Northwestern Journal of Technology and Intellectual Property

Volume 16 | Issue 2 Article 3

2018

SOCIAL CONTRACT: THE DISTRIBUTIVE SIGNIFICANCE OF A NATIVE NATION'S PATENT AGREEMENT WITH ALLERGAN

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N O R T H W E S T E R N
JOURNAL OF TECHNOLOGY
AND
INTELLECTUAL PROPERTY

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November 2018 VOL. 16, NO. 2

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Northwestern Journal of Technology and Intellectual Property
Volume 16, Number 2 (2018)

Notes

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Anne Monjar[1]

ABSTRACT—In 2017, pharmaceutical giant Allergan announced an innovative new agreement with the Saint Regis Mohawk Tribe of upstate New York. Allergan was to transfer ownership of the patent of its successful dry eye drug Restasis to the Tribe in exchange for an exclusive licensing agreement. The hope was that the Tribe's sovereign immunity would protect Allergan's patent from validity challenges, in which the patent was already embroiled, while allowing them to retain its profits.

The agreement drew immediate outrage from policymakers who saw the agreement as a multi-billion-dollar corporation exploiting a legal loophole to unfairly secure its monopoly. Ultimately, the courts agreed – the Federal Circuit recently denied the Tribe's assertion of tribal immunity in a validity challenge against Restasis.

While the agreement rightfully did not survive legal challenge, there are aspects to it that are worth considering against a backdrop of utilitarian theories of intellectual property. In the latter half of the twentieth century, utilitarian justifications for patent protections have come to overshadow earlier distributive theories, which prioritized the public benefits over individual property rights. The Allergan-Saint Regis Mohawk Tribe agreement may not be a true distributive model of intellectual property. However, the ways in which the agreement required the transfer of a title from private ownership to a community, a community that did not traditionally benefit from the intellectual property system, are reminiscent of distributive protections that would greatly improve our increasingly individualistic conception of intellectual property.

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INTRODUCTION

In 2017, pharmaceutical heavyweight Allergan announced an unusual contract with the Saint Regis Mohawk Tribe of upstate New York.[2] Allergan was transferring ownership of its patent in the dry eye drug Restasis to the Tribe in exchange for an exclusive licensing agreement.[3] Through this venture, Allergan hoped to secure the patent, assuming that the Tribe's sovereign immunity would protect the patent from validity challenges by other pharmaceutical companies.[4] There was strong backlash against the arrangement, which lawmakers and consumer advocates saw as the attempt of a multibillion-dollar company to maintain an illegitimate monopoly through a legal loophole, keeping more affordable, innovative medicine out of the market for longer.[5]

Ultimately, both the Patent Trial and Appeal Board (PTAB) and the Federal Circuit agreed, denying the Tribe's claim of sovereign immunity.[6] But while the agreement did not survive legal challenge, there are aspects to it that, when considered in conjunction with the rise of utilitarian justifications for intellectual property, were more progressive than they might have appeared. There has long existed a tension between distributive and utilitarian theories of intellectual property, with the distributive philosophy giving way in the latter half of the twentieth century to a "property right"-centric view.[7] There remain, however, legal mechanisms that can check the utilitarian tendencies of modern intellectual property

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2 Katie Thomas, *How to Protect a Drug Patent? Give It to a Native American Tribe*, N.Y. TIMES (Sept. 8, 2017), https://www.nytimes.com/2017/09/08/health/allergan-patent-tribe.html?mcubz=3&_r=1.

3 *Id.*

4 *Id.*

5 *See Sovereign Immunity and the Intellectual Property System, Hearing Before the Subcomm. on Courts, Intellectual Prop. & the Internet of the H. Comm. on the Judiciary*, 115th Cong. (2017).

6 Saint Regis Mohawk Tribe v. Mylan Pharm., Inc., 896 F.3d 1322, 1325 (Fed. Cir. 2018).

7 *See* Shlomit Yanisky-Ravid, *The Hidden Though Flourishing Justification of Intellectual Property Laws: Distributive Justice, National Versus International Approaches*, 21 LEWIS & CLARK L. REV. 1, 23 (2017).

rights and ensure both competitive markets and public well-being. The Allergan arrangement, though too exclusive to be a true "distributive" model of a patent right, featured some distributive mechanisms. The redirection of revenue from a lucrative patent to a population otherwise not served by the intellectual property system is an end worth pursuing in our conceptualization of intellectual property rights, and one to meditate on despite the shortcomings of this unusual arrangement.

I. THE ALLERGAN-SAINT REGIS MOHAWK TRIBE AGREEMENT

The Saint Regis Mohawk Tribe lies an hour and a half southwest of Montreal, just below the Saint Lawrence River, an island-spotted stretch of waterway winding northeast from the Great Lakes to Quebec, dividing the U.S. and Canada.[89] The heavily forested, frigid landscape is home to just over 3,000 people who consider themselves part of a larger Mohawk community comprising Canadian tribal lands as well.[10] Like many native nations in the U.S., the Saint Regis Tribe, formally recognized as a sovereign entity by the federal government in the 1960s, relies on a local casino for economic sustainability.[11] Still, the reservation struggles with poverty, with a median income that falls well below the national median.[12]

But the Saint Regis Tribe recently undertook a new economic initiative, one that brought them into the spotlight in both medical and legal fields. The Tribe has taken advantage of a questionable idiosyncrasy in the patent system to tap, rather easily, into a rich source of annual income.

On September 8, 2017, the pharmaceutical company Allergan, a global, multibillion-dollar company boasting such products as Botox, announced it

[8] SAINT REGIS MOHAWK TRIBE, https://www.srmt-nsn.gov/ (last visited Nov. 5, 2018) [https://perma.cc/RV5B-63WX].

[9] *Saint Lawrence River*, BRITANNICA.COM, https://www.britannica.com/place/Saint-Lawrence-River (last visited Nov. 5, 2018) [https://perma.cc/8D8F-GPRC].

[10] *St. Regis Mohawk Reservation, Franklin County, New York: Census 2010 Total Population*, AMERICAN FACTFINDER, https://factfinder.census.gov/bkmk/cf/1.0/en/place/St. Regis Mohawk Reservation, Franklin County, New York/POPULATION/DECENNIAL_CNT (last visited Nov. 5, 2018) [https://perma.cc/B3T6-88B8].

[11] *Culture and History*, SAINT REGIS MOHAWK TRIBE, https://www.srmt-nsn.gov/culture_and_history (last visited Nov. 5, 2018) [https://perma.cc/U78A-FMK6]; *Economic Impact*, SAINT REGIS MOHAWK TRIBE, https://www.srmt-nsn.gov/resolve-the-boundary/economic-impact (last visited Nov. 5, 2018) [https://perma.cc/F9JG-DANF].

[12] *See Selected Economic Characteristics 2012-2016 American Community Survey 5-Year Estimates: St. Regis Mohawk Reservation, Franklin County, New York*, AMERICAN FACTFINDER, https://factfinder.census.gov/bkmk/table/1.0/en/ACS/16_5YR/DP03/0600000US3603364727 (last visited Nov. 5, 2018) [https://perma.cc/46BX-PNYV]; *Income and Poverty in the United States: 2015*, U.S. CENSUS BUREAU, https://www.census.gov/library/publications/2016/demo/p60-256.html (last visited Nov. 5, 2018) [https://perma.cc/84FB-FLZK].

had entered into an arrangement with the Saint Regis Mohawk Tribe.[13] Allergan would be transferring one of its many patents to the Tribe, a dry eye drug called Restasis.[14] Once the Tribe took ownership of the patent, it would grant exclusive licensing rights to Allergan, who would distribute and market the drug.[15] For the transfer, Allergan paid the tribe $13.75 million.[16] As for the annual licensing fee, it would pay another $15 million a year.[17] Under the ownership of the Tribe, Allergan believed that the patent would be protected from validity challenges by the Tribe's sovereign Indian Nation status.[18] The company was unequivocal about its motives. "The Saint Regis Mohawk Tribe and its counsel approached Allergan with a sophisticated opportunity to strengthen the defense of our RESTASIS® intellectual property in the upcoming *inter partes* review proceedings before the Patent Trial and Appeal Board," the Chief Legal Officer stated in a press release, referring to an ongoing validity challenge to Restasis.[19]

The PTAB, created by the America Invents Act (AIA), adjudicates patent validity challenges through its inter partes review process (IPR).[20] The idea behind PTAB was to create a more efficient, streamlined process for reviewing patent validity without a petitioner needing to file a lawsuit.[21] To prevail on a claim of patent invalidity, the petitioner only needs to demonstrate, "by [a] preponderance of the evidence," that the patent is invalid—an easier threshold to meet than the "clear and convincing evidence" standard required in federal court.[22] Once the PTAB issues a decision, the petitioner is estopped from raising patent validity in any subsequent lawsuits.[23] Because it is now easier to successfully challenge

[13] *Our Products*, ALLERGAN, https://www.allergan.com/products/key-products/specialty-products (last visited Nov. 5, 2018) [https://perma.cc/2JZ6-VM2F]; *see also* Thomas, *supra* note 2.

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Allergan and Saint Regis Mohawk Tribe Announce Agreements Regarding RESTASIS® Patents*, ALLERGAN, https://www.allergan.com/news/news/thomson-reuters/allergan-and-saint-regis-mohawk-tribe-announce-agr (last visited Nov. 5, 2019) [https://perma.cc/6VY4-UPMK]*; see also* Thomas, *supra* note 2.

[20] 35 U.S.C. §§ 6(a), 311 (2012); *see also* Adam Davidson, *Why Is Allergan Partnering with the St. Regis Mohawk Tribe?* NEW YORKER (Nov. 20, 2017), https://www.newyorker.com/magazine/2017/11/20/why-is-allergan-partnering-with-the-st-regis-mohawk-tribe [https://perma.cc/3MTQ-D87V].

[21] Joseph Lavelle, *The Impact of Inter Partes Review on Patent Litigation*, DLA PIPER: INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS (Sept. 4, 2013), https://www.dlapiper.com/en/us/insights/publications/2013/09/the-impact-of-inter-partes-review-on-patent-liti__/ [https://perma.cc/2RXT-8MK7].

[22] *Id.*

[23] *Id.*

patent invalidity through IPR, a patent immune from such a challenge is much more valuable to its holder.[24] Critically, the provision of the AIA outlining IPR is written such that it does not clearly apply to sovereign entities, like states or Native American nations.[25] With the patent actually belonging to the Tribe, Allergan thought it would be immunized from revocation by the PTAB. Because of the licensing agreement, Allergan would be the sole recipient of Restasis's revenue through its 2024 expiration date.[26]

Other pharmaceutical companies were, unsurprisingly, intrigued. A representative from Teva Pharmaceutical stated the company would be "interested" to see the response of regulatory agencies.[27] Government officials were far less receptive to the arrangement, which they saw as a multibillion-dollar company greedily skirting patent rules and regulations and exploiting tribal law. Within weeks, Senator Sherrod Brown (D-OH) issued a statement condemning the deal and vowed to make Congress "close loopholes that drug companies exploit to avoid competition."[28] On November 2, 2017, the House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet convened for the Sovereign Immunity and the Intellectual Property System Hearing, where witnesses from private industries, trade associations, and academia opined on the dangers of the Allergan precedent.[29] The chairman of the Subcommittee, Bob Goodlatte (R-VA), stated that he "share[d] the concern about the recent instances of private companies paying to 'rent' sovereign immunity of Native American tribes to protect their intellectual property. Tribal sovereign immunity was never intended to serve the interests of private companies unrelated to the tribes."[30] The contract, the consensus seemed to be, was an abuse of tribal sovereignty that damaged the intellectual property system. When invalid patents remain in place, public welfare suffers; an expensive brand-name drug may dominate a market while a company with a more affordable, generic version must wait until the patent expires rather than point out the patent's shortcomings. (That is, in fact, the case with Allergan; drugmakers Teva and Mylan filed applications to challenge the validity of the Restasis patent. They

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24 Davidson, *supra* note 20.

25 *Id.*

26 Thomas, *supra* note 2.

27 *Id.*

28 Jan Wolfe, *U.S. Senator Slams Allergan Patent Deal with Native-American Tribe*, REUTERS (Sept. 20, 2017), https://www.reuters.com/article/legal-allergan-patents/u-s-senator-slams-allergan-patent-deal-with-native-american-tribe-idUSKCN1BQ2BE [https://perma.cc/4D3Y-CNG3].

29 *Sovereign Immunity and the Intellectual Property System: Hearing Before the Subcomm. on Courts, Intellectual Property, and the Internet of the H. Comm. on the Judiciary*, 115th Cong. (2017).

30 *Id.* (statement of Bob Goodlatte, Chairman Comm. on Judiciary).

notified the PTAB of their plans to create a generic drug.[31] Allergan sued Teva and Mylan for infringement while the validity challenge was underway.[32])

Predictably, Mylan Pharmaceuticals filed an IPR proceeding against the Saint Regis Mohawk Tribe, providing the PTAB an opportunity to set the record straight on the scope of IPR.[33] The PTAB held that an IPR proceeding is more like a federal administrative proceeding than a lawsuit, and that therefore the Saint Regis Tribe could not assert tribal immunity.[34] The Court of Appeals for the Federal Circuit affirmed.[35]

Legally, *Mylan Pharmaceuticals* closed the loophole of tribal immunity. And supporters of a dynamic medical research and development market that creates effective, affordable treatments for consumers probably support this solution, too. Yet, there are nuances to this arrangement that ought to give us pause in condemning it. Not the least of which were the benefits the patent transfer provided to the Saint Regis Mohawk Tribe—a steady source of revenue to boost its ailing economy.[36] Though we might think Allergan was taking unfair advantage of a systemic loophole by entering into this agreement, it is harder to fault the Saint Regis Tribe for finding and taking a meaningful economic opportunity for its community. Tribal sovereignty as we know it today is, after all, a legal status conferred upon native communities in recognition of the displacement and dispossession experienced by generations of indigenous peoples at the hands of colonial powers.[37] Tribal rights to self-determination have been contested, withdrawn, and circumscribed by federal and state governments since the early days of the republic.[38] The legislation that currently allows for and governs their independent status, the Indian Self-Determination and Education Assistance Act of 1975, 25 U.S.C.A. § 5301, is always subject to

31 Joe Mullin, *Judge Wants to Know if Allergan's Tribal Patent Deal Is a "Sham"*, ARS TECHNICA (Oct. 10, 2017), https://arstechnica.com/tech-policy/2017/10/judge-wants-to-know-if-allergans-tribal-patent-deal-is-a-sham/ [https://perma.cc/4TPG-JEAJ].

32 *Id*.

33 Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe, 2018 WL 1100950, at *6 (P.T.A.B. Feb. 23, 2018).

34 *Id.* at *7.

35 Saint Regis Mohawk Tribe v. Mylan Pharm. Inc., 896 F.3d 1322, 1325 (Fed. Cir. 2018).

36 *Economic Development*, SAINT REGIS MOHAWK TRIBE, https://www.srmt-nsn.gov/economic-development (last visited Nov. 5, 2018) [https://www.srmt-nsn.gov/economic-development].

37 Geoffrey D. Strommer & Stephen D. Osborne, *The History, Status, and Future of Tribal Self-Governance Under the Indian Self-Determination and Education Act*, 39 AM. INDIAN L. REV. 1 (2014).

38 *Id.* at 3–4.

Congressional amendment or even revocation.[39] In other words, tribes are only as sovereign as the federal government allows them to be.[40]

Furthermore, there has long existed a tension between current intellectual property laws and Indian tribes' rights to secure, protect, and preserve their cultures. Trademark law is the area where this conflict has played out the most. In 1990, Congress amended the Indian Arts and Crafts Act, 25 U.S.C.A. § 305, to allow trademark protection for individual Indians and tribes.[41] The law has paved the way for some high-profile challenges to the use of native names and icons, including the Oglala Lakota Tribe's challenge to the use of Crazy Horse's name on alcoholic beverages,[42] and the Navajo Nation's challenge of Urban Outfitters' use of the Navajo name on more than twenty products.[43] Moreover, "biopiracy" remains a controversy in patent law: the commercialization of Native American knowledge of plants' medicinal properties in mainstream pharmaceuticals.[44] Indigenous peoples have not, historically, received any direct benefits from the intellectual property system.[45]

While the dissolution of this agreement will certainly have an impact on a disadvantaged community, we should also pause to consider the nature of the transaction itself. Allergan essentially transferred its own patent title to another party and, in the process, distributed the rewards it would have received from that patent to the other party. To be sure, the revenue the Saint Regis Tribe would have received from Allergan was a small fraction of total profits made from Restasis.[46] However, the shift in ownership of this patent is significant in relation to the longer story of how patent rights have become property rights, overshadowing distributive theories of intellectual property.

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39 *Id.*

40 *Id.*

41 Robert J. Miller, *American Indian and Tribal Intellectual Property Rights*, 13 TUL. J. TECH. & INTELL. PROP. 179, 180 (2010).

42 *Id.* at 181.

43 David Schwartz, *Navajo Nation Settles Trademark Suit Against Urban Outfitters*, REUTERS (Nov. 18, 2016), https://www.reuters.com/article/us-navajo-urbanoutfitters/navajo-nation-settles-trademark-suit-against-urban-outfitters-idUSKBN13D2QA [https://perma.cc/9YRD-5PBK].

44 Laurie Anne Whitt, *Indigenous Peoples, Intellectual Property & the New Imperial Science*, 23 OKLA. CITY U. L. REV. 211, 247 (1998).

45 *See generally* Erica-Irene Daes, *Intellectual Property and Indigenous Peoples*, 95 AM. SOC'Y INT'L L. PROC. 143, 143 (2001).

46 Thomas, *supra* note 2.

II. "DISTRIBUTIVE" V. PROPERTY RIGHT THEORIES OF INTELLECTUAL PROPERTY

The legal understanding of the role of intellectual property rights underwent a sea change in the latter half of the twentieth century. Patents, copyrights, and trademarks historically served the greater end of incentivizing creativity and innovation for the benefit of the public.[47] The Supreme Court articulated this idea in *Twentieth Century Music Corp. v. Aiken*: "The ultimate aim is, by this incentive, to stimulate artistic creativity for the general public good."[48] An intellectual property right was granted only insofar as it would "'enlarge' the creative pie."[49] The patent system also expressed this value, operating primarily as an incentive-based system for societal advancements.[50] Jerome H. Reichman describes the structure of intellectual property rights in the early twentieth century as "islands of protection in a sea of free competition"; intellectual property was to enhance competition and innovation, not stifle it.[51] Rochelle Dreyfuss and Susy Frankel expound on this theory:

> Debates in the literature, in policy circles, and in courts were primarily *quantitative*, concerned with *how much* exclusivity was needed to balance the interest in protection against the access needs of the public. . . . Thus, while the subject matter of protection may have been expanding, there were many ways in which governments retained significant flexibilities to contour the "continent" to benefit the public.[52]

The laws and treaties comprising domestic and global intellectual property policy reflected this view, too. The Berne and Paris Conventions referred to the individual vested with an intellectual property right as an "author," as opposed to later treaties that referred to "rights-holders" and "owners."[53] Similarly, both Berne and Paris allowed member nations flexibility to maintain public-protective policies in spite of the obligation to protect foreign works.[54] Under Berne, for example, states were permitted to translate books into local languages without the author's permission.[55]

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47 Rochelle Dreyfuss & Susy Frankel, *From Incentive to Commodity to Asset: How International Law Is Reconceptualizing Intellectual Property*, 36 MICH. J. INT'L L. 557, 557–58 (2015).

48 422 U.S. 151, 156 (1975).

49 Molly Shaffer Van Houweling, *Distributive Values in Copyright*, 83 TEX. L. REV. 1535, 1539 (2005).

50 Dreyfus & Frankel, *supra* note 47.

51 Jerome H. Reichman, *Nurturing a Transnational System of Innovation*, 16 J. TRANSNAT'L L. & POL. 143, 145 (2007).

52 Dreyfus & Frankel, *supra* note 47, at 558.

53 *Id.* at 564.

54 *Id.* at 563.

55 *Id.*

In recent years, the conceptualization of intellectual property rights, and the rhetoric used to describe them, has focused on walling off property rights from outside users. We have confused the ends of intellectual property rights with the means; the value of a patent, for instance, comes not from the benefits of the innovation it protects, but from the patent itself—that is, the exclusive monopoly bestowed by the patent. The "right to exclude" has matched or exceeded the public benefit as the value driving intellectual property enforcement. A number of factors have driven this shift in mindset, including the globalization of trade and the accompanying view of intellectual property as a commodity and an asset rather than a tool with which to increase the number and quantity of commodities and assets.[56]

The 1995 Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), for instance, strengthened existing intellectual property rights, mandated enforcement mechanisms in participating states, and diminished the ability of states to protect local interests.[57] Under the Paris Convention, countries could require patent grantees to "work the invention" in that locality to create further industry in that jurisdiction; TRIPS constrains such allowances.[58] Additionally, TRIPS obligates all member states to vigorously enforce intellectual property rights through injunctions, monetary awards, and the seizure of infringing goods.[59] Member countries must impose criminal penalties for willful infringement.[60] And any flexibilities or perceived weaknesses in TRIPS have been tightened by subsequent international agreements like WIPO and the Trans-Pacific Partnership Agreement.[61] According to Dreyfuss and Frankel, "the changes create new norms regarding the appropriate level of protection and excludability and an unraveling of the incentive-based rationale for protection."[62]

These shifts in global trade law, too, have occurred against the backdrop of a law and economics-based justification for the rise of intellectual property rights.[63] This theory focuses on efficiency and utilitarianism.[64] Social welfare, through this lens, is the economic maximization of scientific

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[56] *Id.* at 558.

[57] *Id.* at 563–65.

[58] *Id.* at 563.

[59] *Id.* at 564.

[60] *Id.* at 564–65.

[61] *Id.* at 566–67.

[62] *Id.* at 570.

[63] Yanisky-Ravid, *supra* note 7 ("Over the years, the utilitarian-economic-efficiency theories of the law and economics approach have been widely cited as the dominant justification for the exclusive allocation of intellectual property rights to financial stakeholders.").

[64] *Id.*

and cultural goods.[65] One of the consequences of this focus, writes Shlomit Yanisky-Ravid, is that incentives are now, more often than not, given to firms and employers rather than individuals.[66] This dynamic, he writes, is at odds with the distributive value of intellectual property, which ought to be used as a mechanism for a just allocation of resources.[67] Peter Lee similarly argues that "strict exclusive rights" dampen the distributive effects of patents; he criticizes the utilitarian goals of "allocating resources to maximize aggregate welfare" and advocates distributive justice as "a normative principle favoring equality of access in resource allocation."[68] Margaret Chon reaches roughly the same assessment, arguing that the emphasis on utility maximization "ignores distributional consequences."[69]

The pharmaceutical industry is perhaps the most paradigmatic example of an industry realizing the consequences of a utilitarian-based intellectual property rationale. Prescription drugs and other medical treatments are more expensive than ever, pricing many consumers out of proper healthcare.[70] As Lee notes:

> [P]atents enable supracompetitive prices for medicines, diagnostic agents, and agricultural innovations. . . . Patented drugs can be vastly more expensive than generic equivalents. As noted, the average worldwide price for ARVs [antiretrovirals] that treat HIV/AIDS decreased by two orders of magnitude upon expiration for key patents. . . . Patent-enabled access constraints, which raise prices for all consumers, have clear implications for distributive justice. . . .[71]

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[65] *Id.*; *see also* Brett Frischmann, *Capabilities, Spillovers, and Intellectual Progress: Toward a Human Flourishing Theory for Intellectual Property*, 14(1/2) REV. ECON. RES. ON COPYRIGHT ISSUES 1, 14–15 (2017) (distinguishing between traditional utilitarian welfare economics, in which aggregate welfare of society is measured by utility, happiness, pleasure, preference satisfactions, or some comparable measure, and the capabilities approach that seeks to escape welfare maximization as the end by rejecting exclusive reliance on conventional economic measures and replacing them with the opportunities to realize actual, "real-life" achievements).

[66] Yanisky-Ravid, *supra* note 7, at 20 ("The beneficiaries of this intellectual property rights allocation have been supported by United States courts, which validate contracts transferring intellectual property rights to firms, employers, or other economically oriented entities, thereby diluting—to the point of destruction—the rights of authors and inventors, especially in the case of employee-inventors and creators.").

[67] *Id.* at 19.

[68] Peter Lee, *Toward A Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917, 921 (2009).

[69] Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2832 (2006).

[70] Aimee Picchi, *Prognosis for Rx in 2017: More Painful Drug-Price Hikes*, CBS NEWS (Dec. 30, 2016), https://www.cbsnews.com/news/drug-prices-to-rise-12-percent-in-2017/ [https://perma.cc/5YYZ-5ZJY].

[71] Lee, *supra* note 68, at 931–32.

When generic drug companies, like those challenging Allergan's patents, can't enter the market due to a preexisting patent, the patented drug can be priced as high as the patent owner likes. In addition to Lee's ARV example, pharmaceutical companies have come under fire recently for increasing the price of EpiPens,[72] muscular dystrophy treatments,[73] and heroin overdose antidotes.[74]

The creation of the PTAB was, in fact, an effort to provide a more efficient avenue for challenges to patents and for patent holders to appeal adverse decisions.[75] Rather than litigate in federal court, a plaintiff may challenge the validity of the patent through an IPR, looking to prior art to determine whether the challenged patent is obvious or anticipated.[76] And while the Board has provided a venue to hear patent claims without clogging the federal court system, it has not changed the fundamental nature of patent rights as they stand today. A patent, even a valid one, can hold up the entry of generic drugmakers for twenty years.[77]

While efforts to loosen the sanctions dictated by TRIPS and WIPO have stalled, there is some effort in the international arena to refocus global intellectual property protections to more distributive ends.[78] In 2004, for instance, the WIPO General Assembly called for several initiatives: a moratorium on expanding intellectual property rights, more attention paid to the social and economic costs of stringent intellectual property protections, and "non-proprietary systems of creativity and innovation, such as Wikipedia."[79] The Assembly also proposed a Treaty on Access to

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72 Tara Parker-Pope & Rachel Rabkin Peachman, *EpiPen Price Rise Sparks Concern for Allergy Sufferers*, N.Y. TIMES (Aug. 22, 2016, 6:05 PM), https://well.blogs.nytimes.com/2016/08/22/epipen-price-rise-sparks-concern-for-allergy-sufferers/?_r=0 [https://perma.cc/5B4K-D7KU].

73 Lisa Schencker, *Marathon Sheds $89,000 Muscular Dystrophy Drug After Pricing Uproar*, CHI. TRIB. (Mar. 16, 2017, 4:57 PM), http://www.chicagotribune.com/business/ct-marathon-sells-89000-drug-0317-biz-20170316-story.html [https://perma.cc/5WM5-2UNK].

74 Shefali Luthra, *Massive Price Hike for Lifesaving Opioid Overdose Antidote*, SCI. AM. (Feb. 2, 2017), https://www.scientificamerican.com/article/massive-price-hike-for-lifesaving-opioid-overdose-antidote1/ [https://perma.cc/GCH7-LA57].

75 Bob Steinberg & Jonathan Strang, *Why the Patent Trial and Appeal Board Should Fully Decide Institute Petitions*, LAW.COM (Sept. 11, 2017, 12:46 AM), https://www.law.com/sites/almstaff/2017/09/11/why-the-patent-trial-and-appeal-board-should-fully-decide-instituted-petitions/ [https://perma.cc/LKB9-5SBU].

76 1 MARK A. LEMLEY ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE: 2016 § III-181 (2016). This is the proceeding generic drugmakers are using to challenge the Restasis patent. Thomas, *supra* note 2.

77 35 U.S.C.A. § 156 (West, Westlaw through Pub. L. No. 115-223).

78 Lawrence R. Helfer, *Toward a Human Rights Framework for Intellectual Property*, 40 U.C. DAVIS L. REV. 971, 973 (2007).

79 *Id.* at 1011–12.

Knowledge that outlines potential exceptions to patent protection for certain types of subject matter.[80]

At the most global levels of lawmaking, the human consequences of aggressive intellectual property protections and the importance of distributive outlets in the intellectual property system are being acknowledged. It is against this backdrop that the Allergan-Saint Regis Mohawk agreement takes on unique significance as a quasi-distributive legal instrument.

III. DISTRIBUTIVE SOLUTIONS

There are strong historical and contemporary examples of legal mechanisms designed to enhance public access while also conferring protection on patent owners. Examining these arrangements offers insight into how other countries have protected the public interest in the face of patent protections, and how some version of the Allergan arrangement might fit into that framework.

A. Working Requirements

The first of these is known as a "patent working requirement," a condition of patent rights that the holder "work" the patent in any jurisdiction where its rights are enforced.[81] To work a patent might mean to simply import the good into the area of protection or to manufacture it there.[82] Working requirements originated in English common law, where royal patents were sometimes granted to foreigners who were willing to teach locals how to use the art.[83] These early patent conditions, writes Marketa Trimble, "were consistent with the countries' initial approaches to their patent systems, which were guided by the notion that patents were expected to serve domestic industry."[84] Simply put, to be granted the privileges of intellectual property protection, one was expected to give back to the community in which they received them.

TRIPS has arguably limited the right of member states to impose working requirements through the provision of the agreement that prohibits discrimination based on the place of invention.[85] However, that theory is as yet untested, and many countries still have some form of a working

80 *Id.* at 1012–13.

81 Marketa Trimble, *Patent Working Requirements: Historical and Comparative Perspectives*, 6 U.C. IRVINE L. REV. 483 (2016).

82 *Id.* at 489.

83 *Id.* at 488.

84 *Id.* at 487.

85 *Id.* at 496.

requirement, including India and Brazil.[86] Trimble argues that the U.S. requirement that patent claims "enable" future inventors and detail the "best mode" of creation are aimed at similar goals of enhanced domestic industry.[87]

B. Compulsory Licensing

In Thailand, regulators have taken the bold step of issuing compulsory licenses to protect public health.[88] Thailand has a national mandate to provide accessible healthcare to its citizens, and is permitted by flexibilities in TRIPS to issue licenses to the extent necessary to protect public health.[89] In 2006, after taking steps to negotiate with the owner of a patent that treats HIV/AIDS without success, Thailand authorized its Government Pharmaceutical Organization to manufacture generic versions.[90] The move drew ire from major patent holders, but as Cynthia Ho writes, "Thailand believes in a public interest orientation to patent rights with the view that patients must come before profits."[91]

Even in the U.S., there are still ways that the patent system uses public-oriented, distributive methods to enhance public health. In instances where the innovation is the product of taxpayer funding, at either the state or federal level, there are ways in which the government can require the resulting patent to benefit the residents that funded it, though they are often hesitant to do so.[92] The Bayh-Dole Act of 1980, for instance, allows recipients of federal funding to take title to their taxpayer-funded inventions.[93] However, the Act focuses on promoting the "utilization of inventions," "free competition and enterprise" without unduly encumbering future research and discovery, and "public availability."[94] Access is key. As Peter Lee points out, the National Institute of Health (NIH) cites these provisions in their guidelines, stating

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86 *Id.* at 496–97.

87 *See id.* at 499.

88 Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1065–66 (2009).

89 *Id.* Theoretically, any country is authorized to do so. *Id.* at 1067 ("Contrary to the bluster of pharmaceutical giants, compulsory licenses are an essential part of national and international laws. The WTO rules allow member states to issue compulsory licenses to protect public health according to their own criteria; indeed, the Doha Public Health Declaration clearly affirms that each country has the 'freedom to determine the grounds upon which compulsory licenses are granted.'").

90 *Id.* at 1066–67.

91 *Id.* at 1066; *see also Thailand Issues Compulsory License for Patented Aids Drug*, INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT (Dec. 13, 2006), https://www.ictsd.org/bridges-news/bridges/news/thailand-issues-compulsory-licence-for-patented-aids-drug [https://perma.cc/9QTL-CQM6].

92 *See generally* Lee, *supra* note 68, at 944–46.

93 Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–212 (2012)).

94 *Id.* § 200.

that when NIH funding recipients take title to their inventions, they have "obligations to promote utilization, commercialization, and public availability of these inventions."[95] A separate provision of Bayh-Dole, 35 U.S.C. § 202(a), though rarely acted on, in fact allows funding agencies to refuse the issuance of a patent in "exceptional circumstances" when doing so would "better promote the policy and objectives of the Act."[96]

Similarly, in the State of California, recipients of state biomedical research funding have a number of distributive obligations attached to any title they take.[97] In 2004, the state passed Proposition 71, creating the California Institute for Regenerative Medicine (CIRM), which administers grants for biomedical research—specifically, stem cell research.[98] Recipients of CIRM grants are allowed to take title to their inventions, but must engage in a revenue-sharing model with the Institute and guarantee that any treatment resulting from CIRM-funded research will be available to the state's uninsured.[99] "At its core," Lee writes, "Proposition 71 is a public health initiative."[100]

It is important to note that these rules circumscribing patent protection—a working requirement, a compulsory license, or other accessibility requirements—are attached to patents. They are considered part of the privilege granted by the intellectual property system, not exceptions to an otherwise inviolate property right. Within these frameworks, patents are not wholly exclusionary rights, but inherently distributive mechanisms that balance certain inventors' rights with the public good. The patent holder has an affirmative duty to the public to distribute the benefits of his creation to society in an equitable, accessible manner.

IV. THE ALLERGAN-SAINT REGIS AGREEMENT AND THE DISTRIBUTIVE MODEL

The arrangement between Allergan and the Saint Regis Mohawk Tribe was hardly a paragon of distributive values at work in the intellectual property system. The agreement was, in some ways, quite asymmetrical in the benefits it bestowed on the tribe compared to the lucrative right retained by Allergan. The licensing fees paid to the Tribe by Allergan would have been, after all, a small percentage of the annual revenue the drug will likely make for the company, to say nothing of the added value of insulation from

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95 Lee, *supra* note 68, at 953.
96 35 U.S.C. § 202(a) (201); Lee, *supra* note 68, at 954.
97 *Id.* at 922.
98 *Id.* at 962.
99 *Id.* at 962–63.
100 *Id.* at 962.

a validity challenge.[101] More importantly, the licensing right given to Allergan was exclusive, giving the company the sole ability to manufacture, distribute, and sell (at any price it liked) the drug in question.[102]

Still, fundamentally, the arrangement mimicked the kind of distributive mechanisms we might imagine for a patent system that mandated public benefits as a condition of protection. The Saint Regis Tribe agreed to act as a type of trustee for Restasis, ensuring its safekeeping from challenge and Allergan's continued revenue from it; in exchange for that protection, Allergan distributed some of its profits to the Tribe.[103] In the same way a working requirement insists on benefits for the communities protecting the patents, or a CIRM-funded patent insists on revenue sharing by its holder, Allergan was required to share a piece of its fortune to receive the kind of protection it wanted.

Perhaps even more significantly, Allergan gave up its ownership of Restasis to receive full protection. Under this scheme, protection is not synonymous with ownership, and one does not imply the other. Its development of Restasis merely gave Allergan a privilege in its licensing. To be sure, that privilege was more exclusionary than a true distributive method would be. But Allergan was forced to relinquish possession of its patent and distribute some of the benefits of that possession to the Saint Regis Mohawk Tribe, a community that almost certainly would not otherwise benefit from the intellectual property system. Despite the exclusionary, lopsided nature of the agreement, it bespeaks more distributive value than is often found in our patent system.

We might imagine arrangements that feature the distributive aspects of this arrangement—the automatic transfer of title, the revenue sharing, and the benefits to underserved population—without its exclusionary attributes, and without its effect of insulating the patent from challenge. It is also possible to imagine schemes that might distribute the benefits of the Restasis patent more broadly. In the spirit of early working requirements, Allergan might be asked to open a clinic in the sovereign entity giving refuge to its patent, for instance. Or the licensing arrangement between the tribe and Allergan might be less exclusionary, granting Allergan some exclusive privileges for a provisional period, then opening the patent up to wider manufacturing.

While Allergan was, probably rightly, barred from opening and exploiting this legal loophole to protect itself, the nuances of their escape

101 Thomas, *supra* note 2.
102 *Id.*
103 *Id.*

from the system are illuminating. They have, after all, bargained for protection by fulfilling a social duty to those offering that protection.