Harmony and Disharmony in International Patent Law
East-West Center Think Piece by Colleen V. Chien[1]
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One of the purposes of the Trans-Pacific Partnership (TPP) is to harmonize standards and create a uniform climate for trade and investment. As lawmakers deliberate the terms of the deal, they must consider what the long-term impact of agreeing to its sweeping provisions will be. As they do so, they should keep in mind that the gaps between the agreed-upon principles and local implementation, and the differences between local implementation – some of them by design – are often quite great. Drawing upon the existing literature, this short essay provides a survey of the extent of harmony and disharmony in the 20 years that have passed since ratification of the TRIPS agreement, with a focus on its patent provisions. After considering the framework for harmonization that the TPP and TRIPS share, I discuss and provide examples of three types of differences: differences between the minimum standards that are negotiated and compliance with them, differences between the substantive principles agreed to and the actual laws that implement them (and the procedural contexts in which they operate), and differences between the laws as enacted and the laws that are applied.

[1] Associate Professor, Santa Clara University School of Law, former Senior Advisor, Intellectual Property and Innovation White House Office of Science and Technology Policy. This paper was prepared as a contribution to January 2015 workshop on Mega-Regionalism: New Challenges for Trade and Innovation, organized by the East-West Center and SAIS Europe, The Johns Hopkins University. Comments from Dieter Ernst and Michael Plummer, and research assistance from Robert Zhou are gratefully acknowledged. Any remaining errors are the fault of the author. Comments are welcome at colleenchien@gmail.com.

Introduction

The purpose of trade agreements is to reduce barriers to trade. The rationale for including intellectual property provisions within such agreements is that, although patent and copyright laws are unlike tariffs, differences between the patent laws of various countries will discourage trade as it increases the cost of complying with varied, non-harmonized regimes. If countries agree, for example, that changing the formulation of a pharmaceutical drug is a patentable advance, a pharmaceutical company can rely on that knowledge to make long-term investments in such improvements, and not worry about the availability of exclusive rights. A single, international level of protection enables countries to focus on their respective strengths, and to capture efficiencies that flow from comparative advantage.

Efforts to harmonize intellectual property law internationally date back to 1883, with the adoption of the Paris Convention for the Protection of Industrial Property ("Paris Convention"), whose most notable achievement was to establish the principle of national treatment.[2] The Trade-Related Aspects on Intellectual Property Rights (TRIPS) agreement is the most important and comprehensive modern international intellectual property (IP) treaty, with the goal of establishing minimum substantive international standards. Its adoption in 1995 in many ways was a landmark, encompassing over 150 countries, and establishing mechanisms for dealing with noncompliance.[3] Two decades later, the IP Chapter of the Trans-Pacific Partnership (TPP) proposes to harmonize policies relating to patents, regulatory test data, trademarks, geographical indications, copyrights, trade secrets, IP enforcement, criminal penalties for trade secret theft, IP liability for state-owned enterprise, anti-counterfeiting provisions, and additional subject matter,[4] among over a dozen countries.[5] As with TRIPS, TPP would require changes in law in order to comply with mandatory obligations created under the agreement.

Regardless of what the actual provisions say, the way in which the agreement, like TRIPs, was actually formed – secretively, without the benefit of public deliberation and debate, and only by coupling IP with many other areas, which is perceived to have enabled developed countries to use their markets as leverage to force stronger IP provisions in exchange for greater market access – create legitimacy problems [6] that imperil its adoption.[7] The IP

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[2] Rochelle Cooper Dreyfuss, *The Leahy-Smith America Invents Act, a New Paradigm for International Harmonisation?* 24 Sing. Acad. L.J. 669, __ (2012)

[3] William J. Davey, *the WTO Dispute Settlement System: The First Ten Years*, 8 J. Int'l Econ. L. 17, 32 (2005).

[4] U.S. Trade Representative Blog, *The Trans-Pacific Partnership* (Nov. 5, 2015), https://medium.com/the-trans-pacific-partnership/intellectual-property-3479efdc7adf#.ygpf5a1hv

[5] The United States, Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam

[6] Dreyfuss, supra note ___, at 677.

[7] Colleen V. Chien and Quentin Palfrey, *One Last Chance For A Pro-Transparency Trade Legacy for Obama* (working title), 2016

provisions have consistently been among the most controversial, called a deal that the whole world may have to pay the "price [of] in the form of worse health and unnecessary deaths" by Nobel prize winner Joseph Stiglitz for example. They have attracting stinging criticism for overrepresenting the interests of contentholders[8] as a result of informational and institutional capture caused in part by the systematic departure of trade negotiators from the government and into the private sectors who they were once regulating.[9]

However high, the costs might be worth it, to TPP proponents, if the goal of TPP – the achievement of uniformly high standards – is achieved. But the track record of TRIPS twenty years after its passage creates much doubt. On one hand, TRIPS, notwithstanding its flexibilities, has been criticized for discouraging experimentation among public policies in a way consistent with flexibilities provided by the Act.[10] But on the other hand, rightsholders, disappointed with how TRIPS has been implemented, particularly with respect to compulsory licensing, have shifted their focus to other policy regimes and venues.[11] The failures of many of these attempts (e.g. the Substantive Patent Law Treaty (SPLT) and Anti-Counterfeiting Trade Agreement (ACTA)) suggest that the consensus that TRIPS was able to achieve was remarkable.

Disharmony by Design

TRIPS and TPP share some features that make it worthwhile to consider TRIPS' record of harmonization when evaluating TPP's prospects. Some of the disharmony among countries' implementations of TRIPS has been by design – as recounted below, the TRIPS Agreement (and subsequent amendments) incorporate safeguards that affirm countries' sovereignty, the relevance of competitive interests, frameworks for deviating from the agreement, and commitments to access to medicines. So, largely, does TPP.

Any difference in the implementation of TRIPS standards, therefore, might have been predicted, for example, by its opening Article, which states that member countries "shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement

[8] Timothy B. Lee, *Here's why Obama trade negotiators push the interests of Hollywood and drug companies,* November 26, 2013. https://www.washingtonpost.com/news/the-switch/wp/2013/11/26/heres-why-obama-trade-negotiators-push-the-interests-of-hollywood-and-drug-companies/

[9] Timothy B. Lee, *Here's why Obama trade negotiators push the interests of Hollywood and drug companies,* November 26, 2013. https://www.washingtonpost.com/news/the-switch/wp/2013/11/26/heres-why-obama-trade-negotiators-push-the-interests-of-hollywood-and-drug-companies/

[10] See, e.g. Molly Land, *Rebalancing TRIPS*, 33 Mich. J. Int'l L. 433, 434 (2012).

[11] See generally Peter Yu, *TRIPS and Its Achilles' Heel* (Drake University Legal Studies Research Paper Series, Research Paper No. 11-31, 2011).

within their own legal system and practice."[12] TPP's IP chapter uses exactly the same language.[13] In addition, TRIPS does not purport to replace substantive IP laws, rather it only imposes minimum standards upon all member countries of the WTO. The language of the agreement specifically allows TRIPS members, when shaping their domestic laws and regulations, to "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement,"[14] as well as to take "appropriate measures, provided that they are consistent with the provisions of this Agreement, [] to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." [15] Article 18.3 of the TPP incorporates this language verbatim and extends on it, as described below.

The principal that exceptions and limitations to the agreement are permitted under certain limited circumstances is enshrined in both agreements.[16] So, too, is the Doha Declaration, which in 2001 confirmed that "patents would not prohibit countries' ability to use compulsory licensing to address public health needs,"[17] and the 2005 amendment to Article 31 of the TRIPS agreement, which enabled countries lacking the capacity to manufacture generic pharmaceuticals under domestic compulsory licenses to import them.[18]

In 2014, prominent IP scholars across the world drafted the *Declaration on Patent Protection: Regulatory Sovereignty under TRIPS*, in order to "clarify some of the regulatory options states still retain under international law, in particular the TRIPS Agreement."[19] Drawing upon some of the flexibilities cited earlier, as well as other provisions of the law, the Declaration interprets, potentially too expansively,[20] the regulatory discretion that national legislators have in implementing their own patent systems.[21] However, some provisions leave less room for discretion. Article 33 specifies that "the term of protection available shall not end

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[12] Dongwook Chun, *Justifying Patent Harmonization*, 12 Asper Rev. Int'l Bus. & Trade L. 99, 100 (2012).
[13] TPP Article 18.5
[14] TRIPS, art. 8.
[15] Id.
[16] Otherwise known as the "three-step test"; cf. TRIPS Articles 17, 26, and 30 and TPP Articles 18.21, 18.40, and 18.65.
[17] Donald Harris, *TRIPS after Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. Intell. Pro. L. 367, 386 (2011).
[18] Id.
[19] Matthias Lamping etc. al., *Declaration on Patent Protection - Regulatory Sovereignty under TRIPS*, 45 IIC - Int'l Rev. Intell. Prop. & Competition L. 679 (2014).
[20] Rochelle Dreyfuss & Estaban Donoso, *On Aiding Technical Development: the Max Planck Declaration on Patent Protection*, 6 U.C. Irvine L. Rev., forthcoming. (Abstract), calling the Declaration's interpretation of the flexibilities afforded by TRIPS "aggressive" and failing to give guidance to countries that seek to maximize innovation, as opposed to consumer interests.
[21] Lamping et al., supra note ___

before the expiration of a period of twenty years counted from the filing date," seemingly foreclosing proposals for differential terms, e.g. shorter for certain technology patents, and longer for certain drug patents,[22] for different types of inventions.

In the sections that follow, I draw upon existing literature to describe the ways in which harmony within international agreements accommodates, and in some cases supports, the disharmonies foreshadowed by these provisions, as well as forces harmonization where it would not otherwise have happened. Part I looks in particular at compliance with TRIPS' mandates, and finds that the record of dispute resolution procedures supports that TRIPS has allowed for significant country-level tailoring, though it has also, taking the example of the US, compelled countries to both take and abstain from actions it would not have taken in the absence of the agreement. Part II explores variations in country-level implementation of the inventive step requirement in patent law and the design of post-grant patent challenges. Part III reviews "twin" patent application studies, including my own, that trace what happens when the same patent application is filed in multiple jurisdictions, demonstrating that even standards that are harmonized can lead to dramatically different outcomes when applied.

Part I: Disharmonies in TRIPS Compliance

Countries that do not comply with TRIPS provisions are subject to dispute resolution procedures to ensure their compliance. One way to assess the extent to which TRIPS has achieved its harmonization aims is through the dispute settlement system within the WTO. Reviewing 15 years of dispute settlement proceedings, Joost Pauwelyn has concluded that TRIPS was "the dog that barked but did not bite,"[23] by which he means that concerns that TRIPS would significantly constrain national policy formation have largely not materialized. Pauwelyn reports that 23 of the 27 TRIPS disputes filed in the first 15 years following TRIPS enactment were lodged during the first five years of TRIPS (at an annual rate of between 3 and 6 cases), but that since 2000, less than 1 case has been brought per year, on average. There has been no "flood of IP disputes," no aggressive enforcement by developed against developing countries, and TRIPS disputes settled more frequently than other WTO disputes (67% v. 58%).[24]

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[22] See, e.g. Tabarrock, Alexander, *Patent Theory and Patent Law*, 1 Contributions to Econ. Analysis & Pol'y 1 (2002); Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. Rev. 672 (2004) and other references described in Brian J. Love, *Chapter on Patent Duration*, Handbook of Peter S. Menell & David L. Schwartz (eds.), Research Handbook on the Economics of Intellectual Property Law (Vol. II -- Analytical Methods) (Edward Elgar Publishing, 2016)

[23] Joost Pauwelyn, *The Dog that Barked that Didn't Bite: 15 Years of Intellectual Property Disputes at the WTO*, 1 J. Int'l Disp. Settlement 389 (2010).

[24] Id.

Edward Lee's parallel study does not dispute these findings, but does point out that fears that developed countries would use the Agreement to force changes in others' laws has not been entirely unfounded.[25] While there have been few IP disputes, the majority of them have been initiated by the United States and Europe.[26] However, the targets of the disputes have also been developed countries, again, with the United States, Europe, and Canada all found to have been in violation.[27] Strikingly, the United States is the only country to have been found in violation of TRIPS provisions that has, of yet, failed to change its laws in order to comply. (See Table ___).

Table __: Times Taken by Member Countries to Comply with Decisions Finding TRIPS Violations

TIME TAKEN BY MEMBER TO COMPLY WITH WTO DECISION	
MEMBER AND DISPUTE	TIME TO COMPLY
India – Pharmaceutical Patents ("mailbox rule")	15 months fixed
Canada – Pharmaceutical Patents	4 months fixed
Canada — Patent Term	9 months fixed
EU — Trademark and GIs	1 year fixed
China — IP Rights	1 year fixed
U.S. — Section 110(5)	10 years + counting*
U.S. – Havana Club Rum	9 years + counting*

Source: Edward Lee, *Measuring TRIPS Compliance and Defense: the WTO Compliance Scoreboard*, 18 J. Intell. Prop. L. 401 (2011). *Compliance times for the US calculated as of 2011.

However, to initiate a dispute requires significant governmental resources and much of the shaping of national laws happens in the shadow of dispute resolution, including through technical assistance. In addition, commentators have noted that United States enforcement efforts seem to have moved away from the multilateral WTO dispute settlement system and reverted to unilateral efforts such as the Special 301,[28] a mechanism that allows for a possible retaliatory trade action against a country which fails to provide adequate protection for United States' IP rights, as well as through the pursuit of commitments that go beyond TRIPS ("TRIPS-plus"), in TPP and other recent free trade agreements.[29] As a result, dispute resolution

[25] Edward Lee, *Measuring TRIPS Compliance and Defense: the WTO Compliance Scoreboard*, 18 J. Intell. Prop. L. 401 (2011).
[26] Id. at 405.
[27] Id. at 410.
[28] Office of the United States Trade Representative, 2010 Special 301 Report, Annex 1 (2010), available at http://www.ustr.gov/web/frm_send/1906
[29] Harris, supra note __ at 374.

outcomes provide at best an incomplete indicia of the extent to which TRIPS has succeeded or failed in its aims.

Another way of measuring the harmonizing power of international IP agreements is the degree to which agreements have been the "but-for" cause of domestic activities – compelling countries to take or not take steps, because of an agreement, and conversely, failing to prevent the adoption of measures that, in theory at least, contravene the aims of its provisions. A review of the experience of the United States provides examples of all three dynamics. For example, over the objections of a number of stakeholders including independent inventors and Nobel Laureates,[30] it passed provisions of the America Invents Act "with an eye toward harmonization,"[31] by moving the United States in the direction of the rest of the world through its substantial adoption of a first-to-file system, expansion of source of prior art to all geographies, and limiting of the best mode requirement.[32] The United States has also been prevented by the provisions of the TRIPS agreement that require patent owners to receive 20-year terms[33] to be able to enact shorter, say three- to five-year durations for software patents.[34] The TRIPS agreement's commitment to technology neutrality, which requires patents to be "available for any inventions, whether products or processes, in all fields of technology,"[35] at least seemingly, has prevented the United States Congress from enacting laws that would treat software differently than other types of technological inventions.[36] However, it has not prevented the Supreme Court of the United States from taking significant steps to curtail the patenting of abstract inventions[37] and human genes,[38] or prevented Congress from enacting special provisions to be developed to challenge patents over financial inventions, specifically excluding "technological inventions"[39] to avoid running afoul of TRIPS. These "exceptions" to technology neutrality in patents join pre-existing technology-specific provisions, for example, that prevent surgeons from being prosecuted for infringement of diagnostic patents in the

[30] See Colleen Chien, *Exclusionary and Diffusionary Levers in Patent Law*, __ Southern Cal. L. Rev. ___ (2016).
[31] Dreyfuss, supra note __ at 679
[32] Id. at ___
[33] TRIPS Article 33
[34] As suggested, e.g. by Richard Posner, http://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/
[35] TRIPS Article 27
[36] See Colleen Chien, *Tailoring the Patent System to Work for Technology Patents* (2012), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2176520.
[37] See, e.g. *Bilski v. Kappos*, 130 S. Ct. 3218 (2010)*, Alice Corp. v. CLS Bank Intern.,* 134 S. Ct. 2347 (2014)
[38] *Ass'n for Molecular Pathology v. Myriad,* 133 S. Ct. 2107 (2013)
[39] Pub. L. 112–29, §18

United States[40] and surgical methods from being patented in Japan and the UK,[41] and certain computer programs from being patented in the Europe.[42]

Part II. Disharmonies in the Application and Contexts of Domestic Patent Law

Though TRIPS has clearly provided harmonizing pressure, it is unclear how deep this pressure extends. TRIPS and TPP explicitly state that "[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."[43] This clearly contemplates that specific provisions implementing the same legal principle may look quite different from country to country. In addition, the agreements, as described above, sanction the adoption of measures to address other, non-innovation priorities, including public health and technology transfer, although only to the extent that they are consistent with the other terms of the agreements.[44] Article 18.4 of the TPP includes additional language that acknowledges that the agreement is formed in a broader context in which Parties need to "(a) promote innovation and creativity; (b) facilitate the diffusion of information, knowledge, technology, culture and the arts; and (c) foster competition and open and efficient markets."[45] Below, we provide an example of how countries have used their discretion to implement one particular requirement – the "inventive step" requirement – in four different jurisdictions. We then consider the procedural context of patentability decisions, focusing specifically on post-grant challenges to patent validity, with reference to the policies of several countries.

1. Implementation of the "Inventive Step" requirement in the US, India, Japan, and Europe

The TRIPS Agreement requires countries to grant patents to inventions that are "new, involve an inventive step and are capable of industrial application."[46] However, countries have tailored their implementation of this international requirement in response to domestic pressures and needs.[47] In the United States, section 103 of the Patent Act specifies that patents are to be granted not on inventions that represent an "inventive step" but on those that meet

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[40] 35 U.S.C. 287(c)
[41] Described, e.g. in Toshiko Takenaka, et al., GLOBAL ISSUES IN PATENT LAW 73-74 (2010).
[42] See EPC Article 52
[43] Dongwook Chun, *Justifying Patent Harmonization*, 12 Asper Rev. Int'l Bus. & Trade L. 99, 100 (2012).
44 Described supra, *Disharmony by Design*
[45] TPP Article 18.4
[46] TRIPS, art. 27(1).
[47] See Amy Kapczynski, *Harmonization and Its Discontents: a Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 Cal. L. Rev. 1571, 1589 (2009) (commenting on India's decision to adopt "an exceptionally high threshold for inventive step"); Timo Minssen, *Meanwhile on the Other Side of the Pond: Why Biopharmaceutical Inventions that were "Obvious to Try" Still Might be Non-Obvious Part I*, 9 Chi.-Kent J. Intell. Prop. 60, 61 (2010) (comparing application of the inventive step/obviousness analysis in Europe and the U.S.).

the "nonobviousness" requirement.[48] In Europe, according to Article 56 of the European Patent Convention, "an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art." The Japanese standard resembles the US approach, asking: "(1) what is the prior art? (2) what are the differences between the claimed invention and the prior art? And (3) would the invention be obvious to a person with ordinary skill in the art?" [49] Europe's approach, instead, is to ask "(1) what is the closest prior art? (2) what is the objective problem solved by the invention? And (3) was the solution reached by the invention obvious to a person with ordinary skill in the art?."[50]

The formulations, and how they are interpreted, can also vary. In the US, Congress has delegated responsibility for patent law largely to the courts, and in 2007, the Supreme Court reinterpreted the obviousness standard, doing away with the test that had been developed by the lower appellate court that hears patent cases exclusively – the Federal Circuit – as rigid and formalistic.[51] This decision was one of a string of decisions that were seen as providing a corrective to the Federal Circuit's elevation of patent rights over the rights of consumers and other interests,[52] culminating in the Federal Circuit having the highest reversal rate of any circuit court in the US. From 1999-2008, the Supreme Court reversed and vacated in 25 of 30 cases on review from the Federal Circuit, a rate of 83.3%.[53] The next most-reversed was the Ninth Circuit, at 80%, and the median rate across all circuits was 68.29%.[54] Considering only patent appeals, the Federal Circuit's performance is worse—the Supreme Court reversed and vacated 13 out of 14 decisions during the 1999-2008 period.[55]

India's inventive step standard has been described as "exceptionally high."[56] It requires inventions to contain "a feature [] that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious

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[48] 35 U.S.C. § 103 (a) (2011) (A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made)

[49] Amy Nelson, *Obviousness or Inventive Step as Applied to Nucleic Acid Molecules: a Global Perspective*, 6 N.C. J.L. & Tech. 1, 30 (2004-05).

[50] Id.

[51] KSR Intern. Co. v. Teleflex Inc., 550 U.S. 398 (2007)

[52] Described, e.g. in Chien, Cotter and Posner, *Redesigning Patent Law* (forthcoming), Chapter 2.

[53] Roy E. Hofer, *Supreme Court Reversal Rates: Evaluating the Federal Courts of Appeals*, 2 Landslide (2010), *available at* http://www.americanbar.org/content/dam/aba/migrated/intelprop/magazine/LandslideJan2010_Hofer.authcheckdam.pdf.

[54] Id.

[55] Id.

[56] Amy Kapczynski, *Harmonization and Its Discontents: a Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 Cal. L. Rev. 1571, 1579 (2009).

to a person skilled in the art,"[57] in order to be patentable. In addition to specifying that an invention be "not obvious to a person skilled in the art," the US standard, India erects an additional hurdle – that the invention include a technical advance or have economic significance – in order to be patentable. Depending on how it is applied, this standard could likely be used to exclude a host of inventions that might otherwise be patentable based on standards used by other countries, Amy Kapczynski has observed. [58] She characterizes this standard, as well as a host of other substantive provisions of the Indian Patent system, including novel limitations on subject matter, compulsory licensing provisions, patent misuse standards to constrain voluntary licensing activity, and limits on injunctive remedies, as evidence of the extensive and underappreciated flexibilities that TRIPS affords.[59]

2. Post-Grant Patent Challenges

The impact of harmonized patent standards depends on the procedures that are available to support their administration, and in particular, procedures that are available to challenge patents. In Europe, post grant proceedings have long been a well-recognized way to correct Patent Office error – opposition proceedings at the European Patent Office (EPO), which are used to review 5-8 % of issued patents, have resulted in the partial or total invalidation of patents close to 70 % of the time, and in German revocation proceedings, 73 % of patents are partially or fully revoked.[60] In recent years, both the US and India have adopted provisions to challenge patents that, while merely procedural, arguably impact the rights of patentholders just as significantly as have substantive provisions. The diversity of these provisions underscores that even when substantive laws are harmonized, they take effect in disharmonized environments that can include, e.g. variable procedures for challenging patents.

In the US, concerns about low-quality patents caused by the relaxing of standards by the Federal Circuit in the 1990s[61] led to the redesign of post-grant challenges in 2011. In the US, since 1981, patentees and third parties have been able to seek reexamination of issued patents if a "substantial new question of patentability,"[62] with respect to novelty or nonobviousness, for example, due to a new piece of prior art or a change in the law, is presented. However, neither *ex parte* nor *inter partes* reexam procedures were used much, due in part to their uncertain review periods and the inability to consider outside evidence.[63] The America Invents Act of 2011 created three new ways for members of the public to challenge issued patents: *inter partes* review (IPR), the covered business method transitional program (CBM), and post-

[57] The Patent Amendment Act, No. 15 of 2005, § 2(ja), INDIA CODE (2005).
[58] Kapczynski, supra note __at 1593.
[59] Id. at 1589-1616.
[60] For cites, see Colleen Chien & Christian Helmers, *Inter Partes Review and the Design of Post-Grant Patent* Reviews, Stan. Tech. L. Rev. ___ (forthcoming).
[61] Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 Fed. Cir. B.J. 539, ____(2012)
[62] 35 U.S.C. 303(a)
[63] Matal, supra note ___, at ____.

grant review (PGR). These redesigned procedures for challenging patents, in particular IPR, have been much more popular than their predecessors. While the USPTO received an average of 10 requests per year in the first five years of inter partes reexamination, in the second full year of inter partes review, the Patent Trial and Appeal Board (PTAB) of the USPTO received 1,310 requests, a massive increase.[64] An estimated 12% of litigated patents has been subject to petition,[65] and about 25% of challenged patent claims have been invalidated,[66] while 84% of patents to reach a final decision have been.[67]

India features two ways to challenge the validity of issued patents - post-grant oppositions before the patent offices and patent revocation proceedings that may be initiated before the Intellectual Property Appeal Board or via a counterclaim in an infringement suit. It also offers pre-grant opposition procedures that can be initiated by any third party on a broad set of grounds.[68] In China post-grant review is the only option to invalidate a patent, court relief is not available. Thus, the only way to invalidate a patent is through the Chinese Patent Office (SIPO)'s Patent Review and Adjudication Board (PRAB) which corresponds to the PTAB in the US. Uniquely, SIPO can also decide on infringement.[69]

Part III. Disharmonies between the Laws as Implemented and the Laws as Applied (the Case of Patent Quality)

The final and perhaps least appreciated form of disharmony is also the most important to individual rightsholders – what happens when the same claim to patent rights is evaluated by different jurisdictions? Even if country formulations of the law vary, what matters is whether, when applied, they produce consistent or inconsistent outcomes, the most important of which are the rights and remedies available. In this section we consider patent application outcomes, focusing in particular on the submission of a single patent application to multiple patent offices, as a way to measure the extent of harmony or disharmony between the laws on the books and the laws applied.

Take for example US Patent 6,032,137, which covers a way of depositing a check by imaging and sending it, rather than physically transferring it to the bank. [70] The inventor, Claudio Ballard, tried for several years to develop the invention. Though he failed, the

[64] Chien & Helmers, supra note ___ at 3-4.
[65] UnifiedPatents, Outcomes at the PTAB (as of May 2015), http://unifiedpatents.com/outcomes-at-the-ptab-as-of-may-2015/ (last visited Feb. 1, 2016)
[66] USPTO, *Inter Partes* Review Petitions Terminated to Date (Apr. 30, 2015), http://www.uspto.gov/sites/default/files/documents/inter_partes_review_petitions_%2004%2030%202015_0.pdf , see also Colleen Chien, *The Scariest Number in the Patent Reform Debate Is also Wrong*, POLITICO (Jun. 3, 2015), http://www.politico.com/agenda/story/2015/06/the-scariest-number-in-the-patent-debate-is-also-wrong-000068
[67] USPTO, Patent Trial and Appeal Board Update (Feb. 19, 2015), slide 15, http://www.uspto.gov/sites/default/files/documents/20150219_PPAC_PTAB_Update.pdf
[68] Kapczynski, supra note __at 1598-1600.
[69] Chien & Helmers, supra note ___, at ___.
[70] U.S Patent No. 6,032,137 (issued Feb 29, 2000).

technology thrived, and his company, DataTreasury, sued dozens of banks for their use of check imaging.[71] In 2013, Fidelity National Information Services, after being sued by Ballard, asked the USPTO to take a second look at the Ballard patents. It agreed. In 2015, a panel of patent judges revoked the '137 patent as overly broad and vague, and therefore invalid.[72] By that time DataTreasury and its two employees had collected $350M in licensing fees.[73] There is no counterpart to this now-invalidated patent in Europe though it was not for a lack of trying. The application that matured into the US patent was also the basis of seven patent applications at the EPO,[74] but none were granted.[75] While some applications were withdrawn from EPO prosecution, others were denied.[76]

Previous efforts to measure what happens when the same patent application is submitted to different patent offices report wide variability.[77] Analyzing a cohort of patent applications submitted to the Australian, European, and Japanese Patent Offices from 1990-1995 that matched as equivalents 9,618 US patents,[78] Jensen and his colleagues found that the Australian Patent Office granted almost all (86%) of these applications, while the JPO granted less than half of them (42.6%) and the EPO grant rate was between (74%) these two figures.[79] In a related analysis, Dietmar Harhoff and Stuart Graham analyzed the EPO counterparts of a sample of 2,474 US patents litigated from 1963-2003 and their nonlitigated counterparts, and reported comparable grant rates, between EPO grant rates of 68% (among counterparts to non-litigated US patents) and 80% (among counterparts litigated US patents), as compared to US patents (100% grant rate).[80]

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[71] For a longer description and cites, See Chien, Cotter, and Posner, supra note ___ at Chapter 3.

[72] Matthew Bultman, *DataTreasury Patents Nixed by PTAB in AIA Review*, LAW360 (Apr. 29, 2015), http://www.law360.com/articles/649511/datatreasury-patents-nixed-by-ptab-in-aia-review.

[73] Alex Lawson, *Controversial DataTreasury Patents Face Biz Method Review*, LAW360 (Nov. 8, 2013), http://www.law360.com/articles/487185/controversial-datatreasury-patents-face-biz-method-review.

[74] See "also published as" section at http://www.google.com/patents/US6032137 (listing related applications EP1008086A2,EP1008086A4, EP1688876A2,EP1688876A3, EP1986148A1,EP2267652A1, EP2267653A1)

[75] Id. (showing no "B" or granted, EP publications)

[76] Author's analysis based on the EP Register.

[77] Paul H. Jensen et al., *Disharmony in International Patent Office Decisions*, 15 Fed. Cir. B.J. 679 (2005); Elizabeth Webster et al., *Characteristics of International Patent Application Outcomes*, 95 Econ. Letters 362, 368 (2007); Alfons Palangkaraya et al., *Misclassification between Patent Offices: Evidence from a Matched Sample of Patent Applications*, 93.3 Review of Econ. & Stat. 1063, 1075 (2011); Elizabeth Webster et al., *Patent Examination Outcomes and the National Treatment Principle*, 45 The RAND J. Econ. 449, 469 (2014) (finding that local offices tend to favor local applicants)

[78] Paul H. Jensen, *Application pendency times and outcomes across four patent offices* (Intellectual Property Research Institute of Australia Working Paper No. 01/08, Feb. 2008).

[79] Figure 2. These estimates are slightly deflated, as 1.7-13% of applications were still pending at the time of the analysis

[80] Stuart J.H. Graham & Dietmar Harhoff, *Separating Patent Wheat from Chaff: Would the U.S. Benefit from Adopting a Patent Post-Grant Review?* 43 Res. Pol'y 1649, 1659 (2009). In other work by the same authors, they found that EPO equivalents of US litigated patent applications were more likely to be awarded EPO patent

In an original analysis, we created a set of matched EPO – USPTO patent applications from 2002. Patent rights are territorial, so an inventor seeking protection over the same invention in multiple jurisdictions must file multiple applications. If an applicant for a US patent also seeks protection in Europe, she will typically file the same application, with slight modifications,[81] within a year to the European Patent Office or World Intellectual Property Office (WIPO). While there are numerous ways to associate US and EPO patent applications, in our analysis we applied the most conservative approach and matched US patent documents to EPO patent documents with identical priority claims.[82] We included in our set all available EPO and US application pairs from 2002[83] (N=99,221), and traced the fate of each application through the two jurisdictions. We focused first on whether or not the application had been "Granted," a status designated in PATSTAT.[84]

Of applications filed in both jurisdictions, 77% were granted in the US, while only 52% were granted in the EPO. The difference in grant rates was robust across all five invention sectors tracked under the WIPO– in each case, more US than EPO patents resulted. Among technology sectors, the differences were most pronounced for electrical engineering (or "technology") patents (FIG __). While electrical engineering applications had a less than one in two chance of becoming a patent granted by the EPO, it had a greater than three out of four chance of maturing into a US patent,[85] a 34% difference. (FIG___) The difference was less pronounced, but still significant for the other classes of patents. Chemistry and mechanical engineering applications were 17%, and instruments applications, 29% more likely to be awarded in the US as compared to the EPO. (FIG __)

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protection than were equivalents of unlitigated patents (Stuart J.H. Graham & Dietmar Harhoff, *Can Post-Grant Reviews Improve Patent System Design? A Twin Study of US and European Patents* (Center for Economic Policy Research Discussion Paper No. 5680, 2006))

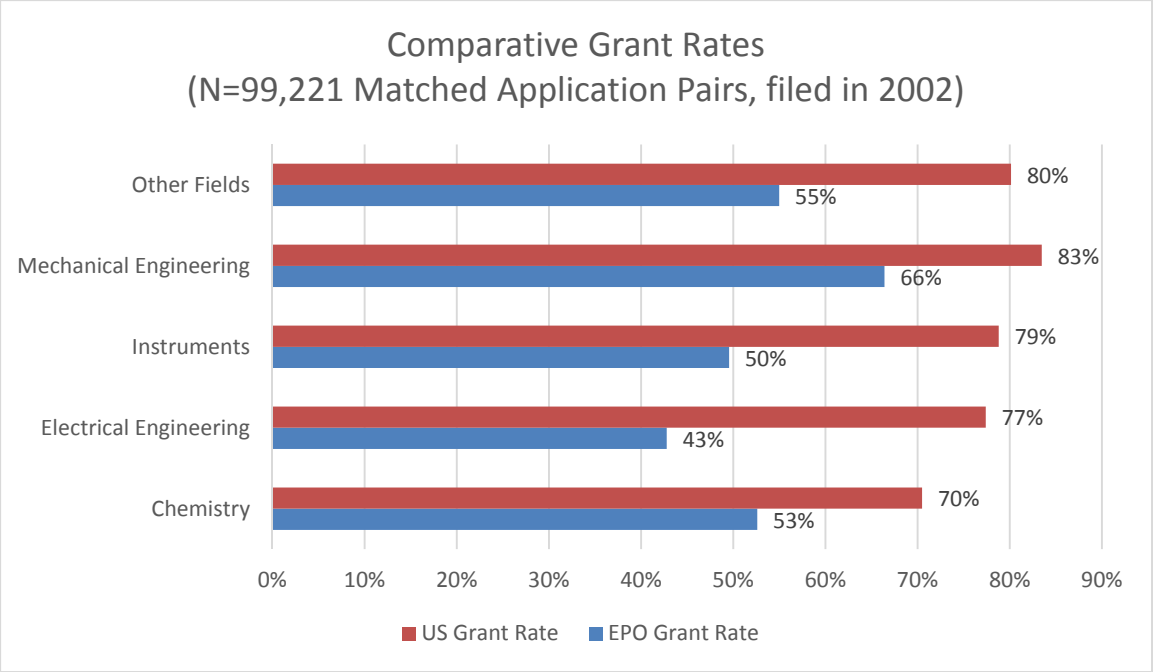
[81] Graham & Harhoff, supra note __

[82] Under the Patent Cooperation Treaty, a claim of "priority" to the first application by the second application confers the important benefit that the second application is treated as if it were filed on the same day as the first application. Subsequent applications can claim priority to one or more applications, within the same or different jurisdictions, creating the possibility of multiple applications within a single patent "family." A patent family, in turn, can be either "simple" or "extended" – the members of a simple family share at least one common priority or "parent," while members of an extended family include documents linked directly or indirectly through common priority claims. Patent families may also be formed through "expert-review," for example through priority information as well as the review of content by experts as performed by the Derwent World Patent Index. See Graham & Harhoff, supra note __; Catalina Martinez, *Patent Families: When Do Definitions Really Matter*, 86 Scientometrics, 39 (2011). We obtained these matches, called "equivalents," from PATSTAT which publishes such matches through the DOCDB database.

[83] That is, with a US filing date of September 2002.

[84] While the "granted" variable is viewed as very reliable by PATSTAT researchers, in two cases, it may not reflect the current status – first, because PATSTAT is not updated in real time, it does not always reflect the most recent months' of grants. Second, where there is a subsequent revocation of a patent, the granted status does not reflect the change in status. These divergences should have limited if any impact on our reported results.

[85] Of the 2,784 applications classified as "electrical engineering," 76%, or 2,105 became US patents, while 43%, or 1,273 became EPO patents.



Source: PATSTAT 2015, Smoch/WIPO, author's analysis [File: Slide 14 data][86]

In every one of the 35 sector subcategories defined by WIPO, we found, the US was more likely to grant a patent than was the EPO.[87] However, it is possible that the results are an artifact of the period of time tested, as the fluctuation in US grant rates over time has been well-documented. To rule out this possibility, we expanded our analysis to a sample that included EPO applications matched to US grants from the period from 1975-2014. We found the relatively lower EPO grant rate to persist over time, consistent with the findings of Cecil Quillen and Christopher Cotropia,[88] and observed that the relative EPO grant rate, in fact, declined over the tested period, though we believe some of the decline is due to time effects. These results confirm and expand upon earlier results.[89]

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[86] Webster et al. also performed calculations Cf Webster, supra note ___ at Fig.3 ____

[87] We performed T-tests on each difference, finding p-values between 0 and 2.49341704573321E-32, allowing us to reject the null hypothesis that the difference in grant rates were the result of chance.

[88] Christopher A. Cotropia et al., *Patent Applications and the Performance of the U.S. Patent and Trademark Office as of FY 2014* (Intellectual Prop. Inst. Research Paper No. 2015-01), Fig. 9, available at http://law.richmond.edu/docs/FY-2014-Update-Figures-and-Tables-1996-2014-29.pdf (documenting a persistently lower EPO grant rate over the period of time 1996 to 2013).

[89] See Jensen et al., Harhoff and Graham described in FN___ (finding the EPO to grant a fraction of US patents in their samples), and Cotropia et al., supra note ___ (documenting a lower EPO grant rate over time). Jensen et al. also reported comparative grant rates by select international patent classifications. While they do not correspond with the industry sectors from WIPO that we considered, they also found relatively smaller differences in the treatment of mechanical and instruments patent applications and relatively larger differences in grant rates of hardware and communications applications. (FIG 3)

The pervasiveness of the gap in grant rates across technology areas between the two jurisdictions is striking. They contribute to a significant level of disharmony in the protections available in specific countries, despite similar, harmonized standards. One major difference that contributes to this difference is the bifurcation of search and examination in Europe, as compared to the unification of these steps in the US.

Though our analysis was limited to US and European applications, Bhaven Sampat and Ken Shadlen, in a forthcoming study, follow the filing and grant of about 277 "twin" drug patent applications filed in six jurisdictions: India, Brazil, the US, Japan, the European Patent Office, South Africa, Mexico, and Argentina.[90] They coded the claims of each application as primary (covering new molecules) or secondary (covering alternative forms of existing molecules) and examine how national grant rates for these types of patents differ. Since overall grant rates can be influenced by the quality of filings, their analyses focus on "twin" applications filed in all six jurisdictions.

They find that, consistent with the results reported earlier, the US has the highest grant rate among patent applications, being the most likely, after South Africa, to grant patents on both primary and secondary drug patents. They also find that although India and Brazil have enacted specific measures to restrict patenting of secondary drug inventions,[91] these measures have had little direct effect on patent examination outcomes. Though grant rates in these countries are lower than in the US, grant rates on secondary patents are not measurably lower than grant rates on primary drug patents.

These results underscore that although government negotiators can agree with each other on the provisions of international agreements, many other factors shape the extent to which countries can in fact rely on the consistent and uniform availability of rights.

CONCLUSION

Multilateral trade agreements are appealing for lawmakers and constituents with special, asymmetric access to negotiators because they appear to be a much faster way to effect sweeping reform than going country by country or through open processes.[92] But those who negotiate and agree to a treaty's terms are different than those who must implement its provisions, and likewise the gaps between the minimum standards that are negotiated and

[90] Bhaven Sampat & Kenneth Shadlen, *The Effects of Restrictions on Secondary Pharmaceutical Patents in Brazil and India*, (Columbia and NBER) (September 28, 2015)

[91] Id. at 3-4: "Section 3(d) of India's post-TRIPS patent law states that new forms of old substances are not patentable (unless they show improved efficacy). In Brazil, pharmaceutical patents cannot be granted by the patent office unless the Brazilian health ministry also approves, and the agency responsible for making these decisions (ANVISA) gives prior consent."

[92] See, e.g. Margot E. Kaminski, *The Capture of International Intellectual Property Law through the U.S. Trade Regime*

compliance with them, differences between the substantive principles agreed to and the actual laws that implement them (and the procedural contexts in which they operate), and differences between the laws as enacted and the laws that are applied, as documented in this essay are significant. Those who advocate for and against such agreements might keep these realities in mind, and be cautious about overstating their likely benefits, as well as their harms.