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What is the Trade-Off: Are New Trade Deals Worth the Changes to Pharmaceutical Patents?

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WHAT IS THE TRADE-OFF: ARE NEW TRADE DEALS WORTH THE CHANGES TO PHARMACEUTICAL PATENTS?

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I. INTRODUCTION

Intellectual property provisions are standard when it comes to trade agreements.¹ Trade agreements and intellectual property standards are advanced together because intellectual property standards are said fair competition and provide for adequate and effective protection and enforcement, thus eliminating a major trade barrier.²

During his presidential campaign, President Trump named fair trade deals and pharmaceutical drug pricing, among others, as his priorities during his presidency.³ Initially, the President named intellectual property as one of the driving forces behind his trade negotiations, focusing his concern on protecting the intellectual property produced by the citizens of the United States from foreign countries' fraudulent behavior.⁴ President Trump has also promised to

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1. See James M. Silbermann, *The North American Free Trade Agreement's Effect on Pharmaceutical Patents: A bitter Pill to Swallow or a Therapeutic Solution?*, 12 J. Contem. Health L. & Pol'y 607, 608 (1996).

2. See *Id.*

3. See President Donald Trump, State of the Union Address, <https://www.govinfo.gov/content/pkg/DCPD-201800064/pdf/DCPD-201800064.pdf>, (Jan. 30, 2018).

4. Executive Summary from Ambassador Robert E. Lighthizer, The President's 2018 Trade Policy Agenda, <https://ustr.gov/sites/default/files/files/Press/Reports/2018/AR/2018%20Annual%20Report%201.pdf> (Mar. 2018). [hereinafter *The President's 2018 Trade Policy Agenda*].

lower pharmaceutical prices for Americans. In 2018 the United States spent an estimated 335 billion on pharmaceutical drugs, this number is anticipated to grow to 345.7 billion by the end of 2019 and 358.7 billion by the end of 2020.⁵ This level of spending makes the United States the top spender on pharmaceuticals in the world.⁶ Because of this, President Trump has made the promise to lower the price of pharmaceutical spending.⁷

Throughout his presidency, President Trump has sought to deliver on his campaign promises, by drastically changing the United States' presence in numerous trade deals.⁸ He has accomplished this through withdrawing from current trade deals, renegotiating others, and forming new trade deals altogether.⁹ A major withdrawal came within the first day of his term when he withdrew from the Trans-Pacific Partnership (TPP) agreement.¹⁰ Another notable change was the abandonment of the North American Free Trade Agreement (NAFTA) and the negotiation of its replacement, the United States-Mexico-Canada Agreement (USMCA).¹¹

Given this change, President Trump has also played an outsized role in changing intellectual property law since trade agreements may have a subsidiary effect of changing substantive nature.¹² For example, the USMCA included sixty-five pages of intellectual property provisions, that expanded provisions previously included in agreements, such as TPP and NAFTA.¹³ Indeed, it may be that President Trump's intellectual property goals—such as lower prescription drug prices—might be undermined by the ripple effects of his agreement.

Section one of this Comment will analyze the promises President Trump has made during his term, focusing on trade reform and pharmaceutical drug prices. Section two of this Comment will demonstrate the disparity between

5. *Prescription Drug Expenditure in the U.S. 1960-2019*, STATISTA.COM (2019), <https://www.statista.com/statistics/184914/prescription-drug-expenditures-in-the-us-since-1960/>.

6. *National Trends in Per Capita Pharmaceutical Spending, 1980-2015*, COMMONWEALTHFUND.ORG, (2015), https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2017_oct_pdf_sarnak_paying_for_rx_exhibits.pdf.

7. *State of the Union Address*, *supra* note 3.

8. See President Donald Trump, *President Trump's First Weekly Address*, <https://www.govinfo.gov/content/pkg/DCPD-201700078/pdf/DCPD-201700078.pdf>, (Jan. 28, 2017).

9. *The President's 2018 Trade Policy Agenda*, *supra* note 4.

10. President Donald Trump, *President Trump's First Weekly Address*, *supra* note 6.

11. U.S.-Mex.-Can. Agreement, §20, Proposed Draft, Nov. 30, 2018. [<https://perma.cc/M3YZ-974N>].

12. See Marney L. Cheek, *The Limits of Informal Regulatory Cooperation in International Affairs: A Review of the Global Intellectual Property Regime*, 33 Geo. Wash. Int'l L. Rev. 277, 283 (2001).

13. U.S.-Mex.-Can. Agreement, §20, Dec. 13, 2019.

the promises made and the proposed provisions of the USMCA. Further, showing how the lack of intellectual property expertise during trade negotiations will prevent President Trump from fulfilling his promise to lower pharmaceutical drug prices. Finally, section three of this Comment will argue in favor of mandating that the United States Patent and Trademark Office (USPTO) be present during trade negotiations, in hopes of, in the future, being able to accomplish goals for trade without negatively impacting consumers through intellectual property changes.

II. PROMISES MADE

Every presidential candidate makes promises and sets goals for their term. The overwhelming theme of President Trump's promises is this: America first.¹⁴ President Trump promised to accomplish this through extensive trade reform and lowering pharmaceutical drug prices. This section will analyze these promises and how President Trump intends to carry them out.

During President Trump's inaugural address, he said, "Every decision on trade . . . will be made to benefit American workers and American families. . . . America will start winning again, winning like never before."¹⁵ During his first day in office, President Trump withdrew from the TPP, deeming it "a disastrous deal for our workers" and vowing to pursue one-on-one deals that protect Americans.¹⁶ Within his first two years of office, NAFTA had been abandoned and made way for the newly negotiated USMCA.¹⁷ In the 2018 State of the Union address, President Trump exclaimed that "America has . . . finally turned the page on decades of unfair trade deals. . . . From now on, we expect trading relationships to be fair and, very importantly, reciprocal."¹⁸ These are just a few examples of how President Trump has committed to his promise of trade reform.

A significant overlap exists between intellectual property and trade reform. It is clear that the Trump Administration recognizes this intersection. In 2018, the White House published a thirty-three-page document explaining the President's trade policy agenda.¹⁹ This agenda highlights five major pillars driving President Trump's trade negotiations.²⁰ Two of these five pillars involve intellectual property.²¹ The first pillar is supporting our national

14. See President Donald Trump, *Inaugural Address*, (Jan. 20, 2017).

15. *Inaugural Address*, *supra* note 14.

16. *First weekly address*, *supra* note 8.

17. U.S.-Mex.-Can. Agreement, §20, Proposed Draft, *supra* note 11.

18. *State of the Union*, *supra* note 3.

19. *The President's 2018 Trade Policy Agenda*, *supra* note 4.

20. *The President's 2018 Trade Policy Agenda*, *supra* note 4.

21. *The President's 2018 Trade Policy Agenda*, *supra* note 4.

security, stating that the national security strategy relies heavily on the United States “preserv[ing] our lead in research and technology and protect[ing] our economy from competitors who unfairly acquire our intellectual property.”²² The second pillar, that involves intellectual property, is “negotiating trade deals that work for all Americans.”²³ This pillar particular refers to the need to reform NAFTA.²⁴ The trade agenda states that the renegotiation of NAFTA has two primary goals: 1) to “[i]mprove the U.S. trade balance and reduce the trade deficit with the NAFTA countries;” and, 2) to bring the provisions concerning digital trade, intellectual property, and cybersecurity into the 21st century.²⁵

In addition, the USTR publishes a Special 301 Report every year that further emphasizes the importance of intellectual property during trade deals.²⁶ This report states, “[o]ne of the top priorities for the Trump Administration is to . . . provide adequate and effective protection and enforcement of U.S. intellectual property [] rights.”²⁷ The special 301 report is an annual review of intellectual property protection and enforcement in United States trading partners.²⁸ The purpose of the report is to call out and expose harmful intellectual property practices by other countries.²⁹ These reports are not unique to the Trump Administration, and intellectual property has been a main priority of the USTR for some time.³⁰

The mention of intellectual property in both the trade agenda and the Special 301 Reports demonstrates that the Trump Administration recognizes that intellectual property protection goes hand in hand with trade negotiations.³¹ In fact, intellectual property is a key selling point when it comes to dealings with many United States trading partners.³² But, despite the great importance placed on intellectual property, there is a fundamental lacking of intellectual property knowledge among the President, the USTR, and the general American public, which leads to unfulfilled goals and promises.

22. *The President’s 2018 Trade Policy Agenda*, *supra* note 4.

23. *The President’s 2018 Trade Policy Agenda*, *supra* note 4.

24. *The President’s 2018 Trade Policy Agenda*, *supra* note 4.

25. *The President’s 2018 Trade Policy Agenda*, *supra* note 4.

26. OFF. OF U.S. TR. REP., Special 301 Rep. (2017); *see also*, OFF. OF U.S. TR. REP., Special 301 Rep. (2018).

27. *Special 301 Rep.*, *supra* note 26.

28. *Special 301 Rep.*, *supra* note 26.

29. *Special 301 Rep.*, *supra* note 26.

30. *Special 301 Rep.*, *supra* note 26.

31. *See* OFF. OF U.S. TR. REP., Special 301 Rep. (2017); *See also*, Executive Summary from Ambassador Robert E. Lighthizer, *The President’s 2018 Trade Policy Agenda* (Mar. 2018).

32. *Limits of informal reg.*, *supra* note 12.

III. PROMISES IN PLACE?

This administration has moved quickly to make changes and to effectuate promises of the President. Within his first week in office, President Trump began working on his promise of trade reform.³³ This section will analyze the disconnect between the promises made and the policy that has been put into effect. This section will also explain that the disconnect resulted from a lack of intellectual property understanding. Although President Trump has worked on numerous trade agreements,³⁴ this section will primarily focus on the USMCA.

The USMCA is a trilateral agreement between the United States, Mexico, and Canada.³⁵ This agreement replaced NAFTA, which President Trump deemed to be “the worst trade deal ever made.”³⁶ President Trump claims the USMCA is “the most advanced trade deal in the world with ambitious provisions on . . . patents.”³⁷ The goal of the USMCA was to bring trade agreements into the 21st century and set forth a template for future trade agreements under the Trump Administration.³⁸ President Trump stated that the USMCA embodies three pillars that he hopes will drive trade negotiations in the future, including: fairness; “ambitious provisions on digital trade; intellectual property; [and] services . . . designed to protect our competitive edge”; and, new provisions designed to eliminate unfair trading practices.³⁹

The proposed draft of the USMCA contained sixty-four pages of intellectual property provisions, some of which resemble the provisions proposed by the United States in the TPP, some of which are the same as NAFTA, and some that are new altogether.⁴⁰ Notably, the USMCA includes a number of provisions that may undermine a key element of the Trump agenda in intellectual property policy: the lowering of prescription drug prices. A primary example of this is when President Trump promised during his 2018 State of the Union address, “One of my greatest priorities is to reduce the price of prescription drugs. . . . And prices will come down substantially. Watch.”⁴¹ Lowering pharmaceutical drug prices is something most American’s yearn for.

33. *First weekly address*, *supra* note 8.

34. *See* Executive Summary from Ambassador Robert E. Lighthizer, *The President’s 2018 Trade Policy Agenda* (Mar. 2018). *See also*, Executive Summary from Ambassador Robert E. Lighthizer, *The President’s 2019 Trade Policy Agenda* (Mar. 2019).

35. U.S.-Mex.-Can. Agreement, *supra* note 13.

36. U.S.-Mex.-Can. Agreement, *supra* note 13.

37. U.S.-Mex.-Can. Agreement, *supra* note 13.

38. U.S.-Mex.-Can. Agreement, *supra* note 13.

39. U.S.-Mex.-Can. Agreement, *supra* note 13.

40. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, PUBLICCITIZEN.ORG, (Jan. 21. 2019), <https://www.citizen.org/sites/default/files/nafta-2.0-pharmaceutical-related-patent-provisions.pdf>.

41. *State of the Union*, *supra* note 3.

It has been found that many American's have opted to forego prescribed medication due to high prices and the inability to pay.⁴² However, President Trump anticipates being able to lower drug prices through providing "speed access to breakthrough cures and affordable generic drugs," citing that "last year, the FDA approved more new and generic drugs . . . than ever before."⁴³ This is a promise that President Trump believes, is an economic issue that can be solved through agency expediency.⁴⁴ However, pharmaceutical drug pricing, at its core, is an intellectual property issue that has now been affected by the provisions set forth in the numerous trade negotiations.⁴⁵

The proposed draft of the USMCA included a number of provisions that impact pharmaceutical drugs and biologics, including, patentable subject matter and secondary patents, patent term extension, market exclusivity for small molecules and biologics, and patent linkage.⁴⁶ Patents provide their owner with the "right to exclude others from making, using, offering for sale, or selling the invention throughout the United States."⁴⁷ Therefore, so long as the brand pharmaceutical companies own the patents, they have an exclusive monopoly over that pharmaceutical drug. This limits generic manufacturers from offering more affordable alternatives, in turn keeping pharmaceutical drug prices high.⁴⁸ The proposed provisions involving pharmaceuticals and biologics contained in the USMCA are pharma-friendly.⁴⁹ Meaning, they provide exclusivity that favors pharmaceutical manufacturers.⁵⁰ The inclusion of these pharma-friendly provisions highlights the disconnect between President Trump's promise to lower pharmaceutical drug prices and the negotiation of this trade agreement.

Ultimately, several of the proposed provisions that impacted pharmaceutical drug pricing were removed from the agreement because these provisions were not approved by Congress.⁵¹ The House of Representatives noted in their report:

The USMCA, as originally negotiated, would have locked-in practices that lead to high drug prices [and] hindered the generic competition that

42. *National trends per capita*, *supra* note 6.

43. *State of the Union*, *supra* note 3.

44. *State of the Union*, *supra* note 3.

45. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, *supra* note 40.

46. U.S.-Mex.-Can. Agreement, §20.48(2), Proposed Draft, *supra* note 11.

47. 35 U.S.C. § 154(a)(1), (2013).

48. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, *supra* note 40.

49. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, *supra* note 40.

50. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, *supra* note 40.

51. H.R. REP NO. 116-358, pt. 1(b) at 10 (2019).

brings down prices. . . . The [revised] Agreement now preserves Congress's power to pass laws that bring down high prescription drug costs. . . . The [revised] Agreement creates a balance between encouraging the competition that brings greater access to medicines at lower costs to patients and supporting pharmaceutical innovation.⁵²

Even though many of the “pharma-friendly” provisions were removed from the agreement, it is important to understand how these provisions would have prevented the President from delivering on his promise to lower pharmaceutical drug patents. Understanding how trade negotiations impact substantive law highlights the need for expert advisers to be present during trade negotiations.

Article 20.36 of the proposed USMCA allows for patents, including pharmaceutical patents, on new uses of known products, new methods of using known products, or new processes of known products.⁵³ Obtaining a new patent for a slight change to a known invention is typically known as evergreening.⁵⁴ The objective of evergreening is to “extend the life of patent protection through patenting [] minor changes in active pharmaceutical ingredients of existing pharmaceutical products . . . , inert ingredients, formulations, dosages, and combinations.”⁵⁵ The provision has since been removed from the agreement.⁵⁶ In the December 19, 2019 House Report, it noted, “[t]his provision would have locked in the practice of ‘patent evergreening,’ in which pharmaceutical companies . . . [can] block generic competition and price reductions.”⁵⁷ The provision had to be removed in order to align the goal of lowering pharmaceutical prices with the effect the provisions would have on intellectual property law.

In addition to the broader subject-matter provisions, the proposed USMCA also provided for market exclusivity regardless of patent status.⁵⁸ Article 20.48(2)(a), provided three years of additional market exclusivity even to previously approved pharmaceutical products that cover a new indication, formula, or method of administration.⁵⁹ This would be considered another form of evergreening, because slight modifications, even to off-patent medicines, would result in three additional years of protection, which would prevent generic competitors from entering the market. This provision has since been

52. *H.R. REP NO. 116-358, supra* note 51.

53. *See* U.S.-Mex.-Can. Agreement, §20.36, Proposed Draft, *supra* note 11.

54. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions, supra* note 40.

55. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions, supra* note 40.

56. U.S.-Mex.-Can. Agreement, *supra* note 13.

57. *H.R. REP NO. 116-358, pt. 1(b) at 10 (2019), supra* note 51.

58. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions, supra* note 40.

59. *See* U.S.-Mex.-Can. Agreement, §20.48(2), Proposed Draft, *supra* note 11.

removed from the agreement, the House Report indicating that removal of this provision was necessary to avoid locking the United States into patent evergreening.⁶⁰

Article 20.49 of the proposed draft broadens the definition of biologics.⁶¹ Currently 42 U.S.C. § 262(i)(1) defines a biological product as meaning “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.”⁶² The proposed USMCA broadened this definition to include any products that are or contains any of the components listed above.⁶³ The broadening of this provision potentially subjects more biological products to monopoly control.⁶⁴ If more products fall under monopoly control, then fewer generic competitors can enter the marketplace, resulting in high drug prices.⁶⁵ The scope of this provision contradicts President Trump’s promise to lower drug prices.

The proposed USMCA, also, would lock the United States into market exclusivity of both pharmaceutical drugs and biologics.⁶⁶ Market exclusivity means that no other manufacturer may be permitted to market a similar drug for five years. The market exclusivity provision for biologics contained in article 20.49, provides for a term of ten years.⁶⁷ Market exclusivity provisions create additional delays to a generic alternative’s entrance to the market.⁶⁸ All references to biologics, including those in the market exclusivity provisions, have since been removed from the agreement.⁶⁹ The House Report indicated that biologics “are some of the most expensive drugs on the market,” and providing at least ten years of market exclusivity for biologics would not allow Congress any space to create policies that would drive down the high price of biologics.⁷⁰

The minority of the House Report noted that they believed the majority’s interpretation of the effects of including provisions on biologics was incorrect.

60. H.R. REP NO. 116-358, *supra* note 51.

61. See U.S.-Mex.-Can. Agreement, §20.49, Proposed Draft *supra* note 11.

62. 42 U.S.C. § 262(i)(1), (2017).

63. See U.S.-Mex.-Can. Agreement, §20.49, Proposed Draft, *supra* note 11.

64. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, *supra* note 40.

65. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, *supra* note 40.

66. U.S.-Mex.-Can. Agreement, § 20.48-20.49, Proposed Draft *supra* note 11.

67. U.S.-Mex.-Can. Agreement, § 20.49, Proposed Draft *supra* note 11.

68. U.S.-Mex.-Can. Agreement, § 20.49, Proposed Draft *supra* note 11.

69. U.S.-Mex.-Can. Agreement, *supra* note 13.

70. H.R. REP NO. 116-358, *supra* note 51.

⁷¹ The minority explained that the provisions would not increase drug prices and that remaining silent on the issue of biologics only allows for a lower level of protection. ⁷² The disagreement among members in the House is another reason that an expert in intellectual property should be present during trade negotiations. An expert's familiarity with the current law and knowledge of how proposed provisions would affect, both, the law and the market is a way to ensure that the United States is meeting the expectations of its constituents and still promoting innovation.

Article 20.51 of the proposed USMCA linked the marketing approval process to the status of the patent. ⁷³ This creates a barrier for generic competitors because it provides for notification to the original patent holder when a competitor is seeking to register for market approval. ⁷⁴ This provides the original patent holder with notice and time to file an infringement suit against any competitors. ⁷⁵ The financial benefit the original pharmaceutical manufacturer receives by deterring competitors incentivizes litigation and, in turn, deters generic competitors from attempting to enter the market. ⁷⁶ This provision has since been removed from the agreement in an effort to incentivize generic competition that the original provision would have discouraged. ⁷⁷

As discussed previously, many of the provisions included in the draft of the USMCA do not drastically alter United States intellectual property law. However, signing those provisions into an agreement would have prevented the United States from future reform. ⁷⁸ When President Trump signed what he deemed to be "the most modern, up-to-date, and balanced trade agreement in the history of our country," he also signed off on numerous provisions that would not have lowered pharmaceutical prices. ⁷⁹ Many of the pharma-friendly provisions have since been removed from the agreement, and now the agreement better aligns with the goals of promoting innovation and lowering pharmaceutical prices. ⁸⁰ However, as indicated above, there was some disagreement as to the actual impact that these provisions would have and if their removal was necessary. ⁸¹ Intellectual property is a technical field of the

71. H.R. REP NO. 116-358, *supra* note 51.

72. H.R. REP NO. 116-358, *supra* note 51.

73. *See* United-States-Mexico-Canada Agreement, §20.51, Proposed Draft, (Nov. 30, 2018).

74. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, *supra* note 40.

75. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, *supra* note 40.

76. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, *supra* note 40.

77. H.R. REP NO. 116-358, *supra* note 51.

78. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, *supra* note 40.

79. President Donald Trump, *Remarks by President Trump on U.S.-Mex.-Can. Agreement*.

80. H.R. REP NO. 116-358, *supra* note 51.

81. H.R. REP NO. 116-358, *supra* note 51.

law and, as such, any agreements that would impact intellectual property should be assessed or advised by an expert. Although Congress was ultimately able to better align the provisions of the USMCA with the goals of the President, having an expert present during trade negotiations would allow for trade agreements to align with our nation's goals from the start.

IV. HOW TO RECONCILE THE DISCONNECT BETWEEN PROMISES MADE AND PROMISES KEPT?

The lack of understanding demonstrated by the disconnect between President Trump's promise to lower drug prices and the signing off on pharmaceutical intellectual property provisions is an issue that is prevalent in intellectual property policy. Most people do not possess a technical understanding of intellectual property law. Yet often times, intellectual property policy decisions are made during trade negotiations by people like President Trump and officers and advisors from the USTR. That is why this section will discuss the importance of amending the enumerated powers of the USPTO to include a mandatory presence at trade negotiations that involve intellectual property.

Trade agreements have a ripple effect, once they are enacted they impact the market and can result in substantive changes to existing laws.⁸² An example of substantive US law being changed as a result of trade agreements is in 1993 the United States entered into the Trade Related Aspects of Intellectual Property (TRIPS) agreement.⁸³ After negotiations were completed, the United States had to impose additional infringement liability to cover "offers to sell."⁸⁴ In 1994 the statutory language of 35 U.S.C. § 271(a) was amended to reflect the terms of the TRIPS agreement.⁸⁵ The proposed provisions of the USMCA would have also had a ripple effect—the provisions, as drafted, would have locked the United States into practices that would limit generic competition and lead to high pharmaceutical prices.⁸⁶ The effect the proposed provisions would have had highlights the issue that goals are not being met during negotiations.

Intellectual property is an important part of the law and is recognized as such. Not only has intellectual property been listed as a main priority of the USTR because it is a driving force behind most trade negotiations, but it also affects several other areas of the economy.⁸⁷ Intellectual property has also been

82. Check, *supra* note 8.

83. TRIPS agreement, https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

84. *Rotec Indus. V. Mitsubishi Corp.*, 215 F.3d 1246 (Fed. Cir. 2000).

85. *Id.*

86. H.R. REP NO. 116-358, *supra* note 51.

87. See OFF. OF U.S. TR. REP., Special 301 Rep., *supra* note 26.

cited by the President as a priority for his administration.⁸⁸ Intellectual property policy is something that effects all Americans, even if they are unaware of the inner workings of intellectual property. Americans are asking for change when it comes to pharmaceutical prices and want the government to deliver on that; one way of doing so is through intellectual property provisions in trade agreements.

The disconnect this Comment presents, between what President Trump promised and the proposed provisions of the USMCA, is just one example. That is why it is important to amend the enumerated powers of the USPTO to include being present at trade negotiations. This change is necessary to ensure that intellectual property provisions align with the goals set forth, do not substantively change intellectual property policy and are carefully weighed against the potential effects on other areas of the economy.

Currently, 35 U.S.C. §§ 2(b)(8)-(10) states that the USPTO involvement in trade negotiations is strictly advisory.⁸⁹ This means intellectual property is not being created by intellectual property experts, but rather, it is being created by USTR negotiators and lawmakers.⁹⁰ The USPTO was tasked with the advisory role because Congress wanted to maintain a policy link between intellectual property experts and their lawmaking counterparts.⁹¹ During the USMCA negotiations, the USPTO assisted by “providing extensive information on the state of intellectual property protection and enforcement in many countries.”⁹² However, providing information and being present during negotiations to ensure the provisions are meeting all goals and expectations are very different.

Patent practice is a technical skill that requires licensing through the USPTO. Currently, the Office of the United States Trade Representative (USTR) does not have a single member that is registered with the USPTO.⁹³ The position of Chief Innovation and Intellectual Property Negotiator is left empty.⁹⁴ The acting Assistant United States Representative for Innovation and Intellectual Property is not a registered patent practitioner.⁹⁵ The USTR has

88. *The President's 2018 Trade Policy Agenda*, *supra* note 4.

89. 35 U.S.C. §§ 2(b)(8)-(10), (2011).

90. Cheek, *supra* note 8.

91. Omnibus Patent Act 1997, Senate Report 105-42, page 32,105-42, <https://www.congress.gov/105/crpt/srpt42/CRPT-105srpt42.pdf>.

92. USPTO, PPAC annual report 2018, https://www.uspto.gov/sites/default/files/documents/PPAC_2018_Annual_Report_2.pdf.

93. Biographies of Key Officials, USTR.GOV, <https://ustr.gov/about-us/biographies-key-officials> (Searched all the names of officers and advisors of the trade committee on the USPTO's database of patent practitioners (<https://oedci.uspto.gov/OEDCI/practitionerSearchEntry>), (no one working for the USTR is a registered patent practitioner.)

94. Biographies of Key Officials, USTR, *supra* note 93.

95. Biographies of Key Officials, USTR, *supra* note 93.

advisory committees that report on the drafted provisions after the fact.⁹⁶ In the report on intellectual property, the committee raised many concerns that aligned with the concerns expressed by Congress during their hearing for ratification of the agreement.⁹⁷ However, many of these concerns were not addressed until Congress removed the provisions of concern more than a year later.⁹⁸ Although some of the officials present during negotiations may have familiarity with patents and intellectual property, nobody sitting in on these trade deals has adequate expertise to be drafting intellectual property provisions.

The lack of experts during the negotiation of the USMCA resulted in an agreement that would have rendered President Trump unable to deliver on the promise to lower pharmaceutical drug prices. Pharmaceutical drug prices would not have been lowered because the intellectual property provisions included in the proposed USMCA, involving pharmaceutical drugs and biologics, locked the United States into long patent terms, market exclusivity and other methods of favoring brand name pharmaceutical companies.⁹⁹ This, in turn, would have kept generic drugs off the market for longer, keeping the price of pharmaceuticals high.¹⁰⁰ Congress was able to amend the agreement to better align with the goals the President had in mind, however, that still resulted in disagreement among parties.¹⁰¹ Intellectual property is a technical field and experts should be the ones who are creating, advising, and informing lawmakers and negotiators on intellectual property provisions.

As discussed above, 35 U.S.C. §§ 2(b)(8)-(10) states that the USPTO involvement in trade negotiations is strictly advisory.¹⁰² This advisory role is carried out by providing “technical assistance” by way of providing information to the USTR regarding intellectual property law.¹⁰³ This is not enough to ensure that the way policy is created aligns with the importance placed on the policy after it is created. It is not enough to ensure that the policy aligns with the goals for that policy. That is why the statute should be amended to mandate the USPTO’s presence during trade negotiations that involve intellectual property policy.

96. ITAC-13 Report, *Report of the Industry Trade Advisory Committee on Intellectual property rights*, (Sept. 2018).

97. H.R. REP NO. 116-358, pt. 1(b) at 10, *supra* note 51.

98. ITAC-13 Report, *Report of the Industry Trade Advisory Committee on Intellectual property rights*, Sept. 2018. *See also*, U.S.-Mex.-Can. Agreement, §20, *supra* note 11.

99. U.S.-Mex.-Can. Agreement, §20, Proposed Draft, *supra* note 11.

100. *NAFTA 2.0 Chapter 20 Pharmaceutical-Related Patent Provisions*, *supra* note 40.

101. *See*, H.R. REP NO. 116-358, pt. 1(b), *supra* note 51 at 10.

102. 35 U.S.C. §§ 2(b)(8)-(10), *supra* note 89.

103. USPTO, PPAC annual report 2018, *supra* note 92.

Mandating the USPTO's presence during trade negotiations is one way to ensure that trade deals accurately reflect the goals they intended to achieve and that the ripple effect of the trade agreement will not impact the current law. In 1997 the USPTO became an independent government corporation.¹⁰⁴ Prior to this the USPTO was a subsidiary agency of the Department of Commerce.¹⁰⁵ The push to make the USPTO a separate entity arose out of wanting to increase efficiency administering patents.¹⁰⁶ Despite becoming an independent government corporation, Congress maintained the policy link between the USPTO and the Department of Commerce.¹⁰⁷ This was done so that the USPTO could advise and inform on policy that dealt with intellectual property law.¹⁰⁸ It is clear that the maintenance of this policy link was because Congress recognized that the USPTO are the experts in the intellectual property field and should be the ones helping to create and advise on intellectual property law.¹⁰⁹

Twenty years ago, Congress was right to maintain a policy link between the USPTO and the Department of Commerce. They knew that it was the experts who needed to be the ones counseling and informing policy changes. If intellectual property policy is as important to the USTR, the President and trade agreements as it appears to be, then the way intellectual property policy is handled during trade negotiations should not be enough for the USTR, the President or Americans. One way to ensure that trade agreements have a limited ripple effect on current laws, effectuates the promises made by the President to the people, and still meets the goals of intellectual property law, is to mandate the presence of the USPTO at trade negotiations. Mandating the USPTO's presence during trade negotiations would mean not having to rely on after the fact changes to provisions to ensure that the United States' needs are being met.

V. CONCLUSION

President Trump said during his inaugural address, "I will fight for you with every breath in my body, and I will never, ever let you down."¹¹⁰ However, that fight, the fight for the American people requires experts' knowledge and understanding. It is impossible to ask one office to provide all the expertise necessary to fulfill every promise made. Mandating the USPTO's presence during trade negotiations supports the President's fight and will benefit

104. Omnibus Patent Act 1997, Senate Report 105-42, *supra* note 91 at 33.

105. Omnibus Patent Act 1997, Senate Report 105-42, *supra* note 91 at 33.

106. Omnibus Patent Act 1997, Senate Report 105-42, *supra* note 91 at 33.

107. Omnibus Patent Act 1997, Senate Report 105-42, *supra* note 91 at 33.

108. Omnibus Patent Act 1997, Senate Report 105-42, *supra* note 91 at 33.

109. Omnibus Patent Act 1997, Senate Report 105-42, *supra* note 91 at 33.

110. *Inaugural address*, *supra* note 14.

American consumers by allowing the President to deliver on his promises. Although the USMCA was eventually revised to better align with the President's promises, mandating the USPTO's presence during trade negotiations will be a more effective way to align intellectual property provisions with their intended effect. Therefore, the current statute 35 U.S.C. §§ 2(b)(8)-(10) should be amended to require the USPTO be present during trade negotiations when intellectual property is involved. The convergence of the USTR's trade expertise with the USPTO's intellectual property expertise will allow for trade negotiations to better meet the needs of consumers on all fronts and will better position the President to fulfill his promises to and fight for the American people.