University of Georgia Law

Journal of Intellectual Property Law

Volume 24 | Issue 1 Article 5

October 2016

Combating the Anti-trade Movement: Evaluating the Trans-Pacific Partnership's Place in International Patent Law

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NOTES

COMBATING THE ANTI-TRADE MOVEMENT: EVALUATING THE TRANS-PACIFIC PARTNERSHIP'S PLACE IN INTERNATIONAL PATENT LAW

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I. INTRODUCTION

The Trans-Pacific Partnership (TPP) is a free trade agreement among twelve Pacific Rim countries: Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam.[1] Each of these countries is also a signatory of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS), which currently provides the international intellectual property standards.[2] Despite failing to reach an agreement during the negotiations in July 2015,[3] the countries met again in September 2015 to continue efforts to finalize the treaty.[4] On October 5, 2015, the twelve countries announced that the treaty had been finalized, although the final version of the treaty was not signed at that time.[5] After the TPP was finalized, the United States Trade Representative released the final text of the Intellectual Property Chapter.[6]

The TPP contains a wide range of provisions on traditional trade topics, such as tariffs, non-tariff barriers, intellectual property, and dispute settlement, and on a number of non-traditional trade topics, such as labor, telecommunications, and e-commerce.[7] The wide variety of topics the treaty addresses and the non-transparent manner in which negotiations have been conducted have fueled the controversy surrounding the treaty.[8]

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[1] OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, OVERVIEW OF THE TRANS PACIFIC PARTNERSHIP (2009), https://ustr.gov/tpp/overview-of-the-TPP.

[2] WORLD INTELLECTUAL PROPERTY ORGANIZATION, CONTRACTING PARTIES/SIGNATORIES: AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS AGREEMENT), http://www.wipo.int/wipo/ex/on/other_treaties/parties/jsp?treaty_id=231&grove-id=22 (last visited Dec. 16, 2016) [hereinafter WIPO].

[3] *See* OFF. OF THE U.S. TRADE REP., JOINT STATEMENT BY TPP MINISTERS (July 2015).

[4] *See* OFF. OF THE U.S. TRADE REP., UNITED STATES TO HOST TRANS-PACIFIC PARTNERSHIP TRADE MINISTERS' MEETING IN ATLANTA (Sept. 2015), https://ustr.gov/about-us/policy-offices/press-releases/2015/September/United-States-host-trans-pacific.

[5] Jackie Calmes, *Trans-Pacific Partnership Trade Deal is Reached but Faces Scrutiny in Congress*, N.Y. TIMES (Oct. 5, 2015), http://www.nytimes.com/2015/10/06/business/trans-pacific-partnership-trade-deal-is-reached.html.

[6] Trans-Pacific Partnership Agreement, Ch. 18, *drafted* Oct. 5, 2015, https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf [hereinafter TPP].

[7] *See* OFF. OF THE U.S. TRADE REP., TPP ISSUE-BY-ISSUE INFORMATION CENTER, https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-issue-issue-negotiating-objectives (last visited Dec. 16, 2016).

[8] *See, e.g.*, *Trans-Pacific Partnership (TPP): Job Loss, Lower Wages, and Higher Drug Prices*, PUBLIC CITIZEN, http://www.citizen.org/TPP (last visited Dec. 16, 2016) (stating that the TPP is not a "free trade" agreement as it only specifically addresses trade issues in five of the twenty-nine draft chapters).

Despite the controversy surrounding the TPP, this agreement follows other significant trade agreements in covering intellectual property. The North American Free Trade Agreement (NAFTA), which was implemented in 1994, was an agreement among the United States, Mexico, and Canada.[9] The NAFTA provisions provided that patents be made 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."[10] Additionally, NAFTA sought to protect trade by ensuring that intellectual property rights, including patent protections, were not enforced so as to offer protection to domestic products.[11] As a result, the United States had to permit reliance on activities occurring in other NAFTA countries to prove a date of invention and adopt a twenty-year patent term.[12] Since the implementation of NAFTA, numerous trade agreements between the United States and other countries have implemented similar intellectual property provisions.[13]

Additionally, the United States entered into TRIPS as part of the Uruguay Rounds Agreement in 1994, which was finalized through the Marrakesh Agreement and established the World Trade Organization (WTO).[14] TRIPS is the most significant step taken to date towards the creation of a uniform system of intellectual property rights and enforcement. For patents, TRIPS provides that "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."[15] TRIPS also provides an international mechanism for resolving disputes that arise regarding intellectual property rights. The Dispute Settlement Body (DSB) of the WTO hears cases arising under TRIPS and these cases are subjected to the procedures

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[9] North American Free Trade Agreement, art. 1709:1, Dec. 17 1992, 107 Stat. 2061 [hereinafter NAFTA].

[10] *Id.*

[11] *NAFTA: The First Major International Trade Agreement to Protect IP Rights*, MILLER CANFIELD, http://www.millercanfield.com/media/article/200162_IP%20Rights.pdf (last visited Dec. 16, 2016).

[12] *Id.*

[13] *See, e.g.*, Korea Free Trade Agreement, ch. 18, U.S.-S. Kor., June 30, 2007, 19 U.S.C. § 3805 (note to statute confirming the United States and Korean Free Trade Agreement Implementation Act).

[14] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 407 [hereinafter TRIPS].

[15] *Id.* art. 27:1.

established under the Dispute Settlement Understanding (DSU).[16] Additionally, TRIPS provides the foundation for the TPP's Intellectual Property Chapter.[17]

In Part II, this Note will examine the domestic patent protections in the United States and the international patent provisions established under TRIPS and how the DSB has resolved conflicts that arise under TRIPS' patent provisions. In Part III, this Note will evaluate how the TPP's patent provisions fit within the framework established by NAFTA and TRIPS. To do so, this Note will explore any changes to existing United States patent provisions that might occur through the adoption of the TPP. Finally, in Part IV, this Note will examine the economic benefits that will accrue to the United States through the adoption of the patent provisions in the TPP. Additionally, this Note will explain why the accrual of economic benefits outweighs the public health concerns at the center of the controversy surrounding the TPP patent provisions.

II. BACKGROUND

The intellectual property provisions of the TPP will have to fit into the existing framework provided for patents in TRIPS, to which the United States Code (U.S.C.) already conforms. The U.S.C. provides the existing domestic framework for patent protection and enforcement, including potential remedies. Meanwhile, TRIPS provides the international framework for patent protection and enforcement.

A. PATENTABLE MATERIAL UNDER THE UNITED STATES' DOMESTIC PATENT PROVISIONS

The United States has enacted statutes to determine a product's patentability. For example, 35 U.S.C. § 101 states that "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" is patentable.[18] Under this standard, the United States allows inventors patent new products, processes, and novel improvements of existing goods. The courts in the United States have

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[16] *Id.* art. 64:1; *see generally* Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU] (the DSU permits DSB panels and the appellate body to hear disputes arising under TRIPS).

[17] *See, e.g.*, TPP, *supra* note 6, art. 18.1 (definition of "intellectual property" relies on concepts covered under TRIPS).

[18] 35 U.S.C. § 101 (2012).

interpreted the utility requirement to require merely that a purported invention have some beneficial use.[19] Additionally, the United States only requires that an inventor set forth the best mode of application when applying for a patent.[20] This allows inventors to specify one use of a product when applying for a patent while also having the option to renew the product when a new use for the product is discovered. This option allows inventors to extend their exclusive use of a product through a practice known as "evergreening."[21] Evergreening is a popular practice for pharmaceutical companies, which extend the effective life of their patent, often well beyond the statutory period of twenty years, to prevent cheaper generic drugs from entering the market.[22]

Furthermore, under the utility prong of analysis, the Supreme Court has held that the invention must have an actual function at the time the inventor files for the patent to fulfill the utility requirement in 35 U.S.C. § 101.[23] The fact that an invention may have a possible use does not make the invention patentable. If there is no definitive use for the invention when the inventor files for the patent, the patent will be rejected.[24]

Once an inventor has shown a product's utility, he must still demonstrate the invention's novelty. Under 35 U.S.C. § 102 (a), a person will be granted a patent unless "the claimed invention was patented, described in a printed publication (or in public use), on sale, or otherwise available to the public before the effective filing date of the claimed invention."[25] While the prior patent or description is applicable to actions taken in the United States and abroad, the public use, availability to the public, and sale of a prior invention exclusions require that the actions be taken only in the United States.[26] Under 35 U.S.C. § 102(a), there is a presumption that an invention is novel.[27] While there are exceptions to the rule established in 35 U.S.C. § 102,[28] these

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[19] *See, e.g.*, Brenner v. Manson, 383 U.S. 519, 532–33 (1966) (citing the utility requirements first set forth in Bedford v. Hunt, 3 F. Cas. 37 (C.C.D. Mass. 1817)).

[20] 35 U.S.C. § 112(a) (2012).

[21] Burcu Kilic, *What is Patentable Under the Trans-Pacific Partnership? An Analysis of the Free Trade Agreement's Patentability Provisions from a Public Health Perspective*, 40 YALE J. INT'L L. ONLINE 1, 2–3 (2015).

[22] *Id.* at 4–5.

[23] *See Brenner*, 383 U.S. at 532–33.

[24] *Id.*

[25] 35 U.S.C. § 102(a)(1) (2012).

[26] *Id.* § 102(a)–(b).

[27] *Id.* § 102(a).

[28] *See generally id.* § 102(b) (enumerating exceptions to the prior art requirement of 35 U.S.C. § 102(a)).

exceptions address when an invention should be granted a patent even when prohibited under 35 U.S.C. § 102(a).

Additionally, the United States requires that an invention be of a non-obvious subject matter. Under 35 U.S.C. § 103 states that "[a] patent for a claimed invention may not be obtained . . . 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."[29] This section requires that the subject matter of the claimed invention must be obvious to a person having ordinary skill in the relevant art.[30] The Supreme Court has held that under 35 U.S.C. § 103, four factors must be used to evaluate the obviousness, or lack thereof, of a claimed invention: (1) the level of ordinary skill in the art; (2) scope and content of the prior art; (3) differences between the claimed invention and the prior art, and; (4) secondary considerations.[31]

Courts have determined the level of ordinary skill in the art by evaluating the qualifications of the inventor, the education level of a typical worker in the art, how quickly new innovations arise in the art, and the sophistication of the technology used in the art.[32] Furthermore, courts have evaluated the scope and content of prior art by examining 35 U.S.C. § 102 to determine what qualifies as prior art.[33] The definition of prior art is restrained by requiring that invention and the prior art must fall within the same art or another art which is reasonably pertinent to the invention to prevent an invention from being patentable.[34] Additionally, courts have found that there must be some appreciable difference between the prior art and the claimed invention; otherwise, the claimed invention would be barred under 35 U.S.C. § 102.[35] Finally, the courts evaluate a number of secondary considerations, including objective indicia of non-obviousness, such as the commercial success of the prior art, the failure of others to solve the problem the invention addresses, and the need for the invention.[36]

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[29] *Id.* § 103.

[30] *Id.*

[31] Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17–18 (1966).

[32] *Id.*

[33] *Id.* at 15.

[34] *Id.*

[35] *See, e.g.*, Bonito Boats v. Thunder Craft Boats, 489 U.S. 141, 150 (1989) (finding that an invention which is not sufficiently different from the prior art fails under both the novelty and non-obvious tests).

[36] Reiner v. I. Leon Co., 285 F.2d 501, 503–04 (2d Cir. 1960).

B. RIGHTS CONFERRED TO PATENT HOLDERS IN THE UNITED STATES

The United States patent statutory framework confers certain rights upon patent holders. For a patented product, no party may make, use, offer for sale, sell, or import the product within the United States without the patent holder's consent.[37] Additionally, for any patented process, no party may use, offer for sale, sell, or import the process within the United States.[38] These prohibitions, combined with enforcement mechanisms, allow patent holders to exercise a near monopoly on the market for their invention for the twenty years the patent remains in effect.

C. POTENTIAL REMEDIES IN THE UNITED STATES FOR PATENT INFRINGEMENT

In the United States, the remedies for a patent infringement claim lie in civil court, not criminal court.[39] A party is found to have infringed upon a patent when they make, use, offer to sell, or sell any patented invention without the patent owner's permission.[40] Additionally, the United States also prohibits the sale or importation of any component of a patented invention that constitutes a material aspect of the invention.[41] If the court determines that a party has violated 35 U.S.C. § 271, then a number of remedies are available to the complaining party.

The United States civil enforcement of patents allows the recovery of many different forms of damages. First, injured parties can seek injunctive relief to prevent continued infringement.[42] If a party does not wish to seek injunctive relief, the courts can also award compensatory damages to the injured party.[43] Compensatory damages must not be less than a reasonable royalty for the use of the invention, including costs and interest, as determined by the court.[44] Finally, the courts can award reasonable attorney fees to the prevailing party in exceptional circumstances.[45] A potential amendment to this section is before Congress, which would change the requirement for attorney fees from exceptional circumstances to bringing or contesting an action in a manner that

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[37] 35 U.S.C. § 154(d)(1)(A)(i) (2012).
[38] *Id.* § 154(d)(1)(A)(ii).
[39] *Id.* § 281.
[40] *Id.* § 271(a).
[41] *Id.* § 271(c).
[42] *Id.* § 283.
[43] *Id.* § 284.
[44] *Id.*
[45] *Id.* § 285.

is not objectively reasonable.[46] This amendment would make the award of attorney fees more readily available.[47]

D. PATENTABILITY PROVISIONS UNDER TRIPS AND NAFTA

TRIPS, signed in 1994, is a multilateral agreement creating uniform, minimum requirements for the patentability of inventions.[48] As of 2015, TRIPS had 161 contracting parties.[49] Furthermore, TRIPS provides a similar framework for the patentability of a product as that found in United States statutes.

Article 27 of TRIPS details the patentable subject matter under the agreement. This article states that "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."[50] Footnote 5 to the agreement states that the phrase "inventive step" is synonymous with a non-obvious use, while the phrase "capable of industrial application" is synonymous with useful.[51] Additionally, Article 33 provides for a twenty year patent term.[52] However, Article 27 does not allow the renewal of a patent when a new use of an existing product is discovered, thereby preventing inventors from undertaking evergreening.[53]

Article 27 also provides limited exceptions to the patentability of inventions. Under this article, countries may exclude inventions from patentability if doing so "is necessary to protect *ordre public* or morality, including to protect human, animal, or plant life. . . ."[54] Article 27 further states that countries can exclude "diagnostic, therapeutic and surgical methods for treatments of humans or animals, and genetically modified plants and animals."[55] These exceptions are limited so that countries cannot exclude inventions from patentability merely because the patentability of the products is prohibited under their law,[56] meaning that the presumption for patentability found in 35 U.S.C. §§ 101–103 is also present under TRIPS.

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46 S. REP. NO. 114-1, at 1137 (2015).
47 *Id.*
48 *See* TRIPS, *supra* note 14.
49 *See* WIPO, *supra* note 2.
50 *See* TRIPS, *supra* note 14, art. 27:1.
51 *See id.* art. 27:1 n.5.
52 *See id.* art. 33.
53 *See* Kilic, *supra* note 21, at 4.
54 *See* TRIPS, *supra* note 14, art. 27:2.
55 *Id.* art. 27:3.
56 *Id.* art. 27:2.

Another important provision in TRIPS is Article 31, which allows for the compulsory licensing of patented inventions.[57] Through the compulsory licensing mechanism, individual countries can permit the production of generic pharmaceuticals. To do so, the country must have made reasonable efforts to obtain authorization from the right holder.[58] If the patent holder fails to address the request from the licensee within a reasonable time, the country can mandate that a license be granted, so long as the country will produce the product predominantly for the domestic market.[59] However, if a country obtains a license under Article 31, the country must pay the patent holder "adequate remuneration in the circumstances."[60]

In 1994, the United States entered into NAFTA with Mexico and Canada.[61] This free trade agreement also addresses intellectual property concerns. Article 1709:1 of NAFTA provides that patents are 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."[62] NAFTA, like TRIPS, correlates "inventive step" with non-obvious uses and "capable of industrial application" with useful.[63] NAFTA also contains the same exclusions to patentability that are present in TRIPS, though NAFTA also permits the exclusion of biological processes for the creation of plants or animals.[64] Furthermore, under NAFTA, like in the United States and under TRIPS, an invention is presumably eligible for a patent.[65]

E. RIGHTS CONFERRED TO PATENT HOLDERS UNDER TRIPS AND NAFTA

The rights conferred upon patent holders under TRIPS and NAFTA are substantially similar. Under TRIPS Article 28:1(a), a patented product cannot be made, used, offered for sale, sold, or imported without the patent holder's consent.[66] Additionally, under TRIPS Article 28:1(b), a patented process cannot

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[57] *Id.* art. 31.

[58] *Id.* art. 31(b).

[59] *Id.* art. 31(b), (f).

[60] *Id.* art. 31(h).

[61] *See* NAFTA, *supra* note 9.

[62] *Id.* art. 1709:1.

[63] *Id.*

[64] *Compare* TRIPS, *supra* note 14, art. 27:2–3 (enumerating exceptions from patentability on moral grounds, for medical processes, and genetically modified organisms), *with* NAFTA, *supra* note 9, art. 1709:2–3 (enumerating exceptions from patentability on moral grounds, for medical processes, genetically modified organisms, and biological processes).

[65] NAFTA, *supra* note 9, art. 1709:1 (stating that "each Party *shall* make patents available" (emphasis added)).

[66] *See* TRIPS, *supra* note 14, art. 28:1(a).

be used, offered for sale, sold, or imported without the patent holder's consent.[67]

Meanwhile, under NAFTA Article 1709:5(a), a patented product cannot be made, used, or sold without the patent holder's consent.[68] The only difference between the NAFTA provision regarding patented products and the corresponding TRIPS and United States provisions is that under NAFTA, offering a patented product for sale is not patent infringement unless the product is actually sold.[69] Although, the United States requirement is stricter than the NAFTA requirements, the United States complies with NAFTA because NAFTA merely provides a minimum standard for patent protection. Finally, under NAFTA Article 1709:5(b), a patented process cannot be used, sold, or imported without the patent holder's consent.[70] Again, the restriction on offering a patented process for sale is absent under NAFTA while it is present under TRIPS and the United States provisions.[71]

While differences exist between the NAFTA provisions and the United States and TRIPS provisions, these differences do not represent material differences among the schemes, as offering a product or process for sale is an element of actually selling the product. Therefore, under NAFTA the act must be completed, while under TRIPS and the United States provisions, the act of selling does not need to be completed.

F. DOMESTIC ENFORCEMENT OF PATENT PROVISIONS UNDER TRIPS AND NAFTA

While both NAFTA and TRIPS provide a framework for minimum protections for patent holders, both treaties allow countries to institute policies which provide more extensive protection for patent rights.[72] Additionally, both treaties provide that the signatory countries shall make the domestic civil courts available for any suit involving patent infringement.[73] Under TRIPS and NAFTA, the civil courts have the authority to award the patent holder injunctive relief,[74] compensatory damages,[75] and reasonable attorney fees.[76]

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67 *Id.* art. 28:1(b).
68 *See* NAFTA, *supra* note 9, art. 1709:5(a).
69 *Compare id.*, *with* TRIPS, *supra* note 14, art. 28:1(a); 35 U.S.C. § 271(a).
70 *See* NAFTA, *supra* note 9, art. 1709:5(b).
71 *Compare id.*, *with* TRIPS, *supra* note 14, art. 28:1(b); 35 U.S.C. § 271(a).
72 *See* TRIPS, *supra* note 14, art. 1:1; NAFTA, *supra* note 9, art. 1702.
73 *See* TRIPS, *supra* note 14, art. 42; NAFTA, *supra* note 9, art. 1715(1).
74 *See* TRIPS, *supra* note 14, art. 44:1; NAFTA, *supra* note 9, art. 1715(2)(c).
75 *See* TRIPS, *supra* note 14, art. 45:1; NAFTA, *supra* note 9, art. 1715(2)(d).
76 *See* TRIPS, *supra* note 14, art. 45:2; NAFTA, *supra* note 9, art. 1715(2)(e).

Additionally, under NAFTA, a court may award compensation, including compensatory damages and attorney fees, to a party accused of infringement when the complaining party has abused the enforcement procedures.[77] However, the treaty does not define abuse of the enforcement procedures and the NAFTA dispute resolution body has not addressed the issue. Therefore, it remains unclear under what circumstances a party accused of infringement under NAFTA can recover attorney fees or compensatory damages.

G. INTERPRETATION OF TRIPS PROVISIONS BY THE DISPUTE SETTLEMENT BODY OF THE WTO

While evaluating the NAFTA patent provisions is beneficial to examine the framework of international patent agreements, the agreement does not provide an effective avenue for interpretation of the agreement, as NAFTA disputes are settled through arbitration.[78] However, TRIPS provides an effective instrument for interpretation of the treaty terms, as the agreement is subject to dispute resolution in the DSB of the WTO.[79] However, since TRIPS was adopted in 1994, the member countries have only brought nine cases before a DSB panel.[80] Of these nine panel cases, only four have dealt directly with the patent provisions.[81] Furthermore, the India—Patents cases dealt with the implementation of TRIPS provisions when TRIPS came into effect, rendering these decisions obsolete in evaluating the regular TRIPS scheme, as India was granted certain concessions while implementing TRIPS.[82] Meanwhile, the trademark dispute between the United States and China regarding Chinese censorship of trademarked materials best demonstrates how the DSB panels will

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[77] *See* NAFTA, *supra* note 9, art. 1715(2)(f).

[78] *Overview of the Dispute Settlement Provisions*, NAFTA Secretariat, https://www.nafta-sec-alena.org/Home/Dispute-Settlement/Overview-of-the-Dispute-Settlement-Provisions (last visited Oct. 25, 2015).

[79] *See* TRIPS, *supra* note 14, art. 64.

[80] Marina Foltea, *WTO Cases Involving TRIPS Agreement*, Turin University (Nov. 18, 2013), http://www.turin-ip.com/paste-editions/2013-edition/training-material-2013/Ms.%20Foltea/Lecture%2018nov13.pdf.

[81] *Dispute Settlement Cases in the Area of TRIPS (as of March 2015)*, World Trade Organization, https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/6_tabledscases_e.pdf (last visited Oct. 25, 2015).

[82] Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/AB/R (adopted Dec. 19, 1997) [hereinafter *India – Patents*]; Panel Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS79/3 (adopted Nov. 27, 1997) [hereinafter *India – Patents II*].

apply TRIPS enforcement provisions.[83] These panel and appellate body decisions highlight how the member countries and DSB interpret TRIPS provisions.

While China—IPRs addresses the United States' concerns about China's censorship of trademarked material and how China disposes of censored material, the case provides analysis of TRIPS Article 41, which states that enforcement measures under TRIPS shall be made available under each member countries' laws.[84] The panel held that China's policy did not allow countries whose goods violated the censorship provision an actual opportunity to gain relief for any violation.[85] The panel reasoned that although China allowed countries to appeal any decisions regarding the rejection of a trademark to the Chinese courts, these appellate procedures failed to provide an effective opportunity for relief under TRIPS Articles 44, 45, 46, and 50.[86] While the Appellate Body decided this case in the context of a dispute about trademarks, this interpretation of Article 41 should also apply to any dispute brought under the patent provisions of TRIPS. Therefore, under the patent provisions, countries must afford an effective opportunity for relief and effective appellate procedures.

Additionally, in *Canada-Patent Term*, the Appellate Body interpreted Canada's implementation of TRIPS Article 33, which requires members to provide a patent period of twenty years from the filing date.[87] The appellate body held that Article 33 requires that each country, upon adopting TRIPS, should implement an effective patent period of at least twenty years from the filing date.[88] This decision demonstrates the Appellate Body's tendency to apply the plain meaning of TRIPS provisions.

Finally, in *Canada-Pharmaceutical Patents*, the panel evaluated whether elements of Canada's Patent Act fell under the general exceptions to TRIPS patent provisions found in TRIPS Article 30.[89] The panel interpreted Article 27.1 to prohibit both *de jure* and *de facto* discrimination based on a product's field of technology.[90] However, the panel held that the European Community (EC) had not provided sufficient evidence that the stockpiling provision of Canada's

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[83] Panel Report, *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WTO Doc. WT/DS362/R (adopted Jan. 26, 2009) [hereinafter *China – IPRs*].

[84] *See* TRIPS, *supra* note 14, art. 41.

[85] *See China – IPRs*, *supra* note 83, ¶ 7.178.

[86] *See id.* ¶ 7.179.

[87] *See* TRIPS, *supra* note 14, art. 33.

[88] Appellate Body Report, *Canada – Term of Patent Protection*, ¶ 85, WTO Doc. WT/DS170/AB/R (adopted Sept. 18, 2000) [hereinafter *Canada – Patent Term*].

[89] Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/R (adopted Mar. 17, 2000) [hereinafter *Canada – Pharmaceutical Patents*].

[90] *Id.* ¶ 7.98.

Patent Act was a violation of TRIPS Article 27.1.[91] Additionally, the panel highlighted that the EC had conceded that Canada's Patent Act did not limit its actions solely to pharmaceutical products.[92] Since the European Community, the complaining party, failed to prove their prima facie case, the panel found no violation of Article 30.

These cases demonstrate that the DSB interpret TRIPS provisions narrowly. In these cases, with the exception of China—IPRs, the panels and appellate body strictly interpreted the terms of the treaty. However, in China—IPRs the panel interpreted TRIPS Article 41 to require an effective avenue for relief in domestic courts, rather than just the possibility for relief.[93] The panel's interpretation of Article 41 represents a slight expansion of the TRIPS provisions.

Finally, the lack of cases brought before the DSB under TRIPS[94] demonstrates either that member countries have largely brought their domestic regulations into conformance with TRIPS or that member countries are wary of bringing disputes under TRIPS lest they upset the delicate balance that prevails in international trade. Despite the lack of complaints brought under TRIPS, the cases that have been brought under TRIPS demonstrate that countries either conform to the TRIPS provisions or other member countries will bring a complaint before the DSB for any gross deviations from the TRIPS provisions.

H. UNITED STATES TRADE PROMOTION AUTHORITY AND THE IMPLEMENTATION OF THE TRANS-PACIFIC PARTNERSHIP

With the finalization of the TPP, the final terms of the treaty must be signed by the negotiating parties. After the treaty is signed, the United States Congress must ratify the treaty. As with most trade agreements, the TPP will go through ratification as a congressional-executive agreement, which merely requires that both houses of Congress pass the implementing legislation rather than requiring two-thirds of the Senate voting to ratify the treaty.[95] The United States Congress confirmed that the TPP would be subjected to the congressional-executive agreement procedure, commonly referred to as "fast track"

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[91] *Id.* ¶¶ 7.99–7.100.

[92] *Id.* ¶ 7.95.

[93] *See China – IPRs*, *supra* note 83, ¶ 7.165.

[94] *See* Foltea, *supra* note 80, at 5 (showing that only 3% of all complaints filed in the WTO have been brought under TRIPS).

[95] *See* Jane M. Smith et al., *Why Certain Trade Agreements Are Approved as Congressional-Executive Agreements Rather Than Treaties*, *Congressional Research Service*, https://www.fas.org/sgp/crs/misc/97-896.pdf (last visited Oct. 25, 2015).

procedures, when both houses passed the Trade Promotion Authority Act (TPA) on June 24, 2015.[96]

TPA provides guidelines for the negotiations of any trade agreement, including objectives for the negotiation of intellectual property provisions in the TPP. Congress set out explicit objectives for the negotiation of intellectual property provisions, including that during negotiations, the executive branch should seek to "promote the adequate and effective protection of intellectual property rights."[97] Congress reasoned that the most effective way to protect intellectual property rights was through the full implementation of TRIPS by all negotiating parties.[98] This requirement would ensure that the intellectual property provisions of any trade agreement would reflect the standards in the United States and provide strong enforcement mechanisms against the infringement of intellectual property rights.[99]

Furthermore, TPA states that if the executive branch fulfills the objectives set forth in 19 U.S.C. § 4201, then both houses of Congress will either adopt or reject the implementing legislation for the treaty without amendment.[100] However, 19 U.S.C. § 4205 provides other procedures that the executive branch must follow, such as publically releasing the final version of the agreement at least sixty days prior to entering into the agreement.[101] These provisions ensure that Congress is well informed of the terms of the agreement prior to a vote on the implementing legislation. These provisions are important because the implementing legislation of a congressional-executive agreement does not enumerate the provisions of the agreement; it merely states Congress's decision to adopt the terms of the agreement.[102]

Therefore, TPA ensures that Congress will either adopt or reject the final terms of the TPP with no amendments made to those terms during the ratification process. The lack of amendments during the ratification process is important for the analysis of the TPP's final terms. Since Congress cannot change the obligations the United States will incur if the treaty is adopted and ratified, the terms can be examined with certainty.

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[96] Jonathan Weisman, *Trade Authority Bill Wins Final Approval in Senate*, June 24, 2015, N.Y. TIMES, http://www.nytimes.com/2015/06/25/business/trade-pact-senate-vote-obama.html.

[97] 19 U.S.C. § 4201(b)(5) (2012).

[98] *Id.* § 4201(b)(5)(A)(i)–(v).

[99] *Id.*

[100] *Id.* § 4205(a)(1)(F).

[101] *Id.* § 4205(a)(1)(B).

[102] *See*, *e.g.*, *id.* § 3311(a)(1) (stating that "Congress approves the North American Free Trade Agreement entered into on December 17, 1992").

III. ANALYSIS

On October 5, 2015, the negotiating countries agreed on the final draft of the TPP.[103] However, since the agreement has not been signed, no country has an obligation to implement the final terms.[104] However, the official release of the TPP provisions will allow the already vigorous public discourse regarding the desirability of the treaty to continue. By analyzing the terms of the final Intellectual Property Chapter, as released by the United State Trade Representative (USTR), this Note will evaluate how these terms fit within the existing framework of patent provisions established through TRIPS and within the United States. Additionally, these terms allow the analysis of the benefits that will accrue to the United States through the adoption of the TPP Intellectual Property Chapter.

A. FINAL TERMS OF THE TRANS-PACIFIC PARTNERSHIP INTELLECTUAL PROPERTY CHAPTER ON PRODUCT PATENTABILITY

Many argue that the TPP would establish an intellectual property regime that is commonly referred to as a "TRIPS-plus Agreement," meaning that the terms of the TPP will expand on the intellectual property provisions found in TRIPS.[105] However, the final terms of the TPP show that the patentability provisions would not expand the TRIPS regime. TPP Article 18.37 (1) provides that "each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application."[106] Footnote 30 to the agreement defines "an inventive step" and "capable of industrial application" as synonymous with "non-obvious" and "useful."[107] When comparing this provision with TRIPS Article 27, the two provisions are exactly the same. Both provisions provide that a product is patentable if it is new, involves an inventive step, and is capable of industrial

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[103] *See* Calmes, *supra* note 5.

[104] Jonathan Weisman, *Trade Authority Bill Wins Final Approval in Senate*, N.Y. TIMES (June 24, 2015), http://www.nytimes.com/2015/06/25/business/trade-pact-senate-vote-obama.html.

[105] *See*, *e.g.*, *Trading Away Health: How the US's Intellectual Property Demands for the Trans-Pacific Partnership Agreement Threaten Access to Medicines*, MÉDECINS SANS FRONTIÈRES (MSF) ACCESS CAMPAIGN, Aug. 2012, https://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Briefing_TPP_Eng_2012_update.pdf (arguing that TPP provisions would create a TRIPS-plus regime).

[106] *See* TPP, *supra* note 6, art. 18.37(1).

[107] *See id.* art. 30.

application.[108] Additionally, the footnote to each provision defines "an inventive step" and "capable of industrial application" as synonymous with "non-obvious" and "useful."[109] Therefore, the terms of the TPP do not create additional obligations regarding the general patentability of products under TRIPS. Furthermore, since the domestic U.S. patent provisions have already been brought into alignment with the TRIPS provisions, the TPP would not affect the patentability provisions found in 19 U.S.C. §§ 101–103. Finally, since the TPP is silent regarding the patent period, the TRIPS patent period of twenty years will remain in effect.[110]

While the general terms of patentability are the same under the TPP as those established by TRIPS, the TPP does further clarify the definition of a product's usefulness. Article 18.37(2) states that each member should make patents available for inventions which are "new uses of a known product, new methods of using a known product, or new processes of using a known product."[111] Although this provision merely serves to clarify what constitutes an inventive step under the TPP, there is no equivalent provision in TRIPS, and the DSB has not had the opportunity to decide whether the TPP definition of an "inventive step" would also apply under TRIPS. Therefore, this provision could represent a slight extension of TRIPS regarding what constitutes an inventive step.

However, the additional provision in the TPP would not affect the domestic provisions in the United States. In the United States, domestic law provides a presumption that a product is a novel concept.[112] A product is deemed not to be novel, and therefore it is not patentable, only if a like product has already been patented, is described in a printed publication, or available for public use.[113] Therefore, the TPP provision allowing for the patentability of any new use of an existing product would be permissible under the presumption of patentability present in the United States.

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[108] *Compare id.* art. 18.37(1), *with* TRIPS, *supra* note 14, art. 27.

[109] TPP, *supra* note 6, n.30; TRIPS, *supra* note 14, n.5.

[110] *See* TPP, *supra* note 6 (noting that the TPP Patent Provisions are silent regarding patent term lengths).

[111] *See id.* art. 18.37(2).

[112] 35 U.S.C. § 282 (2012).

[113] *Id.* § 102(a).

B. IMPORTANCE OF EXCEPTIONS TO PATENTABILITY UNDER THE TPP FOR ALLEVIATING CONCERNS ABOUT PUBLIC HEALTH

The TPP provides for the same general exceptions to patentability that can be found in TRIPS. TPP Article 18.37(3) provides that a country may exclude products from patentability if it is necessary to protect public morality, to protect human, animal, or plant life.[114] Additionally, each party can exclude diagnostic and surgical methods from patentability.[115] Finally, under the TPP, a country can exclude microorganisms and biological processes from patentability.[116] When comparing these general exceptions found in the TPP to those found in TRIPS Articles 27.2 and 27.3, each provision allows for the exclusion of the same products.[117] Additionally, the TPP provides that the compulsory licensing provisions in TRIPS Article 31 still apply to the TPP patent provisions.[118] Therefore, the general exceptions of the TPP do not limit the corresponding general exceptions found under TRIPS.

These exceptions to the TPP serve to limit concerns that pharmaceutical companies will attempt to extend the patent period of essential medicines.[119] One of the major concerns regarding the TPP patent provisions is that the provisions will allow pharmaceutical companies to prevent the advent of generic drugs through the practice of "evergreening."[120] However, Article 18.37 (3) provides that countries can refuse to grant a patent if doing so would be harmful to human life or health.[121] Additionally, the TPP also invokes the Doha Declaration on the TRIPS Agreement and Public Health.[122] The Doha Declaration recognized the gravity of public health problems and stated that TRIPS should be part of the international action taken to address these public health concerns.[123] To do so, the declaration allows countries to use the exceptions in TRIPS to promote access to medicines.[124] Furthermore, TPP Article 18.6 (1)(a) allows countries to invoke the Doha Declaration to protect

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114 *See* TPP, *supra* note 6, art. 18.37(3).

115 *See id.*

116 *See id.* art. 18.37(3)–(4).

117 *Compare id.*, *with* TRIPS, *supra* note 14, arts. 27:2–:3.

118 *See* TPP, *supra* note 6, art. 18.41 (stating that nothing in the TPP limits a Party's rights under TRIPS Article 31).

119 *See, e.g.*, Kilic, *supra* note 21.

120 *Id.*

121 *See* TPP, *supra* note 6, art. 18.37(3).

122 *See id.* art. 18.50(3).

123 Ministerial Declaration, *Ministerial Conference — Fourth Session*, WT/MIN(01)/DEC/1 (Nov. 14, 2001).

124 *Id.* ¶ 4.

public health without fear of violating the TPP.[125] These provisions provide countries with the instruments necessary to combat "evergreening" and serve to alleviate concerns that the TPP patent provisions will endanger international public health initiatives, which rely on generic drugs.

Additionally, Article 18.53, which defines a new pharmaceutical product as a chemical entity that has not been previously patented in the country,[126] could possibly be used to further limit the patentability of medicines. While this article references the pharmaceutical data protection provisions in Article 18.50, it is possible that this definition of a new pharmaceutical product could be used to prohibit evergreening.

Regardless of the applicability of Article 18.53 to the patentability of pharmaceuticals, the TPP provides exceptions to patentability consistent with the exceptions in TRIPS. Countries can use these exceptions to combat potential abuse of the domestic patent regime. These exceptions serve to alleviate the concerns about the potential detrimental effect of the TPP on public health.

C. FINAL TERMS OF THE TRANS-PACIFIC PARTNERSHIP ON ENFORCEMENT OF PATENT PROVISIONS

The TPP provides enforcement provisions similar to those found in TRIPS. TPP Article 18.71(1) provides that "[e]ach Party shall ensure that enforcement procedures as specified in this Section are available under its law so as to permit effective action against any act of infringement. . . ."[127] This provision in the TPP corresponds with Article 41 of TRIPS, which provides that "[m]embers shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement. . . ."[128] The TPP provision regarding the obligation to implement a domestic scheme to enforce provisions of the agreement is exactly the same as the provision found in TRIPS.

Since the TPP and TRIPS both create the obligation to create a domestic scheme to enforce the relevant provisions of the agreements, the relevant provisions must be evaluated to determine if the TPP creates additional obligations. First, under TPP Article 18.74(1), the remedy for any infringement of a patent will lie in civil courts, not criminal courts.[129] The civil remedy for

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125 *See* TPP, *supra* note 6, art. 18.6(1)(a).
126 *See id.* art. 18.53.
127 *See id.* art. 18.71(1).
128 *See* TRIPS, *supra* note 14, art. 41.
129 *See* TPP, *supra* note 6, art. 18.74(1).

patent infringement is also found in the United States domestic regime[130] and TRIPS.[131]

Second, the TPP states that compensatory damages must be available to the complaining party should they prevail over the infringing party.[132] Compensatory damages may include lost profits, fair market value of the infringed goods, or suggested retail price.[133] TRIPS, like the TPP, allows for the recovery of compensatory damages when the complaining party prevails.[134] However, TRIPS does not explain which losses can be used to calculate compensatory damages. The drafters of the TPP illustrate what constitutes compensatory damages while the TRIPS drafters fail to do so. This additional clarity does create obligations beyond those found in TRIPS, as domestic courts are now restricted in how they can calculate compensatory damages. Additionally, these TPP provisions will restrict the calculation of compensatory damages for patent infringement in the United States, as the United States currently only provides a minimum amount for compensatory damages, equivalent to a reasonable royalty fee.[135]

The TPP also permits domestic courts to grant injunctive relief to a complaining party, as long as such relief conforms to TRIPS Article 44.[136] Since this provision relies on TRIPS Article 44 to limit its applicability, this provision clearly adheres to the TRIPS enforcement provision regarding injunctive relief. However, the TPP also states that should any party request a temporary injunction prior to litigation and abuse the relief, that party shall "provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered. . . ."[137] This provision is in place to prevent parties from frivolously requesting a preliminary injunction. However, TRIPS has no such provision.[138] Therefore, this provision creates a new obligation for the parties to the TPP. Additionally, the United States does not have any such provision in the existing enforcement regime.[139] Therefore, the United States will have to amend 19 U.S.C. § 283 to include provisions allowing a wrongfully enjoined party to recover against the complaining party.

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130 35 U.S.C. § 281 (2012).
131 *See* TRIPS, *supra* note 14, art. 42.
132 *Id.* TPP, *supra* note 6, art. 18.74(3).
133 *See id.* art. 18.74(4).
134 *See* TRIPS, *supra* note 14, art. 45:1.
135 35 U.S.C. § 284 (2012).
136 *See* TPP, *supra* note 6, art. 18.74(5).
137 *See id.* art. 18.74(15).
138 *See* TRIPS, *supra* note 14.
139 *See* 19 U.S.C. § 283.

Finally, the TPP dictates that each country should allow the prevailing party to recover their reasonable attorney fees.[140] This provision is compatible with the TRIPS regime, which also allows the recovery of reasonable attorney fees.[141] Therefore, the TPP does not create a new obligation regarding the recovery of attorney fees. Furthermore, this TPP provision does not necessitate a change to the United States domestic policy, as the United States already allows for the recovery of reasonable attorney fees.[142]

D. ECONOMIC BENEFITS THAT WILL ACCRUE TO THE UNITED STATES UNDER THE PATENT REGIME IN THE TRANS-PACIFIC PARTNERSHIP

The TPP intellectual property provisions represent a potential boom for the United States economy. While many argue that the TPP will be harmful to the United States, these concerns do not address the benefits that will accrue to the United States under the intellectual property provisions.[143] Instead, the concerns around the intellectual property provisions focus on the effects on public health in other countries, which are addressed earlier in this Note. Additionally, the United States stands to gain significant benefits from the implementation of the intellectual property provisions in the TPP.

The United States economy relies on IP-intensive industries. In 2010, IP-intensive industries made up 34.8% of the United States' Gross Domestic Product (GDP), accounted for 60.7% of the United States' merchandise exports, provided 18.8% of American jobs, and accounted for 19% of all United States private services exports in 2007.[144] Patent-intensive industries alone made up 5.3% of the United States' GDP and provided 2.7% of American jobs.[145] Additionally, between 2010 and 2011, patent-intensive industries experienced a 2.3% growth rate, which outpaced the non-IP-intensive industries in the United States.[146] The significant increase in patents granted between 2013 and 2014 further demonstrates the growth of patent-intensive

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140 TPP, *supra* note 6, art. 18.74(11).

141 *See* TRIPS, *supra* note 14, art. 45:2.

142 35 U.S.C. § 285.

143 *See, e.g.*, Richard Trumka, *The Trans-Pacific Partnership Is a Bad Deal for American Workers*, TIME (Oct. 8, 2015), http://time.com/4065267/trans-pacific-partnership-american-workers.

144 *Intellectual Property and the U.S. Economy: Industries in Focus*, Economics and Statistics Administration and United States Patent and Trademark Office (Mar. 2012), http://www.uspto.gov/sites/default/files/news/publications/IP_Report_March_2012.pdf.

145 *Id.*

146 *Id.*

industries within the United States.[147] This economic data highlights the importance of IP-intensive industries within the United States economy.

The importance of IP-intensive industries, specifically patent-intensive industries, demonstrates the possible impact of any changes to the intellectual property regime resulting from the TPP. The TPP will serve to create uniform patent provisions in the twelve signing countries. The importance of this uniformity cannot be understated. The twelve parties to the TPP combine to make up nearly 40% of global GDP, providing an exceptionally large, uniform market for United States' patent-intensive industries.[148] Additionally, the United States will have to make no significant changes to the existing domestic regime to conform to the TPP.[149] Meanwhile, countries that have not implemented effective intellectual property protection schemes will have to raise their domestic standards to conform to the TPP.[150] The TPP implements these stringent intellectual property standards to promote innovation in patent-intensive industries, benefitting those countries that have strong patent-intensive industries, such as the United States.[151]

By creating uniformity in the market and opening new markets to United States industries, the TPP will induce the patent-intensive industries within the United States to expand the exportation of their products, as the uncertainty costs inherent in a non-uniform system will no longer dissuade the exportation of products. Additionally, the uniform provisions and intensive enforcement mechanisms in the TPP will prevent the distribution of infringing products, and producers within the United States will then increase exports to fill the resulting deficit in products.

As detailed above, the TPP presents American patent-intensive industries with the opportunity to expand their growth. As production of existing products increases and new products are invented, the patent-intensive industries will continue to increase their contribution to the United States' GDP and the number of jobs these industries create within the United States. Through the implementation of the TPP, the United States will accrue benefits to domestic production and employment.

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147 *See* U.S. PATENT AND TRADEMARK OFFICE, U.S. PATENT STATISTICS CHART: CALENDAR YEARS 1963–2014 (2015) (indicating that patent grants increased from 302,948 in 2013 to 326,033 in 2014, a 7.6% increase).

148 *See* OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, *supra* note 1.

149 Derek Scissors, *Grading the Trans-Pacific Partnership*, AMERICAN ENTERPRISE INSTITUTE (Dec. 9, 2015), https://www.aei.org/wp-content/uploads//2015/12/Grading-the-Trans-Pacific-Partnership-on-trade.

150 *Id.*

151 *Id.*

E. THE TPP IS DEAD. LONG LIVE THE TPP

During the 2016 campaign for President of the United States, free trade agreements took center stage in the discussion. First, Democratic hopeful Bernie Sanders bemoaned the dangers of the TPP during the Democratic primary.[152] Then, during the general election, Donald Trump began to echo some of Senator Sanders's hostility toward free trade. In June 2016, Donald Trump gave a speech in which he vowed to either renegotiate or withdraw from NAFTA and to withdraw from the TPP.[153] However, Trump's criticisms were focused more intently on convincing voters that free trade agreements were at fault for job loss in the United States,[154] rather than any complaints about the form of modern trade agreements, which incorporate several different topics. However, with Donald Trump winning the election, it is unlikely that TPP will become law in the United States.[155] Further demonstrating the likely demise of the TPP, several senators have announced that the TPP will not pass through the lame duck Congress before President Obama's term ends.[156]

Despite these setbacks towards the ratification of the TPP, the arguments made in this Note are still applicable. It is unlikely that the template of modern trade treaties will change significantly because of Trump's election. The arguments regarding the economic benefits that would accrue to patent-intensive industries will continue to foster a desire to protect domestic patent-intensive industries during the negotiation of international trade agreements. Additionally, the loss of status in Southeast Asia and the possibility of China's resurgence in the area could lead to the resuscitation of the TPP, as the United States will likely want to continue to check Chinese political and economic growth in the region.[157]

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[152] *See, e.g.*, Arnie Seipel, *Sanders Centers Platform Fight on Trans-Pacific Trade Deal*, NPR (July 3, 2016, 12:50 PM), http://www.npr.org/2016/07/03/484574128/sanders-centers-platform-fight-on-trans-pacific-trade-deal.

[153] Russell Berman, *Trump's Shockingly Specific Speech on Trade*, THE ATLANTIC (June 28, 2016), http://www.theatlantic.com/politics/archive/2016/06/Donald-trumps-shockingly-specific-speech-on-trade/489194.

[154] *Id.*

[155] *See Fact Check: Donald Trump's First 100 Days Action Plan*, NPR (Nov. 10, 2016), http://www.npr.org/2016/11/10/501597652/fact-check-donald-trumps-first-100-days-action-plan.

[156] Elise Laboot & Nicole Gaouette, *TPP defeat, future of US–Asian alliances sour Obama's final trip* (Nov. 14, 2016, 8:41 AM), http://www.cnn.com/2016/11/14/politics/tpp-trade-deal-trump-oba ma-trip.

[157] *Id. See also* Ian Talley, *Trump's Vow to Target China's Currency Could be First Step to Trade War*, WALL ST. J. (Nov. 15, 2016, 12:40 PM), http://www.wsj.com/articles/donald-trumps-pledge-to-get-tough-on-china-raises-threat-of-trade-war-1478804077 (demonstrating that the Trump Administration will likely take a hard line on issues concerning the rise of China).

While the current climate lends an air of uncertainty to the future of trade agreements, it is unlikely that trade agreements will significantly change in the coming years. Nations have been committed to liberalizing trade since the end of World War II, with the ratification of GATT 1947.[158] Additionally, for the past twenty-five years, nations around the world have entered into agreements which combine traditional trade topics with other provisions, including intellectual property provisions. It is unlikely that the current setback to the TPP will change the template that has developed in the past twenty-five years.

IV. CONCLUSION

Since negotiations began on the TPP, the agreement has faced extensive criticism. Many parties were concerned the agreement would significantly alter the international patent regime established in TRIPS. However, the TPP does not materially alter the existing scheme for the patentability of products and patent enforcement. Instead, the treaty merely clarifies ambiguous provisions in TRIPS, while United States domestic provisions will remain unchanged.

Additionally, the TPP's drafters took steps to alleviate the public health concerns surrounding the treaty by explicitly allowing for patent exceptions to protect human health and life. The agreement will allow countries to reject product patents when granting the patent would threaten human health or life, either by invoking the exceptions in Article 18.37(3) or Article 18.50(3) and the Doha Declaration. Additionally, the TPP allows countries to continue using the compulsory patent licensing scheme under TRIPS Article 31.

Finally, the TPP will have minimal effect on the existing patent regime in the United States, as the domestic regime already conforms to the TRIPS agreement. Yet the TPP will create a large, uniform international market, which approaches the rigorous patent standards found in the United States. These raised standards will allow domestic patent-intensive industries to increase their exports. Subsequently, these industries will continue to grow and increase domestic employment levels and GDP. These benefits, combined with the alleviation of public health concerns, demonstrate that the TPP patent provisions will greatly benefit the United States.

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158 *See, e.g.*, General Agreement on Tariffs and Trade (1947) Preamble, Oct. 30, 1947.