NATIONAL SOVEREIGNTY AND INTERNATIONAL PATENT LAW

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INTRODUCTION

You know you made a good choice to participate in a symposium when you find the mere title of the symposium stimulating. That is my happy circumstance. I see intellectual property (IP) law as an interesting hybrid of public law and private law; though, in the end, if forced to choose one label, I would call it fundamentally private law. Even so, I also believe strongly in acknowledging and in some cases repairing those aspects of IP law that affect resource distribution. And for IP law, "public values" could not be a more relevant topic. A lively recent debate asks what are the ultimate normative foundations of the field, pitting welfare maximization against more deontological values; yet, though students of IP law argue forcefully over *which* public

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values are the heart of the field, few or none argue that the field has nothing to do with public values at all. There is tacit agreement that the bulk and complexity of the IP system cannot be justified without resort to some grand, overarching purpose. The rewards to authors and inventors, the licensing transactions and other business deals built on IP rights, and the employment of public administrative and judicial resources to resolve disputes all have significance beyond the money earned by creative people. Likewise, the businesses and industries built on protecting intangible assets, and the outcomes of individual enforcement actions impact numerous players in the IP ecosystem, and not just creative professionals. All of these are the operational gears and pulleys of the IP machine, but the machine itself has a higher purpose. It is in place to enact, promote, and reflect public values.

The tradition in IP scholarship provides two primary ways to discuss issues such as these. One is to talk about the Big Picture: to look at the overall shape of IP law (or one of its constituent parts, i.e., patent, copyright, etc.) with an eye toward understanding its fundamental driving principles and unified conceptual structure. The other is to plunge with vigor into a single issue or doctrine, in an attempt to understand the complex issues encoded into it. In this short symposium piece, I am going to choose the latter. I will use a single issue in IP law to see what it can tell us about the interaction between distribution, public values, and private law.

The issue is international IP treaties. More particularly, I will look into the delegation of national sovereignty in each of two major treaties, the Paris Convention of 1883 and the Trade Related Aspects of Intellectual Property (TRIPs) Agreement of 1995. In terms of the themes in this Article, my major points are these:

1. The distributive impact of the two treaties operates at the level of global consumers and global IP creators; the treaties thus deviate from the conventional conception of redistribution, which tends to focus on distributive impacts within individual countries. This is both a novel, global conception of redistribution and a significant deviation from the nationalist/mercantilist roots of national IP systems, especially as reflected in the history of early patent statutes around the world.

2. The aim of both treaties is to facilitate acquisition and (in the case of TRIPs) enforcement of IP rights by non-nationals. The stated objective is to give non-nationals rights as similar as

possible to those of nationals ("national treatment"). The Paris Convention, which has the limited goal of making it easier for a citizen of one country to acquire IP rights in other countries, grew out of a cosmopolitan movement in the late nineteenth century that emphasized the sharing of knowledge and information. It was originally an adjunct of the international science and technology exposition movement, and can be said to reflect the public value of encouraging the exchange of ideas. It does this by preserving the chance for a non-national to obtain a patent on terms equal to those of a citizen of the patent-granting state.

3. The TRIPs treaty has been criticized since before it was ratified for transferring too much lawmaking power to private (read: corporate) hands. It represents (in this view) the ascension of a political economy in which public international lawmaking has been hijacked by private interests.[1] Though I surely see flaws in the TRIPs Agreement, I would defend it from the strongest of these claims. It has served companies in IP-intensive industries, true, but it has conferred benefits on many countries outside of Europe, the United States, and Japan. It has helped spur some countries forward in the evolution of high value-added industries, as intended. And it has helped create conditions that encourage overseas investment.

IP treaties help non-citizens acquire IP rights. In the case of TRIPs, the treaty governs to some extent the standards under which those rights are granted. To achieve these goals, individual countries had to agree to abide by a common set of procedures (Paris Convention) and rules/doctrines (TRIPs). Thus in the end, though the treaties aim to facilitate the grant of classic private law entitlements, they achieve that end by demanding the surrender of some degree of discretion at the national level (i.e., the discretion to treat non-citizens differently from citizens). They can thus be seen as requiring the surrender of some national sovereignty, in exchange for membership in a semi-globalized system of IP protection.

As we will see, the treaties emerged from vastly different eras, and so in my view they make vastly different demands on countries

1. *See generally* AFTER PUBLIC LAW (Cormac Mac Amhlaigh et al. eds., 2013); CITIZENSHIP, MARKETS, AND THE STATE (Colin Crouch et al. eds., 2001).

wishing to sign on to them. The Paris Convention has a narrow focus: facilitating IP acquisition by non-nationals. It requires only a small surrender of sovereignty, just that degree of discretion that would allow a national IP system to treat non-nationals differently. TRIPs is more ambitious and demands a greater surrender of sovereign discretion. TRIPs goes beyond the "procedural fairness" of the Paris Convention, stipulating minimum substantive standards and providing (at least in theory) an enforcement mechanism for compliance.

We will get to a discussion of how the surrender of sovereignty affects resource distribution and to a review of the public values this system embodies. For now, I can summarize by saying that individual states have the right to choose whether to opt into these IP treaties. They do so through classic public law mechanisms (i.e., treaty consideration, ratification, and accession). And they do so for reasons reflecting public values: a decision to value creative contributors, from home and abroad; a belief that free exchange of information benefits the domestic polity; and so on. But these values are put in practice through the award of IP rights—which as I said, I consider essentially private law rights. So, the public values embodied in national sovereignty and the right to partially surrender it are expressed ultimately through the vehicle of individual private law rights.

To understand the relationship between sovereignty and national IP systems, we need to first go back to the early days of patent protection. It is against this decidedly non-cosmopolitan, non-globalist backdrop that the treaties we are interested in first arose.

I. PATENT TREATIES AND NATIONAL SOVEREIGNTY

Patent law began as a strictly mercantilist policy instrument. The granting of rights or privileges by the state was understood to be for the benefit of the granting state and its citizens and no one else. But by the late nineteenth century, state self-interest expanded to include protection of domestic inventors whose products were increasingly sold on international markets. So, in the first wave of international harmonization, culminating in the Paris Convention of 1883, individual nations made common cause to streamline patenting of inventions in multiple jurisdictions. A small degree of state sovereignty was surrendered, in exchange for a regime that in theory might benefit inventors in all member states of the Convention. Then in the 1990s, the second wave of patent harmonization crested with the TRIPs Treaty, part of the Uruguay Round of agreements that created the World Trade Organization. By linking new, substantive

standards for IP protection with other trade preferences and policies, TRIPs appealed to the diverging national interests of signatory nations. To bridge this divergence, TRIPs required a greater surrender of sovereignty than the Paris Convention. A more thoroughgoing quid pro quo is latent in the text and background of TRIPs as compared to Paris.

The differences between the Paris Convention and TRIPs raise some important questions. How exactly do international patent treaties constrain the discretion of sovereign nations? And how powerful are these constraints in the case of each individual treaty? More importantly, how powerful should they be?

I look at two specific problems in sovereignty to provide answers. The Paris Convention defines an international priority filing as the basis for the right to file counterpart patent applications in Convention member states. Yet, national laws are in conflict over rules for determining invention ownership at the time of the international filing. Should the law of the priority application country be used to determine ownership, or the law of each subsequent country where a counterpart is filed?

TRIPs requires signatory countries to apply three traditional requirements of patentability, novelty, inventive step (nonobviousness), and utility. Canadian courts have applied a variant on this latter requirement, utility, almost exclusively to pharmaceutical patents.[2] The Canadian version of the test resulted in a skyrocketing invalidity rate for these patents when compared to historical norms. Should the traditional parameters of the utility doctrine limit the ability of Canada's sovereign courts to craft doctrine in this area?

I believe that the Paris Convention was drafted in an era when national sovereignty was a stronger baseline assumption in international patent law. So, it should arguably be interpreted in a way that preserves as much sovereign discretion as possible. There is a very plausible argument that the text of the Convention supports applying the law of the international priority country to the question of ownership of invention rights. But under the sovereignty-maximizing interpretive rule I would apply to the Convention, there is a good case

2. In 2017 the Canadian Supreme Court jettisoned the promise utility doctrine that had been at the center of the *Eli Lilly* arbitration. *See* AstraZeneca Canada Inc. v. Apotex, Inc., [2017] S.C.R. 36 (Can. S.C.C.); *see also* discussion *infra* note 50.

that each subsequent country where an application is filed should be permitted to apply its own rules of ownership.

TRIPs requires greater surrender of sovereignty. Thus, I would support a TRIPs arbitration panel in finding that Canada is out of compliance with the Agreement because its courts have stretched and disfigured the traditional utility standard so essentially that it is not a utility test at all. I recognize, however, that TRIPs leaves much greater discretion in other doctrinal areas of patent law, in particular disclosure/enablement, which suggests that future Canadian cases might well invalidate at least some pharmaceutical patents on the basis of enablement rather than lack of utility.

So, how much sovereignty does a nation surrender when signing an international patent treaty? The answer depends on the text of the treaty, but also on what that text (and other surrounding facts) tells us about background assumptions concerning sovereignty at the time of signing. If harmonization continues in the future—not a sure thing from the vantage point of 2020—the same analysis will apply to any treaties that are signed. In the constant push and pull between patent law's mercantilist roots, and its globalizing aspirations, the historical moment of treaty-making will leave a lasting mark.

A. Paris, 1883

The history of patent harmonization tracks the growth in international trade over time. Until 1800, there was a long period characterized by persistently low international trade flows. According to most estimates, the sum of exports and imports throughout the world before 1810 never exceeded more than 10% of global annual GDP.[3] This changed over the course of the nineteenth century, when technological advances triggered a period of marked growth in world trade, in what has been called the "first wave of globalization."[4] The Paris Convention of 1883 was a creature of its time: the coming of globalization to the patent world.

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3. *See* Esteban Ortiz-Ospina, Diane Beltekian & Max Roser, *Trade and Globalization*, OUR WORLD IN DATA 14 (2018), https://ourworldindata.org/international-trade#data-sources [https://perma.cc/UH3M-HHGA].

4. David S. Jacks, Christopher M. Meissner & Dennis Novy, *Trade Costs in the First Wave of Globalization* 1 (Nat'l Bureau of Econ. Research, Working Paper No. 12602, 2006); *see* ANGUS MADDISON, THE WORLD ECONOMY: A MILLENNIAL PERSPECTIVE 95–101 (2001) (describing global growth in trade and GDP between 1820 and 1913).

The first wave of globalization came to a screeching halt with the beginning of the First World War. The decline of free trade liberalism, and the rise of nationalism, presaged not only war but also economic stagnation. There was a sizeable reduction on international trade in the interwar period. After the Second World War, trade growth picked up once again. Advances in communications (e.g., worldwide phone lines, satellite technology, mobile phones, and the Internet) and transportation (e.g., containerization, larger ocean transport vessels, and road construction) spread the word and paved the way for an ever-growing stream of international trade. Today the sum of exports and imports across nations is higher than 50% of global GNP.[5] Put another way, over half of the goods and services consumed in the world originate somewhere other than the place of consumption.

It was against this broad backdrop that representatives from eleven nations gathered in Paris in 1883. But in this broader context, two more proximate causes precipitated the drafting of the Convention. The first was the wave of international scientific, technical, and cultural "expositions" that so excited and stimulated the developed world in the nineteenth century. And the second was the formation of postal and telegraph unions, at the transnational level, for coordination of transnational communication.[6]

The great expositions of the nineteenth century occurred in London (1851), Vienna (1873), and Paris (1878). The goal of these events was to showcase, in one place, the "state of the art" in many diverse fields and to teach interested people from many countries the most up-to-date ideas and technologies. Although there was widespread excitement among participants,[7] exhibitors were concerned that their ideas would be shown without any form of legal protection.[8] The risk of piracy was explicitly reflected in a number of bilateral and provisional forms of protection, which were put in place prior to the exhibitions in a hasty and ad hoc sort of way.[9] The inadequacy of these solutions was apparent to all, so a convocation of

5. *See* Ortiz-Ospina, Beltekian & Roser, *supra* note 3.

6. *See* SAM RICKETSON, THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY: A COMMENTARY 5–6 (2015).

7. Petra Moser, *How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World's Fairs*, 95 AM. ECON. REV. 1214, 1216 (Sept. 2005) ("At a time when London had fewer than two million inhabitants, [the 1851 "Crystal Palace" Exhibition] attracted more than six million people . . . .").

8. *See* RICKETSON, *supra* note 6, at 30.

9. *See id.* at 25–30.

experts was called in conjunction with the Vienna Exhibition of 1873. This led directly to a parallel meeting in Paris in 1878, which produced the first draft of what would become the Paris Convention of 1883. The elites who ran these meetings—there was usually a Baron this, or Count Von that, at the lectern—did not speak explicitly of the need to surrender some degree of national sovereignty to achieve uniformity. They spoke only of protecting inventors and entrepreneurs, and of the obvious need to somehow coordinate parallel national patent filings. But the solutions they arrived at reflected an implicit understanding that they were to solve a limited problem, and that as a result only fairly minimal commitments would be required of the prospective member nations.

It is often said that the Paris Convention reflects only limited substantive harmonization, and that its overall impact falls primarily on patent procedures. There is a sense in which this is true; for example, no country commits to employing an inventive step (or nonobviousness) requirement, let alone agrees on how stringently to apply such a standard. At the same time, it is generally understood that a sovereign nation may treat its citizens differently from those of other nations. The very idea of citizenship shows as much. Thus, when a country agrees to treat non-nationals just as it treats citizens, it does commit to a restriction in its sovereign prerogatives. Thus the central idea of the Paris Convention, the national treatment principle of Article 2,[10] does represent the surrender of some national discretion.

Likewise, it is certainly within the purview of a national government to require that legal documents be filed in an office of the government, in order to give those documents effect within the country. And so, the concept of international priority in Article 4,[11] perhaps the most widely used feature of the Paris Convention, also represents a small concession of sovereign power.

Yet both of these important components of the 1883 Convention can also be seen as fairly minimalist intrusions into sovereignty. National treatment requires no change in the substantive law applied to a nation's citizens; it just requires non-citizens to be treated equally. And the international priority system makes no demands on the details or requirements of patent prosecution. It merely requires that an initial filing in another Convention country be given the same effect as if it were made initially in the national patent office. It should also be

10. *See* Paris Convention for the Protection of Industrial Property art. 2, Mar. 20, 1883, 21 U.S.T. 1583 (last revised Sept. 28, 1979).

11. *Id.* at art. 4.

mentioned that the Convention adopts a "national option" solution for compulsory working and compulsory licensing.[12] This was adopted intentionally as a compromise between the forces of "nationalism" and "internationalism"—a further sign of the limits of sovereign surrender embedded in the text of the Convention.[13]

After the successful conclusion of the Paris Convention in the late nineteenth century, further efforts at harmonizing worldwide patent law bore little fruit for nearly another century. This lull in activity was in part due to the success of the Paris Convention, which established a sufficient legal framework so that inventors and their firms could obtain some level of effective protection in most commercially important countries. Yet, the process for obtaining protection remained quite cumbersome. Patent applications still had to be filed in every jurisdiction in which protection was desired, and applicants still had to deal with the divergent rules and standards of the world's many individual patent jurisdictions. Nevertheless, the international business community seemed to have little interest in investing time and resources for further consolidation and harmonization of world patent law. And perhaps too, the world's nations were not ready in the first half of the twentieth century for the kind of international cooperation necessary to consolidate and harmonize global patent standards.

The next major developments would not occur until the 1970s. That decade saw two international agreements concluded—the Patent

12. *See id.* at arts. 5(A)(2), 5(A)(4).

> (2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work. . . .
>
> (4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons.

Id.

13. *See* EDITH TILTON PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 60–87 (1951) (describing the very instructive history of the Convention).

Cooperation Treaty or PCT,[14] and the European Patent Convention or EPC.[15]

Both of these innovations were directed to the same problem—the burden on applicants of having to file numerous applications to obtain transnational patent protection. Both were also variations of the same solution—consolidation of various national processes into a single international mechanism.

Of the two solutions, the PCT is the less dramatic, though it applies to more countries. It establishes an international application process by which inventors may file a single patent application in any patent office of a jurisdiction bound by the agreement. The PCT application process has two phases: an "international phase," during which an international searching authority (which can be the national patent office) conducts a prior art search; and the "national phase," during which the applicant must prosecute the application through the patent office of each country where protection is sought. In essence, the PCT provides a uniform procedural framework for filing applications in multiple nations and consolidates one aspect of patent prosecution: prior art searching. The PCT does not, however, eliminate the necessity of separately prosecuting multiple national applications to obtain protection in multiple countries.[16]

In contrast to the PCT, the European Patent Convention is far more aggressive in establishing a transnational patent process. It establishes a centralized office for patent prosecution for each of its thirty-eight member states, the European Patent Office (EPO), which performs the normal administrative tasks of searching the prior art, examining the application, and determining patentability. If the examination process concludes in favor of the applicant, the EPO is authorized to issue a patent that provides rights in *all* EPC countries designated by the applicant. The applicant does not have to go through any additional prosecution in the national offices.

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14. *See generally* Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231.

15. *See* EUROPEAN PATENT OFFICE, http://www.european-patent-office.org/legal/epc/e/ma1.html [https://perma.cc/UV8M-QYSD] (last visited Mar. 2, 2020).

16. The PCT has been a modest success. For example, the USPTO received in fiscal year 2006 about 52,000 PCT international applications—a substantial number that is nonetheless dwarfed by the over 417,000 domestic applications filed in the same year. USPTO, PERFORMANCE AND ACCOUNTABILITY REPORT FISCAL YEAR 2006 16 (2006). But applicants are often drawn to the PCT application process not because of its simplicity but because of its procedural benefits in delaying patent prosecution at the national level.

There are two major limitations on the EPC. First, it applies only to thirty-eight European nations; the PCT, by contrast, applies to more than a hundred nations.[17] Second, the EPC unifies only the administrative functions of national patent systems. The European patent issued by the EPO is not, in theory, a single transnational patent but a "bundle" of national patents that are enforced through the various national courts of the EPC countries. The nations of Europe are considering other measures that would further unify their patent systems. For example, the proposed Unified Patent and Unified Patent Court (UPC) would establish true European-wide patents, with centralized enforcement. Agreements establishing the unified patent and unified court have been signed in Europe; but neither has yet entered into force because the requisite thirteen countries have not yet ratified the agreements.[18]

Both the PCT and the EPC were directed to consolidating the international process of patent prosecution. In the 1980s and 1990s, however, the targets of reform changed; the international business community began to tackle the more ambitious project of harmonization, i.e., creating uniform substantive standards of intellectual property protection. The change in goals had a number of catalysts. Intellectual property was increasing in value and was beginning to take on a more central role in business planning and strategy. The establishment of the Federal Circuit in 1982 was both a consequence of this trend, and a partial cause of its continuation. Moreover, world trade was becoming increasingly important to the economies of the United States and other industrialized nations. Markets in developing countries were no longer insignificant, and these countries had traditionally resisted strong intellectual property protection. This led to a new wave of harmonization that culminated in an historical treaty signed in 1995.

17. *See* EUROPEAN PATENT OFFICE, *Member States of the European Patent Organization*, https://www.epo.org/about-us/foundation/member-states.html [https://perma.cc/VDL5-R6AM] (last visited Mar. 2, 2020); WORLD INTELLECTUAL PROP. ORG., *The PCT Now Has 153 Contracting States*, https://www.wipo.int/pct/en/pct_contracting_states.html [https://perma.cc/GPF5-RU4T] (last visited Mar. 2, 2020).

18. *See generally* Council Directive 16351/12 of Jan. 11, 2013, Agreement on a Unified Patent Court.

B. Uruguay, 1995

To pursue harmonization, the business community in the United States and Europe needed a new institutional structure. This community thought that the existing structure—the World Intellectual Property Organization—would not do. WIPO was created in 1970 as the successor organization to the United International Bureau for the Protection of Intellectual Property, which had been established in 1893 to administer the Paris Convention and the Berne Convention for the Protection of Artistic and Literary Works, the primary international copyright treaty created in 1886. WIPO's work in patent law had largely been limited to educational efforts; the many newly formed nations from the 1960s and 1970s were thought to need instruction on the ways and means of national patent systems. Then in 1974, WIPO officially became a specialized agency of the United Nations—a forum not thought to be particularly friendly to Western business interests.

Aware of the increasing importance of intellectual property and of WIPO's slow progress in harmonization throughout the 1970s and 1980s, the business community was on the lookout for an alternative institutional structure for harmonization. When influential CEOs from twelve large U.S. companies came together to strengthen IP rights, they settled on a novel solution: grafting IP onto issues of international trade. The reasoning behind formation of this powerful club, known simply as the IP Committee, was sound. The members knew that a major new trade treaty was in the works under the auspices of the General Agreement on Tariffs and Trade (GATT). And they knew that corporate interests had much greater clout in the GATT negotiation process than they did at WIPO. Thus was born the germ of the idea that later grew into the GATT treaty on Trade Related Aspects of Intellectual Property (TRIPs).

The details of the "IP as trade" campaign are quite interesting. The complex effort to sell the idea to U.S. negotiators, national governments, and professional groups shows just how much the members of the IP Committee valued stronger IP rights. While many argue that negotiators from developing countries did not fully perceive the import of what they were agreeing to in the IP area, it is also true that lowered tariffs for agricultural and manufacturing exports were a powerful incentive to strengthen national IP regimes. Regardless of the process, and putting aside for a moment whether TRIPs was in the self-interest of many of its signatories, the end result is quite significant. TRIPs represents a concession of sovereignty in the IP

field on the part of many countries that goes very far beyond the limited national impact of the Paris Convention of 1883. A good deal of national discretion was traded away in exchange for membership in the TRIPs club.

The catalogue of TRIPs minimum requirements is long and well-known. The Agreement ended the wide variation in the treatment of pharmaceutical inventions across the world, to name one much-noted example. But perhaps the biggest change to international IP law was in enforcement. The WTO Dispute Settlement Board (DSB) is authorized to receive complaints, arbitrate disputes, and—most importantly—assess compensatory remedies for violations of TRIPs. The Paris Convention, designed to appeal to national self-interest in a limited sphere, never really needed much enforcement. But the much meatier TRIPs obligations, it was understood, would be a much more tempting target for corner-cutting or outright defiance. And so, the DSB was created.

DSB remedies can take many forms, as can be seen from a sampling of IP-related cases. In the infamous "US – Section 110(5) of the U.S. Copyright Act" case, the passage of a revised public performance provision in U.S. copyright law was successfully challenged by the European Union.[19] Shrinking the public performance right, by eliminating royalties from some business establishments, harmed holders of composition copyrights in the EU.[20] The penalty was a one-time payment of $2.3 million for three years' worth of harm, together with a formal demand that the United States amend its Copyright Act to come back into compliance with TRIPs.[21]

A few years after the DSB decision, the United States Trade Representative (U.S.T.R.), responsible for TRIPs matters, reported that it was still in consultation with Congress. Presumably, those consultations are ongoing in a formal sense, but not in any real sense; there, the matter has stood for over thirteen years, with the U.S.T.R.

19. *See* Dispute Settlement, *United States—Section 110(5) of the US Copyright Act—Recourse to Arbitration Under the* DSU, WTO Doc. WT/DS160 (Nov. 9, 2001), https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds160_e.htm [https://perma.cc/9NT8-HT2F].

20. *See* WORLD TRADE ORG., *US – Section 110(5) Copyright Act (DS160)*, *in* WTO DISPUTE SETTLEMENT: ONE-PAGE CASE SUMMARIES (1995–2018) 66 (2019).

21. The EU suspended further arbitration because the parties were working toward a mutually satisfactory agreement. Dispute Settlement, *supra* note 19 ("The United States has thereafter presented status reports to the DSB informing that the US Administration will work closely with the US Congress and will continue to confer with the European Union in order to reach a mutually satisfactory resolution of this matter.").

webpage still reporting this as a "pending" matter.[22] The lesson being that, though TRIPs has more teeth than the Paris Convention, it is not exactly a tiger. It is more like an eight-week-old kitten. Even so, some consequences are better than no consequences. Nations do not yield sovereignty in large dollops, and the sovereignty they do cede is at times meted out in little dribs and drabs. Such is the pace of progress in the world of IP harmonization.

Although the post-TRIPs amendments in domestic U.S. law are important, they pale in comparison to the revolutionary changes the agreement makes to the intellectual property regimes of many developing countries. To summarize the highlights, all signatories of the Uruguay Round treaty (which, under the agreement, become members of the newly created World Trade Organization) are obligated to:

- Include virtually all important commercial fields within the ambit of patentable subject matter, a major change for those countries that have traditionally refused to enforce pharmaceutical patents on public health/access grounds;
- Test patent applications for the presence of an "inventive step" and "industrial application," which are expressly defined as synonymous with the U.S. requirements of, respectively, nonobviousness and utility;
- Curtail the practice of granting compulsory licenses for patented technology, by (1) requiring a good faith attempt to license voluntarily, (2) limiting duration, (3) requiring termination if conditions change, and (4) requiring compensation, subject to judicial review.[23]

22. *See Section 110(5) of US Copyright Act*, OFF. OF THE U.S. TRADE REP., https://ustr.gov/issue-areas/enforcement/dispute-settlement-proceedings/united-states-section-1105-us-copyright-ac [https://perma.cc/5MSZ-94VB] (last visited Mar. 2, 2020) ("Dispute Status: Pending"); *see also* Dispute Settlement, *supra* note 19 (noting the "[c]urrent status" of DSB 160 as "Authorization to retaliate requested (including 22.6 arbitration)"). This is all a little like saying (hypothetically—this is made up) that the 1976 U.S. Presidential election is still "pending" because the Socialist Workers Party never conceded the result, unhappy that its official .2% vote tally did not match its own internal calculations that it had instead earned .3%.

23. *See* Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 27, 31, 33 I.L.M. 1197 (1994) [hereinafter GATT]. This Article has since been amended by the inclusion of new Article 41bis, which permits WTO member states greater discretion in requiring compulsory licensing of patents covering drugs that are to be exported to countries meeting the original

TRIPs also requires signatory nations to establish certain civil and administrative procedures; to provide parties access to evidence held by opposing parties; to make available injunctions, damages, preliminary relief, and other remedies for acts of infringement; to impose certain border control measures; and to establish criminal penalties in the case of counterfeited copyrighted goods.[24] In short, TRIPs thoroughly regulates the domestic intellectual property law of the signatory nations.

II. SOVEREIGNTY AFTER PARIS: INTERNATIONAL PRIORITY AND INVENTION OWNERSHIP

We can trace out the effects on sovereignty of the two waves of harmonization, through the device of case studies. For the Paris Convention, we consider the controversial provision on ownership of the international priority right in Article 4. For TRIPs, we use a current dispute over the Canadian utility standard as applied to pharmaceutical patents. We start with the first example.

A line of European cases has held that the inventive entity that files a priority application must have full assignment of the international priority right on the date of filing. In these rulings, any later-added inventor must also have assigned his, her, or their priority right to the invention claimed in the priority application. And all these assignments must be in hand by the time of the priority filing. Under these cases, a U.S. inventor who has assigned his or her entire "right, title and interest" to an invention, or who is under a duty to assign by virtue of a pre-invention employment agreement, is *not* properly within the inventive entity making the priority filing. This is because these cases require an explicit post-invention, pre-priority filing of the

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compulsory licensing criteria of Article 31. *See Amendment of the TRIPS Agreement*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm [https://perma.cc/LM5W-HDPY] (last visited Mar. 2, 2020) (providing a list of signatory nations under TRIPs that have to date accepted the Article 31bis amendment; when two-thirds of the members accept, it will take effect); *see also* Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 928 (2007). *But see* Ann Marie Effingham, *Trips Agreement Article 31(b): The Need for Revision*, 46 SETON HALL L. REV. 883, 884 (2016); Dina Halajian, *Inadequacy of TRIPs & the Compulsory License: Why Broad Compulsory Licensing Is Not a Viable Solution to the Access to Medicine Problem*, 38 BROOK. J. INT'L L. 1191, 1192 (2013) (critiquing TRIPS).

24. *See* GATT, *supra* note 23, at arts. 42–61.

international priority right.[25] Without that explicit assignment, the assignee that files a foreign counterpart to a U.S. application is missing rights from one inventor at the time of the U.S. priority filing. And an assignment that comes after the U.S. priority filing comes too late because then the inventive entity that owned rights at the time of the priority filing is a different inventive entity than the one that files the foreign counterpart applications.

A variation on this occurs when a patent applicant makes changes in a patent's named inventors after the international priority filing. Once again, this causes a mismatch between the inventive entity that filed the original priority application and the entity that files the foreign counterparts. In many of these cases, the later-added inventors did not make an explicit assignment of rights in the specific claimed invention covered in the priority application as of the time of the priority filing—because they were not named inventors as of that time. In other words, the only way to have a valid application in Europe, based on a first Paris Convention filing in another country, is to have received assignments from inventors who did not know they were inventors at the time of the initial Convention filing. This is of course unlikely.

These scenarios have led to loss of the international priority date. After newly-named inventors have assigned their international priority right, the application can be filed again. But it will not receive the original priority date. Its effective date will be the date of the second (post-assignment) filing. This can be deadly. Intervening prior art—patents and scientific publications by others, made available after the initial (invalid) international priority date but before the new European filing date—can kill the patent.

This result frustrates the expectations of U.S. patent owners. First, under U.S. law, the standard assignment of all "right, title and interest" in an invention works an assignment of the international priority rights.[26] And second, under the rules of application ownership

25. *See, e.g.*, Tribunaux de grande instance [TGI] [ordinary court of original jurisdiction] Paris, Jan. 30, 2009, PIBD 2009, 899, III, 1162 (failing to explicitly mention international priority right in assignments meant corporate applicant for French national patent did not have ownership rights at time of filing and hence the French counterpart did not merit the benefit of the U.S. priority filing date).

26. *See, e,g.*, Popp v. Newport News Shipbuilding & Dry Dock Co., 5 F.2d 962, 962 (3d Cir. 1925).

> [W]e concur in the opinion of the Circuit Court, that Louis, having *sold* this *invention*, and doubt existing whether the purchasers would obtain a patent for it, intended by this contract and by exhibit D to secure to them the benefit

in the United States, pre-assignment of rights (typically in an employment agreement signed at commencement of employment) vests all future ownership in the corporate employer.[27] Hence, U.S. law presumes that the international priority right for any later-made and later-claimed invention is already "pre-owned" by the corporate employer. This is especially important in the absence of an explicit assignment of rights in a specific and just-made invention. These explicit assignments are customary, even when a blanket pre-assignment is in place; but sometimes, as with an inventor not named in the first (priority) application, no explicit assignment is obtained before the first filing, and the employer must rely on blanket pre-assignments. European case law considers the international priority right to be a distinctive and independent right that only passes when an inventor explicitly assigns that right *by name* after an invention and before the first priority filing. Failure to meet this condition means that the applicant loses the priority date, therefore sacrificing the chief benefit accorded compliance with the Paris Convention.

The dispute between European and U.S. patent interests involves a number of legal sources, but the genesis of the issue is Article 4 of the Paris Convention, which looks like this:

> A.
>
> (1) Any person who has duly filed an application for a patent, . . . in one of the countries of the Union, or his successor in title, shall enjoy, for the purpose of filing in the other countries, a right of priority during the periods hereinafter fixed.
>
> (2) Any filing that is equivalent to a regular national filing under the domestic legislation of any country of the Union or under bilateral or

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> of the exclusive *use* of that invention . . . so long as [it] was protected by *any patent* founded on his right [as] an inventor.

Mason & Hamlin Organ Co., 92 U.S. 724, 727–28 (1875) (fourth emphasis added); RIDSDALE ELLIS, PATENT ASSIGNMENTS 400 (3d ed. 1955) ("There seems to be one essential requirement for the passing of foreign rights without express mention thereof, viz., an assignment of the *invention*.").

27. *See* FilmTec Corp. v. Allied–Signal Inc., 939 F.2d 1568, 1572 (Fed. Cir. 1991) (explaining that "[o]nce the invention is made and [the] application for [a] patent is filed, . . . legal title to the rights accruing thereunder would be in the assignee," under an employment agreement automatically vesting title in the employer at the moment an invention is made, via a clause saying the new employee "hereby assigns" his or her interest in future inventions). In addition, U.S. law will imply an obligation to assign invention rights even when an inventor has not signed an employment agreement, so long as the inventor was, as the cases say, "employed to invent." *See, e.g.*, Teets v. Chromalloy Gas Turbine Corp., 83 F.3d 403, 407 (Fed. Cir. 1996).

> multilateral treaties concluded between countries of the Union shall be recognized as giving rise to the right of priority.
>
> (3) By a regular national filing is meant any filing that is adequate to establish the date on which the application was filed in the country concerned, whatever may be the subsequent fate of the application. . . .
>
> D.
>
> (1) Any person desiring to take advantage of the priority of a previous filing shall be required to make a declaration indicating the date of such filing and the country in which it was made. Each country shall determine the latest date on which such declaration must be made.[28]

These parts of the Paris Convention establish two principles. First, under Article 4(A)(3), the appropriate law for determining whether a patent application establishes a right to priority is *the law of the country of filing*. Article 4(A)(3) provides that the right of priority attaches to *applications* and not merely to specific "persons," as under Article 4(A)(1). It is true that Article 4(A)(1) says that "[a]ny person who has duly filed an application for a patent . . . shall enjoy . . . a right of priority."[29] But Article 4(A)(2) says that "[a]ny filing that is equivalent to a regular national filing *under the domestic legislation of any country of the Union* . . . shall be recognized as giving rise to the right of priority."[30]

Under cases such as *Edwards Life Sciences AG v. Cook Biotech, Inc.*,[31] European courts have dealt with the following situation. A priority application is filed naming multiple inventors. But at the time of the priority filing, one or more of those inventors has not yet explicitly assigned his or her foreign priority right in the specific invention to the employer/assignee. The holding in *Edwards* was that the phrase "[a]ny person" in Article 4(A)(1) means that the right of priority attaches only to the legal person having explicit ownership of that right on the date of the priority filing.[32] Thus, under the facts of *Edwards* and similar cases, assignment of the priority right after the date of priority filing comes too late: the "person" who owns the right

28. Paris Convention for the Protection of Industrial Property, *supra* note 10, at art. 4.

29. *Id.* at art. 4(A)(1).

30. *Id.* at art. 4(A)(2).

31. *See generally* [2009] EWHC (Pat) 1304, [2009] F.S.R. 27 (appeal taken from Eng.).

32. *See id.* at [92]–[93].

after the subsequent assignment is a different "person" than the entity who filed the priority application.[33]

The problem with this interpretation is that it completely ignores the remainder of Article 4. The gist is this: when Article 4(A)(1) says "[a]ny person who has *duly filed* an application for a patent, . . . shall enjoy, for the purpose of filing in the other countries, a right of priority," we must look to the remainder of Article 4 to see what "duly filed" means.[34] In a nutshell, it means: filed in accordance with the domestic law of the country of the priority filing. Because domestic U.S. law does not require a separate and specific assignment of the international priority right, no such assignment is necessary to "duly file" a viable application in the United States. Hence, cases like *Edwards Life Sciences* are wrong.

Article 4(A)(2) says that the way to decide whether a "person" has "duly filed" an application is to see if the application by that person "is equivalent to a regular national filing under the domestic legislation of any country of the Union."[35] If the filing under 4(A)(2), by the person under 4(A)(1), is "equivalent to" a regular national filing, then 4(A)(2) says that filing "shall be recognized as giving rise to the right of priority."[36]

It is perfectly acceptable in the United States to file an application without having in place an explicit assignment of rights to that specific claimed invention.[37] The inventor's oath or declaration

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33. *See also* Case T-0062/05, GE Plastics Japan K.K. v. Koninklijke DSM N.V., 2006 EPO § 3.13, p. 31, *available at* http://www.epo.org/law-practice/case-law-appeals/pdf/t050062eu1.pdf [https://perma.cc/MF7G-ER36] (decision under EPC Article 87, the EPC version of Paris Article 4). Holding that a transfer of rights between GE Japan and parent company General Electric, Inc., had not worked a transfer of priority rights in the Japanese application on which the EPO application in question was based because "although [the purported transfer document] refer[ed], in general, to foreign patent applications[, it] fails to specify explicitly the countries for which General Electric should indeed file a patent application." *Id. But see* Case T-0205/14, Teva Pharm. Indus. Ltd. v. Hexal AG, 2015 EPO, at § 3.7.6, p. 43, *available at* http://www.epo.org/law-practice/case-law-appeals/pdf/t140205eu1.pdf [https://perma.cc/U89A-RYKY] ("[T]he right of priority derived from the US provisional applications . . . had been transferred to the respondent [by operation of the Israeli service invention statute] before the date of filing of the international application . . . .").

34. Paris Convention for the Protection of Industrial Property, *supra* note 10, at art. 4(A)(1) (emphasis added).

35. *Id.* at art. 4(A)(2).

36. *Id.*

37. *See* 37 C.F.R. § 3.73(c) (2012) (requiring proof of chain of title prior to action by assignee such as a response to a rejection; title may be proven, e.g., by

simply requires a statement that the named inventors believe they are the true inventors, and that they understand the contents of the application.[38] It is tradition to include a copy of an explicit assignment of rights to an invention, but it is not required; and of course, the traditional assignment of "all right, title and interest" to the invention is sufficient to demonstrate that the assignee has full rights in the invention and is authorized to prosecute the application.

Moreover, U.S. prosecution may proceed even without the cooperation of an inventor, let alone without an explicit assignment. As the Federal Circuit said in *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*:

> Instances of inventors refusing even to cooperate in obtaining issuance of a patent to be owned by an assignee are common and machinery is provided in 37 C.F.R. § 1.47 to deal with them. Section 1.47 provides that *either a joint inventor or a proper assignee may file the application without the consent or signature of the inventor*, just so the oath or declaration is accompanied by a petition including proof of pertinent facts. It is clear, therefore, that the PTO does not allow the inventor to erect that type of obstacle to obtaining patent protection. Such forethought is necessary, as otherwise an inventor's changed self interest might nullify a proper assignment.[39]

Under U.S. law, the person who files a priority application may also make technical corrections to the patent's list of inventors.[40] Doing so does not sacrifice the filing person's filing date. So, under the "domestic legislation" of the United States (i.e., Article 4(A)(2)), a person may "duly file[]" an application which makes it a "regular national filing," even if the inventive entity on the application changes after the initial filing. The only requirement is that the person who files must be able to show that it has ownership rights to the work of each named inventor of the claimed invention.

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evidence of an assignment from the named inventor(s), any time prior to assignee action—which typically does not begin until a year or more after filing).

38. 37 C.F.R. § 1.63 (2015) (explaining an "[i]nventor's oath or declaration").

39. Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 447 (Fed. Cir. 1986) (emphasis added), *cert. denied*, 484 U.S. 823 (1989). The situation in *Bausch & Lomb* is now handled under 37 C.F.R. § 1.64 (2012) (providing for a substitute statement of facts in lieu of inventor's oath or declaration). The rules regarding assignee prosecution of applications were liberalized under the AIA.

40. *See* 37 C.F.R. § 1.41(b) (2015) and 37 C.F.R. § 1.48(a) (2013) (providing original filing and change of inventorship provisions); *see also* Manual of Patent Examination Procedures § 6.02.01(c) (providing an explanation of "[c]orrection of Inventorship").

In sum, a "regular national filing" under Article 4(A)(2) of the Paris Convention need not, in the United States, come prior to assignment of the priority filing right. Article 4(A)(3) of the Convention says: "By a regular national filing is meant any filing that is adequate to establish the date on which the application was filed in the country concerned, whatever may be the subsequent fate of the application." A U.S. application made prior to assignment of a priority right is unquestionably a "filing that is adequate to establish the date on which the application was filed."

Article 4(A)(2) and 4(A)(3) arguably establish that the law of the *country of filing* is the proper place to look to determine whether the filing made by the "person" under Article 4(A)(1) is capable of establishing a right of priority. Article 4(A)(2) provides that "the domestic legislation of any country of the Union" controls, while Article 4(A)(3) states that it is "adequate to establish the date on which the application was filed in the country concerned."[41] So, the problem with cases such as *Edwards* is that they look at Article 4(A)(1) in isolation instead of in context.

Left up to me, I would interpret this to mean that the priority right does indeed attach to a "person" under Article 4(A)(1), but this is defined as a "person" is only protected if he or she makes a filing "adequate" to establish a priority date *under the law of the country of filing*. If the person who files later receives an assignment of the international priority right—or later adds new named inventors—the original filing is no less "adequate." Even if the original-filing person ends up with more rights, or ends up being a different inventive entity, that person still made a valid priority filing. Domestic law says so, and the Paris Convention must follow this law. If the domestic jurisdiction is not hyper-technical with respect to the pre-filing assignments or post-filing adjustment in the inventive entity, Article 4 says this must be honoured.

Therefore, if under U.S. law the original priority filing made in the United States is made by a "person" who has the right to file an application *under U.S. law* on the date of the priority filing, then that "person" (and/or its successors) properly obtains and possesses a right to priority. And so, references appearing after this priority date are not prior art to the invention claimed in the priority application.

41. Paris Convention for the Protection of Industrial Property, *supra* note 10, at art. 4(A)(2)–(3).

A. Treaty Context and Interpretation

Despite what I think is a perfectly plausible case for my reading of Article 4, I concede that there is room for a different approach. It might well be argued that in close cases, the "minimalist" nature of the Paris Convention's surrender of sovereignty should come into play. Under this approach, even if I am right about the ultimate meaning of Article 4, considerable deference is due to national courts in interpreting what it means. The upshot, if this approach be taken, is this: only a national court interpretation that is facially impossible or absurd should result in condemnation or correction at the level of the Paris Union. A national court that interpreted the one-year priority period to mean nine months, for example, would fit this description. Beyond this quite unusual case, national courts would have to be given the final word on what the Paris Convention means.

Another way to put this is that important domestic policies should be allowed to influence Treaty interpretations under a minimalist treaty such as Paris. It is evident from the European cases that the courts there consider the international priority right to be a distinctive "stick" in the inventor's bundle of rights. They also seem to take the view that, to favor the situation of inventors, only explicit assignments of rights should be allowed to take away a right from an inventor. The latter view especially is consistent with longstanding continental traditions. Under a pro-personality—or Kantian—approach to IP rights, the individual creator is the focus of attention and the favoured party before the courts. It is natural, when taking this view, to disfavor implied transfers of creators' rights; this tends to divest creative people of the very rights they are thought to have earned through the act of creation. Thus, only when it is crystal clear that an inventor meant to surrender rights to an employer should such a transfer be given effect.

Quite pragmatic arguments—of a distinctly American flavor—may be made on the other side of this issue.[42] The efficiency gains that follow from liberal concentration of rights in a single entity are well understood, and legal policy that favors this has been said to be superior to a "pro-inventor" strain of thought. Yet the whole point here is that this quite plausible approach must be limited to the U.S. context from which it springs. Because the Paris Convention does not ask much in the way of ceding national sovereignty, other sovereign

42. *See* Robert P. Merges, *The Law and Economics of Employee Inventions*, 13 HARV. J.L. & TECH. 1, 2–3 (1999) (presenting one such set of arguments).

members of the European Convention might be convinced to recognize that their domestic policies ought not be binding outside their home jurisdiction. This is, at least, a reasonable (if not unquestionably superior) approach to treaty interpretation.

III. SOVEREIGNTY AFTER URUGUAY/TRIPS: CANADIAN UTILITY DOCTRINE[43]

Having completed a case study under the Paris Convention, let us now take up a case for contrast. How should treaty interpretation work under the 1995 TRIPs Agreement? To see, we will use a current dispute over the utility requirement in Canada.

In 2014, Eli Lilly Company charged the Government of Canada with violating the substantive patent harmonization standards of the North American Free Trade Agreement (NAFTA).[44] Lilly's complaint was that a newly developed version of the traditional utility requirement raised the standard for patentability far beyond Canada's historical standard (in place when NAFTA and TRIPs were signed), and in fact beyond the consensus standard applied throughout the world.[45] The text on which Lilly's challenge is based, Article 17 of

43. Disclosure: I was an expert witness on U.S. patent law for Eli Lilly in this arbitration. *See* Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Expert Report of Professor Robert P. Merges, ¶ 1 (Sept. 29, 2014); Transcript of Direct Presentation and Testimony of Professor Merges, Eli Lilly & Co. v. Gov't of Canada, ICSID Case No. UNCT/14/2, 1278-1417 (June 3, 2016) [hereinafter Eli Lilly Arbitration]. *See generally* Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Second Expert Report of Professor Robert P. Merges (Sept. 10, 2015) [hereinafter Eli Lilly Second Expert Report].

44. *See* Eli Lilly Arbitration, *supra* note 43, at ¶¶ 3–4; *see also* North American Free Trade Agreement art. 1709(1), Dec. 17, 1992, 32 I.L.M. 289 ("[E]ach Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application."). The final phrase—"capable of industrial application"—is explicitly defined as a precise synonym for "utility." *Id.* It is this final requirement—"capable of industrial application"—that is at issue in the Eli Lilly case. *Id.* Note that NAFTA is currently scheduled to be replaced by a new U.S.–Mexico–Canada Agreement (USMCA) negotiated in 2018 but not yet in effect. *See* OFFICE OF THE U.S. TRADE REPRESENTATIVE, *United States-Mexico-Canada Agreement*, https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement [https://perma.cc/K6DR-9H58] (last visited Mar. 2, 2020).

45. *See* Eli Lilly & Co. v. Canada, Case No. UNCT/14/2, Claimant's Memorial, ¶¶ 60–61 (Sept. 29, 2014) [hereinafter Claimant's Memorial]. Lilly also argued that the actions of the Canadian courts violated other provisions of NAFTA. *See id.* A "Memorial" in a UNCITRAL or NAFTA arbitration is essentially a brief for a party to the arbitration.

NAFTA, is identical to the substantive harmonization standard in TRIPs.[46] So, Lilly's request could as easily have been framed as a challenge under TRIPs. Because TRIPs has much greater world coverage, I will analyze the Canadian utility doctrine as an alleged violation of TRIPs.[47]

The Eli Lilly case against Canada raises a number of complex and important issues. At its heart, however, it poses a distinct challenge to Canadian national sovereignty: a private U.S.-based company is arguing that Canadian court interpretation of Canada's patent statute has deviated from Canada's treaty commitment to TRIPs. This is a striking claim. Can it be justified? Can Canada really have surrendered so much sovereign discretion in signing the TRIPs treaty that its own domestic courts are constrained in their development of statute-based case law under its national patent act?

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46. TRIPS Article 27.1 states, "Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." GATT, *supra* note 23, at art. 27.1. Footnote five, which comes at the end of this sentence, reads, "For the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively." *Id.* NAFTA Article 1709(1):

> Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful", respectively.

North American Free Trade Agreement, *supra* note 44, at art. 1709(1).

47. There are some procedural differences between the treaty enforcement mechanisms of NAFTA and TRIPS. NAFTA settles disputes through state-party investor dispute settlement arbitration panels, such as the one that will decide *Eli Lilly v. Canada*. *See* North American Free Trade Agreement, *supra* note 44, at 642–44. TRIPS on the other hand uses a Dispute Settlement Body, which is limited to state vs. state disputes. *See* WORLD TRADE ORG., *Understanding the WTO: Settling Disputes*, https://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm [https://perma.cc/N7ZR-JUUY] (last visited Mar. 2, 2020). At times, however, private investors may invoke TRIPS rules and norms in the context of bilateral investments treaties (BITs), under which state-investor disputes are often handled in arbitration or arbitration-like proceedings. *See* Henning Grosse Ruse-Kahn, *Litigating Intellectual Property Rights in Investor-State Arbitration: From Plain Packaging to Patent Revocation*, INV. TREATY NEWS (Nov. 18, 2014), http://www.iisd.org/itn/2014/11/18/litigating-intellectual-property-rights-in-investor-state-arbitration-from-plain-packaging-to-patent-revocation/ [https://perma.cc/ED7J-R5D5].

On the other hand, if court-developed doctrine is unreachable under TRIPs, then what exactly does harmonization mean? If courts are free to interpret and adapt domestic law in the same way they always have, does TRIPs have any binding force or practical effect?

In what follows I try to answer these questions. My position has two parts. First, only an extreme and egregious departure from harmonized rules will warrant a finding that TRIPs has been violated. Second, when this violation emanates from national courts, the nation as a whole is no less responsible for a remedy under TRIPs. A signatory such as Canada, in other words, must maintain adherence to the TRIPs treaty, whether treaty violations emanate from executive action, legislation, *or* court decisions. Because IP law is made at all levels of government, all levels must be held accountable for treaty violations. Put differently, there is nothing sacred about court-made law; if it results in a deviation from agreed-upon standards, it is still a violation of the treaty. And it must be remedied.

A. Why Canadian Utility Doctrine Arguably Violated TRIPs

Canadian patent law has deviated radically from traditional principles in place in Canada, the United States, and elsewhere for many years.[48] Until the Canadian Supreme Court changed course recently, the basic standard of practical utility had been replaced in Canada with an imposingly high evidentiary standard for proof of utility, which goes under the name of the "promise of utility" doctrine.[49]

Under the promise of utility doctrine, which was created in Canadian case law beginning in 2005, the invalidity rate for pharmaceutical patents far exceeds any outcome ever seen under traditional utility doctrine. Of the sixty-three pharmaceutical patent

48. *See generally* Prentice v. Dominion Rubber Co., [1928] Ex. C.R. 196 (Can. Ex. Ct.) (emphasizing that a "slight amount" of utility is all that is required).

49. The "promise utility" doctrine that was the subject of the Eli Lilly NAFTA arbitration was—subsequent to resolution of that arbitration—unilaterally overruled by the Canadian Supreme Court. *See* AstraZeneca Canada Inc. v. Apotex Inc., [2017] 1 S.C.R. 943, ¶ 55 (Can. S.C.C.).

> The [Canadian Patent] Act does not prescribe the degree or quantum of usefulness required, or that every potential use be realized—a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date.

Id. Thus although Eli Lilly ultimately lost in the NAFTA tribunal, its position prevailed soon afterward in the highest Canadian court.

cases since 2005 in which utility was raised as an invalidity defense, patents were invalidated in twenty-five cases. This invalidity rate of almost 40% is striking compared to historical norms. Utility is routinely described as a "low bar" or "minimalist standard." And even though chemical and pharmaceutical cases form a large portion of those raising a serious utility issue, nothing like a 40% invalidity rate has ever been seen with this doctrine in any country that employs it.

This is especially striking when comparing non-pharmaceutical cases in Canada. None of the eight non-pharmaceutical cases in Canada since 2005 have resulted in invalidation. This is not unusual; U.S. case law goes years without the report of a patent invalidated for lack of utility. Common sense, as well as expert statistical significance testing, shows that the Canadian utility doctrine is an extreme and unprecedented variant of traditional tests.[50] It is extreme enough, in fact, that it quite arguably represents a deviation from the TRIPs treaty. The treaty requires that Canada and the other two signatory nations adhere to this principle: "[P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are . . . capable of industrial application," i.e., that they are useful.[51] When a new, unprecedented super-utility test is introduced that goes radically far beyond the traditional test (in place when the Treaty was signed), that new test violates the treaty obligation. Patents are *not* available in Canada when a claimed invention is shown to be useful under traditional standards. Inventions must be super-useful (i.e., shown to fulfill the "promise" inherent in the patent specification) to be patentable there. TRIPs forbids this.

How does the "promise" doctrine work? It was the basis, for example, of the Canadian court decision invalidating Eli Lilly's Canadian atomexetine (Straterra) patent (Number 2,209,735) ('735 patent), which covered treatments of Attention Deficit Hyperactivity Disorder (ADHD). That patent claimed, using a standard pharma patent claim format, "A method of treating attention-deficit/hyperactivity disorder comprising administering to a patient in need of such treatment an effective amount of tomoxetine."[52] The patentee introduced evidence of an FDA Phase I pilot study of twenty-

50. *See* Eli Lilly & Co. v. Canada, ICSID Case No. UNCT/14/2, Expert Report of Professor Bruce Levin (Sept. 7, 2015) (reporting raw data and statistical significance tests).

51. GATT, *supra* note 23, at art. 27.1.

52. Treatment of Attention Deficit/Hyperactivity Disorder, U.S. Patent No. 5,658,590, col. 4 l. 24–26 (filed Jan. 11, 1995) (issued Aug. 19, 1997).

one patients treated with atomexetine over a period of seven weeks.[53] Eleven of the twenty-one patients studied showed a 30% or greater reduction in ADHD symptoms during the study.[54]

Traditional utility standards do *not* require FDA studies of any kind to demonstrate utility.[55] The mere *announcement* of a pending Phase I study is taken, under the USPTO MPEP, as per se evidence of utility. Yet the Canadian courts found that (1) the '735 patent "promises" treatment of *chronic* ADHD lasting over a long period of time;[56] and (2) the pilot study, showing only short-term efficacy, failed to prove the "promised" utility.[57] The proof of efficacy asked for under

53. T. Spencer et al., *An Open-label, Dose-ranging Study of Atomoxetine in Children with Attention Deficit Hyperactivity Disorder*, 11 J. OF CHILD & ADOLESCENT PSYCHOPHARMACOLOGY 251, 251 (2001).

54. *Id.*

55. *In re* Brana, 51 F.3d 1560, 1564 (Fed. Cir. 1995). U.S. law also does not require any proof of a high degree of efficacy, either; only bare "workability" is called for. *See, e.g.*, Transco Prods. Inc. v. Performance Contracting, Inc., No. 96-1336, 1997 U.S. App. LEXIS 21294, at *5 (Fed. Cir. Aug. 13, 1997) ("[O]nly when a claimed invention has total incapacity to achieve what is claimed is it deemed inoperable."); *see also* Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft, 945 F.2d 1546, 1553 (Fed. Cir. 1991) ("It is not required that a particular characteristic set forth in the prosecution history be achieved in order to satisfy § 101 [utility].").

56. Novopharm Ltd. v. Eli Lilly & Co., [2010] F.C. 915, ¶ 93 (Can. Fed. Ct.), *aff'd*, [2011] F.C.A. 220 ("[U]tility is assessed against the inventive promise of the patent. An invention is only useful if it does what the inventor claims it will do. In this case the requirement of utility would be met if, at the Canadian filing date of the '735 Patent, there was sufficient evidence that atomoxetine was clinically useful in treating some patients with ADHD or, alternatively, that such efficacy could be soundly predicted.").

57. Novopharm Ltd. v. Eli Lilly & Co., [2011] F.C.A. 220, ¶ 36 (Can. Fed. Ct.). The Court of Appeals, affirming the trial court, made this clear: "[When the trial court judge said that treatment of chronic ADHD was 'implicit in the promise' made, to treat ADHD,] he was simply interpreting what 'treatment' means in this patent in the context of ADHD, a chronic disorder requiring sustained treatment." *Id.* at ¶ 21. The heightened standard being applied was also evidence from the Court of Appeals' statements about the degree of utility required to meet the "promise" doctrine:

> A POSITA [person of skill in the art] would thus understand the promise to mean that atomoxetine will alleviate the symptoms of the disorder in some patients to a clinically meaningful extent. This is not to say that the promise means that clinicians will necessarily prescribe atomoxetine for their patients, because there may be more effective medicines available on the market. The promise does mean, however, that atomoxetine would be regarded by a physician as a realistic option for the treatment of ADHD.

Id. at ¶ 23.

Canadian doctrine is far above any recognizable, traditional test applied in Canada before 2005, and applied elsewhere to this day.[58]

One case doesn't make for a TRIPs violation, of course, but this is quite representative. Scholars and practitioners in Canada noted the rise of the unprecedented "promise" doctrine and the dire consequences for pharmaceutical patents that it entailed. The statistics quoted earlier show these observers were not out of line. The simple fact is that the "promise" doctrine is a complete aberration with respect to worldwide utility tests.

Further proof can be found in this fact. Another successful Eli Lilly product, Zyprexa (olanzapine), treats depression. Lilly filed patent applications in eighty-one separate countries, given the potentially large market for depression treatments.[59] The patent was granted (found valid) in every country, and challenged for invalidity in twenty-four countries. It was found valid after challenge in all

58. *See id.* Neither of the Canadian court's statements is consistent with the traditional test of utility. In the U.S. case of *Cross v. Iizuka*, for example, the Federal Circuit specifically rejected the argument that the invention in question lacked utility due to the absence of proof of therapeutic (i.e., clinical) effectiveness:

> Cross' position is that the stated purpose or sole contemplated utility of the invention of Iizuka is to provide a novel class of compounds which provide "practical use" as "therapeutical medicines for diseases caused by thromboxane A_2," and therefore the Board erred in its finding as to the stated utility of the Japanese priority application.

753 F.2d 1040, 1045 (Fed. Cir. 1985). The Federal Circuit held,

> The Board has found that the Japanese priority application of Iizuka disclosed a practical utility for the [claimed] compounds . . . in the inhibition of thromboxane synthetase in human or bovine platelet microsomes, i.e., an *in vitro* utility. Clearly, this stated utility as found by the Board has been delimited with sufficient specificity to satisfy the threshold requirements of [earlier cases]. The stated utility of the Japanese priority application is directed to a specific pharmacological activity possessed by the [claimed] imidazole derivatives . . . the inhibition of thromboxane synthetase *in vitro*.

Id. at 1048. It is manifest that no responsible doctor would extrapolate from effectiveness in the lab against "platelet microsomes" to a fully safe and effective compound to administer to a suffering human being. *Id.* Yet that is the standard set up by the promise doctrine in the context of this patent: the claimed compound must be "regarded by a physician as a realistic option for the treatment of ADHD." *Novopharm*, [2011] F.C.A. 220, at ¶ 36. This standard is so far beyond operability that it really has little to do with the classical law of utility. It carries the ring of an FDA clinical approval standard. This may be a good standard to apply before drugs are approved for the market but it has little to do with historically established tests for utility in patent law.

59. *See* Eli Lilly Second Expert Report, *supra* note 43, at ¶ 47.

countries[60] but one—Canada—where it was invalidated for failure to meet the "promise" standard for utility.[61] The extensive clinical testing reported in the specification was not enough to establish utility in Canada; instead, some comments about better activity and fewer side effects (in the specification, not the claims) were seized on as an unfulfilled "promise."[62]

B. On Not "Freezing" Doctrinal Development in National Courts: "Normal" Doctrinal Variation Versus Radical Doctrinal Abrogation/Revolution

One obvious counterargument to the point made here is that signing a treaty should not "freeze" national doctrinal development. So yes, Canada agreed to employ the "capable of industrial use" (utility) standard, among others, in granting patents after TRIPs took effect. But this cannot mean that the permissible boundaries and features of Canadian utility doctrine were frozen for all time when it joined TRIPs in 1995.

But if Canada has deviated, so has the United States, right? Under this theory, the United States is arguably wildly out of compliance also. The doctrine of equivalents has shrunk in the United States since 1995. The written description requirement has been either revived or invented, depending on your view; but in any event, § 112 jurisprudence is very different today than it was in 1994. Injunctions are no longer automatic after *eBay Inc. v. MercExchange. L.L.C.*[63] Willfulness, inequitable conduct, damages, and nonobviousness have all changed in important ways under U.S. law after 1995.

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60. Lilly's patents for Zyprexa were upheld everywhere other than Slovenia (where a single claim as found to lack novelty) and Saudi Arabia (where priority dates were the basis of invalidation, but where a Gulf Cooperation Council patent remained valid and enforceable).

61. Eli Lilly Canada Inc. v. Novopharm Ltd., [2011] F.C. 1288, ¶ 209 (Can. Fed. Ct.). This opinion is remarkable for (1) admitting that the Zyprexa patent met the traditional Canadian utility standard (the "scintilla of utility" test), but (2) was not useful under the "promise" doctrine, (3) despite numerous human studies on safety and a pilot study of eight patients on efficacy, where six of the eight patients showed a positive response to the treatment of depression. Again, the culprit was the artificially high "promise" of the patent. *Id.* In the court's words, "the promise of the patent is that olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion with a better side-effects profile than other known antipsychotics." *Id.* This despite the fact that the claim in the patent made no mention of "marked superiority" or superior side-effects profile.

62. *Id.*

63. *See* eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).

One thing to note at the outset is that the TRIPs text only specifically mentions four requirements for granting patents. Recall that Article 27.1 says "[s]ubject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[64] This paragraph constrains WTO member nations to apply at least these four patent doctrines: (1) patentable subject matter ("all fields of technology"); (2) novelty; (3) inventive step/nonobviousness; and (4) capable of industrial application/utility. Having said this, two points must be made. First, there are unquestionably a number of traditional patent requirements which are *not* listed, most importantly, disclosure/enablement. Second, when the treaty mandates that patents "shall be available for any inventions . . . provided that they are new, involve an inventive step, and are [useful]," how tightly does this constrain the course of development in the case law regarding these standards?[65]

The first question is an interesting one. It is not apparent in the record of either NAFTA or TRIPs why this list was included, but other standards (such as disclosure) were left out. Perhaps disclosure varies more widely than these four "core" requirements. In any event there is a good case to be made that the exclusion of disclosure from the mandatory list leaves more room for doctrinal variation in this area

64. GATT, *supra* note 23, art. 27.1. The paragraphs 2 and 3 referred to in the text carve out patentable subject matter areas over which signatory nations retain complete discretion:

> 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
>
> 3. Members may also exclude from patentability:
>
> > (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
> >
> > (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Id. at arts. 27.2–27.3.

65. *Id.* at art. 27.1.

across countries. As long as disclosure doctrine does not in effect exclude an entire area of technology, for example, it might be defensible even if it changes considerably in scope in the years after accession to TRIPs.

On the question of the permissible degree of variation in the listed doctrines, here an argument may be made based on accepted standards of interpretation in international law. The basic law of treaty interpretation is set out in the Vienna Convention on the Law of Treaties.[66] Article 31.1 of the Vienna Convention says, "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."[67] The "ordinary meaning . . . in . . . context" of terms such as novelty, inventive step, and utility, includes the normal, traditional degree of doctrinal variation present and accepted at the time the treaty is signed.[68] But it does not include radical and extreme departures from the ordinary meaning in context. Thus, the text supports a degree of doctrinal variation that is within the parameters of accepted practice in the relevant field. But it excludes unprecedented and radical departures from this degree of variation.

TRIPs thus permits normal variation around the core content of traditional patentability requirements. A slight tightening in the nonobviousness test after the U.S. Supreme Court's decision in *KSR International Co. v. Teleflex Inc*.[69] is a good example. This arguably restored U.S. law to its traditional contours, which had been modified by the Federal Circuit through the device of the "teaching, suggestion, or motivation" (TSM) test.[70] Empirical research shows that in the immediate aftermath of *KSR*, the Federal Circuit invalidated patents at a rate eleven percentage points higher than before *KSR*.[71] Even

66. *See* Vienna Convention on the Law of Treaties art. 31, Jan. 27, 1980, 115 U.N.T.S. 331, 340.

67. *Id.* at art. 31.1.

68. *Id.*

69. *See* 550 U.S. 398, 419 (2007) (holding that obviousness is a general principle rather than a rigid rule).

70. Taryn Elliott, *Post*-KSR *Obviousness: The Effects of the Patent and Trademark Office's Exemplary Rationales on Patent Litigation*, 16 GEO. MASON L. REV. 1011, 1094 (2009) ("*KSR* did not create a fundamental change in the obviousness standard; it merely shifted the focus back to the *Graham* [*v. John Deere Co*., 383 U.S. 1 (1966)] factors and established a standard that is flexible enough to protect the policies underlying the obviousness inquiry.").

71. Jason Rantanen, *The Federal Circuit's New Obviousness Jurisprudence: An Empirical Study*, 16 STAN. TECH. L. REV. 709, 737 (2013) (reporting an increase from 46% to 57% in findings of obviousness on appeal and comparing the pre-*KSR* and post-*KSR* periods).

assuming this is a permanent change in U.S. law, and not a temporary response to a recent Supreme Court opinion, it does not represent a radical re-writing of what it means for an invention to be nonobvious. It represents instead the normal variation around a core concept of patentability.

Now compare this to the changes wrought by Canada's promise utility doctrine. Eli Lilly's data show that the rate of inutility rulings in pharmaceutical cases in Canada increased from essentially 0% to 40% after the advent of the promise utility doctrine.[72] This represents not normal legal variation, but a seismic change in the fabric of the law. Further evidence of the radical nature of the promise utility doctrine comes in the fate of the two Eli Lilly patents mentioned earlier. They have survived patent office review in a large number of countries, as well as litigation in others. Each of these national patent systems applies standard tests of patentability, though naturally some small degree of variation is assumed and permitted under TRIPs. The outcome of a cross-jurisdictional analysis of the validity of the Zyprexa and Strattera patents yields a generally uniform result—the patents are valid, and upheld where challenged, particularly with regard to utility.[73]

There is one glaring exception: Canada. As these case studies suggest, and as the aggregate data show convincingly, Canadian law has evolved what amounts to an additional, and very rigorous, test of patentability that invalidates a large portion of pharmaceutical patents. This is not normal legal variation. It is a striking legal innovation. It renders Canadian law highly divergent from the worldwide norm. Whatever this new test is called, it represents a radical departure from traditional concepts of utility. And that makes it, quite arguably, a violation of the TRIPs Agreement.

CONCLUSION

There are several points to take home from all this: (1) the Paris Convention of 1883 was a minimalist Treaty, requiring a minimum of state sovereignty to be surrendered during and after the Treaty-making process; (2) TRIPs in 1995 was quite a bit more substantive, and required a concomitant cession of national discretion; and (3) the two different contexts strongly imply an interpretive rule in close cases. Regarding this latter point, under the Paris Convention, states retain

72. Claimant's Memorial, *supra* note 45, at ¶ 222.
73. *See supra* note 60 and accompanying text.

discretion unless the Treaty very clearly provides otherwise, as with the right of international priority, while under TRIPs, greater constraints on state discretion are permitted and assumed to be part of the bargain states struck when they signed TRIPs and joined the WTO.

The TRIPs interpretive bias means that states made real commitments when they joined. The case of the promise doctrine in Canada is illustrative.[74] Though at least some of the aberrant case outcomes I described might have been reached through alternative doctrines, over which greater national discretion was reserved by TRIPs, application of traditional utility principles to reach results completely at odds with traditional requirements arguably represents a violation of TRIPs. Extreme variation from accepted norms at the time of accession, amounting to a complete rewriting of one of the agreed-upon requirements for patentability, can violate the Treaty. This is not equivalent to saying that TRIPs froze all doctrinal variation in signatory countries as of 1994. Traditional variation around core principles was and remains a part of patent law, even after TRIPs. In addition, of course, the Treaty itself can be revised.[75] So, nations that sign TRIPs can do a number of things to change patent doctrine, in ways that do not violate the Treaty. They can vary doctrine around traditional core principles, they can change doctrine in areas not covered by the Treaty, and they can suggest amendments to the Treaty.

What they cannot do is purport to apply traditional principles in ways that violate the basic premises and traditional contours of those principles. This they committed to foreswear when they acceded to TRIPs. Under the Paris Convention, much greater leeway can and should be given in these instances but not under TRIPs. The very different postures and contexts of the two Treaties point to different degrees of national discretion in IP policy.

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74. Another intriguing case is section 101 jurisprudence in the United States. Arguably, if recent Supreme Court cases are applied strictly, the United States might be said to be in violation of Article 27, requiring patents to be available in "all fields of technology." GATT, *supra* note 23, art. 27.1. It may be too early yet to say whether U.S. doctrine in this area has clearly become violative of Article 27. And some recent case law in the software suggests that the recent Court cases may not be applied so strictly as to eliminate software from the domain of patentability. But this area bears watching for purposes of TRIPs compliance.

75. *See* HOLGER HESTERMEYER, HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES 256, 274 (2007) (describing "Doha Declaration" and subsequent TRIPs amendment of Article 31 in 2005, allowing export of pharmaceutical products from signatory nations, so as to facilitate application of an appropriate compulsory licensing in an importing country).

Nations may exercise the right to value IP-protected creations, and one way they may do so is to surrender some of their sovereignty by joining a treaty. But the treaty context can and should be taken into account when analyzing national duties and requirements under those treaties. The choice to accede to a treaty that has its purpose the award of private rights expresses important public values on the part of each signatory nation. But the use of a private law instrument—a state-backed property right—has consequences. It may constrain post-signing discretion in various ways. That is simply the price to be paid when the vehicle chosen to express national values is a private right awarded to individuals. Property grants no doubt embody significant public values. But to give effect to this choice, where a treaty such as TRIPs requires significant constraints on national discretion, those constraints must have some teeth. Otherwise the private rights that emerge from the IP-granting process will have little reliable value. And that undermines the public values embodied in the treaty commitment in the first place.