting a complete ban on use of sovereign immunity as a defense in IPR, and additionally
to “prevent tribal sovereign immunity from being used in declaratory judgment actions, where a company that expects to be accused of infringing files a suit to invalidate a patent” (Text: S.2514 — 115th Congress [2017-2018]). A review of the PACED Act’s text presents itself as unnecessarily broad and reactive in nature, outlining an overall elimination of sovereign status to be carved out in the area of patent law, potentially without proper and thorough research put into the its development. For example, although Senator MacCaskill alludes that PACED is necessary “before others follow suit”. However, Attorney Michael Shore, representing Allergan and the St. Regis Mohawk Tribe has stated “We approached a couple of tribes with the idea and they thought we were insane,” (IP Watchdog, 2018).

Even more so unanticipated and unwarranted, PACED carves out more liberally available sovereign immunity protections for foreign actors, as referred to within the Foreign Sovereign Immunities Act (“FSIA”). The provisions of the FSIA seek to balance the interests of the United States and protection of foreign states within United States Courts, generally providing that while foreign states are not automatically immune to suits within United States Courts, each particular case against a foreign state actor claiming sovereign status should be decided fairly within the United States Courts to serve the interest of justice. This is of course a less ubiquitous application of sovereign immunity protections than provided for domestic states within the United States Courts, as described within the Constitution and precedent United States case law.

Despite such, PACE takes a less stringent stance on how the FSIA should be applied to foreign states within patent law than for domestic counterparts, stating that for such foreign actors, “the Patent Trial and Appeal Board, shall determine whether the patent owner
is immune from jurisdiction in accordance with chapter 97 of title 28 as if the Patent Trial and Appeal Board were a Court of the United States” (Text: S.2514 — 115th Congress [2017-2018]). This finding directly conflicts with the Allergan decision rendered by the United States Court of Appeals for the Federal Circuit, in which the entire premise of non-application of sovereign immunity was the PTAB not qualifying as an extension of the Court of the United States. This provision, though adding insult to injury to domestic state entities, does not fully exemplify the remaining sophomoric propositions wrought within PACED.

The title of PACED may appear as a valiant effort to control rising drug costs and prevent actions like those taken in Allergan, but the avenue and methodology employed in the Bill will only further propagate the problem. Removing sovereign immunity isn’t solely the “blow to big pharma” that congress intended, it is a disruption of the delicate balance of research and invention ecosystems that exists between public and private patent actors and serves to advance science for the good of mankind. PACED intends to prevent assignment to Native American Tribes or other sovereigns to limit pharmaceutical giants from exploiting immunity, however, it doesn’t even begin to consider that where the Regis Mohawk Tribe lacked participation in the industry, state academics thrive through collaboration and legitimate involvement in the life sciences. These academics are not only enabled by such financially, but are additionally provided with leverage in which to enter into confidential disclosure agreements with private business entities and access research materials, developments, and early stage inventions that optimize public research laboratories, avoiding obsoletism that could otherwise render their pursuits stagnant in a profit and revenue driven industry.
ii. Investigatory Aim I: PACED analysis

The aim of this investigation is to determine if PACED is fair, reasonable, and based on the proper application of sovereign immunity as provided for not only in the life sciences field but through the authority and intent of the very origination and application history of sovereign immunity throughout the entirety of United States History. It is believed that PACED does not uphold the intent of either sovereign immunity status nor the intent and purpose of patenting activities, including the role of public entities in patents and licensing. The hypothesis is based on the history and purpose of sovereign immunity, case decisions that the U.S. Federal Courts have made in relation to sovereign immunity, the symbiotic relationship between public and private entities in life sciences patents, and the provisions enacted into U.S. patent law as specifically related to public actors. These factors are suited to determine whether or not the intention of the U.S. Government and rulings of its courts have been synonymous with what PACED would accomplish. Additionally, these considerations will answer or predict whether PACED will have a positive or negative impact on society as a whole. All of the preceding factors will establish the appropriateness, or lack thereof, of PACED.

To determine the appropriateness of the Bill set forth, I examined several categories of cases where a question of sovereign immunity was decided on. A wide scope of cases where a question of sovereign immunity was considered were reviewed, and ultimately 71 cases were identified and sorted into categories to be further analyzed in data sets. Categories used identified whether or not sovereign immunity was upheld, abrogated, or limited in some aspect and additionally whether or not the substantive issues of the case
related to patent law or not. Additionally, the historical application and purpose of sovereign immunity was reviewed, beginning with its inception and the intended protections granted to the sovereign states in consideration for their joining of a union and subjecting to the limited governance of what would become the United States Federal Government. These factors were reviewed in conjunction with the limited discretion and authority given to Congress to abrogate sovereign immunity, and the threshold necessary for such to occur, particularly in light of the PACED bill. PACED was analyzed in connection with the aforementioned factors for its legality, appropriateness, and adherence to the history and formidability of sovereign immunity and to the course of dealing between parties in patent law. Interestingly, public interest and benefit proved an essential factor to consider in light of PACED, and the well-seeming intentions of the proposed bill may be averse to its own claimed purpose.

iii. Investigatory Aim II: Historical application of sovereign immunity

Consideration of the above factors, including analysis and comparison of precedent case law will assist in understanding the actual balance of powers (both private and public actors) within the patent system. This study will also examine current use and evaluation of any abuse of sovereign immunity within patent law, to provide prospective on the appropriateness and need for the provisions within PACED (or lack thereof). This analysis will be performed in light of the scathing judgement received from the general public, U.S. Congress, and the U.S. Court of Appeals for the Federal Circuit pursuant to the Allergan and St. Regis Mohawk Tribe case.
Data analysis of the applicable case law and its ratios within the data of decisions on sovereign immunity will provide information that could indicate a correlation or bias towards patent law over other areas of law wherein a question of sovereign immunity has been raised. If the data analysis indicates that there is a much higher likelihood of a patent law case having sovereign immunity abrogated or restricted than in other areas of law, this information would identify an area needing further examination and potential future study.

As provided for in this study, data analysis and results can then be used to create graphs, linear regression models, histograms, and other useful tools to encapsulate and present the data, visually conveying the purpose and problem of the study in a more convenient and accessible form.

iv. Investigatory Aim III: Sovereign Actors in the Life Sciences and Biotech

The significance of this investigation is twofold. The first is to evaluate the legal, historical, and societal considerations of how sovereign immunity should be properly applied within the patenting process, including IPR and other extended arms of the U.S. Court of the Federal Circuit. This will focus on the proposed terms within PACED, and include the analysis of PACED in relation to the threshold and authority of Congress to consider abrogation of sovereign status. The second is the larger application and preservation of the positive benefit that life science patenting affords to society. Through collaborative efforts of both private and public actors, innovation in the United States has flourished and expanded upon the dissemination of knowledge. The public has enjoyed accessibility to cutting edge scientific information, knowledge, and discovery as new intellectual property is
shared through the patenting process. Life sciences researchers have been duly benefitted, receiving well-deserved funding through private research sponsors and freely sharing knowledge through various institutions within both the private and public sector, to the benefit of all. If the protections of sovereign immunity were eliminated within the patenting process, public academics and universities would have to reconsider the extent of their participation. Unlike their private counterparts, these public entities lack the resources, staff attorneys, and finances to subject themselves to the almost constant litigation that key private entities involved in patent law have engaged in throughout recent years. This would also limit the negotiating power of public universities when exploring collaborations with private partners, the results of which could lead to a cascade of unintended consequences. For example, public universities routinely negotiate a “publication clause” into their agreements with private research sponsors. If stripped of negotiating power, private sponsors and collaborative entities could further disadvantage these public entities, including the exclusion of any publication rights. This, obviously, denies the public and other life science researchers access to valuable publications in peer reviewed journals, and the effects would trickle down to those who rely on these publications to acquire knowledge and training in the field. Therefore, the scope of this problem has the potential to affect not only universities seeking patents to disseminate knowledge and encourage their research faculty, but also the public’s accessibility to innovation and associated treatments and student’s pursuits of knowledge and required training to work within the sciences.
Definition of Terms

“Federal Tort Claims Act”: A carved out exception to Federal Sovereign immunity which served to waive federal immunity for numerous types of torts claims.

“Foreign Sovereign Immunity Act (“FSIA”)”:

United States law, codified at Title 28, §§ 1330, 1332, 1391, 1441, and 1602–1611 of the United States Code, that establishes the limitations regarding suit of a foreign public entity in Federal U.S. Court.

“Inter Partes Review (“IPR”)”:

A procedure for challenging the validity of a patent, including those already issued by the USPTO.

“Leahy-Smith America Invents Act or America Invents Act (“AIA”)”:

United States federal statute that was passed by Congress and was signed into law September 16, 2011.

“The Preserving Access to Cost Effective Drugs Act (“PACED”)”:

A bill to amend title 35, United States Code, to provide that a patent owner may not assert sovereign immunity as a defense in certain actions before the United States Patent and Trademark Office, and for other purposes.

“Private Sector (“business”, “company”, “for-profit actor”, “private patent actor”)

An operating entity not under direct government control.

“Patent Trial and Appeal Board (“PTAB”)

the designated authority of the USPTO to conduct trials, including inter partes, post-grant, and covered business method patent reviews and derivation proceedings; hears appeals from adverse examiner decisions in patent applications and reexamination proceedings.

“Public Sector (“public academic”, “public actor”, “public patent actor”)

An operating entity controlled by the government that does not seek to or obtain a profit from its operations.

“Sovereign Immunity”: Sovereign immunity refers to the fact that the government cannot be sued without its consent as provided for in part within the Eleventh Amendment to the Constitution.

“The Eleventh Amendment”: effectively immunizes the actions of state governments from review in federal court.

“Tucker Act”: A federal statute of the United States by which the United States government has waived its sovereign immunity with respect to certain lawsuits. Specifically, including claims for damages arising from the Constitution, a federal statute or regulation, and claims in cases not arising in tort. Codified in 28 U.S.C. §§ 1346(a) and 1491.

“U.S. Const. Amend. XI”: An amendment to the Constitution of the United States of America which bars federal suits against an unconsenting state brought by its own citizens.

Background of the Problem

The legal governance of the United States Patent and Trademark Office (USPTO), has been facing significant challenges to its authority in recent years, with the amount of litigation and federal legal review only intensifying. In fact, patent law, particularly in the areas where science, medicine, and biotechnology interject, demonstrates areas of the law ripe with jurisdictional challenges, unexpected precedent decision, and a category of business entities colloquially known as “trolls”, able to profit solely on their acquisition and protection of coveted patent rights. In its current climate, patent law faces several juxtapositions that threaten to significantly impact its operations, provisions for patenting entities, and, arguably, even the overall intent, purpose, and philosophical backbone of the patenting process itself.

If the purpose and intent of patenting activities was questioned, such inquiry would produce varying results depending on the party asked. However, the historical purpose of the patent system was to encourage dissemination of ideas, new inventions, and information to be dispersed among the public and other inventors. Keeping inventions secretive does not propagate the innovation, discovery, enhancement, improvement and advancement of society that patenting was designed to foster and promote. Thus, the patenting process acts to provide protection to an inventor, to eliminate the fear that would otherwise incline inventors to keep such vital information and inventions entirely confidential. Using patenting as a
vector to both share the information and protect the inventors allows for greater efficiency and scope of growth, as inventors can learn from and improve upon the disclosed information and ideas.

Despite this philanthropic objective of the patenting process in general, it is now widely accepted that the process of patenting is simply a business venture, to obtain a patent and either practice or license the ability to practice the patent, in either scenario a profit-generating pursuit. However, examination of the entities and patent actors who operate in this arena illustrates the dichotomy between these two ideas of patenting purpose. This is due to the operations of non-profits, including academic institutions and state-controlled entities, in the patenting and licensing market alongside the industry’s globally-controlling giants. To distinguish these two groups, they are referred to as the “business sector” (for-profit entities and corporations) and the “public sector” (not-for-profit, government institutions).

The business sector utilizes the gross majority of patenting activities. In 2016, 151,000 USPTO patents were assigned in the United States. Among these, the private sector received 85%, the academic sector as a whole received 4%, and the government sector received 1%. (Chapter 8 | Invention, Knowledge Transfer, and Innovation, 2018). In 2016, 308,000 of the 409,000 Science and Engineering publications produced in the U.S. were attributed to academic authors, in comparison to the 6,600 USPTO patents assigned to that same group of U.S. academic owners (Chapter 8 | Invention, Knowledge Transfer, and Innovation, 2018). The difference in patents obtained by different entities relates back not
only to the status of the entity itself but to the mission and motivations of each, and their collective relationships with each other.

Table 1: U.S Patent Activity

<table>
<thead>
<tr>
<th>Calendar Year</th>
<th>Utility Patent Applications (a)</th>
<th>Design Patent Applications</th>
<th>Plant Patent Applications</th>
<th>Utility Patents (b) (a)</th>
<th>Design Patents (b) (a)</th>
<th>Plant Patents (b) (a)</th>
<th>Percent Patents to Foreign Applicants (a)</th>
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<tbody>
<tr>
<td>2015</td>
<td>568,010</td>
<td>30,917</td>
<td>1,140</td>
<td>258,007</td>
<td>7,074</td>
<td>0.028</td>
<td>149,763</td>
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<tr>
<td>2014</td>
<td>578,832</td>
<td>35,576</td>
<td>2,965</td>
<td>300,578</td>
<td>7,072</td>
<td>0.024</td>
<td>146,999</td>
</tr>
<tr>
<td>2013</td>
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<td>36,054</td>
<td>1,048</td>
<td>277,825</td>
<td>7,074</td>
<td>0.027</td>
<td>134,891</td>
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<tr>
<td>2012</td>
<td>542,315</td>
<td>32,395</td>
<td>1,149</td>
<td>253,315</td>
<td>8,985</td>
<td>0.035</td>
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<td>503,782</td>
<td>30,867</td>
<td>1,110</td>
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Source: https://www.uspto.gov/web/offices/ac/ido/oeip/taf/h_counts.htm
Support for Public Actors in Patents

The history and intention of public and non-profit actors in the patent field is especially important to consider in understanding the problem such actors now face. Within the life sciences, a symbiotic relationship has existed and thrived between private corporations and not-for-profit academics, particularly universities and public institutions. In fact, many of the key changes to patent law have been designed to continue to benefit public academics and foster the dissemination of inventions and ideas between both private and public.

An example that illustrates the intended role of public actors in patents and the life sciences is found within the Bayh-Dole Act (35 U.S.C . § 200-212). The Bayh-Dole Act ("Bayh-Dole"), (also known as the “Patent and Trademark Law Amendments Act”), was enacted in 1980 to specifically address intellectual property that arises from federally funded research. Though much disagreement exists in Bayh-Dole’s interpretation and application, the key change made was in relation to ownership of inventions made through federal funding. Prior to Bayh-Dole, an inventor working on federally funded grants or contracts was obligated to assign their invention to the federal government. Bayh-Dole was introduced to change this obligation and allow for inventors within a university, qualified small business, or non-profit institution to retain ownership of the invention within the entity (Foley Hoag, LLP, 2017).
Bayh-Dole was developed during a time of economic turmoil within the United States. At the time, billions of dollars was being invested by the federal government into research and development, leading to the United States Government accumulating thousands of patents. However, utilization was almost nonexistent, with less than 5% of those patents being commercially licensed (Foley Hoag, LLP, 2017).

Disagreement exists as to whether the provisions of Bayh-Dole eliminated or added to existing issues. The provisions of Bayh-Dole acted to decentralize federal control over federally funded inventions, instead placing the authority for pursuing commercialization on the inventor and inventor’s employer (recipient of the federal grant or contract). Of course, particular conditions and responsibilities came along with this vested authority, however, so did various new issues and problems further complicated by Bayh-Dole.

For example, critics and proponents of Bayh-Dole not only disagree on its interpretation and implementation, but also on how Bayh-Dole affects contractual relationships between parties. Provisions within Bayh-Dole have been interpreted to allow inventors at academics to keep their rights to a particular invention, even if the University had contracted to assign the rights to a private entity (Verspagen, 2006). This has led to academics and Universities seeing Bayh-Dole as restricting their ability to agree to assign inventions prior to their conception (in the terms of a Sponsored Research Agreement or other research collaboration with a private company), so that they are not agreeing to assign invention rights that the principal investigator and inventor has every right to retain for themselves. Concurrently, it has led to private companies insisting that the same invention rights be pre-assigned, to avoid the inventor later retaining the rights for themselves. It has
further muddled the definition of what is or isn’t considered ‘federally funded’ and applicable to Bayh-Dole, leading to escalated negotiations between public and private actors in their attempts to enter Sponsored Research Agreements. Academics, already not having the upper hand in relation to private sponsors, became responsible for “fighting their own battles”, so to speak, but then still owing particular duties and stipulations to the federal funding source nonetheless. Arguably, Bayh-Dole may have set out to solve a problem and give more authority and power to academics and public institutions, but in actuality may have had the opposite effect.

Multiple examples of carve-out language intended to apply to public patent actors clearly evidence the acknowledgement and purpose of public roles in the patenting realm. Upon inception of Bayh-Dole, the Federal Government sought to stimulate innovation in the United States, and similarly wanted to extend its own involvement in the field. As such, provisions were provided for public entities to act on behalf of the federal government in obtaining and generating new inventions and ideas on behalf of the public (Verspagen, 2006). This consideration highlights why sovereign status is important to uphold to remain aligned with the objectives of public actor involvement in patenting.

Additionally, public academics do not operate with the same motivating factors as private corporations. The goal and furtherance of public universities is to provide a public benefit to the greater good of society and share freely and openly information, knowledge, and ideas. The mission statement of public universities include goals of providing “public services that advance knowledge and improve the lives of the people within the [state], the nation, and the world.” (Source: University of Massachusetts Mission Statement, Trustee
Document T05-024, 2005). Rather than being driven by profit margins, consumerism, commercialization, and revenue generation, public academics have differing sources of motivation behind their activities within the life sciences and biotechnology. The operations of a public academic both benefit and rely on the activities of its scientists and professors, referred to as “PIs”, or “Principal Investigators” in the grants and contracts realm. Academic PIs are motivated by their own pursuit of science and career advancement of their status within the academic, particularly towards the objective of authoring publications that contribute to achievement and maintenance of tenure status. In order to fund a PI’s research, they identify and collaborate with private sponsors, apply for public and private grants and contracts, and develop proposals to submit in response to known topics provided by individual federal departments, such as “NIH” or the National Institute of Health.

Not only do research pursuits fund the PI’s laboratory and benefit associated graduate students, post-doctorate students, and other laboratory staff, but additionally, the institution is benefitted from the ‘indirect, overhead, and fringe’ costs included in the sponsorship, contract, or grant budget. The PI is incentivized by the reciprocal affect on his or her career advancement and status at the academic institution as well as in their publications within peer-reviewed scientific journals, and the academic becomes further incentivized to produce innovative and significant scientific achievements and research, which will attract even more talent, sponsorships, and resources. Academics must adhere to particular requirements in order to preserve their non-profit and tax-exempt status, which further refines focus on the PI’s scientific development and the dissemination of public benefit and scientific innovation of the institution.
In the same vein, the actions taken by a public academic which are afforded the protections of sovereign immunity are not likely to align with those of a private entity. To illustrate the gross extent of discrepancy between the two, in 2012 alone there were more than 5,000 patent law cases initiated. Conversely, State Universities have been involved in eight (8) total patent infringement cases in the 110 years between 1880-1990 (Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank, 527 U.S. 627, 1999). Similarly, the academic principles to disseminate information have allotted tax exemption status to many universities and institutions, which aids in not only performing the research itself but in contracting with third parties and private sponsors. Tax exempt status, unlike sovereign immunity, has not faced potential elimination even when public Universities are actively participating and benefitting the patent process. This begs the question of other factors or entities that may be the source of influence to remove sovereign immunity protections. Could the monetary influence of private corporations, under pressure within the current patent arena, have led or contributed to the prospect of stripping public patent actors of their sovereign status?

Though no evidence of a scheme of private entity influence currently exists, the private sector has certainly contributed to the attention brought to patent law in general and to the alleged “unfair playing field” enjoyed by public patent actors. Large pharmaceutical companies have brought several cases to the level of the U.S. Appeals Court for the Federal Circuit and have commonly referred to IPR proceedings as “death squads” designed to increase “kill rates” on patents. Further, public entities have been treated as easy targets by
the private sector, due to their tendency not to bring suit against others who misuse or ‘pirate’ their confidential information.

In one particular court, the United States District Court for the Eastern District of Texas, in Marshall, Texas, private entities exploited a Plaintiff-lean bias of the Court in relation to patent law. This “forum shopping” continued and eventually became so prominent that stricter jurisdictional provisions were enacted to prevent Plaintiffs from choosing to file in Marshall, Texas unless the Defendant met particular requirements. This change was enacted with just cause, as in 2015 alone, there were 5,819 new patent cases filed in the United States. Out of these, more than 25% (1,686) of those ended up before one justice: Judge Rodney Gilstrap in the Marshall courthouse of the United States District Court for the Eastern District of Texas (Rogers, K., 2016).

Prior to the change in jurisdictional forum rules, the Eastern District of Texas was such a critical playing field that South Korean technology company Samsung spent nearly a million dollars on community developments, including the creation and maintenance of an outdoor ice skating rink placed directly outside of the Marshall U.S. District Courthouse. In 2012, an op-ed even referred to Samsung as ‘the South Korean Company that has fortunately become Marshall’s benefactor’ (For Samsung…., 2015). Demonstrations of this nature provide a poignant demonstration of the sharp contrast between the resources and measures taken between public and private entities in patent law. Conversely, if a public academic were charged with competing with a private entity such as Samsung, the academic would face a nearly immediate forced choice to forfeit its activities within patent law. In turn, this would defunct the innovation, dissemination of research, and myriad of peer-reviewed
publications that public academics proliferate for societal benefit.

It is abundantly clear that universities in this respect do not have the ability nor the desire to act ‘commercially’ in the same manner as private entities. Contrary to some arguments that have been raised, participation in the patenting process does not, in itself, conclude that a public university has crossed the line of acting congruent with private entities. That same participation in patenting merely sparked enough commercial interest within public universities to encourage them to share and disseminate their knowledge beyond their own laboratories and academic research partners. If public entities were to cease participating in patenting activities, their research activities and knowledge would lack the catalyst for growth that has been observed in the business partnerships made between the private and public sector. This is especially true for the biotech and life sciences realm, where, as a National Institute of Health (‘NIH”) publication points out: “Transferring technology between academic and industry scientists in the biological sciences used to occur informally and by chance as scientists conversed at meetings. However, recent breakthroughs in molecular biology and biotechnology and their potential commercial implications have led to more formal and aggressive efforts. Technology transfer is important in the interests of industrial competition. The shift has been toward the promotion of collaborative research relationships between publicly supported scientists in universities and federal laboratories and those in the private sector.”

Parallel support is seen on the Federal level of review and has been enacted into law designed to facilitate the collaborative research relationships between public universities and private companies. The NIH reports that “Laws such as the Stevenson-Wydler Technology
Innovation Act of 1980 (P.L. 96-480), the Small Business Innovation Development Act of 1982 (P.L. 97-219), the Federal Technology Transfer Act of 1986 (P.L. 99-502), and recent proposals to liberalize patent policies have strengthened the emphasis on technology transfer in the nation's science agencies.” Thus, support for the free participation of public entities in the patenting system, absent any restraint or alteration of their public status, is well supported by public policy, law, and the mutually beneficial relationships forged between university and private industry. Such being true, it is difficult to ascertain how Congress could have arrived at the now-proposed PACED Act after any undertakings of reasonable and diligent review. Aside from the consequences and unforeseen challenges that an affirmative vote for PACED would, more likely than not, set into action, the abrogation of sovereign immunity requires a burden that the Act does not provide the requisite evidence to assert.

Unsurprisingly, key pharmaceutical companies have expressed their support for the provisions within PACED, and for the limitation of sovereign immunity application within patent law. Clearly this is incongruent with Senator McCaskill’s stated intent of PACED, which, by her own admission, seeks to punish and restrict actions like those taken by the St. Regis’s Mohawk Tribe and Allergan. As she stated, Senator McCaskill believes that PACED and its provisions are necessary “before others follow suit”, a statement which assumes that additional Native American Tribes and State academics would engage in the same “renting” of sovereign status if such was propositioned by a company like Allergan. This is not indicated by existing statements of Native American Tribes, nor by the frequent and significant level involvement of state academics within life science patents, which has occurred for over two hundred years without such occurring (Departments, 2018).
Therefore, the premise on which the necessity of PACED is based appears to lack significant evidence or understanding of the relationships between private and public patent actors.

PACED also presents in its text, an overall goal of reducing and maintaining prescription drug prices to benefit the public. However, it is questionable whether PACED would have an impact on lowering or preserving access to low-cost pharmaceuticals, and alternatively if PACED would lead to an increase in prices. This would be directly tied to the effect of PACED on disadvantaging public academics. Without sovereign immunity for academics to use as a bargaining chip in the contract and sponsored research negotiation process, academics would be materially burdened due to their financial discrepancies as compared to private companies. During negotiation of key contractual provisions such as indemnification, ownership of inventions, licensing terms, governing law, choice of forum, and limitation of liability, state academics are able to leverage their sovereign status as a supporting basis for insisting on particular provisions. Further, application of sovereign immunity assures academics from having to acquire and reserve the exorbitant costs associated with patent challenges and lawsuits, both of which are to be reasonably anticipated as commonplace in the current patent law climate. Without the shield and protection that sovereign immunity provides, academics would be easily forced out of the patenting arena and would likely agree to turn over all patent filing rights to private sponsors of research, if such sponsors were still even interested in collaborating and funding academic entities that had been stripped of all their leverage and bargaining power. Even if sponsored research persisted, sovereign academics would no longer file for and own patents. This eliminates the intentions and rulings of the judicial and legislative branches which have ruled
that patents are to be a “public right” (Oil States), and enacted legal provisions to vest authority and intellectual property rights with federally funded inventors in lieu of the Federal Government (Bayh-Dole).

Congress’ Power to Abrogate

Examination of whether or not Congress actually has the power to abrogate state immunity in this situation produces questionable results. In order to abrogate state immunity, Congress must show a 14th Amendment violation. According to established doctrine of the United States Constitution, Congress may only abrogate a state’s immunity to suit when necessary to enforce the important constitutional rights guaranteed by the Fourteenth Amendment. As the Supreme Court has stated, “The Eleventh Amendment and the principle of state sovereignty which it embodies are necessarily limited by the enforcement provisions of the Fourteenth Amendment. Congress may, in determining what is ‘appropriate legislation’ for the purpose of enforcing the provisions of the Fourteenth Amendment, provide for private suits against states or state officials which are constitutionally impermissible in other contexts.” Fitzpatrick v. Bitzer, 427 U.S. 445, 456 (1976). Though, some ability to decide on a case at hand is provided to the justices of the U.S. Courts, as stated by the Supreme Court: “Federal courts can exercise jurisdiction when the state attempts to deny a civil right to a citizen, in violation of the Fourteenth Amendment. For this to happen, Congress must specifically intend for the statute to abrogate the state’s immunity.” Quern v. Jordan, 440 U.S. 332 (1979). So, even with the limited capacity of
judicial review permitted on the matter of sovereign immunity, an issue of due process and violation of the rights of the fourteenth amendment still must be shown through a specific intention of Congress for a statute to abrogate SI.

A Fourteenth Amendment challenge to sovereign immunity is hardly an insignificant feat and carries with it a formidable standard and legal threshold for Congress to show. This standard has been interpreted by the Supreme of the United States as to require a response by Congress to a “pattern of irrational state transgressions” (Board of Trustees of U. of Ala. v. Garrett, 531 U.S. 356; 2001). This limitation as decided by the Supreme Court is meant to place a semblance of check and balance by which Congress cannot unnecessarily override the state’s sovereign immunity (Tenn. v. Lane, 541 U.S. 509; 2004). Our study seeks to evaluate the PACED bill to ascertain whether or not Congress has met the requisite burden and showing to abrogate the sovereign immunity as PACED proposes to abrogate for the purposes of patent law. We hypothesize that such burden has not been met within the provisions put forth by PACED.

The History of Sovereign Immunity

The doctrine of sovereign immunity in the United States has faced only limited challenges and served as a treasured crux of those who are afforded its protections. The immunity from lawsuits is applicable to both Federal and State entities, and contains self-restrictive terms of, in general, only subject to limitation when the entity itself waives such immunity. Despite the United States Federal Government waiving limited immunity through the Federal Tort Claims Act and the Tucker Act, the United States Supreme Court ruled via
Price v. United States, 174 U.S. 373, 375-76 (1899), that ‘the government is not liable to suit unless it consents thereto, and its liability in suit cannot be extended beyond the plain language of the statute authorizing it’, and with such decision the Supreme Court affixed rigid borders at this narrow scope of self-determined immunity waiver by the government.

As could be expected, pursuits of private claimants, academics, and other interested parties have explored and challenged the legal problem inherent to sovereign immunity by posing the question: in what situations will sovereign immunity itself face jurisdiction of the courts and, in what scenarios, if any, does sovereign immunity not apply? An important distinction exists between state and federal sovereign immunity and tribal sovereign immunity held by Native American tribes in the United States. Considerations of case law and other scholarly examples ascertain the differences in how each has been interpreted and applied within United States History, as well as the implications of each that may have influenced the decision of Allergan.

Immunity of the states has been historically affirmed by US Federal Courts and, arguably, held to even more stringent and less malleable boundaries than federal statutory provisions. For example, in Alden v. Maine, the decision of the court conveyed “a State will therefore not be subject to suit in federal court unless it has consented to suit, either expressly or in the "plan of the convention” which referred to any such applicable Constitutional Amendments (Alden v. Maine, 527 U.S. 706 1999). Additional challenges throughout United States history has led to decisions defining other limited exceptions to sovereign immunity, such as the US/p immunity Suits brought against a state by the United States ("US/p suits") or brought by another state ("state/p suits") (Caminker, 1999). It has been
further described and consistently held by the U.S. Circuit Courts that ‘whether congress has the authority to abrogate a states’ immunity’ is a question of ‘history, practice, precedent, and the constitution’s structure’ (Alden v. Maine, 527 U.S. 706 1999).

Article I of the Constitution has provided Congress with some delegated power to subject States to private suits. However, this had been previously applied to exclude any such objectives that the States have a means of otherwise achieving within themselves, as contained within the findings of Parden v. Terminal R. Co. of Ala. Docks Dept., 377 U. S. 184, 190-194. Proceeding precedent disagreed, per the ruling of College Savings Bank v. Florida Prepaid Postsecondary Ed. Expense Bd., ante, at 680. Pp. 731-735. Much like the current climate of patent law, it has been at time unclear whether a case’s finding was intended by the court to apply universally or be considered as relevant to a case-by-case basis.

Course of Dealings Between Private and Public Entities in Biotechnology and Life Sciences

The relationship between public entities and private companies within patent law warrants the upholding of sovereign immunity in any patent proceedings. The history of collaboration between these two types of entities is well established within the field, with scholarly publications arguing that “patents on university inventions may be necessary to stimulate technology transfer from universities to private firms” and that in order to foster innovation, interaction is important because “the development of technology and innovation
is a learning process, in which technology transfer is greatly facilitated by direct contact between researchers” (Verspagen, 2006). Further, specific provisions such as the Bayh-Dole act have been introduced with the goal of continuing to develop partnerships and collaborations between public and private entities. “With the introduction in 1980 of the so-called Bayh-Dole Act, which gave US universities the right to patent discoveries resulting from federally funded research, this debate was decided in favour of those supporting active patenting by universities” (Verspagen, 2006). This yields beneficial results for the two parties as well as the field in general, and arguably expands to the general public’s benefit of the innovation, inventions, and treatment methods that can arise out of biotech patenting.

The sharing of knowledge and ideas has an unsurmountable impact on the overall innovation of the biotechnology field in relation to a society, and, to the society in general. “Knowledge is an important factor of production and leads to both greater varieties of consumption goods and increased productivity in producing them. Using knowledge throughout the global economic system can in principle be realized at relatively little extra cost in addition to the costs induced by the original developer of the knowledge” (Verspagen, 2006).

The sharing and dissemination of knowledge within biotechnology and the life sciences can be understood through an illustrative metaphor. If scientific knowledge and discovery were an electrical current, the vector through which it traveled would be the research and ownership of patent rights by academics, aided by the conductive effect of contracts and licensing agreements. When contracting with private companies, public academics insist on particular terms due to their mission, scientific and public interest motivations, and sovereign entity status. For example, the majority if not all of public
academics require that collaborative and sponsored research agreements contain clauses that enable the right to publications for the academic’s principal investigator. This ensures that the research and innovation does not remain secretive and instead can be disseminated to the public as well as used for educational benefit. If the private entity objects to any ‘confidential information’ in the publication, contracts will typically require that the private entity provide or permit alternative language to enable the publication or allow a brief waiting period for the company to file on any intellectual property prior to publication.

In exclusive licensing agreements, public academics insert provisions assuring that the licenses will be practiced, which prevents secrecy and enables public access. Similar additional contractual provisions serve the same intent and benefit, and consistently contain language to benefit society and taxpayers as a whole rather than the academic’s own separate interest(s). Based on the foregoing, the following problems and questions with regard to PACED arise: Does PACED address an actual problem or merely try to anticipate and prematurely react to an unripe, moot assumption? If PACED does anticipate or address a problem, does it actually accomplish the objective that it purports to? Or, does PACED apply punitive measures to a benign and even virtuous class of patent actors in its punishment of public state entities?

Our study will further analyze and examine the appropriateness of PACED in relation to the already established course of dealings between these parties, and how these valuable relationships could be impacted. In order to fully address the challenges posed to PACED, it is important to understand the particular proceedings involved, chiefly, inter partes review of the USPTO.
Public Rights Doctrine and Inter Partes Review

Those who oppose sovereign immunity application within patent law have asserted the argument that at a minimum, sovereign immunity should not apply to IPR proceedings as a part of the patenting process, under the premise that IPR does not represent a federal jurisdictional body in the same manner as a Court of Law, and as such sovereign immunity from suit does not apply. This study will evaluate the relevant case law and application of existing administrative review to determine if the argument to abrogate sovereign immunity within IPRs holds merit.

Question and Hypothesis

Our study attempts to define what should or shouldn’t constitute ‘plan of the convention’, and the ‘history, practice, and precedent’ in relation to State entities participating in Intellectual Property Law and Patent Law. The legal problems we aim to resolve are:


Does applicable law, history of sovereign immunity, case law review, public policy, and the relationship between private and public entities within life sciences and biotechnology patenting indicate that sovereign immunity should be limited as related to patent law? Would an exception to sovereign immunity in the patent arena
contradict the legal and historical precedent on which sovereign immunity was granted?

2. Evaluation of the legality and appropriateness of the PACED Act:

Does PACED represent a fair application of Sovereign Immunity based on the history and application of both sovereign immunity as related to states, and patent law as practiced in the life sciences? Or, is the potential benefit and purported goal of PACED far outweighed by the stripping of Sovereign Immunity of State actors?

We hypothesize that:

1. The historical and legal case history, law, dissemination of information in the life sciences, and other precedent regarding sovereign immunity and its application in patent law, will support the upholding of sovereign immunity protection for public academic patent actors and additionally, preserving the sovereign status of state academic universities is supported by patent law, pursuant to the purpose and scope of sovereign immunity; and

2. PACED does not meet the legal burden required for an abrogation of Sovereign Immunity enacted by Congress.
Implications of Research

This thesis will address a problem in the field and additionally create a drafted solution to the problem. The problem to be addressed will be need for the consideration of and exploring potential justification for an exception to sovereign immunity when applied to public entity patent actors. The newly modified area of patent law has faced criticism and legal challenges posed by both public and private actors since the inception of the America Invents Act in 2012. Recent precedent findings of the USPTO and the United States Federal Circuit courts have amplified the need for further exploration of the role of public non-profit entities involved in patenting, particularly state academics performing research and inventing within the life sciences, as the status of their sovereign immunity may be jeopardized. Further, private for-profit entities have claimed that sovereign immunity in itself creates inequity of the two parties, but these businesses have not presented data or other research findings that purport the significant and gross disparities between the two entities in relation to their patenting activities.

The existing foundation of research, legal cases review, and patent law provisions provides a basis for the importance of our proposed study. Our hypothesis will serve not only to answer and provide objective and unbiased review of the claims of inequity between patenting actors but will also serve to preempt further complications of recently passed court findings and tension from for-profit businesses, particularly through the creation of standard and criteria on which to “test” equity of a public entity patent actor against that of a private patent actor. Our hypothesis and proposed study indicates an efficient next pursuit to respond to these problems within the field, as evidenced by the foregoing.
The larger implication is the effect that PACED could have on biology and the life sciences, especially in consideration of public benefit. If PACED limits the actions of state entities in patenting and the relationship between state universities and private corporations, innovation and shared knowledge within the sciences will suffer. As a result, a lack of innovation and accessibility of inventions and information to the public will yield even greater unfavorable consequences, including but not limited to an elimination or slow-down of inventions and innovations in the sciences and medical field, impact on economics and the finances available to sponsor research, decreased access of the public to treatment and progressive, innovative therapies, and additional consequential results.
Chapter II
Materials and Methods

This study located, reviewed, and analyzed case law decisions handed down on the topic of sovereign immunity and patent law. Overall, cases were evaluated on the basis of sovereign immunity status to determine if the significant number of Justices rendered a decision in favor of sovereign immunity protections and their application, or in a manner that limited, restricted, or prevented a defendant from claiming sovereign immunity from suit.

This analysis included separating and categorizing cases that related to ‘general application of sovereign immunity’ from ‘patent related sovereign immunity cases’ and further probing the case law findings to investigate a potential bias towards the restriction of sovereign immunity in relation to patent law cases (as compared to the findings made in non-patent related general application cases). The question being investigated was as to whether or not there is a significantly higher rate of abrogating or restricting sovereign immunity protection in relation to patent law over the “general” non-patent related sovereign immunity cases. Using the data gathered from analysis of precedent case law, this study used a z score test for two population proportions to determine if this potential correlation between patent law cases and a higher likelihood of restriction of sovereign immunity was present in the case law studied.

Cases were sourced from a variety of search engines and legal texts, towards the goal of obtaining samples and population data as large as reasonably possible. First, cases were

Next, three electronic search engines were used: Westlaw, Google Scholar Caselaw Search, and Lexis-Nexis. For each search engine, the following terms were input: 1. “patent; sovereign immunity”; 2. “biotech; sovereign immunity”; 3. “science; technology; sovereign immunity”; 4. “sovereign immunity applied”; and 5. “sovereign immunity limited”. The results of each search were examined using the first three pages of each search result and any applicable cases were included within the population and samples of cases. Cases were eliminated if the involvement of either patent law or sovereign immunity were not significant and did not fit the operational definitions of the study criteria.

Rate of Sovereign Immunity Limitation

The rate of upholding sovereign immunity status within the entirety of the caselaw available and reviewed for this study was found to be 63.3%. Within only the patent related cases, sovereign status was upheld in 56% of cases. In the non-patent related cases, (general question of SI in various topics), sovereign immunity was upheld 67.39% of the time.
Data Analysis: Z-Score

Case law review was used to sort cases into categories of “upheld sovereign immunity- patent related”, “upheld sovereign immunity- non-patent related”, “limited sovereign immunity- patent related” and “limited sovereign immunity- non-patent related”. The percentage occurrence of each group demographic was then calculated out of a percentage of the whole (all of the cases studied). Next, using the percentages of occurrence for each category, the proportions as compared to the whole were entered into a Z Score calculation, which was done using a Significance Level of 0.01 and a two-tailed hypothesis.

Identification of Cases

Cases were identified within the time of 1793-2018, using various scholarly sources as a summary, as well as through the use of several different legal search engines as aforementioned. Cases were sourced and reviewed from both text source summaries and electronic search methods for the express purpose of locating a general pool of unbiased case law, as exhaustive as possible. The processes ensured that all “key” cases were appropriately included. This yielded 71 cases for review which were then separated into cases that overlapped between patent law and sovereign immunity (25 cases), and general question of sovereign immunity (53 cases).
Criteria

Cases were analyzed and split into categories of either (1) upholding sovereign immunity or (2) limiting or removing the applicability of sovereign immunity in some way. To be considered as upholding sovereign immunity, a case must have been completely barred and the sovereign party rendered immune from the proposed suit entirely due to sovereign status. Cases that were categorized as limiting sovereign immunity included any limitation, change, narrowed scope, or other way to effect sovereign immunity that was applied within the case. This included cases where sovereign immunity was completely discarded, so long as the defendant was still an actual public sovereign entity.

Public Policy

Our study evaluated the public policy effects of sovereign immunity in patent law through several different vectors. This was done through the identification and analysis into the relationship between public universities and private companies as well as by studying varying case law on the topic of patents. Particularly, key cases such as “OIL STATES ENERGY SERVICES, LLC v. GREENE’S ENERGY GROUP, LLC, ET AL.” through which the Supreme Court asserted their finding that patents should be considered “public franchises” for the purpose of IPR reviews and the question of their constitutionality.
Evaluation of PACED

The appropriateness and legality of PACED was evaluated through the criteria set forth by the Supreme Court which defines the burden that must be shown by Congress in order to limit the scope of sovereign immunity status of a state. Additionally, implications on life sciences application, dynamics of the biotech industry, and public policy considerations were used to evaluate whether or not PACED should be introduced as law. The historical purpose and application of sovereign immunity was an additional factor used in consideration of this Act.

Analytical Tools

Analytical tools used were mainly comprised of operational definitions and case law guidance, as appropriate, to the relevant criteria as aforementioned. These criteria and tools were construed as objectively as possible as not to introduce bias during case law review. As such, the criteria used were applied on a “no” or “yes” qualitative basis (in relation to whether or not sovereign immunity was upheld in the case) rather than attempts to create any sub-categories that may have opened up analysis to more subjective means.

Research Limitations

This study identified several limitations in its objectives, seen through both practical and technical routes. First, in the selection of case law. Though this study undertook efforts to the best extent possible in order to identify and analyze a broad scope and properly
reflective sample of case law decisions in its review, it is possible that reliability of the sample to represent and encompass the entire population is limited. To correct for this, a future review could locate a technically advanced method to identify the entire population of cases within a more narrowly defined time period.

Additionally, the discrepancy in judgements on the cases reviewed may affect reliability. For particular cases, similar fact patterns received varying decisions as handed down by different courts and/or justices. So, precedent case law may or may not have been respected or upheld in ensuing cases before different jurisdictional bodies. This could affect the data of this study as indicating a bias or significant correlation without accounting for third party variables, one of which being the particular judge’s discrepancy used to hand down the decision. Third party variables could be present in the nature of the case themselves. For example, in the Allergan case, strong condemnation from society and the PTAB process impacted the notoriety of the case and attracted significant attention to it. The court may have then been acting out of a public interest benefit. At the very least, factors in relation to the “public good” likely influence justices rendering their decisions, even just in terms of implicit or sub-conscious biases.

Our research and results may also contain the influence of internal and external limitations. Internal limitations include the availability of case law for analyzation. Due to the novelty of the AIA and the unique overlap between patent law and sovereign immunity, limited case law was available to be analyzed for purposes of sovereign immunity application to patent law. Negating the effect of this limitation was attempted by examining patent law cases with sovereign entities as parties within the United States Federal Circuit Courts.
Generalizability of results may limit the findings of our study as the data may prove variable in relation to different subcategories of public actors in patent law or in specific entities themselves (i.e. data may present one public university as different from another despite their similar establishment and equivalent categorization).

A prominent external limitation of this study is the continued pending issuance and review of pertinent decisions that would impact the value of our findings. For example, the most critical of these pending reviews would be the appeal in the case of Allergan and the proposed PACED Act, though other vital in-process patent law cases additionally exist that could impact the material in our study. Nonetheless, the evolving political climate in relation the patent law and sovereign immunity may continue to present with unanticipated challenges or limitations for our study to navigate.
Chapter III

Results

Federal law and precedent case law decisions were researched and analyzed to identify the historical application and scope of sovereign immunity in practice. Overall, seventy-one cases were identified as applicable and analyzation identified a significant trend towards the application of sovereign immunity and expansion of its scope, favored considerably in place of narrowing the scope of sovereign immunity and limiting the application of its affordances.

Cases Identified

Table 2: Cases Analyzed

<table>
<thead>
<tr>
<th>SOVEREIGN IMMUNITY</th>
<th>FOR</th>
<th>AGAINST</th>
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<tbody>
<tr>
<td>Cohens v. Virginia</td>
<td>Chisholm v Georgia</td>
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<tr>
<td>US v Clarke</td>
<td>New Hampshire v Ramsey</td>
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<tr>
<td>US v Melermore</td>
<td>Langford v US</td>
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<tr>
<td>Hill v US</td>
<td>Lapides v Board of Regents of Univ of Georgia</td>
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<tr>
<td>Beers v Arkansas</td>
<td>Clark v Barnard</td>
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<tr>
<td>Briggs v Light Boats</td>
<td>Community College v Katz</td>
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<tr>
<td>Nichols v US</td>
<td>Michigan v Bay Mills Indian Comty</td>
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<tr>
<td>Gibbons v US</td>
<td>State Contracting and Engineering Corp v Florida</td>
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<tr>
<td>US v Lee</td>
<td>In Re Charter Oak Associates</td>
<td></td>
</tr>
<tr>
<td>Monaco v Mississippi</td>
<td>In Re Straight</td>
<td></td>
</tr>
<tr>
<td>Kawanakaoa v Polyblank</td>
<td>South Dakota v North Carolina</td>
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<tr>
<td>Keifer &amp; Keifer v RFC</td>
<td>Fitzpatrick v Bitzer</td>
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<tr>
<td>US v Shaw</td>
<td>Nevada v Hall</td>
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<tr>
<td>Younger v Harris</td>
<td>Reata Const Corp v City of Dallas</td>
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<td>Stone v Powell</td>
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<tr>
<td>Hans v Louisiana</td>
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<tr>
<td>Seminole Tribe of Florida v Florida</td>
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<tr>
<td>Atascadero State Hospital v. Scanlon</td>
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<tr>
<td>Wihtol v Crow</td>
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<tr>
<td>Stewart v. North Carolina</td>
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<tr>
<td>Native Village of Noatak v Blatchford</td>
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<td></td>
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<tr>
<td>The Principality of Monaco v Mississippi</td>
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<tr>
<td>New Hampshire v Louisiana</td>
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<tr>
<td>Ford Motor Co v Department of Treasury</td>
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<td>Testa v Katt</td>
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<td>Krozer v New Haven</td>
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<tr>
<td>City of Amarillo v Martin</td>
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<tr>
<td>McCloskey v Mueller</td>
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<tr>
<td>Dawkins v Baltimore City PD</td>
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<tr>
<td>McMillian v Johnson</td>
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<tr>
<td>Federal Maritime Comm’n v South Carolina Ports</td>
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<tr>
<td>Oklahoma Tax Comm’n v Potawatomi Tribe</td>
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<tr>
<td>Yanero v Davis</td>
<td></td>
<td></td>
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<tr>
<td>Florida Prepaid Postsecondary Education Expense Board v. College Savings</td>
<td>Vas-Cath v Univ. of Missouri (REVERSED) (later limited)</td>
<td></td>
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<tr>
<td>Alden v Maine</td>
<td>McCullogh v Maryland</td>
<td></td>
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<tr>
<td>Idaho v Couer D’Alene Tribe</td>
<td>Regents of the Univ. of California v Eli Lilly and Co</td>
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<tr>
<td></td>
<td>Regents of the Univ of New Mexico v Knight</td>
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<tr>
<td></td>
<td>Mylan Pharm Inc et al v Saint Regis Mohawk Tribe</td>
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</tbody>
</table>
Case Law Review

Out of the 71 cases analyzed relating to sovereign immunity, 45 of them dismissed the case entirely on the basis of sovereign immunity barring suit. Only 26 cases permitted the suit to continue, though, each of these cases still only provided a limitation to the application or scope of sovereign immunity; none of the cases studied were found to have negated sovereign immunity altogether.

The jurisdictional demographics of cases analyzed were as follows. Out of the number of overall cases, thirty-eight were heard within the United States Supreme Court, nineteen were heard by one of the United States Court of Appeals (within several different circuits, but most commonly the Federal Circuit), and seven were within a United States District Court. Four were heard at the level of a state Supreme Court, and three were within the USPTO conducted by patent judges of PTAB.
For the cases within the United States Supreme Court, thirty-three were relating to sovereign immunity with no patent or biotech overlap, and five contained elements of both patent and sovereign immunity. Twenty-six cases were “for” or upheld sovereign immunity (twenty-three non-patent and three patent overlap) and twelve limited or abrogated sovereign immunity (ten non-patent and two patent overlap).

United States Court of Appeals cases contained eight non-patent cases and eleven patent related, with eight “for” sovereign immunity (five non-patent and three patent overlap) and eleven “against” sovereign immunity (three non-patent and eight patent overlap).

United States District Court cases included four non-patent cases and three patent related cases. All four non-patent cases were “for” sovereign immunity, and these respective cases were held within the districts of Southern Florida, Massachusetts, Kansas, and Southern Iowa. Of the three patent overlap cases, two were “for” sovereign immunity in the districts of Eastern California and Western Texas, and one was “against” sovereign immunity, held in the district for Southern Indiana.

Four cases were held within Supreme Courts of varying states, including two non-patent related cases that upheld sovereign immunity in Florida and Kentucky and two non-patent case “against” sovereign immunity, heard within the Supreme Courts of Texas and New Hampshire. Lastly, three patent and sovereign immunity overlap cases were decided before PTAB (USPTO), and all three upheld sovereign immunity.

Case year ranged from 1792 to 2018, with no preference for particular years but instead emphasis on accumulating as large of a sample of applicable cases as practically possible. Case demographics are further provided in Table 3: Jurisdictional Demographics of Cases:
Table 3: Jurisdictional Demographics of Cases

<table>
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<tr>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. Supreme Court</td>
<td>23</td>
<td>10</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>U.S. Court of Appeals</td>
<td>5</td>
<td>3</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>U.S. District Court</td>
<td>4 (Southern Florida, Massachusetts, Kansas, Southern Iowa)</td>
<td>0</td>
<td>2 (Eastern California, Western Texas)</td>
<td>1 (Southern Indiana)</td>
</tr>
<tr>
<td>State Supreme Courts</td>
<td>2 (Florida, Kentucky)</td>
<td>2 (Texas, New Hampshire)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>PTAB/USPTO</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

The hypothesis tested was whether or not there was a statistically significant increase in the occurrence and incidence rate of sovereign immunity being limited within patent law cases as compared to the entirety of other substantive law subjects.
Table 4: Data Showing Case Numbers for each category studied

<table>
<thead>
<tr>
<th>Category</th>
<th>UPHOLDING SI</th>
<th>LIMITING SI</th>
<th># OF CASES STUDIED</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATENT RELATED CASES</td>
<td>14</td>
<td>11</td>
<td>25</td>
</tr>
<tr>
<td>NON-PATENT RELATED</td>
<td>31</td>
<td>15</td>
<td>46</td>
</tr>
<tr>
<td>TOTAL CASES</td>
<td>45</td>
<td>26</td>
<td>71</td>
</tr>
</tbody>
</table>

Table 5: Data Showing Percentages for each category studied

<table>
<thead>
<tr>
<th>Category</th>
<th>UPHOLDING SI</th>
<th>LIMITING SI</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATENT RELATED</td>
<td>56%</td>
<td>44%</td>
</tr>
<tr>
<td>NON-PATENT RELATED</td>
<td>67.39%</td>
<td>32.60%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>63.38%</td>
<td>36.61%</td>
</tr>
</tbody>
</table>

When Z-Score test was calculated for each, the results indicated as follows:

Patent related cases upholding sovereign immunity v. total cases upholding sovereign immunity showed a significantly different result, with a p-value of 0, and the result was significant a p<0.01 with two-tails. Patent related cases upholding sovereign immunity v.
Non-Patent cases upholding sovereign immunity showed a significantly different result, with a p-value of 0, and the result was significant at p<0.01 with two-tails. However, when the Z score was calculated for the Non-Patent related cases as compared to the total number of cases, the result was not significant. Results indicated that the Z-Score is -0.4442. The p-value is 0.65994, and therefore the result is not significant at p <0.01. The proportion of Yes or No responses for Observation 1 is 0.326. The proportion for Observation 2 is 0.366.

Application of Sovereign Immunity

Sovereign Immunity continues to exist as one of the most longstanding and arguably important aspect of the formation of the United States of America. Not only does dual sovereignty ensure that checks and balances maintain a homeostasis of the powers designated to the states and the federal government, but, sovereign immunity provides for limited and uniquely specific circumstances in which sovereign entities can be subjected to suit within the Courts of the United States Federal Government. Over the course of history within the United States, sovereign immunity has been repeatedly affirmed and rarely limited in its scope or application.

The inception of sovereign immunity is simultaneous with the inception of the United States of America. This fact alone signifies the reverence and importance of upholding sovereign rights, which were provided in exchange for a state’s unification, loyalty, and submission to the limited jurisdiction of the Federal Government, which was provided for via the dual sovereignty doctrine, granting limited powers to both Federal and State entities for the benefit of forming the union we all remain a part of. The USSC has repeatedly
emphasized the importance of limiting Congress’s power over sovereign immunity to what has been prescribed for the extent and scope of such power. The Supreme Court provided an example of Congress’s overreaching and abuse of its authority in the Tennessee v. Lane matter, stating “In Boerne, we held that Congress had exceeded its § 5 authority when it enacted the Religious Freedom Restoration Act of 1993 (RFRA), (107 Stat. 1488, 42 U.S. C. § 2000). We began by noting that Congress enacted RFRA "in direct response" to our decision in Employment Div., Dept. of Human Resources of Ore. v. Smith, 494 U.S. 872 (1990), for the stated purpose of "restor[ing]" a constitutional rule that Smith had rejected. (521 U. S., at 512, 515). Though the respondent attempted to defend the statute as a reasonable means of enforcing the Free Exercise Clause as interpreted in Smith, we concluded that RFRA was "so out of proportion" to that objective that it could be understood only as an attempt to work a "substantive change in constitutional protections." 521 U. S., at 529, 532. Indeed, that was the very purpose of the law. (Tennessee v Lane, 541 U.S. 509, 124 S. Ct. 1978, 158 L. Ed. 2d 820, 2004 U.S. LEXIS 3386).

The most unequivocally clear representation and ruling of the Supreme Court occurred within the Florida Prepaid case, wherein the Court decided specifically in relation to patent law litigation and sovereign immunity. As stated, “This Court further defined the contours of Boerne's "congruence and proportionality" test in Florida Prepaid Post-secondary Ed. Expense Bd. v. College Savings Bank, 527 U.S. 627 (1999). At issue in that case was the validity of the Patent and Plant Variety Protection Remedy Clarification Act (hereinafter Patent Remedy Act), a statutory amendment Congress enacted in the wake of the U.S. Supreme Court’s decision in Atascadero State Hospital v. Scanlon, 473 U.S. 234 (1985), to clarify its intent to abrogate state sovereign immunity from patent infringement suits. Florida
Prepaid, 527 U. S., at 631-632. Noting the virtually complete absence of a history of unconstitutional patent infringement on the part of the States, as well as the Act's expansive coverage, the Court concluded that the Patent Remedy Act's apparent aim was to serve the Article I concerns of "provid[ing] a uniform remedy for patent infringement and . . . plac[ing] States on the same footing as private parties under that regime," and not to enforce the guarantees of the Fourteenth Amendment. Id., at 647-648. (Tennessee v. Lane, 541 U.S. 509, 124 S.Ct. 1978, 158 L.Ed.2d 820; 2004).

Another legal consideration which holds its basis within the Eleventh Amendment is the Hans Presumption, which established the premise that, for any question of ambiguity regarding whether or not sovereign immunity should apply, there should be a state presumption against being subjected to private suits, particularly for matters that were "anomalous and unheard of when the Constitution was adopted" (Hans v. Louisiana, 134 U.S. 1, 18).

Course of Dealings Between Private & Public Entities- Biotechnology & Life Sciences

This study found that several important aspects of the relationship between private and public entities within the fields of biotechnology and life science patenting, indicate that PACED and/or any other proposed limitations to sovereign immunity would reap more harm than benefit. The following factors contributed to this assertion:
Symbiotic Relationship

The symbiotic and mutually beneficial relationship of private companies and public universities is a well-known channel of sharing knowledge, ideas, basic research, and inventions, which has contributed to the rise in United States innovation post-World War II. This has served the intentions of the Bayh-Dole Act, which acknowledges this information exchange channel and aimed to foster its strengthening. PACED would contribute to the stripping away of this shared knowledge access point, as public entities would have less bargaining power, more fear of lawsuit (regardless of actual harm caused) and would lack the financial bolstering of their private counterparts. Private entities would no longer rely on public universities to the same extent if their participation in the patenting process declined, and license agreements between the two entities would dwindle in connection with decreased patents held by state universities.

Currently, private entities are unrivaled in their overwhelming abundance of patents as compared to public universities, as provided for in the statistical figures below:
1. UNIVERSITY OF CALIFORNIA, THE REGENTS OF ......................................................... 524
2. MASSACHUSETTS INSTITUTE OF TECHNOLOGY .................................................. 306
3. UNIVERSITY OF TEXAS .................................................................................. 219
4. STANFORD UNIVERSITY ............................................................................. 204
5. TSINGHUA UNIVERSITY ........................................................................... 176
6. KING FAHD UNIVERSITY OF PETROLEUM AND MINERALS ..................... 167
7. JOHNS HOPKINS UNIVERSITY ...................................................................... 164
8. WISCONSIN ALUMNI RESEARCH FOUNDATION .......................................... 162
9. HARVARD COLLEGE, PRESIDENT AND FELLOWS ........................................ 156
10. CALIFORNIA INSTITUTE OF TECHNOLOGY ............................................... 150
11. UNIVERSITY OF MICHIGAN ......................................................................... 128
12. UNIVERSITY OF SOUTH FLORIDA ................................................................. 116
13. UNIVERSITY OF FLORIDA RESEARCH FOUNDATION, INCORPORATED/UNIVERSITY OF FLORIDA .................................................. 111
14. NORTHWESTERN UNIVERSITY ...................................................................... 106
15. CORNELL UNIVERSITY ................................................................................ 102
16. UNIVERSITY OF PENNSYLVANIA ................................................................. 102
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<td>WAYNE STATE UNIVERSITY</td>
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### 2017 Patent Owners

**Numerical Listing**

Use care in interpreting the "percent change from 2016" column. The total number of patents granted by the USPTO in 2017 was 505,228, up 3.1% from 2016. The percent change for an individual organization could be affected by mergers, acquisitions, divestitures, inconsistent treatment of subsidiaries in 2018 and 2017, and many other factors.

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As illustrated, the top University granted U.S. utility patents in 2017 received 524 patents, as compared to industry’s top for the same year at 8,996. Further, the first seventy-three companies listed on the private industry’s top patent earners were all, separately, granted more patents than the highest patent recipient on the University list. These statistics quickly deflate any argument that public Universities are operating within the same scope and intensity as private corporations within patent law.

The United States has acknowledged the beneficial relationship between these parties, and the importance of sovereign immunity rights of the states. In its decision on Xechem International, Inc. v. The University of Texas M.D. Anderson Cancer Center, 03-1406, 2004, the United State Court of Appeals for the Federal Circuit (“the Court”) held that: “Eleventh Amendment immunity may be abrogated “only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent could a deprivation of property without due process result,” thereby invoking the Fourteenth Amendment. Florida Prepaid, 527 U.S. at 643, 119 S.Ct. 2199.” The Court also referred to lack of a “pattern of patent infringement by the States,” id. at 640, 119 S.Ct. 2199, in suggesting that legislative remedy had not been shown to be necessary. Through this ruling, the Court investigated any potential pattern of abuse of sovereign immunity within patenting by the states and was unable to find existence of such. This alone speaks magnitudes regarding the substantial differences in pursuit of patents between the public and private sector, as the patenting process and the same “pattern of patent infringement suits” is well-documented and increasingly abundant when examining private entities.
Figure 5: Patent Lawsuits 1980-2010

Source: Patent Litigation Study Discusses Dealing with NPEs, 2014
Figure 6: Patents Granted v. Cases Filed, 1998-2017

Figure 7: Companies Sued the Most Over Patents, 2015

Source: McCarthy, N., & Richter, F., 2015
In a report of the most sued companies for patent infringement, statistics purport that “There were 3,499 patent litigation cases in 2011 and this is projected to hit 6,100 in 2015. Legal action over intellectual property infringements often involve tech companies. Apple have found themselves in the crosshairs 35 times so far this year, while Samsung has endured 33 litigation cases in the first half of 2015.” (McCarthy, N., & Richter, F., 2015)

In sharp contrast, only 8 patent infringement actions occurred against the states in the 110 years between 1880 and 1990. Such is not to say that, if sovereign immunity were to be abrogated from such suits, lawsuits or IPR proceedings may be filed in greater numbers against state actors, whether or not any substantive wrong committed by the state existed. This is consistent with the nature and current climate of patent law in general, and according to the U.S. Court of Appeals for the Federal Circuit, state universities appear to be the gleaming exception to the norm. Within the “Florida prepaid” decision, the Court stated that, after an investigation and review into the actions of the states alleging patent infringements, the Court found “the evidence of patent infringements by the states to be lacking and Congress identified no pattern of patent infringement by the states, let alone a pattern of constitutional violations.” (College Savings Bank v. Florida Prepaid Postsecondary Ed. Expense Bd., ante, at 680. Pp. 731-735).

If SI was limited within patenting, public universities would be at a significant risk of being taken advantage of, pirated from, or otherwise manipulated by private entities. This statement is not made without precedent; currently, private entities routinely engage in behavior that undermines the position of their public counterparts, under the knowledge and experience that public entities rarely, if ever, will engage in proactive litigation to protect
their intellectual property. This is true in the overwhelming majority of scenarios, even when blatant theft or misuse of intellectual property has occurred.

IP Theft

Intellectual Property theft is a universal and large-scale problem, one which capitalizes on the inventions of others regardless of whether the IP belongs to public or private entities. Despite the lack of preference for victims, public entities appear to be particularly vulnerable to security-based IP theft. One potential cause could be the discrepancy in financial designation towards cybersecurity and funding for advanced internet technologies, as compared to private entity counterparts. Even if financial deviation is not a current contributor to academics being overwhelming IP theft targets, stripping financial security of public academics through loss of their patenting activity secondary to PACED. Even with increases in security at universities, they remain a target through both external hacking attacks and internal “spies” from foreign locations. This is thought to be directly related to the overwhelming amount of significant research performed and housed at universities in the United States.

These security threats to public academics and other institutions such as medical facilities, are attracting more and more warning from federal officials, such as in Houston where the FBI warned of credible threats in August of 2018. “FBI officials warned top leaders of Texas academic and medical institutions Wednesday about security threats from foreign adversaries, the first step in a new initiative the bureau plans to replicate around the country” (Ackerman, 2018). The initiative included more than 100 academic officials and
focused on how the institutions can better partner with the FBI to prevent the theft of intellectual property and research. “We want to establish, cultivate, and enhance public-private relationships to mitigate attempts by foreign adversaries to steal from our institutions for their benefit,” said FBI Special Agent in Charge Perrye K. Turner (Ackerman, 2018).

According to the 2017 “Update to the IP Commission Report”, “IP theft pervades international trade in goods and services due to lack of legal enforcement and national industrial policies that encourage IP theft by public, quasi-private, and private entities.”. “We have found no evidence that casts doubt on the estimate provided by the Office of the Director of National Intelligence in November 2015 that economic espionage through hacking costs $400 billion per year. At this rate, the United States has suffered over $1.2 trillion in economic damage since the publication of the original IP Commission Report more than three years ago.” (Update to the IP Commission report. (2017).

The loss to academic institutions has only multiplied. In June of 2015, the Counterintelligence Strategic Partnership Intelligence Note (SPIN) publication focused on “Preventing Loss of Academic Research” (Theft of US R&D, 2018). In April of 2018, the American Institute of Physics published “Theft of US R&D by Other Nations Grabs Attention of Science Committee” wherein the article explains that “At an April 11 hearing, House Science Committee leaders expressed deep concern about the scope of foreign espionage campaigns targeted at U.S. academic institutions and sought advice on how to implement countermeasures while maintaining an open research enterprise.” As the federal government of the United States proposes solutions to try to combat this problem, it also acknowledged academics as a unique target, “It’s across basically every discipline,” said Wray. “And I think the level of naivete on the part of the academic sector about this creates
its own issues. They’re exploiting the very open research and development environment that we have, which we all revere” (Rogin, 2018).

The open research and development environment referenced is the same such environment that attracts private entities to seek out academic research partners. The use of “open” to describe the research environment and nature of scientists at academics cannot be overstated. Often, the technology management or contracts office are the only formidable bottleneck preventing scientists from freely sharing valuable IP with whomever expresses interest, a practice that was increasingly more common in previous years. However, as patent activity by academics continues to increase, more emphasis is placed on educating scientists about the protection and essential benefits provided by contractual research collaborations, confidentiality agreements with private entities prior to sponsorship, and other contractual safeguards. With these in place, collaborations between academics and private sponsors leads to inventions, filing for patents on intellectual property, and authoring publications. Patent activity not only provides academics with leverage and bargaining power during negotiation of research agreements, but additionally places significant emphasis on security and privacy of university IP to enable continued inventorship and patent ownership.

License Agreement Terms

One of the key benefits of the relationship between public and private patent actors is the ability of public entities to obtain patents (as provided for in the Bayh-Dole Act) and license the rights to those patents to private entities. This helps the public dissemination and
sharing of knowledge in two distinct ways. First, it brings in valuable revenue back to the public university which can be used to fund further research, provide educational advancement, scholarships, or other public benefits. Second, public universities unequivocally provide diligent use and practice clauses within their licensing agreement terms. This means that, when the patent is licensed out to a company, the company must practice and make diligent commercial efforts to publicly provide benefit of the patent. For example, if the license was for the marketing and commercial use of a pharmaceutical product, the license terms would require that the company market and provide the pharmaceutical to the public, barring any extreme or unforeseen circumstances that may restrict such. These terms are not the same when a license is provided between two private industry entities, as the private entities are not working along the same public-benefit mission statement that is inherent to public universities. To eliminate sovereign immunity, and, in turn, severely decrease the patent activities of public universities, these license agreements would be reduced or eliminated and there would be less accountability to ensure that patent licenses are not purchased by corporations to purposefully restrict practice and accessibility to the public. This concern is not unwarranted; in a blog publication put out by the White House on June 4\textsuperscript{th}, 2013, it was stated that “patent trolls” who are “costing the economy billions of dollars and undermining American Innovation” do exactly that. And, these patent trolls are only increasing. The same white house report provides that “In the last two years, the number of lawsuits bought by patent trolls has nearly tripled, and account for 62\% of all patent lawsuits in America.” (Taking on Patent Trolls to Protect American Innovation, 2013).
A valid question exists as to whether or not IPR review specifically should uphold sovereign immunity protection. This focuses on whether or not the IPR proceedings and proceedings of the USPTO comprise a “Federal administrative proceeding” that would not be subject to sovereign immunity since it is not within a Federal Court system. To evaluate this
question, the “Oil States” case first provides information regarding the constitutionality of IPR proceedings. In the ruling, the Justices of the Supreme court decided that “(i) The grant of a patent falls within the public-rights doctrine. United States v. Duell, 172 U. S. 576, 582–583. Granting a patent involves a matter “arising between the government and others.” Ex parte Bakelite Corp., 279 U. S. 438, 451. Specifically, patents are “public franchises.” Seymour v. Osborne, 11 Wall. 516, 533. Additionally, granting patents is one of “the constitutional functions” that can be carried out by “the executive or legislative departments” without “‘judicial determination.’” Crowell v. Benson, 285 U. S. 22, 50–51. Pp. 7–8. From this decision, the Court aligns itself with the notion that IPR and USPTO proceedings are arms of the pertinent authorities who are justified in making constitutional decisions, at least in respect to granting patents.

The USSC additionally included in their ruling the express intent to include IPR as a process of granting patents, stating that “(ii) Inter partes review involves the same basic matter as the grant of a patent. It is “a second look at an earlier . . . grant,” Cuozzo Speed Technologies, LLC v. Lee, 579 U. S. and it involves the same interests as the original grant, see Duell, supra, at 586. That inter partes review occurs after the patent has issued does not make a difference here. Patents remain “subject to [the Board’s] authority” to cancel outside of an Article III court, Crowell, supra, at 50, and this Court has recognized that franchises can be qualified in this manner, see, e.g., Louisville Bridge Co. v. United States, 242 U. S. 409, 421. Pp. 8–10. Lastly, the decision concluded that IPR activities were functions of the court, just such functions that were designated to administrative bodies of review, which would not preclude sovereign immunity. “(c) Although patent validity was often decided in 18th-century English courts of law, that history does not establish that inter partes review
violates the “general” principle that “Congress may not ‘withdraw from judicial cognizance any matter which, from its nature, is the subject of a suit at the common law,” Stern v. Marshall, 564 U. S. 462, 484.

A search of relevant case law provided an additional precedent that further supports the finding of our study that IPR and USPTO proceedings should not abrogate sovereign immunity. In Federal Maritime Commission v. South Carolina State Ports Authority, 535 U.S. 743 (U.S. 2002) (“Federal Maritime” case), the question decided was whether a state has sovereign immunity when a private party files a complaint under the Federal Maritime Commission. This question posed in the Federal Maritime case parallels some aspects of the one at hand in our study. This is through the delegation of authority to the Federal Maritime Commission by the U.S. Federal Court system, permitting the Federal Maritime Commission to serve as an extension of the Federal Court, as an administrative body granted a particular scope and extent of what could be viewed as ‘judicial power’. This illustrates a similarity to the inter partes review system through which PTAB is given particular authority by the way of the U.S. Federal Courts. The decision rendered was in favor of the upholding of sovereign immunity, and the suit was barred due to the Eleventh amendment and the sovereign status of the defendant. Throughout the case review of this study, no other precedent case was found that directly addresses this question, other than the fact pattern in the Maritime Case.
Fourteenth Amendment Requirements as Evaluated within PACED

Federal and Constitutional provisions were equally unable to justify the limitation to sovereign immunity application. According to such, Congress does have the power to abrogate sovereign immunity in limited situations, however, the standard that must be established is particularly high. Congress must be able to show that allowing sovereign immunity creates a fourteenth amendment violation and that there is a need for the case to move forward to avoid a due process violation issue. Within the context of PACED, this legal threshold for Congress’s abrogation of sovereign immunity has not been met and PACED falls gravely short of this requirement.

In its text, PACED makes little mention of the requisite burden to be shown in order to abrogate state sovereign immunity. As aforementioned, there are strict and specific circumstances by which Congress may attempt to abrogate the sovereign immunity of the states. Within PACED, it is unequivocally clear that the attempt of the proposed bill is to do such, as it states “a patent owner may not assert sovereign immunity, including the sovereign immunity accorded to an Indian tribe, as a defense in-- (A) any reexamination proceeding under this section, including any appeal to the Patent Trial and Appeal Board; or (b) a review by a court of the United States with respect to a decision reached in a proceeding described in subparagraph (A).”

It is important to consider that not only does PACED propose to eliminate sovereign immunity from PTAB, but additionally includes review by United States Courts, which goes
above and beyond the consideration of the Maritime case, which in itself provides precedent for PTAB proceedings being subject to the upholding of sovereign status.

PACED fails to provide any legal standing or other relevant authority, related to the 14th amendment or otherwise, within its text. The sole reference to any limitations or standards on which PACED could apply simply mentions “(4) Limitation.—This subsection shall apply only to the extent permitted under the 11th amendment to the Constitution of the United States.” Despite the legal burden required, as provided under precedent case law and the 14th amendment, PACED makes no mention of such. However, PACED does expressly caveat that its provisions shall “apply only to the extent permitted under the 11th amendment”. When contrasted with the provisions of the Eleventh Amendment to the United States Constitution, PACED does not purport any substance of value to abrogate sovereign immunity, particularly not to the extent that would overcome a challenge based on the Eleventh Amendment, which provides “The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State” (Amendment XI, Constitution of the United States of America, 1794). The problem with this caveat as provided within PACED is the discrepancies in how “judicial power of the United States” has been recently interpreted by the United States Court of Appeals for the Federal Circuit and the United States Supreme Court. In Oil States, the ruling of the Supreme Court of the United States specified that IPR challenges were not an unconstitutional extension of judicial powers to the USPTO without right to jury trial because patents were not considered a private right. This decision asserted that the patent
review process in an IPR challenge was not a private right entitled to the full judicial review process taking place within the courts of the United States (either the United States Court of Appeals or the Supreme Court of the United States). They were not judicial proceedings and instead were conducted through the USPTO as an administrative body of the Federal Government of the United States. Further, the United States District Court for the Federal Circuit concurred, ruling in Saint Regis Mohawk Tribe, Allergan v. Mylan et al., that the IPR process was neither a judicial review brought within the justice system by one moving party against another party nor an enforcement action brought by the federal government, and is instead a “hybrid”. Therefore, the caveat provided in PACED appears to be empty on its face, since the Eleventh Amendment would be in conflict with recent rulings interpreting IPR challenges as non-judicial proceedings. Instead, IPR has been most recently ruled on as patent challenges that are conducted through the USPTO as an administrative body of the Federal Government of the United States in relation to a public right (patent). Although the Eleventh Amendment is, albeit minimally, provided for within PACED, its terms do not account for the other important historical premises relating to sovereign immunity.

The importance of the Fourteenth Amendment as governing law to set the standard for sovereign immunity abrogation has been made clear and reaffirmed within several Supreme Court rulings. In Tennessee v. Lane, the Supreme Court affirmed the exclusive role of the Fourteenth Amendment in any potential abrogation of Eleventh Amendment immunity, where the Supreme Court asserted in its finding: “In Fitzpatrick v. Bitzer, 427 U.S. 445 (1976), we held that Congress can abrogate a State's sovereign immunity when it does so pursuant to a valid exercise of its power under § 5 of the Fourteenth Amendment to
enforce the substantive guarantees of that Amendment. (Id., at 456). This enforcement power, as we have often acknowledged, is a "broad power indeed." Mississippi Univ. for Women v. Hogan, 458 U.S. 718, 732 (1982). It includes "the authority both to remedy and to deter violation of rights guaranteed [by the Fourteenth Amendment] by prohibiting a somewhat broader swath of conduct, including that which is not itself forbidden by the Amendment's text." Kimel, 528 U. S., at 81. We have thus repeatedly affirmed that "Congress may enact so-called prophylactic legislation that proscribes facially constitutional conduct, in order to prevent and deter unconstitutional conduct." Nevada Dept. of Human Resources v. Hibbs, 538 U.S. 721, 727-728 (2003).” (Tennessee v Lane, 541 U.S. 509, 124 S. Ct. 1978, 158 L. Ed. 2d 820, 2004 U.S. LEXIS 3386)

The Supreme Court went on to state that “When Congress seeks to remedy or prevent unconstitutional discrimination, § 5 authorizes it to enact prophylactic legislation proscribing practices that are discriminatory in effect, if not in intent, to carry out the basic objectives of the Equal Protection Clause. Congress' § 5 power is not, however, unlimited. While Congress must have a wide berth in devising appropriate remedial and preventative measures for unconstitutional actions, those measures may not work a "substantive change in the governing law." Boerne, 521 U. S., at 519. In Boerne, the United States Supreme Court recognized that the line between remedial legislation and substantive redefinition is "not easy to discern," and that "Congress must have wide latitude in determining where it lies." Id., at 519-520. But the U. S. Supreme Court also ruled that "the distinction exists and must be observed," and set forth a test for so observing it: Section 5 legislation is valid if it exhibits "a congruence and proportionality between the injury to be prevented or remedied and the means adopted to that end." Id., at 520.” (Tennessee v Lane, 541 U.S. 509, 124 S. Ct. 1978,
So, the USSC clearly intends to apply the narrowly limited scope for any abrogation of sovereign immunity attempted by Congress, and provides various examples of how extreme and wanton the conduct of the state must be, particularly in reference to discrimination and civil rights violations, a standard that PACED provides no such evidence for meeting.

Positions as “for” or “against” PACED, and the waiver of sovereign immunity in general, typical present as an “all or nothing” viewpoint. However, viable alternatives may exist. For example, some cases, such as Biomedical Patent Management Corporation v. California Department of Health Services, (“Biomedical v. California”) questioned whether or not states could effectively waive their sovereign immunity in patent cases by taking particular actions. In Biomedical v. California, it was questioned whether a state waives its Eleventh Amendment immunity in patent actions by regularly and voluntarily invoking federal jurisdiction to enforce its own patent rights. At the U.S. District and U.S Court of Appeals level, it was decided that California Department of Health Services was not subject to suit and sovereign immunity was upheld, even when California Department of Health Services had waived sovereign immunity in a previous suit as the moving party. The decision affirmed that a previous waiver of sovereign immunity did not extend to another action. The Plaintiff attempted to receive a review by the United States Supreme Court, but, unfortunately, the United States Supreme Court denied petition to hear the case, so, as of current the U.S. Court of Appeals for the Federal Circuit’s decision has not received U.S. Supreme Court review.
In 2017, the USPTO, through PTAB ruled in three different cases that state university-owned patents could not be challenged in inter partes review proceedings. Although, in one of these decisions, PTAB appears to have informally mentioned and then anticipated defeat of a potential avenue for state waiver of sovereign immunity in patent proceedings. In NeoChord, Inc. v. University of Maryland, Case IPR2016-00208 (PTAB May 23, 2017), PTAB found that the University could raise an Eleventh Amendment defense to the inter partes review proceeding against its patent, even though it was exclusively licensed to a commercial entity, but, in its decision, PTAB noted that it had not been argued that Maryland had waived sovereign immunity “by market participation or by accepting a gratuity.” PTAB’s decision then provided a disclaimer that even if a waiver theory had been argued, it would be precluded by the US Supreme Court decision in College Savings Bank v. Florida Prepaid Postsecondary Educ. Expense Bd., 527 U.S. 666 (1999), which the PTAB stated their interpretation of the decision as asserting that “market participation does not constitute a constructive waiver.” PTAB also cited the US Court of Appeals for the Federal Circuit’s decision in Xechem Int’l., Inc. v. Univ. of Tex. M.D. Anderson Cancer Ctr., 382 F.3d 1324 (Fed. Cir. 2004), wherein the decision provided that “the grant of a patent does not constitute a predicate for application of a ‘gratuity doctrine’ waiver because a patent is not a gratuity, i.e., the quid pro quo for receiving a patent is an invention.”

Arguably, legislation yet to be enacted by U.S. Congress, and/or the United States Supreme Court could determine, within cases yet to be presented, that IPR challenges and the patentability challenges conducted within the USPTO should be subject to a specific or partial application of sovereign immunity, however, PACED provides only a ubiquitous
abrogation of all sovereign status for both state and tribal immunity, as subject to the existing interpretation of IPR as a ‘hybrid’ and only partial judicial proceeding in relation to the Eleventh Amendment. Additionally, PACED enters the patent law scene with an incredibly sharp contrast to the prior decision and rulings of PTAB, the Supreme Court, and the U.S. Court of Appeals, all seemingly in response to the actions of Allergan and the Saint Regis Mohawk Tribe.

Interestingly, PACED also sets forth another provision for “Foreign States”, which, essentially states that for any foreign entities, PTAB shall decide on a case by case basis, whether or not sovereign immunity shall apply. This also deviates from the current law on this topic, and, unfittingly, provides foreign entities a greater freedom to assert sovereign immunity than our own 50 United States. According to the Foreign Sovereign Immunities Act of 1976 (“FISA”), clear exceptions to when foreign states may claim immunity apply. One of which is the commercial activity exception, found within 28 U.S.C. § 1605(a)(2). This exception outlines that if a foreign entity is engaged in commercial activity within the United States, sovereign immunity from suit does not apply. Further, application of this FISA exception has already been decided within the United States Court of Appeals for the Federal Circuit, in the 2006 case, “Intel Corporation and Dell Inc., v. Commonwealth Scientific and Industrial Research Organisation, 455 F.3d 1364 (Fed. Cir. 2006), where a suit commenced against an Australian public entity was allowed to continue despite the defendant raising sovereign immunity.

The inclusion of granting less stringency towards foreign entities further distinguishes PACED as a bill that, with all due respect to the drafting senators (Cotton, McCaskill,
Perdue, Ernst, and Toomy), appears to contain little substance or diligent investigation into the practicality or legal precedent regarding what PACED proposes. This includes the consideration of whether or not PACED even provides the relevant legal authority to take its proposed actions.
Chapter IV
Discussion

The results of case law review in this study indicated a significant correlation between the limitation of sovereign immunity and substantive patent law cases. Otherwise stated, the data suggested a higher likelihood of sovereign immunity being limited or abrogated when asserted in patent cases, as compared to other substantive areas of law. Data review and analysis revealed a 11.4% increase in the number of times patent law cases limited sovereign immunity as compared to other areas of law.

The history of sovereign immunity and the vital relationships between private and public actors in the patenting arena indicate that a disservice would be unduly provided to public entities if sovereign immunity protections were denied in relation to patent law. Since the inception of sovereign immunity, the extent of limitations placed on SI have been few and far between, and the majority of any such limitations have not been consistently or universally upheld in each proceeding of judicial review. The application of sovereign status should be appropriately viewed as an entitlement inherent to the properties of a public entity rather than a subject for judicial discretion. This authority comes from the designation of power by the U.S. Government to Congress alone to decide on when sovereign immunity should be abrogated.

The statistics clearly demonstrate an overwhelming gap between the patenting activities of private entities as compared to public universities. Private entities dominate the patent arena both in granted patents and in lawsuits (as either plaintiff or defendant), in revenue, and in IPRs. Accordingly, private institutions also retain an abundance of resources, finances, and attorneys necessary to pursue the number of patents granted and
cases filed to compete in the private sector. Sovereign immunity operates within patent law, in a practical sense, to protect state universities from being immersed in that private sector arena of cut-throat competition, superfluous litigation, and financial grandstanding, of which state universities share neither the desire to or the ability to become a part of.

Although correlation does not prove causation, a significant (negative) correlation existed between the limitation of sovereign immunity within general cases as compared to the limitation of sovereign immunity within only patent related cases. This suggests and infers that there is a higher likelihood of sovereign immunity being struck down if the substantive matters of the case relate to patenting than any other area of law. Further study could examine whether or not influence and subjective bias is a factor here, whether such influence was undertaken with or without the conscious knowledge of such by the court in question. Bias and social condemnation by particular justices has already been seen within the Allergan case, where Judge Bryson insisted that, before he issue his ruling, the parties discuss "or whether the assignment of the patents to the Tribe should be disregarded as a sham.". The case itself prompted the drafting and introduction of the PACED Act, as was proudly touted by Senator McCaskill when she stated, “Any thinking person would look at what this company did and say, ‘That should be illegal.’ Well, I agree,” McCaskill said in a statement. “Congress never imagined tribes would allow themselves to be used by pharmaceutical companies to avoid challenges to patents, and this bill will shut the practice down before others follow suit.” (Erman, M., 2017).

The results of this investigation support the findings consistent with prior case law that sovereign immunity is a capstone of the designation of powers and protections on which the United States of America and its system of Government was built, and as such should be
regarded as the assumption, without restriction or abrogation unless as provided for within
the provisions of the Constitution. The specific nature of patenting proceedings, whether
within the United States Court of Appeals for the Federal Circuit or within the IPR
proceedings of the USPTO, do not rise to the level of legal burden required for Congress to
rightfully and lawfully abrogate the sovereign immunity of the states. The pattern of actions
of the states do not produce evidence or support of the showing that would be required to
place limitations or abrogation of sovereign protections, and there is no consistent pattern of
the states abusing any authority or engaging in patent infringement to a degree of any
material measure.

This study is unprecedented due to the current and rapidly evolving nature of
sovereign immunity as decided within patent law. During the course of this study, several
key cases remain in the process of appeals, and other anticipated decisions have yet to be
handed down. As such, the timeline provided for within this study addressed a critical need;
the proposed changes within the PACED Act have not yet been voted on in the Senate, and,
seemingly, time still exists for the public to become informed, and to contact their
representatives and Senators to urge that the rightful application of the law and of sovereign
immunity be the basis of any voting on PACED. To whatever extent this study may be
accessible as a publication, it may, at its very least, provoke the need for further study and
diligent review of the criteria presented herein, before such an impactful bill as PACED is
voted upon, amended the law of the United States (Title 35, United States Code) to strip
state universities of their protections and bargaining power, eliminating their shield from the
financial power of private corporation behemoths and the abundance of ill-intentioned
“patent trolls”.

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The very essence of what PACED claims to need to protect – the public interest and benefit - risks detrimental harm and punishment, due to not its own shortcomings but the intentional actions of a giant pharmaceutical corporation, Allergan. To punish state universities for no wrong of their own, and subject an entire industry to a lack of sovereign protections into perpetuity, is on its fact a negligent and irresponsible action taken in response to the shock and disdain of the Allergan case rather than a thorough investigative review and diligent inquiry as to the important factors to consider, in order to make a proper informed decision. Our study has begun such efforts and investigation in hopes of provoking and demonstrating the need for such a review, and to the defense of the state sovereignties who simply lack the financial and staffing resources to risk excessive patent litigation and its costs, while operating to the benefit of the public and forging relationships with private entities using their limited negotiation power (which includes sovereign immunity). PACED would further disadvantage these universities and would strip funding that comes back into their research laboratories through patenting and licensing activities.

Conclusion

Sovereign immunity protections face unwarranted abrogation within the field of patent law, putting state Universities at risk. The USPTO, United States Supreme Court, United States District Courts for the Federal Circuit, PTAB, and United States Court of Appeals for the Federal Circuit should continue to uphold the longstanding and valuable protections afforded to public entities within sovereign immunity from suit, as granted to the states in exchange for their joining of the union. In addition, the Senate and House of Representatives should not vote to enact PACED as intended to amend the U.S. Code, Title
35, and should further investigate whether authority of Congress, as provided for within the Fourteenth Amendment, exists to abrogate sovereign immunity of public patent actors.
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Articles
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Appendix

Text of the PACED Act

115TH CONGRESS
2D SESSION

S. 2514

To amend title 35, United States Code, to provide that a patent owner may not assert sovereign immunity as a defense in certain actions before the United States Patent and Trademark Office, and for other purposes.

IN THE SENATE OF THE UNITED STATES
MARCH 7, 2018
Mr. COTTON (for himself, Mrs. McCaskill, Mr. PERDUE, Mrs. ERNST, and Mr. TOOMEY) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

A BILL

To amend title 35, United States Code, to provide that a patent owner may not assert sovereign immunity as a defense in certain actions before the United States Patent and Trademark Office, and for other purposes.

1 Be it enacted by the Senate and House of Representa-
2 tives of the United States of America in Congress assembled,

3 SECTION 1. SHORT TITLE.

4 This Act may be cited as the “Preserving Access to
5 Cost Effective Drugs Act” or the “PACED Act”.

6 SEC. 2. ABROGATION OF SOVEREIGN IMMUNITY.

7 (a) IN GENERAL.—Title 35, United States Code, is
8 amended—
(1) in section 135, by adding at the end the fol-
lowing:

“(g) SOVEREIGN IMMUNITY.—

“(1) DEFINITIONS.—In this subsection—

“(A) the term ‘foreign state’ has the mean-
ing given the term in section 1603(a) of title
28; and

“(B) the term ‘Indian tribe’ has the mean-
ing given the term in section 4(e) of the Indian
Self-Determination and Education Assistance
Act (25 U.S.C. 5304(e)).

“(2) ABROGATION OF SOVEREIGN IMMUNITY.—

Except as provided in paragraph (3), and subject to
paragraph (4), a patent owner may not assert sov-
ereign immunity, including the sovereign immunity
accorded to an Indian tribe, as a defense in—

“(A) a derivation proceeding instituted
under subsection (a); or

“(B) a review by a court of the United
States with respect to a decision reached in a
proceeding described in subparagraph (A).

“(3) IMMUNITY OF FOREIGN STATES.—If a pat-
ent owner is a foreign state, for the purposes of any
proceeding described in paragraph (2)(A), the Pat-
ent Trial and Appeal Board shall determine whether
the patent owner is immune from the jurisdiction of
the Patent Trial and Appeal Board, in accordance
with chapter 97 of title 28 as if the Patent Trial and
Appeal Board were a court of the United States.

“(4) LIMITATION.—This subsection shall apply
only to the extent permitted under the 11th amend-
ment to the Constitution of the United States.”;

(2) in section 296—

(A) in the section heading, by striking

“and State officials” and inserting “,

State officials, and Indian tribes”; and

(B) by adding at the end the following:

“(c) ABRATION OF TRIBAL SOVEREIGN IMMU-
NITY.—

“(1) DEFINITIONS.—In this subsection—

“(A) the term ‘covered claim’ means any
claim, counterclaim, or third-party claim that
arises under—

“(i) this title relating to infringement
of a patent; or

“(ii) section 351 of the Public Health
Service Act (42 U.S.C. 262); and

“(B) the term ‘Indian tribe’ has the mean-
ing given the term in section 4(e) of the Indian
Self-Determination and Education Assistance Act (25 U.S.C. 5304(e)).

“(2) ABROGATION.—In any action that involves a covered claim that is otherwise within the jurisdiction of a court of the United States, an Indian tribe may not assert sovereign immunity as a defense.”;

(3) in section 305—

(A) in the first sentence, by striking “After the” and inserting the following:

“(a) IN GENERAL.—After the”; and

(B) by adding at the end the following:

“(b) SOVEREIGN IMMUNITY.—

“(1) DEFINITIONS.—In this subsection—

“(A) the term ‘foreign state’ has the meaning given the term in section 1603(a) of title 28; and

“(B) the term ‘Indian tribe’ has the meaning given the term in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(e)).

“(2) ABROGATION OF SOVEREIGN IMMUNITY.— Except as provided in paragraph (3), and subject to paragraph (4), a patent owner may not assert sovereign immunity, including the sovereign immunity accorded to an Indian tribe, as a defense in—
“(A) any reexamination proceeding under this section, including any appeal to the Patent Trial and Appeal Board; or

“(B) a review by a court of the United States with respect to a decision reached in a proceeding described in subparagraph (A).

“(3) IMMUNITY OF FOREIGN STATES.—If a patent owner is a foreign state, for the purposes of any proceeding described in paragraph (2)(A), the Office or the Patent Trial and Appeal Board, as applicable, shall determine whether the patent owner is immune from the jurisdiction of the Office or the Patent Trial and Appeal Board, as applicable, in accordance with chapter 97 of title 28 as if the Office or the Patent Trial and Appeal Board, as applicable, were a court of the United States.

“(4) LIMITATION.—This subsection shall apply only to the extent permitted under the 11th amendment to the Constitution of the United States.”;

(4) in section 316, by adding at the end the following:

“(f) SOVEREIGN IMMUNITY.—

“(1) DEFINITIONS.—In this subsection—
“(A) the term ‘foreign state’ has the meaning given the term in section 1603(a) of title 28; and

“(B) the term ‘Indian tribe’ has the meaning given the term in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(e)).

“(2) ABROGATION OF SOVEREIGN IMMUNITY.—Except as provided in paragraph (3), and subject to paragraph (4), a patent owner may not assert sovereign immunity, including the sovereign immunity accorded to an Indian tribe, as a defense in—

“(A) an inter partes review instituted under this chapter; or

“(B) a review by a court of the United States with respect to a decision reached in a proceeding described in subparagraph (A).

“(3) IMMUNITY OF FOREIGN STATES.—If a patent owner is a foreign state, for the purposes of any review described in paragraph (2)(A), the Patent Trial and Appeal Board shall determine whether the patent owner is immune from the jurisdiction of the Patent Trial and Appeal Board, in accordance with chapter 97 of title 28 as if the Patent Trial and Appeal Board were a court of the United States.
“(4) LIMITATION.—This subsection shall apply only to the extent permitted under the 11th amendment to the Constitution of the United States.”; and

“(5) in section 326, by adding at the end the following:

“(f) SOVEREIGN IMMUNITY.—

“(1) DEFINITIONS.—In this subsection—

“(A) the term ‘foreign state’ has the meaning given the term in section 1603(a) of title 28; and

“(B) the term ‘Indian tribe’ has the meaning given the term in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(e)).

“(2) ABROGATION OF SOVEREIGN IMMUNITY.—Except as provided in paragraph (3), and subject to paragraph (4), a patent owner may not assert sovereign immunity, including the sovereign immunity accorded to an Indian tribe, as a defense in—

“(A) a post-grant review instituted under this chapter; or

“(B) a review by a court of the United States with respect to a decision reached in a proceeding described in subparagraph (A).
“(3) Immunity of Foreign States.—If a patent owner is a foreign state, for the purposes of any review described in paragraph (2)(A), the Patent Trial and Appeal Board shall determine whether the patent owner is immune from the jurisdiction of the Patent Trial and Appeal Board, in accordance with chapter 97 of title 28 as if the Patent Trial and Appeal Board were a court of the United States.

“(4) Limitation.—This subsection shall apply only to the extent permitted under the 11th amendment to the Constitution of the United States.”.

(b) Amendments to the Tariff Act of 1930.—

Section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) is amended by adding at the end the following:

“(o) Abrogation of Tribal Sovereign Immunity.—

“(1) Definitions.—In this subsection—

“(A) the term ‘covered person’—

“(i) means a person; and

“(ii) includes—

“(I) an Indian tribe; and

“(II) any other person that claims immunity on account of the sovereign status of an Indian tribe; and

and
“(B) the term ‘Indian tribe’ has the meaning given the term in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304(e)).

“(2) ABROGATION.—In any proceeding under this section, no covered person may assert as a defense the sovereign immunity that is accorded to an Indian tribe.”.

(c) TECHNICAL AND CONFORMING AMENDMENT.— The table of sections for chapter 29 of title 35, United States Code, is amended by striking the item relating to section 296 and inserting the following:

“296. Liability of States, instrumentalities of States, State officials, and Indian tribes for infringement of patents.”.