CREATING A MORE PERMISSIVE PATENTABILITY STANDARD UNDER LANGUAGE FROM THE TPP♦

INTRODUCTION

Each day the separate nations of the world are slowly melding together. Isolationism is no longer plausible in the modern world. Every action has an effect that can easily spread across the entire globe. While this globalization has its upsides and has shaped the modern world, there are downsides due to a lack of privacy and isolation. Inventors and intellectuals as far back as the 1800's started to notice one of these issues.[1] While inventors might have been able to protect their inventions in their respective countries, protection became nearly impossible once other individuals of foreign countries got hold of these new ideas and decided to pass them off as their own.[2] Suddenly, going to global trade shows and technology fairs frightened inventors and bred a community

[1] *WIPO-A Brief History*, WORLD INTELLECTUAL PROP. ORG. [WIPO], http://www.wipo.int/about-wipo/en/history.html (last visited Oct. 25, 2016).

[2] *Id.*

of thieves who would steal and market inventions and claim inventorship in foreign countries.[3] This fear became evident in 1873, when inventors refused to attend the International Exhibition of Inventions in Vienna, Austria due to a fear of foreigners stealing their ideas.[4] This prevalence of stealing had further consequences, stifling innovation since stealing ideas became more lucrative than actually inventing original designs. In an effort to address these problems, the first major international agreement on intellectual property was created: the Paris Convention for the Protection of Industrial Property.[5] While the agreement covered only patents, general trademarks, and industrial designs (along with many subtopics related to these fields), and did not allow for an international intellectual property filing system,[6] it became an important first step in international intellectual property rights.[7]

The World Intellectual Property Organization (WIPO) was formed in the 1970's and shortly thereafter joined the United Nations (UN).[8] Intellectual property rights were no longer limited to individual countries or small groups of countries but instead an individual's rights could become global.[9] The problem is that in the amount of time it took for the world to come together and protect intellectual property rights of all individuals, each country had carved out its own legal system with its own set of intellectual property laws.[10] In an attempt to keep their own rules intact and gain their inventors' global intellectual property protection, countries turned to trade agreements.[11] While trade agreements often need domestic implementation to have an effect upon substantive law, trade agreements have the capacity to completely change countries' laws, including countries like the United States.[12] Trade agreements began to have power in the United States with the passing of the Trade Agreements Act of 1934.[13] From this starting point, Congress kept expanding presidential authority to enter into these agreements, making it easier for these agreements to affect U.S. law.[14]

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3 *See generally id.*
4 *Id.*
5 *Id.*
6 The first international filing system came about in the Madrid Agreement of 1891. *Id.*
7 *Summary of the Paris Convention for the Protection of Industrial Property (1883)*, WORLD INTELLECTUAL PROP. ORG. [WIPO], http://www.wipo.int/treaties/en/ip/paris/summary_paris.html (last visited Oct. 25, 2016).
8 *WIPO*, *supra* note 1.
9 *See generally id.*
10 *See generally id.*
11 *See generally* Amir H. Khoury, *The "Public Health" of the Conventional International Patent Regime & the Ethics of "Ethicals:" Access to Patented Medicines*, 26 CARDOZO ARTS & ENT L.J. 25, 27–28 (2008).
12 *See generally* Isaac Hasson, *Domestic Implementation of International Obligations: The Quest for World Patent Law Harmonization*, 25 B.C. INT'L & COMP. L. REV. 373, 375 (2002).
13 19 U.S.C. §§ 1351–54 (2012).
14 *See, e.g.*, 19 U.S.C. §§ 4201, 4206 (2012).

These agreements all have common construction in that they define trade policy goals, ensure the executive branch adheres to those goals, define the terms the President can enter into for trade agreements, and attempt to preserve Congress' lawmaking power by requiring a formal approval process.[15] If the President complies with this basic structure, the President is granted "fast track" approval of the agreements through Congress.[16] Congress must vote "yes" or "no" on the agreement without modification.[17]

This enhanced power has led to the President's increased legislative influence, even though "fast track was invoked only five times during the 20 years that fast track authority was in effect (1974–94), and since 1999 six pieces of trade legislation was [sic] enacted without fast track. Thus, the pressure on passage of the TPA appears to be more political than substantive."[18] One such congressionally enacted trade agreement which had real substantive effect on the United States was the North Atlantic Free Trade Agreement ("NAFTA").[19] The agreement had such an effect on U.S. patent practice that the United States Patent and Trademark Office (USPTO) had to publish a memorandum post-enactment that pointed out these changes, including changes to the date of invention, the priority dates of inventions, adoption of a twenty-year patent term, and more.[20]

In 1994, the United States signed the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), which further expanded the power of trade agreements over U.S. patent law.[21] TRIPS was an international trade agreement signed by the United States and a number of other countries in an attempt to globalize intellectual property law.[22] But, in signing the agreement, the United States gave up a portion of its sovereignty in domestic patent law.[23] This agreement in

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[15] Kenneth Kopf, *Obama 'Free Trade Agreements' Force Congress's Hand, Create a Constitutional Dilemma*, CNSNEWS.COM (June 16, 2015, 4:58 PM), http://www.cnsnews.com/commentary/kenneth-kopf/obama-free-trade-agreements-force-congresss-hand-create-constitutional.

[16] *Id.*

[17] *Id*.

[18] *Id.* Note that the TPA stands for trade promotion authority, which grants the president the power to fast track the review/approval process for trade agreements.

[19] This was implemented under the North American Free Trade Agreement Implementation Act. 19 U.S.C. §§ 3301, 3311–12 (2012).

[20] U.S. PATENT AND TRADEMARK OFFICE, EFFECTS OF GATT AND NAFTA ON PTO PRACTICE, http://www.uspto.gov/web/offices/com/doc/uruguay/URPAPER.html (last visited Oct. 25, 2016).

[21] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[22] *See generally* Donald P. Harris, *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet Back Against the United States*, 25 NW. J. INT'L L. & BUS. 99 (2004).

[23] *Id.* at 110. ("[T]he United States will have to strengthen its intellectual property regime to comply with TRIPS and possibly TRIPS-plus. By doing so, the United States relinquishes its sovereign power regarding intellectual property laws.")

particular relinquished some domestic intellectual property laws, empowering these types of trade agreements and giving authority to the World Trade Organization (WTO).[24] Following this trend of implementing powerful trade agreements that shape domestic intellectual property law, in February 2016, President Obama signed the Trans-Pacific Partnership ("TPP"), a far-reaching international trade agreement that has heavy implications for domestic and international intellectual property law.[25] Despite this signature, the TPP was never implemented into law, and going forward, the future of the trade deal is unclear.[26]

This Note explores the extensive and differing case law on patent eligibility under 35 U.S.C. § 101 of the Patent Act. This Note then suggests that with the chaotic state of current U.S. case law, section 18 of the TPP may open up the door for change in U.S. patentability analysis, particularly under § 101. While the current case law jurisprudence and the TPP stances on patentability clash, the TPP standard may be more in-line with current U.S. sentiment towards the courts' and the USPTO's § 101 analysis. The current lack of clarity in § 101 case law as well as what many have called an overtly limiting and difficult patent eligible subject matter test—especially in the areas of software and computer-related inventions—has led to this heightened negative sentiment with the current U.S. case law.[27] With current sentiment so high, the TPP standard may provide real potential to rewrite patentability standards. The one obstacle to overcome is that the TPP is currently not very popular in the United States and President Trump has expressed that the United States will abandon the TPP.[28] Despite the apparent death of the TPP, going forward, President Trump should adopt the TPP's patentability language when negotiating future trade deals. This Note points out that if President Trump does not take this action, then Congress can still adopt the language of the TPP. This would expand patentability for a number of patents now thought patent ineligible by current standards. At the same time, the TPP language may

[24] *Id.* at 117–20; U.S. PATENT AND TRADEMARK OFFICE, *supra* note 20.

[25] *Trans Pacific Partnership Trade Deal Signed in Auckland*, BBC (Feb. 4, 2016), http://www.bbc.com/news/business-35480600.

[26] Tim Worstall, *With Trump's Election The TPP Probably Is Dead, Yes - As Is The TTIP*, FORBES (Nov. 11, 2016, 4:35 AM), http://www.forbes.com/sites/timworstall/2016/11/11/with-trumps-election-the-tpp-probably-is-dead-yes-as-is-the-ttip/#d29b49b5b809.

[27] *See, e.g.*, Steven M. Amundson, *The Supreme Court's Decision in Alice Corp. v. CLS Bank Has Taken a Heavy Toll on Patents for Computer-Related Inventions*, LEXOLOGY (Feb. 16, 2016), https://www.lexology.com/library/detail.aspx?g=300e6862-012d-49dd-bed4-ba8ae4477397; Ryan Davis, *Kappos Calls For Abolition Of Section 101 Of Patent Act*, LAW360 (Apr. 12, 2016, 4:32 PM), https://www.law360.com/articles/783604/kappos-calls-for-abolition-of-section-101-of-patent-act.

[28] Peter Baker, *Trump Abandons Trans-Pacific Partnership, Obama's Signature Trade Deal*, N.Y. TIMES (Jan. 23, 2017), https://www.nytimes.com/2017/01/23/us/politics/tpp-trump-trade-nafta.html?_r=0.

provide the final nail in the coffin for certain types of diagnostic methods that the U.S. Supreme Court has refused to reexamine in *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*.[29] This Note argues that President Trump and/or Congress should take the necessary steps to rewrite § 101 patentability standards to match TPP standards, in order to bring some certainty to a market currently in a state of chaos since the U.S. Supreme Court decision in *Alice Corporation v. CLS Bank International*.[30]

Part I of this Note explores the TPP, with a focus on section 18, and the new patentability standard. Part II of this Note will track current U.S. case law on § 101 of the Patent Act. Part III of the Note will compare the differences between the two standards and discuss how adjusting § 101 case law to match the patentability language of the TPP can bring certainty to the patent marketplace as well as help to bring the United States in line with global intellectual property standards. This adjustment can be accomplished through changing 35 U.S.C. § 101 by using language directly from the TPP, implementing TPP-type language in future trade agreements, or Congress implementing TPP-type language in place of the current 35 U.S.C. § 101 language.

I. THE TRANS-PACIFIC PARTNERSHIP AND TRADE AGREEMENTS

A. *Background*

The TPP was a document shrouded in secrecy. The trade agreement negotiations involved 12 countries, including the United States, Mexico, Canada, Japan, and others.[31] All throughout negotiations and until the secret discussions concluded on October 5, 2015, very little was known about what the trade agreement encompassed.[32] Then on October 9, 2015, Wikileaks leaked the final text of the agreement, finally lifting the veil of the secret negotiations.[33] According to the BBC, "[t]he pact aims to deepen economic ties between these nations, slashing tariffs and fostering trade to boost growth,"[34] and the pact may even lead to a single world market among

[29] Sequenom, Inc. v. Ariosa Diagnostics, Inc., 136 S. Ct. 2511 (2016).
[30] Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).
[31] *See generally* Trans-Pacific Partnership Agreement, chap. 18, Feb. 4, 2016, https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text [hereinafter TPP] (The actual full list includes: the United States, Mexico, Canada, Australia, Malaysia, Chile, Singapore, Peru, Vietnam, New Zealand and Brunei Darussalam).
[32] *Id.*
[33] *Id.*; *see Trans-Pacific Partnership Agreement (TPP): Intellectual Property [Rights] Chapter, Consolidated Text*, WIKILEAKS (Oct. 9, 2015), https://wikileaks.org/tpp-ip3/WikiLeaks-TPP-IP-Chapter/WikiLeaks-TPP-IP-Chapter-051015.pdf.
[34] *TPP: What is it and why does it matter?*, BBC (Jan. 27, 2016), http://www.bbc.com/news/business-32498715.

signing nations, much like how the EU market works.[35] To understand the significance of the agreement, the total trade of the nations within the pact make up 40% of worldwide GDP.[36] While this deal is monumental in nature, it is important to note that the signatories have until February 2018 for at least six countries, making up 85% of the group's total economic output, to ratify the agreement.[37]

In the United States, the future of the TPP remains unclear, as President Trump has officially signed a document announcing the United States' plan to abandon the agreement.[38] Even though the U.S. implementation of the TPP seems unlikely, there is still hope that similar patentability language will be implemented in trade deals going forward. Also on President Trump's agenda is his wish to renegotiate NAFTA.[39] With this renegotiation comes the chance that President Trump will not abandon the respected and thoroughly negotiated patentability language of the TPP.[40] Opportunities for pursuing such language are provided by other potential trade deals such as NAFTA. Additionally, TPP-signing parties (especially Japan) have expressed interest in keeping the TPP itself alive, potentially even pulling the United States back into the deal.[41] This may come in the form of a "slimmed down" version of the TPP, which cuts down upon some of the more controversial sections of the agreement.[42] If this option were pursued, the United States should make sure that the TPP patentability language is not altered.

Despite the TPP potentially being off the table, it is important to understand what the TPP proposed and which industries would have been affected. The TPP consists of thirty chapters, covering a wide

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[35] *See generally EU market rules*, EUROPEAN COMM'N, http://ec.europa.eu/small-business/most-of-market/rules/index_en.htm (last visited Oct. 25, 2016).

[36] *TPP: What is it and why does it matter?*, *supra* note 34.

[37] *Id.* This will require the implementation of the agreement by Japan and the United States.

[38] Peter Baker, *Trump Abandons Trans-Pacific Partnership, Obama's Signature Trade Deal*, N.Y. TIMES (Jan. 23, 2017), https://www.nytimes.com/2017/01/23/us/politics/tpp-trump-trade-nafta.html.

[39] *Id.*

[40] Emily Stewart, *Trump Kills TPP, Cutting Off Potential Big Payday for Tech, Retail*, THESTREET (Jan. 24, 2017), https://www.thestreet.com/story/13962847/1/trump-kills-tpp-cutting-off-potential-big-payday-for-tech-retail.html (explaining the popularity of the TPP with numerous tech companies).

[41] Jonathan Soble, *After Trump Rejects Pacific Trade Deal, Japan Fears Repeat of 1980's*, N.Y. TIMES (Jan. 25, 2017), https://www.nytimes.com/2017/01/25/business/trump-tpp-japan-trade.html; *see also New Zealand, Australia Leaders Press for TPP to Move Forward*, 21 BRIDGES 6 (Feb. 23, 2017), http://www.ictsd.org/bridges-news/bridges/news/new-zealand-australia-leaders-press-for-tpp-to-move-forward.; *but see* Mike Blanchfield, *Without TPP, Canada Looks for New Asian Trade Deal*, GLOB. NEWS (Feb. 22, 2017, 5:19 PM), http://globalnews.ca/news/3266365/canada-asian-trade-post-tpp/ (expressing doubt of changing President Trump's mind on the deal).

[42] Anthony Fensom, *While Trump and Abe Eye Bilateral Pact, Australia Keeps TPP Alive*, THE DIPLOMAT (Feb. 12, 2017), http://thediplomat.com/2017/02/while-trump-and-abe-eye-bilateral-pact-australia-keeps-tpp-alive/.

variety of topics including textiles, labor, and intellectual property.[43] One important provision that the TPP addresses is how other international trade agreements will remain in effect, so this new agreement does not cause any signing parties to break their old trade agreements.[44] Despite this, the agreement still reaches "unprecedented worker and environmental protections."[45] As Mireya Solís, a senior fellow at the Brookings Center for East Asia Policy Studies, said in an interview with *The New Yorker*: "I don't know how we got to the point that T.P.P. became a pariah; it is the most far-reaching, progressive, important and advantageous trade pact in two decades."[46] A 2015 study found that, due to trade agreements dated from 2000 until 2014, the United States had a $30.9 billion trade surplus with trade agreement member countries in 2014, compared to a deficit of $2.8 billion with the same countries just the year before the trade agreements were implemented.[47]

Despite this, major opponents of the deal are concerned with the possible increased outsourcing of jobs, pointing to NAFTA.[48] This Note will not cover the effect on employment, the 18,000 tax cuts on U.S. exports,[49] or any of the other thirty sections covered by the TPP, but will instead focus specifically on Chapter 18: the Intellectual Property chapter. President Trump's main opposition to the trade deal lies with the labor and trade sections; he did not specifically mention any objections to Chapter 18.[50] Because of President Trump's lack of stated opposition to Chapter 18, specifically, the patentable subject matter clause of the TPP,[51] it is quite possible that similar TPP patentability language will be implemented in future trade deals. Since the patentability language of Chapter 18 was thoroughly negotiated and fairly popular,[52] the language of this chapter should be used in future trade agreements and eventually be implemented by Congress, thus surviving the potential death of the TPP. Even without the formation of other trade agreements, Congress still has the option of directly

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[43] *See generally* TPP, *supra* note 31.

[44] The Trans-Pacific Partnership Agreement, Initial Provisions and General Definitions, Feb. 4, 2016, https://ustr.gov/sites/default/files/TPP-Chapter-Summary-Initial-Provisions-and-General-Definitions.pdf.

[45] Jeffrey Rothfeder, *Why Obama Is Still Trying to Pass the T.P.P.*, THE NEW YORKER (Sept. 18, 2016), http://www.newyorker.com/business/currency/why-obama-is-still-trying-to-pass-the-t-p-p.

[46] *Id.* The trade pact mentioned from two decades earlier is the North American Free Trade Agreement (NAFTA).

[47] *Id.*

[48] This is despite evidence that NAFTA did not have a massive impact on U.S. jobs. *Id.*

[49] *See generally* TPP, *supra* note 31.

[50] Paul Blake, *Trump and Trade: How the President-Elect Could Tear Up TPP and Nix NAFTA*, ABC NEWS (Nov. 11, 2016, 4:36 PM), http://abcnews.go.com/Business/trump-trade-president-elect-tear-tpp-nix-nafta/story?id=43467294.

[51] *Id.*

[52] *See* Stewart, *supra* note 40.

adopting the TPP language in place of 35 U.S.C. § 101. This alternative option means that the implementation of TPP language can still proceed despite the political fracas which can halt discussion or implementation of international trade agreements.

B. *Chapter 18: Intellectual Property*

The intellectual property chapter of the TPP is extensive and covers patents, copyright, trademarks, trade secrets, and more.[53] This Note will focus only on the patent-related aspects of Chapter 18. Chapter 18 has been one of the most discussed sections of the TPP, besides the patentability section, and has generally received negative feedback.[54] Before delving into the actual substance of this section, it is important to note a few preliminary articles of the document. There are a number of "principles"[55] listed in these preliminary sections, mainly suggesting that if a member of the agreement were to heavily object to a provision under this section, these principles may give some leeway for signatories to avoid implementation.[56] These principles aim to protect a party's right 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 Chapter."[57] Another principle states that measures may be needed "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."[58] These sections point to some flexibility in the intellectual property provisions of the TPP, as long as they do not blatantly contradict Chapter 18.[59] Furthermore, Article 18.11 states that intellectual property exhaustion will not be controlled under Chapter 18.[60] This provision contains a footnote, which states that this provision exists so the TPP will not interfere with other international agreements.[61] This gives signing parties very broad power to change only the limited area of patent exhaustion law within their respective countries as each country sees fit.

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53 *See generally* TPP, *supra* note 31.

54 Mark Summerfield, *Patents and the Trans-Pacific Partnership Agreement, Part 1*, PATENTOLOGY (Nov. 29, 2015, 10:54 PM), http://blog.patentology.com.au/2015/11/patents-and-trans-pacific-partnership.html.

55 TPP, *supra* note 31, at art. 18.3.

56 John T. Aquino, *Biopharma Reaction Divided on TPP Trade Agreement*, BLOOMBERG BNA: HEALTH CARE ON BLOOMBERG LAW (Nov. 6, 2015), http://www.bna.com/biopharma-reaction-divided-n57982063254/.

57 TPP, *supra* note 31, at art. 18.3(1).

58 *Id.* at art. 18.3(2).

59 *Id.* at art. 18.3.

60 *Id.* at art. 18.11.

61 *Id.* at art. 18.7, n.8.

To further enforce pre-existing trade agreements that the parties may be a part of, the TPP requires signatories to be members of a number of prior agreements and conventions, such as the Paris Convention for the Protection of Industrial Property, the Patent Cooperation Treaty (PCT), the UPOV Convention for the Protection of New Varieties of Plants (UPOV 91), and the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.[62] Additionally, the TPP has chapters that affect patents in eight major ways. Article 18.38 creates a year-long grace period for prior art disclosed by the patent applicant or someone with the patent applicant's information for novelty and obviousness claims. Article 18.46 implements a patent term adjustment if there is an unreasonable delay in the issuance of a patent and availability of patent term extensions if a regulatory delay occurs. Article 18.47 creates a ten-year exclusivity period for new agricultural chemical products. Article 18.50 creates a period of at least five years for exclusivity of new pharmaceutical drugs. Article 18.51 creates an exclusivity period of eight years for biologics or a lesser protection of five years "with market outcome comparable to eight."[63] Multiple articles state that market exclusivity does not diminish a patent term for agricultural chemical products, pharmaceutical products, or biologics. Finally, Article 18.37 creates an update on patentable subject matter.[64] This Note will focus on this final provision, Article 18.37 and the TPP patentability standards.

To understand this updated patentability standard, it is important to analyze the actual language of the TPP. The first two paragraphs of Article 18.37 state that patents should be available for any inventions (products, processes, or methods) "in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application."[65] These provisions generally match U.S. law and prior trade agreements.[66] Paragraphs three and four of the TPP state that parties can exclude the following from patentability:

> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) animals other than microorganisms, and

[62] *Id.* at art. 18.7. Note that all of these agreements are fairly widely adopted at this point.

[63] Jeremiah B. Frueauf & John M. Covert, *8 Ways Trans-Pacific Partnership Affects Patent Rights*, LAW360 (Nov. 9, 2015, 11:01 AM), https://www.law360.com/articles/724436/8-ways-trans-pacific-partnership-affects-patent-rights ("The TPP does not explain what other measures or market circumstances are relevant to delivering 'a comparable outcome in the market.'").

[64] *Id.*

[65] TPP, *supra* note 31, at art. 18.37, ¶ 1.

[66] *See id.* at art.18.37, n.30. ("For the purposes of this Section, a Party may deem the terms 'inventive step' and 'capable of industrial application' to be synonymous with the terms 'non-obvious' and 'useful', respectively."); *see generally* TRIPS Agreement, *supra* note 21.

> essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes.
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> 4. A Party may also exclude from patentability plants other than microorganisms. However, consistent with paragraph 1 and subject to paragraph 3, each Party confirms that patents are available at least for inventions that are derived from plants.[67]

Besides this, paragraph three also allows exclusion of inventions in order "to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment . . . ."[68] This section includes a statement requiring that, if a party has a law that prohibits patenting of a certain invention and wants to keep said law, this section cannot be the sole justification to maintain the pre-existing law under the new TPP patentability criteria.[69] With this type of language, it seems as if the TPP vigorously pushes its patent regime, with the apparent morality loop-hole purposely closed. It may also be important to note that there is a current movement in Europe to exclude certain inventions from patentability based on morality concerns.[70] This has led to the denial of patents using human embryos, which is a different result than U.S. case law.[71] Thus, the reason for this section may also be to account for European interests, further diminishing use of this section as a loophole to avoid TPP patentability requirements.

Overall, these provisions are quite broad, granting what is considered a weaker patentability standard.[72] The weaker the standards of patentability, the more patents are issued, potentially creating new types of inventions which can be found patentable.[73] For example, in the case of pharmaceuticals, weak standards lead to easier initial patents, and these patents get granted a period of protection of twenty years.[74] The negative side of this is that weak patents can also lead to a practice in the pharmaceutical industry called "evergreening."[75] This essentially means obtaining secondary patents by taking an existing drug and

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67 TPP, *supra* note 31, at art. 18.37.
68 *Id.*
69 *Id.*
70 *See* Astrid Burhöi, *Moral Exclusions in European Biotechnology Patent Law*, LUNDS UNIVERSITET (2006), 16–19, http://lup.lub.lu.se/luur/download?func=downloadFile&recordOId=1337961&fileOId=1646263; *see generally* Aquino, *supra* note 56.
71 *Id.*
72 Brook K. Baker, *Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere*, PLOS MED. (Mar. 13, 2016), http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001970.
73 *Id.* at 9.
74 *Id.*
75 Inderjit Singh Bansal, et al., *Evergreening: A Controversial Issue in Pharma Milieu.*, 14 J INTELL. PROP. RTS. 299, 299–306 (2009).

performing minor variations, such as new formulations, new methods of use, or new ways to manufacture the drug. This is done to apply for a new patent and artificially extend protection, a practice that is generally frowned upon.[76] Despite this, these weaker patents can also encourage innovation. Inventors are given even more incentive to create new inventions and may not have to worry about technicalities that could preclude protection of their new ideas.[77]

At this point, it is important to explore and compare the language of the TRIPS agreement to that of the TPP. Much like the TPP, the TRIPS agreement uses the same language to define what type of inventions will be patentable (*i.e.*, new, involve inventive steps, and capable of industrial application).[78] Like the TPP, TRIPS also allows for exclusion of "diagnostic, therapeutic, and surgical methods" as well as "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."[79] Unlike the TPP, TRIPS specifically calls for the protection of plant varieties and has some different language in regard to biological processes.[80] Additionally, the TPP has extra language in paragraph two concerning new inventions and the availability of patents for them, which is not nearly as emphasized in TRIPS.[81]

Despite the TPP's fairly similar language, TRIPS suffered from a number of shortcomings in its implementation. TRIPS was not a self-executing document and, hence, required further implementation from Congress to be domestically enacted.[82] Furthermore, when Congress did pass legislation, under the Uruguay Round Agreement Act of 1994 ("URAA"),[83] they specifically stated that, if a conflict with U.S. domestic law arises, then domestic law, not international law, will bind the courts of the United States.[84] Despite this, the URAA was able to change domestic law by enacting the following language:

> (1) expansion of the scope of infringement actions to include offers to sell; (2) the use of inventive activity abroad to satisfy the date of invention criteria for patent applications; (3) the extension of patent protection to a term of twenty years; (4) the publishing of patent

[76] *Id.*
[77] William Hubbard, *The Competitive Advantage Of Weak Patents*, 54 B.C. L. REV. 1909, 1909 (2013).
[78] *See* TRIPS Agreement, *supra* note 21, at art. 27.
[79] *Id.*
[80] *See generally id.*
[81] TPP, *supra* note 31, at art. 18.37.
[82] Adam Isaac Hasson, *Domestic Implementation of International Obligations: The Quest for World Patent Law Harmonization*, 25 B.C. INT'L & COMP. L. REV. 373, 382 (2002).
[83] *See* TRIPS Agreement, *supra* note 21.
[84] *See id.* at 380.

applications eighteen months after filing; and (5) the creation of a provisional application.[85]

Notice that nothing in here mentions patentability standards, and a fair number of TRIPS provisions were excluded.[86] By reaffirming the patentability language of TRIPS and providing an even stronger standard, the TPP seeks to have a real effect upon patentability, which was not achieved by TRIPS.

II. THE PATENTABILITY STANDARD UNDER THE U.S. PATENT ACT

A. *35 U.S.C. § 101*

It has been said that "[p]atentable subject matter standards are particularly important because they serve a threshold or 'gatekeeper' role in the patent system."[87] The federal power to pass patent law comes from the U.S. Constitution. The Constitution states that Congress has the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[88] Despite this grant by the Constitution, it was not until April 10, 1790, that President George Washington signed a bill into law, which created and would later evolve into the modern U.S. patent system.[89] The law gave the Patent Board absolute and non-appealable authority in granting a patent.[90] Few limits were imposed on a patent, one of which was that a patent term was not to exceed 14 years.[91] The subject matter of a patent was defined as "any useful art, manufacture, engine, machine, or device, or any improvement thereon not before known or used."[92] Only three years later, new language was implemented concerning patentability, stating that patents can be granted for "any new and useful art, machine, manufacture or composition of matter and any new and useful improvement on any art, machine, manufacture or composition of matter."[93] It was not until the Patent Act of 1952 that the non-obviousness requirement of modern patent law was added.[94]

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85 *Id.* at 380–81.

86 *See id.*

87 Richard S. Gruner, *In Search of the Undiscovered Country: The Challenge of Describing Patentable Subject Matter*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 395, 428 (2007).

88 U.S. CONST. art. I, § 8, cl. 8.

89 Press Release, U.S. Patent and Trademark Office, *The U.S. Patent System Celebrates 212 Years* (Apr. 9, 2002), https://www.uspto.gov/about-us/news-updates/us-patent-system-celebrates-212-years.

90 *Id.*

91 *Id.*

92 Patent Act of 1790, ch. 7, 1 Stat. 109, 109–12 (1790) (repealed 1793) (The Patent Act of 1790 was the first United States patent statute—"[a]n Act to promote the progress of useful Arts.").

93 Patent Act of 1793, ch. 11, 1 Stat. 318, 318–23 (1793) (repealed 1863).

94 Patent Act of 1952, Pub. L. No. 593, ch. 950, 66 Stat. 792 (current version at 35 U.S.C. § 101

The current standards for patentability are encompassed in 35 U.S.C. § 101. The statute states "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[95] The problem with this section is that a lot of these standards are ambiguous. How do you determine usefulness, or in some cases, even newness?[96] From this ambiguity, a body of case law has sprung to define what is patentable.[97] This standard is still changing today and has led to much frustration and arguments in the scientific and legal community.

B. *Case Law Concerning Patentability*

Due to the vague wording of 35 U.S.C. § 101, along with the absence of actual exceptions to patentability in § 101, much of the interpretation of this section has stemmed from U.S. case law. This section appears to be more of a definition, rather than a statutory requirement—although courts typically have treated it as a statutory requirement. Despite this vagueness, the Patent Trial and Appeal Board ("PTAB") found in *Ex parte Rosario Uceda-Sosa*, that "[t]he Supreme Court cases prove that § 101 is as much a statutory requirement of patentability as §§ 102, 103, and 112."[98] Thus, in order to properly implement 35 U.S.C. § 101, categorical distinctions of non-patentable subject matter were artificially created.[99] One of these early distinctions, which gave rise to modern patent law, was created in *Gottschalk v. Benson*.[100] In this case, the Supreme Court found three categories of inventions non patentable: phenomena of nature, mental processes, and abstract intellectual concepts (later called abstract ideas).[101] The Court's rationale was that these categories of inventions, despite being able to fit the definition under 35 U.S.C. § 101, were "basic tools of scientific and technological work" and, hence, were patent ineligible.[102]

The problem with categories of exclusion is that, as humanity pushes the technological front more and more, new categories of

(2012)).

95 35 U.S.C. § 101 (2012).

96 Note that, arguably, the Supreme Court has even conflated obviousness requirements with the current § 101 test.

97 *See infra* Part II.B.

98 Rosario Uceda-Sosa, B.P.A.I. No. 20040133537A1 1, 7 (Nov. 18, 2008).

99 *See generally* Email of IBM Corporation Comments in Response to "*Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos*," 75 Fed. Reg. 43922 (July 27, 2010) (Sept. 24, 2010) https://www.uspto.gov/sites/default/files/patents/law/comments/bilski/bilski_c_ibm2010sep30.pdf.

100 *See* Gottschalk v. Benson, 409 U.S. 63 (1972).

101 *Id.* at 65.

102 *Id.* at 67.

inventions arise that question these boundaries set by the categories.[103] In order to create a more flexible system, "federal courts have sought to develop a set of patentable subject matter standards that are free of technological details and limitations and that are instead framed in terms of very general features of patentable advances."[104] The first two cases attempting to overcome these specified categories of patentability and create a more permanent test were *Parker v. Flook*,[105] and *Diamond v. Diehr*.[106] In *Parker,* the respondents wished to obtain a patent for a mathematical formula used to update an alarm limit, which would set off an alarm during catalytic conversion processes if the limits for numerous factors were reached.[107] The way in which this alarm limit differed from prior alarms in this field was only in the mathematical formula used to calculate it.[108] The patent examiner assigned to assess the patent found that since granting a patent would just be granting a patent on a mathematical formula, the discovery was not eligible for patent protection.[109] The Supreme Court agreed with the examiner in finding that the discovery was not eligible for patent protection, but in dicta, suggested what may transform the invention into being patent eligible.[110] The Court was mostly focused on how the alarm limit discovery lacked details regarding how to "select the appropriate margin of safety, the weighing factor, or any of the other variables"[111] and did not "contain any disclosure relating to the chemical processes at work, the monitoring of process variables, or the means of setting off an alarm or adjusting an alarm system."[112] "[T]he Court's emphasis in Parker was on the absence of physical instantiation of the method of calculation specified in the patent at issue, not on the need for a mathematical calculation that leads to a physical manipulation or step in every case where a patent is sought."[113] This physical instantiation is what the Court required in order for a patent of this type to have an "inventive concept" strong enough to make it patent eligible.[114] The problem was that the Court did not describe in any detail what these physical features could be that may sway the patentability analysis, so 35 U.S.C. § 101 case law remained unclear.[115]

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103 For examples, think business method patents, software patents, and diagnostic method patents.
104 Gruner, *supra* note 87, at 398.
105 Parker v. Flook, 437 U.S. 584 (1978).
106 Diamond v. Diehr, 450 U.S. 175 (1981).
107 Gruner, *supra* note 87 at 405 (citing *Flook*, 437 U.S. at 584).
108 *Id.* at 405–06 (citing *Flook*, 437 U.S. at 585–86).
109 *Id.* at 406 (citing *Flook*, 437 U.S. at 586).
110 *Id.*
111 *Id.*
112 *Id.*
113 *Id.*
114 *Id.* at 407 (citing *Flook*, 437 U.S. at 594).
115 *Id.*

Seeing this problem, the Supreme Court decided another patentability case only three years later. In *Diehr*, the patent at issue concerned a process for curing synthetic rubber.[116] The process involved constantly measuring and inputting temperature data into a mathematical formula, which was controlled and calculated by a computer.[117] In distinguishing this case from *Parker*, the Court notes that the patent here is not the mathematical process itself but rather the entire process including its use of the mathematical process.[118] In doing so, the Court also notes an important construction of its holding, mainly that mere use of a computer or software does not make the invention patent ineligible.[119] In finding that this computerized method for curing rubber was simply an improvement upon prior patentable mechanical rubber curing methods, the Court found the computerized method to be patent eligible.[120] With this underlying physical process present, simple use of a mathematical formula and a computer was transformed into patentable subject matter. The problem with this decision once again lies with defining the aforementioned physical instantiations:

> In short, while Diehr stands for the relatively uncontroversial rule that a physical manipulation of a functionally significant aspect of a process is sufficient to transform an abstract idea or calculation into a patentable advance, the Court's analysis in this case does not address the harder question regarding the minimum physical features or relationships to physical surrounds that are necessary to place an advance within the range of patentable subject matter.[121]

The Court's physical transformative aspect of an abstract idea test remained unclear, as physical features were not defined in the Court's opinion.

Taking a slight break from patentability questions, the Supreme Court let the Federal Circuit digest the "tests" it had handed down, leading to a string of Federal Circuit decisions on patentability. The first of these Federal Circuit-created tests, the Freeman-Walter Test,[122] was met with much criticism, "[g]iven that the Freeman-Walter test simply substituted one set of ambiguous standards for another . . . ."[123] This led to the practical use of the test waning, and it was finally laid to rest a number of years later by the Federal Circuit.[124] With the abrogation of

116 Diamond v. Diehr, 450 U.S. 175 (1981).
117 *Id.* at 178.
118 *Id.* at 186–87
119 *Id.* at 186.
120 *Id.* at 192.
121 Gruner, *supra* note 87, at 408.
122 *See generally* In re Freeman, 573 F.2d 1237 (C.C.P.A. 1978), *amended by* In re Walter, 618 F.2d 758 (C.C.P.A. 1980).
123 Gruner, *supra* note 87, at 411.
124 *See* State St. Bank & Trust Co. v. Signature Fin. Grp., Inc., 149 F.3d 1368, 1374 (Fed. Cir.

this test, patentability standards became more relaxed.[125] Even old categories of patents long held patent ineligible under the old tests were suddenly patentable under the new patentability criterion.[126] Perhaps the most significant case which relaxed the old tests was *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*,[127] where "the Federal Circuit jettisoned the long-standing doctrine excluding business methods from patentability."[128] The new test found any process that produces a "useful, concrete, and tangible result," to be patent eligible.[129] This test and the lack of prior art in the new patent eligible categories of inventions allowed eligibility for many weak patents,[130] leading to another major reform of patentability standards by the Supreme Court starting in the early 2010's.

C. *Current Patentability Standards and Major Recent Patentability Case Law*

The first of these modern cases involving patentability standards was *Bilski v. Kappos*.[131] *Bilski* questioned the patentability of proprietary software (the claims of which the patent holder admitted did not require a computer to be implemented), which intended to protect consumers from market fluctuations in the energy sector.[132] In its holding, the Supreme Court found that the software was patent ineligible under 35 U.S.C. § 101 rules.[133] In doing so, the Court changed the patent market and effectively overturned the previous "useful, concrete, and tangible result" test from the older *State Street Bank* case.[134] In its decision, the Supreme Court was not trying to define a specific test for patent eligibility, but by a very narrow margin, decided not to disqualify business method patents in general.[135] In coming to this decision, the Court discussed the prior exclusive process patentability

1998), *abrogated by* In re Bilski, 545 F.3d 943 (Fed. Cir. 2008). ("After Diehr and Chakrabarty, the Freeman–Walter–Abele test has little, if any, applicability to determining the presence of statutory subject matter.").

125 *See generally In re* Alappat, 33 F.3d 1526 (Fed. Cir. 1994).

126 *See, e.g.*, *State St. Bank & Trust Co.*, 149 F.3d 1368.

127 *Id.*

128 Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski's Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1299 (2011).

129 Gruner, *supra* note 8787.

130 *See id.* at 418–22.

131 Bilski v. Kappos, 561 U.S. 593 (2010).

132 *Id.* at 594–96.

133 *Id.*

134 Erika Harmon, et al., *IP Update: A Summary of the Supreme Court's Bilski v. Kappos Decision*, FINNEGAN (July 1, 2010), https://www.finnegan.com/en/insights/a-summary-of-the-supreme-court-s-bilski-v-kappos-decision.html.

135 Hayden W. Gregory, *Following the Bilski Near Miss, Can Business Method Patents Survive Alice?*, 7.1 LANDSLIDE 2, 2–4 (2014).

test of the Federal Circuit, dubbed the machine-or-transformation test.[136] The test states that a: "process is patent eligible if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."[137] The Court denied that this was the sole test for determining patentability of a process and instead saw it as one of many tools or clues in making a patentability determination.[138] The Court instead chose to endorse prior cases such as *Benson, Flook,* and *Dier*,[139] endorsing "exceptions for laws of nature, physical phenomena, and abstract ideas."[140] This case left many unanswered questions, such as the following:

> First, concerning the machine-or-transformation test, we had yet to see what kind of "transformation" satisfies the transformation prong. Additionally, if the machine-or-transformation test is no longer the definitive test, how should we use it in method patent claims? If a process satisfies the test, what does this mean? How much weight is it given? With ever-growing technology and scientific development in our society, it was an important question to be answered.[141]

This remaining uncertainty helped lay the ground for the next major Supreme Court case on patentability, *Mayo Collaborative Services v. Prometheus Labs, Inc.*[142] *Mayo* questioned the validity of different patents on diagnostic methods.[143] The Court found that the patents were composed of steps that simply described a law of nature, mainly the correlation between a drug used to treat autoimmune disease and the levels of the metabolites from the drug in the blood stream, without having the extra substance needed to transform the natural correlation into a patentable idea.[144] For its analysis, the Court used a test, later dubbed the Mayo Test.[145] This test first asks whether the patent is directed to a patent ineligible concept.[146] If yes, then there is a question of "whether the claimed processes have transformed these

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136 *Bilski*, 561 U.S. at 612–13 (The machine or transformation test is largely created from the holdings in *State Street Bank & Trust Co.* and *In re Comiskey*, 499 F.3d 1365 (Fed. Cir. 2007).).
137 *Id.* at 593.
138 Caroline E. Whitney, *The Machine-or-Transformation Test Remains Important in Determining the Patentability of Novel Methods*, 19 U. BALT. INTELL. PROP. L.J. 179, 181 (2011).
139 *Dier* and *Flook* are not quite consistent with one another, leading to further problems with the Court's interpretation. The § 101 analysis in *Flook* parses the patent claims and compares it to the prior art, while *Dier* ignores this when testing for § 101. *See* Hon. Paul R. Michel, *Judicial Litigation Reforms Make Comprehensive Patent Legislation Unnecessary as Well as Counterproductive*, 14 NW. J. TECH. & INTELL. PROP. 131, 137 (2016).
140 *Bilski*, 561 U.S. at 603.
141 Whitney, s*upra* note 138, at 181.
142 Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012).
143 *Id.* at 1294.
144 *Id.* at 1298.
145 *Id.* at 1294.
146 *Id.* at 1293–95.

patent ineligible natural laws into patent eligible applications of those laws."[147] Simply put, this second part asks whether the patent provides significantly more than just the patent ineligible concept. The Supreme Court did not clarify whether this test would be used going forward and did not clarify what types of patents fit within these patent ineligible concepts.[148] In doing so, the Court once again left many questions unanswered, which led to more recent Supreme Court cases on patentability.

A year later, the Supreme Court took up a different patentability question in deciding *Association for Molecular Pathology v. Myriad Genetics, Inc*..[149] The issue in *Myriad* boiled down to whether DNA sequences were patent eligible.[150] The DNA sequences in *Myriad* were split into two categories, one in which the DNA were naturally occurring sequences merely isolated outside the body, and the other category consisting of non-naturally occurring spliced DNA sequences.[151] The Court held that the isolated naturally occurring DNA sequences were patent ineligible because they were merely products of nature.[152] As for the non-naturally occurring DNA sequences, the Court found these to be patent eligible, since they were not barred by the product of nature rule.[153] The Court mentioned but purposely refrained from answering patentability questions related to methods performed on or with DNA.[154] As to the actual impact of the case, the scope was perhaps not as expansive as many would have thought. The synthetic DNA that the Court found to be patent eligible is the actual driving factor behind many experiments in the lab today.[155] Still, after the case, questions remained whether artificially constructed sequences of DNA (instead of naturally occurring isolated DNA) were patent eligible.[156] These questions would have to remain unanswered, as the Supreme Court next decided to revisit software and business method patents.

The most recent patentability questions were answered by the Supreme Court in *Alice Corporation v. CLS Bank International*.[157] The patents in *Alice* were comprised of computer-implemented methods to

147 *Id.* at 1294.
148 *See generally id.*
149 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).
150 *See id.* Note that, traditionally, biotech patterns were considered to be rather strong following *Diamond v. Chakrabarty*; *See also* Douglas Robinson and Nina Medlock, *Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents*, 17 INTELL. PROP. & TECH. L.J. 12, 12 (2005).
151 *Myriad*, 133 S. Ct. at 2111.
152 *Id.* at 2119.
153 *Id.*
154 *Id.*
155 Robin Feldman, *Gene Patenting After the U.S. Supreme Court Decision—Does Myriad Matter?*, 26 STAN. L. & POL'Y REV. ONLINE 16 (2014).
156 *Id.*
157 Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).

mitigate "settlement risk."[158] Throughout the course of *Alice*, the Court drew many analogies to *Mayo*[159] and *Bilski*.[160] Following in the footsteps of *Mayo*, the Court decided to use the Mayo Test in determining the patentability question under 35 U.S.C. § 101.[161] The Court first asked whether the patents were directed to a patent ineligible concept, and if so, was the patented invention significantly more than just the actual ineligible concept.[162] In doing so, the Court found that the patents in question were directed to a patent ineligible concept, mainly the abstract idea of intermediated settlement.[163] Turning to the second step, the Court found, since the patents were just an implementation of the abstract idea on a generic computer without more, they did not provide significantly more as required by the Mayo Test.[164]

From what seemed to be a straightforward case, *Alice* actually became known as the case in which "the U.S. Supreme Court issued perhaps its most impactful decision of the 2013-2014 term."[165] Due to the decision in *Alice*, the legal community found that "[g]oing forward, it is clear that the two-step Mayo Test will govern all patent eligibility questions under Section 101."[166] This test led to a widespread invalidation of software and business method patents and the refusal of the USPTO to grant many patents that fit these descriptions.[167] The USPTO even incorporated the Mayo Test directly into their examination guidelines, meaning that this decision would have an even more significant impact than the *Alice* case and its specific patent class of financial software business method patents.[168] People became worried whether any types of software patents would be patent eligible anymore, and whether all the money spent on obtaining these patents would be wasted due to invalidation after this decision.[169] Even industries thought to be beyond the reach of *Alice*, such as biotech industries, felt heavier § 101 rejections because of *Alice*.[170]

158 *See id.*
159 Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012).
160 Bilski v. Kappos, 561 U.S. 593, 603 (2010).
161 *Alice*, 134 S. Ct. at 2356–58.
162 *See generally id.*
163 *Id.* at 2352.
164 *Id.*
165 Kevin R. Casey & Kevin B. Anderson, *The Supreme Court's Six-pack of Patent Cases*, 27.3 INTELL. PROP. & TECH. L. J. 9, 9–13 (2015).
166 Jesse Adland, *Alice Corp v. CLS Bank International: Challenges in Identifying Patentable Subject Matter*, 26.12 INTELL. PROP. & TECH. L. J. 20, 20–24 (2014).
167 *See* Kenneth Adamo et al., *Where Do We Stand One Year After Alice?*, LAW360 (June 17, 2015, 8:27 PM), http://www.law360.com/articles/668773/where-do-we-stand-one-year-after-alice.
168 Jake Freed, *Supreme Court Invalidates Software Patents Directed to Implementing Abstract Ideas*, 20.4 IP LITIG. 3, 3–5 (2014).
169 *See generally* Adamo, *supra* note 167.
170 *See* Table of § 101 Rejections Before and After *Alice*, BILSKI BLOG, http://www.bilskiblog.com/.a/6a011570f4033a970c01b7c8a4dc88970b-pi (last visited Jan. 28,

In addition to Supreme Court action, the legislature and the PTAB have attempted to deal with the issues of patentability as well. In 2012, the PTAB implemented a program called Transitional Program for Covered Business method patents ("CBM Proceedings") as a temporary solution to handle business method patents.[171] "This temporary program allows alleged infringers to challenge the validity of financial-method patents in administrative proceedings before the PTAB."[172] This program was meant to help companies transition into the new market and to address some of the issues caused by non-practicing entities that amass large patent portfolios in the hopes of suing and extracting money from other businesses, dubbed "patent trolls," or Non-Practicing Entities ("NPEs").[173] Not all was positive from these proceedings, as the PTAB aggressively invalidated patents in the CBM Proceedings, making it harder for patent owners to enforce their rights.[174] Furthermore, the alleged NPE problem that these proceedings hoped to correct actually became worse, as an even higher percentages of cases were brought by NPEs.[175] Some have argued that this may be due to heightened filings in NPE friendly courts, which still grant large awards for NPEs. [176]

Furthermore, to adhere to case law (particularly CAFC case law) following the *Alice* decision, the USPTO has reexamined its guidelines, relaxing the heightened standards for patentability somewhat. A number of cases were decided by the Federal Circuit, which may limit the reach of *Alice*. The first of these cases was *DDR Holdings, LLC v. Hotels.com*.[177] The problem with this first case is that it was very narrow and factually driven.[178] The patents at issue were directed at solving an Internet-centric problem and hence could not be characterized as a mere recitation of a prior business method on a

2016).

171 Steven Seidenberg, *Business Method and Software Patents may go Through the Looking Glass After Alice Decision*, ABA JOURNAL, 19–22 (Feb. 1, 2015, 2:40 AM), http://www.abajournal.com/magazine/article/business_method_and_software_patents_may_go_through_the_looking_glass_after.

172 *Id.*

173 *Id.*

174 Douglas R. Nemec & Scott M. Flanz, *After Period of High Invalidation Rates, New US Patent Challenge Procedures May Slow Down to Moderate Pace*, SKADDEN (Apr. 26, 2016) https://www.skadden.com/insights/after-period-high-invalidation-rates-new-us-patent-challenge-procedures-may-slow-down-moder.

175 Brian Fung, *Patent Trolls Now Account for 67 Percent of all New Patent Lawsuits*, THE WASH. POST: THE SWITCH (July 15, 2014) https://www.washingtonpost.com/news/the-switch/wp/2014/07/15/patent-trolls-now-account-for-67-percent-of-all-new-patent-lawsuits/?utm_ term=.dea5c7843ab4.

176 *Id.* Note that with the recent Supreme Court case of *TC Heartland LLC v. Kraft Foods*, filings by NPEs in patent friendly venues may decrease. *See* TC Heartland LLC v. Kraft Foods Grp., 137 S. Ct. 1514 (2017).

177 DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245 (Fed. Cir. 2014).

178 *See generally id.*

generic computing device.[179] While some may have seen this Internet-centric problem solving as a patentability exception for the Mayo Test, the court stated, "[w]e caution, however, that not all claims purporting to address Internet-centric challenges are eligible for patent."[180] This extra bit of information limited the application of this case going forward.

As widespread invalidation continued, one case came out finding a true exception to the Mayo Test. The *Enfish* court finally found a software patent valid under the *Alice* framework. In *Enfish v. Microsoft*,[181] the Federal Circuit found a workaround for the Mayo Test, which essentially skipped the second prong of the Mayo Test—reasoning that the software was found not to be an abstract idea.[182] The court held that "[s]oftware can make non-abstract improvements to computer technology,"[183] which led many courts to no longer assume that software or business method patents were per-se abstract ideas.[184] Since the "significantly more" requirement became very hard to overcome, this opened a door for patents of this type to once again be found to be patent eligible.[185] Unfortunately, the news was not all good for patent owners, as this case was followed shortly after by *TLI Communications v. AV Auto*.[186] The patent in *TLI* was comprised of a method to classify and store digital images.[187] The patent holder in *TLI* tried to argue that the patents fit into the *Enfish* exception and improved basic computer functionality, but the court rejected this argument and invalidated the patent.[188] The work around for the Mayo Test that many in the industry had hoped for was further narrowed, and practitioners feared another narrow fact-specific exception like the patent eligible holding in *Hotels.com.*[189] But after the Federal Circuit announced these two decisions, the USPTO stepped in to clarify the matter.[190] The USPTO issued an Updated Subject Matter Guidelines memorandum

179 *Id.* at 1258–59.
180 *Id.* at 1258.
181 Enfish, LLC v. Microsoft Corp., 822 F.3d 1327 (Fed. Cir. 2016).
182 *See generally id.*
183 *Id.* at 1335.
184 Susan Dierenfeldt-Troy, *The Enfish Decision: Some Light at the End of the Tunnel for Software Patents Since Alice?*, IPWATCHDOG (June 9, 2016), http://www.ipwatchdog.com/2016/06/09/enfish-decision-light-end-tunnel-software-patents-since-alice/id=69733/.
185 *Id.*
186 TLI Commc'ns LLC v. AV Auto., LLC (In re TLI Commc'ns LLC Patent Litig.), 823 F.3d 607 (Fed. Cir. 2016).
187 *Id.* at 609.
188 *Id.* at 612–13.
189 *See* DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245 (Fed. Cir. 2014).
190 Robert W. Bahr, U.S. Patent and Trademark Office, Memorandum on Recent Subject Matter Eligibility Decisions *(Enfish, LLC v. Microsoft Corp. and TLI Communications LLC v. A.V. Automotive, LLC)* (May 19, 2016), https://www.uspto.gov/sites/default/files/documents/ieg-may-2016_enfish_memo.pdf.

that discussed the two cases, stating that the exception under *Enfish* will remain going forward and will be used in conjunction with the *TLI* decision in order to govern questions of patentability.[191] Therefore, the *Enfish* decision still provides a narrow exception to the general Mayo Test, and the USPTO will still consider it for future patent applications.

The most recent case that added significantly to the patentability discussion was *Rapid Litigation v. CellzDirect*.[192] The *Rapid Litigation* case drew a line in patentability between laws of nature, like in the *Myriad* case, and methods involving those laws of nature, the latter of which is patent eligible. The patent involved an inventive process of freezing liver cells in order to improve their survival rate during multiple freeze cycles, as opposed to patenting the idea of them surviving the freezing cycle itself.[193] Basically, the court found "that although the claims involved a natural law, they were not 'directed to' that natural law, but to a process deriving its benefit from that natural law."[194] In doing so, the court distinguished itself from *Ariosa v. Sequenom*,[195] leaving a narrow opening for diagnostic methods to be found patent eligible.

With so many gray areas in patentability case law and new exceptions handed down constantly, the patent market is unstable. Even the USPTO is looking for guidance at this time, evidenced by two roundtable discussions in November and December 2016.[196] The Director for the USPTO at the time, Michelle K. Lee, described the purpose of the discussions as:

> Our goal is to minimize any uncertainty in the patent system by ensuring we not only continue to apply the statute and case law in this area as faithfully as possible, but also understand the impact of the jurisprudence on innovation by assessing what, if any, changes might be helpful to further support innovation.[197]

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191 *Id.*

192 Rapid Litig. Mgmt. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016). Note that later cases which added to the *Alice* discussion mainly point to a case-by-case fact-specific approach taken by the courts, and hence they are not discussed in detail. *See, e.g.*, RecogniCorp, LLC v. Nintendo Co., Ltd., 855 F.3d 1322 (Fed. Cir. 2017) (invention directed to abstract idea of encoding and decoding image data is invalid under the *Mayo* framework); Visual Memory LLC v. NVIDIA Corp., No. 2016-2254 (Fed. Cir. Aug. 15, 2017) (computer-implemented memory system found not to be directed to abstract idea under step one of *Mayo* framework).

193 *Id.* at 1050.

194 Matthew W. Siegal, *Fed. Circ. Clarifies the Test for Patentable Subject Matter*, LAW360 (Aug. 2, 2016), http://www.law360.com/articles/824005/fed-circ-clarifies-the-test-for-patentable-subject-matter.

195 Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015).

196 Dennis Crouch, *USPTO Seeks Further Public Input on Patent Subject Matter Eligibility*, PATENTLY-O (Oct. 14, 2016), https://patentlyo.com/patent/2016/10/further-subject-eligibility.html

197 *Id.*

With the current chaotic state of things and the USPTO being so open to discussion on patentability by the patent community, it is perhaps time for a change in 35 U.S.C. § 101 application and jurisprudence.

III. CHANGING THE CURRENT U.S. PATENTABILITY ANALYSIS TO MATCH THAT OF THE TPP

A. *Contrasting the Two Standards*

There are some significant differences and similarities between U.S. jurisprudence and the patentability language of the TPP worth analyzing. Article 18.37 § 1 of the TPP is written to match the language of 35 U.S.C. § 101 by providing a footnote specially substituting the terms "inventive step" and "capable of industrial application" with "non-obvious" and "useful," which are their § 101 (and 35 U.S.C. § 103 for obviousness) counterparts.[198] Likewise, Article 18.37 § 2 breaks down the categories of products and processes that are patentable to the categories closely in line with the judicially created categories of patentable inventions under 35 U.S.C. § 101.[199]

One section, which contains unclear consequences for U.S. implementation is the last line of Article 18.37 § 2, which states "[a] Party may limit those new processes to those that do not claim the use of the product as such."[200] While not quite clear, it seems as if this line is creating an exception for new processes which merely cover any use of the product, without claiming any meaningful process limitations, or where the claims do not add anything inventive to the use of the product. With this interpretation, it seems as if there could be a carve-out for the *Alice* line of cases involving software patents. Software, and even business method, patents are sometimes claimed as processes, though they also can be claimed as systems (hardware) or products.[201] The TPP specifically only creates the exception for new processes.[202] This creates a potential uncertain patentability exception for software and potentially even business method patents, yet due to unclear

198 TPP, *supra* note 31, at art. 18.37; 35 U.S.C. § 101 (2012). ("For the purposes of this Section, a Party may deem the terms 'inventive step' and 'capable of industrial application' to be synonymous with the terms 'non-obvious' and 'useful', respectively.").

199 For the U.S. Code, these categories are "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101 (2012). For the TPP, these categories are "new uses of a known product, new methods of using a known product, or new processes of using a known product." TPP, *supra* note 31, at art. 18.37, § 2.

200 TPP, *supra* note 31, at art. 18.37, § 2.

201 *See generally* Gene Quinn, *A Guide to Patenting Software: Getting Started*, IPWATCHDOG (Feb. 16, 2013), http://www.ipwatchdog.com/2013/02/16/a-guide-to-patenting-software-getting-started/id=35629/.

202 TPP, *supra* note 31, at art. 18.37 § 2.

language, this may just be included for other reasons.[203]

What is quite unique about the TPP is that it explicitly carves out exceptions to the general patentability rule in the text of the agreement.[204] The U.S.C., on the other hand, does not contain any specific exclusions to patentable subject matter, leaving the courts and jurisprudence to determine patentable subject matter.[205] By creating an open policy for what is patentable and then specifically including certain exceptions to the open policy, it is quite probable that the drafters of the TPP meant for the exceptions listed to be the *only* exceptions towards patentability, as long as it fits within the open framework of Article 18.37 § 1–2.[206] These exceptions are only potential and not mandatory exceptions to patentability, meaning that a signing party can still choose to allow patents for these exceptions.

One interesting exception, which skews just how this agreement may work with U.S. jurisprudence, is the *ordre public* or morality exception.[207] This creates the ability for signing parties to exclude from patentability inventions "which [are] necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment."[208] While some may see this as a backdoor way of keeping all U.S. case law on patentability compatible with the TPP,[209] the next line seems to close this loophole. The line states "provided that such exclusion is not made merely because the exploitation is prohibited by its law."[210] This means that this provision is not merely a workaround that countries can use to fit their individual patentable subject matter standards in under the TPP. This provision strengthens the power of Article 18.37, showing a real consideration by the drafters to create a uniform standard among the signing parties. Another reason for this provision may be to prevent a country with laws that limit commercial exploitation of an invention from claiming that patentability for that invention should also be

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[203] For another reason, one example is found in taking a dose of a certain medicine. If 50 mg of aspirin cures a headache, then taking the same 50 mg of aspirin to lower the risk of a blood clot might be a new use "as such". The language may also be included in order to comply with another country's patent eligible subject matter standards. One example may be New Zealand, in which the law states computer programs are not inventions 'as such' *See The Patent Examination Manual Section 11: Computer programs*, N.Z. INTELLECTUAL PROPERTY OFFICE, https://www.iponz.govt.nz/about-ip/patents/examination-manual/current/computer-programs/#jumpto-a-process-that-is-not-aninvention1. (last visited Sept. 22, 2017).

[204] *See* TPP, *supra* note 31, at art. 18.37, §§ 3–4.

[205] *See supra* Part II.B.

[206] This is quite a common canon of interpretation for when the legislature explicitly creates exceptions to general rule. *See generally* Jacob Scott, *Codified Canons and the Common Law of Interpretation*, 98 GEO. L.J. 341, 363 (2010).

[207] *See* TPP, *supra* note 31, at art. 18.37, § 3.

[208] TPP, *supra* note 31, at art. 18.37, § 3.

[209] Frueauf & Covert, *supra* note 63.

[210] *See* TPP, *supra* note 31, at art. 18.37, § 3.

restricted. This provision may instead require a country to have a noncommercial reason for excluding an invention from patentability. Additionally, it may be possible that this provision instead applies to inventions barred for morality reasons in a country, such as gambling, weapon advancements, or certain types of biotechnology.

B. *Interpreting The Effects of These Differences on U.S. Patentable Subject Matter*

As this Note argues, the language from the TPP should be implemented in place of 35 U.S.C. § 101 and the recent body of case law interpreting this statute. The first substantial change in the United States would be reintroduction of patentability for natural molecules, such as DNA. As previously mentioned, *Myriad* removed isolated DNA sequences that were isolated outside of the human body from cellular components from patentability.[211] In their decision, the Supreme Court did not answer the question of whether synthetically constructed DNA (different from the cDNA at issue) were patent eligible.[212]

By reintroducing patents of this type, the United States could greatly benefit. First, the patentability of DNA would not have the current nuances created by *Myriad*.[213] Isolated DNA sequences separate from the human body, cDNA, and synthetically created DNA would no longer be distinguished, as all of these strands would be patentable. DNA within the human body would remain patent ineligible, thus distinguishing naturally occurring DNA from the DNA obtained for medical and research purposes.[214] With this certainty, researchers once again could have a massive monetary incentive for research. "Without gene patenting, there is virtually no way to bring something profitable to the market."[215] Meaning, without this incentive, it can become nearly impossible for researchers to obtain funding for their projects.[216] Since it takes hundreds of millions of dollars to introduce a new drug to the market, medical research with genes becomes near impossible without this financial support.[217] Only larger companies would be able to engage in this type of research, giving them a massive leg up on smaller research companies, who would be effectively eliminated from the

[211] Feldman, *supra* note 155, at 17.

[212] *Id.*

[213] *See generally* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

[214] *See generally* Feldman, s*upra* note 156.

[215] *The Pros of Gene Patenting*, ASIA-PACIFIC ECONS. BLOG (Jan. 3, 2015), http://apecsec.org/pros-and-cons-of-gene-patenting/.

[216] *Patenting Genes: Pros and Cons*, GENETICS GENERATION, http://knowgenetics.org/patenting-genes-pros-and-cons/ (last visited Nov. 24, 2016).

[217] *Id.*

market.[218] Besides being bad for competition in the market place, this may effectively create a freeriding situation, in which smaller genetic research companies would profit more by exploiting the research of larger companies instead of innovating for themselves. Nevertheless, the arguments against allowing these patents still exist, arguments which include stifling competition and creating a monopoly.[219] The problem here is that, in this specific context, the goal of a limited monopoly is required to fund this extremely costly and greatly beneficial research in the first place.

Contrary to allowing these patents is the TPP's view on patentability of diagnostic methods, which instead of reopening doors for patentability, may lead to their permanent closing. Starting with the *Mayo* decision, and ending with the Supreme Court's denial of certiorari in *Sequenom*,[220] the patentability of diagnostic methods has become almost impossible. A narrow loophole remains after the *Cellzdirect* case, in which claims were not directed to a law of nature but were instead directed to a patent eligible process deriving benefit from that law of nature.[221] By creating a specific exclusion from patentability of diagnostic methods, the TPP seems to be bootstrapping in current U.S. case law on diagnostic methods. The specific exclusion allows signing parties to make their own decisions on patentability of diagnostic methods, which points to keeping the status quo, following the recent jurisprudence.[222]

Furthermore, the language of the TPP also includes exclusions for therapeutic methods and surgical methods.[223] This may lead courts to implement further patentability restrictions in these fields in future cases. This may also lead to uncertainty in the patentability field, instead of the clarity the industry is currently seeking. It is interesting here to note that, the United States originally sought to include a section in the TPP stating that "diagnostic, therapeutic, and surgical methods for the treatment of humans or animals be made available."[224] Due to all negotiating countries opposing this language, the United States was forced to change the language to its current state.[225] With the near death

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[218] *Id.*

[219] *Id.*

[220] Sequenom, Inc. v. Ariosa Diagnostics, Inc., 136 S. Ct. 2511 (2016).

[221] Rapid Litig. Mgmt. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016).

[222] TPP, *supra* note 31, at art. 18.37, § 3.

[223] *Id.* Note that already in U.S. law, 35 U.S.C. § 287(c) contains a surgical method defense for a doctor who performs a patented surgical method. *See* 35 U.S.C. § 287(c) (2016). This may be a reason for the TPP including this exclusion.

[224] *Secret TPP treaty: Advanced Intellectual Property chapter for all 12 nations with negotiating positions*, WIKILEAKS, Nov. 13, 2013, at 28–29, https://wikileaks.org/tpp/static/pdf/Wikileaks-secret-TPP-treaty-IP-chapter.pdf.

[225] Burcu Kilic, Hannah Brennan & Peter Maybarduk, *What Is Patentable Under The Transpacific Partnership? An Analysis Of The Free Trade Agreement's Patentability Provisions*

of the TPP, the United States may once again pursue this language in future 35 U.S.C. § 101 reform or future trade deals.[226] In doing so, the United States may once again risk widespread resistance from other countries, so it should be cautious in pursuing this language. On the other hand, domestically, this type of language could overturn decisions such as *Sequenom* and possibly even *Mayo*. This would bring a level of clarity to patentability standards but may impose a risk of higher medical care costs.[227]

In order to analyze the diagnostic method patentability thoroughly, Justice Linn's concurrence in *Sequenom* is worth reviewing.[228] Justice Linn specifically felt "bound by the sweeping language of the test set out in [*Mayo*]."[229] Justice Linn notes how "no one was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers"[230] and how "it is hard to deny that Sequenom's invention is truly meritorious."[231] Justice Linn felt pigeonholed into making his decision, invaliding what he saw as a revolutionary diagnostic method patent in the medical field.[232] With the old U.S.-proposed language of the TPP, judges would not run into this problem and could implement protection for diagnostic methods. Inventors and researchers could continue to innovate and not worry about the patentability of their innovative diagnostic methods. Patients could continue to receive the benefits of U.S. medical ingenuity.

The last category of patent eligible subject matter that could be affected by language from the TPP would be in the software and business method patent space. Due to what was discussed previously, it is still uncertain whether the TPP language will affect U.S. case law concerning software and business method patents.[233] The extra language of the agreement is just not clear enough to know exactly how it could be implemented in the United States. The first possible interpretation, and the one this Note advocates, is for a more inclusive standard for software and business method patents. By using this language, the TPP would repeal an entire body of confusing case law, which has led to much resentment and uncertainty, and at the extreme, even led some to call for an entire repeal of the underlying statute.[234] Categorically

From A Public Health Perspective, 40.1 YALE J. INT'L L. ONLINE (2015).

[226] Perhaps an even simpler alternative would be the other position argued in this Note: that Congress could directly implement language of this type instead of the current § 101 language.

[227] *See generally* Kilic et al., *supra* note 225.

[228] Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1380–81 (Fed. Cir. 2015) (Linn, C.J., concurring).

[229] *Id.* at 1380.

[230] *Id.* at 1381.

[231] *Id.*

[232] *See generally id.* at 1380–81.

[233] *See supra* Part III.A.

[234] Jorge Goldstein, Michelle Holoubek & Krishan Thakker, *Is it Time To Amend 101?*,

excluding an entire type of invention from patentability, without explicit input from the legislature, can indiscriminately prevent patentability and is an overstepping of power by the judicial branch. Furthermore, as Justice Newman claimed in her concurrence in *BASCOM Global Internet Services. v. AT&T Mobility LLC*: "[as] this case illustrates, these cumbersome procedures for separate determinations of patent eligibility and patentability have added to the cost and uncertainty of patent-supported commerce, with no balancing benefit."[235]

The judicially-created body of law under 35 U.S.C. § 101 is far too confusing and unnecessary for preventing patenting of most inventions that would otherwise not be patentable due to other sections of the Patent Act. The case law seems to usurp the role of other sections of the Patent Act, which are enough on their own to prevent the granting of bad patents.[236] In doing so, these judicially-created doctrines avoid the extensive body of law underlying these other statutes, sometimes contradictorily creating a confusing secondary test for the same factors.[237] With so many of the other patentability sections of the U.S. Code, 35 U.S.C. § 101's original use was as a backup test to prevent some really basic patents from undergoing a thorough USPTO analysis in the first place, unnecessarily tying up USPTO resources.[238] David Kappos, former Director of the USPTO, even goes so far as to claim that with other patent eligibility requirements[239] so well defined, there is no need for 35 U.S.C. § 101 at all.[240] This Note does not go to that extreme, but instead argues that 35 U.S.C. § 101 has gone beyond its originally intended application. The statute should be used for its original purpose of preventing basic patents at the initial patentability review, instead of categorically and sometimes unclearly excluding entire fields from patentability, such as software and business method patents. The problem with trying to amend this with case law exceptions, such as the *Enfish*[241] exceptions or the *Hotels.com* exceptions,[242] is that these tests just add further confusion to the matter. Judges apply these tests in many different ways, and examiners are not always certain how to apply these tests in the application stage of patenting.[243] This is why TPP-type language must be employed,

IPWATCHDOG (Sep. 25, 2016), http://www.ipwatchdog.com/2016/09/25/time-to-amend-101/id=72825/.

235 BASCOM Glob. Internet Servs. v. AT&T Mobility LLC, 827 F.3d 1341, 1352 (Fed. Cir. 2016).

236 *See* Goldstein et al., *supra* note 234.

237 *Id.*

238 Davis, *supra* note 27.

239 *See* 35 U.S.C. §§ 102, 103, 112 (2012).

240 Davis, *supra* note 27.

241 *See* Enfish, LLC v. Microsoft Corp., 822 F.3d 1327 (Fed. Cir. 2016).

242 *See* DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245 (Fed. Cir. 2014).

243 As can be evidenced by the USPTO roundtable discussions mentioned earlier in the paper. *See*

abolishing the recent confusing jurisprudence of 35 U.S.C. § 101 and instead reverting this patentability section to a basic screening mechanism as it was originally intended.

The main argument against amending the language and removing the current jurisprudence on the topic would be a flooding of the patent system with new weak patents. Thus, in order to prove that this problem would not occur, this Note finds it instructive to analyze a patent overturned by 35 U.S.C. § 101 jurisprudence under other patentability requirement sections, in order to show their effectiveness. As an example, this Note will do a basic analysis of the financial software patents at issue under *Alice.*[244] Under its analysis, the Supreme Court found patents under *Alice* to be directed to an abstract idea, without providing "significantly more" required by the Mayo Test.[245] One could see how under an obviousness analysis, or a novelty analysis, the Court could have come to the same conclusion.[246] Simply performing a known method using a computer is not a novel idea, and it certainly is obvious in light of prior financial risk mitigation techniques and simple knowledge that computers exist that can perform this.[247] Thus, a weak patent like that in *Alice* may pass the new patentability scheme under the language of the TPP, yet it will still be caught and prevented by other sections of the Patent Act.

Furthermore, on a global policy scale, this kind of update to 35 U.S.C. § 101 will bring the U.S. patent regime more in line with the rest of the world, while also keeping the United States as a worldwide innovator in technology. Quoted by *Law360*, David Kappos said, "[i]t's time to abolish Section 101, and the reason I say that is that Europe doesn't have 101 and Asia doesn't have 101 and they seem to be doing just fine in constraining patent-eligible subject matter."[248] Additionally, European countries, such as Germany, have been increasingly protecting patent owners, while protection in the United States has been going in the opposite direction.[249] This can especially be seen in the software and business methods field, where despite an express provision on the exclusion of software from patentability in Europe, it is now easier to obtain a software patent there than in the United States.[250] This raises concerns about the United States remaining a leader in worldwide

supra Part II.C.

244 Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347 (2014).

245 *See id.*

246 *See* 35 U.S.C. §§ 102–103 (2012).

247 This basic analysis was implemented using language from both sections of the Patent Act just discussed, without any references to particular prior art.

248 Davis, *supra* note 27.

249 *Id.*

250 Dennis Crouch, *Patenting Software in the US as compared with Europe*, PATENTLYO (Sept. 29, 2014), http://patentlyo.com/patent/2014/09/patenting-software-compared.html.

innovation. As of 2015, the United States is still the largest international patent filer in the world, yet that number is dwindling.[251] While international patents grew 1.7% in 2015, American companies' international patent filings dropped about 6.7%.[252] Countries like China and Japan are responsible for most of the world's new growth.[253] This loss of innovation may be directly linked to the changing patentability standards and uncertainty here in the market.

Lastly, with the United States' changing patentability standard, the United States has misaligned itself with the language from the TRIPS agreement, and language from the TPP could help realign the United States with TRIPS. Since the United States signed TRIPS in 1994,[254] there has been significant change in the patentability case law.[255] With substantially the same underlying language between the two agreements,[256] it seems as if the language of the TPP further points to repealing the current case law and going back to the patentability analysis embraced by the TRIPS agreement. Surely, with the substantial changes to U.S. law since the time of TRIPS, the patentability language of the TPP would have differed if negotiators wished to keep these recent U.S. patentability cases. A lack of change further enforces the proposition that advocates in the executive branch want to see the legislature step up and correct 35 U.S.C. § 101 jurisprudence.

CONCLUSION

The U.S. Constitution states that Congress has the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[257] The patent system as a whole stems from this, and any legislation aimed at changing the patent system must keep this in mind. In recent years, jurisprudence has led the United States away from this basic principle of promoting the progress of science and the useful arts. Patentability has been restricted, and in turn, innovators have fewer incentives to innovate. In order to keep the United States' place as a top world innovator in science and technology, it is time for the legislature to take action. Even though the TPP is potentially dead in the United States, the patentability clause of the TPP can be used for future trade deals, as well as be directly implemented into future legislation by Congress. Only by taking such proactive, patent-friendly

[251] *US Still World Leader in Patent Filings*, PHYS.ORG (Mar. 16, 2016), http://phys.org/news/2016-03-world-leader-patent.html.
[252] *Id.*
[253] *Id.*
[254] TRIPS Agreement, *supra* note 21.
[255] *See supra* Part II.
[256] *See supra* Part I.B.
[257] U.S. CONST. art. I, § 8, cl. 8.

measures can the United States remain a top innovator in the world market.

Ryan Thorne[*]

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