SCHOOL OF LAW
TEXAS A&M UNIVERSITY

Texas A&M Journal of Property Law

Volume 5
Number 3 *Student Articles*

Article 3

6-1-2019

Biologics Under a New NAFTA: How TPP Fixed NAFTA's Intellectual Property Provisions But Not Its Investment Provisions

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BIOLOGICS UNDER A NEW NAFTA: HOW TPP FIXED NAFTA'S INTELLECTUAL PROPERTY PROVISIONS BUT NOT ITS INVESTMENT PROVISIONS

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ABSTRACT

Scientific developments, such as biologics and personalized medicine, have created an entirely new category of pharmaceutical drugs that were not considered when the North American Free Trade Agreement ("NAFTA") was adopted in 1994. However, the rise of biologics has increased demand for a reconfigured NAFTA, particularly with respect to Chapter 17, which outlines NAFTA's robust intellectual property standards, as well as Chapter 11, which both lays out the framework for foreign investment under NAFTA and introduces a controversial mechanism referred to as the investor-state dispute settlement mechanism ("ISDS"). The intellectual property provisions of the original NAFTA should be revised to mirror the similar provisions of the Trans-Pacific Partnership ("TPP") Agreement, which better accommodates new medical advances. However, despite criticism of their lack of transparency, the investment provisions of the original NAFTA are likely sufficient to grant medical patent-rights holders the investment protection that they seek because they strengthen transparency, which is ultimately good for business.

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I. INTRODUCTION

Following United States ("U.S.") President Donald Trump's May 2017 announcement of his administration's intent to renegotiate the North American Free Trade Agreement ("NAFTA" or "the Agreement"),[1] renewed and increased attention has focused on NAFTA's treatment of intellectual property rights and foreign investment.[2] This Note will focus on both of these aspects of NAFTA as they relate to intellectual property protection for NAFTA signatories. In particular, this Note will examine the shortcomings of both the intellectual property and investment provisions of NAFTA as the two lines of defense that NAFTA offers companies within the signatory states to protect their intellectual property abroad.

In 1992, the U.S. adopted the trilateral agreement with Canada and Mexico called NAFTA.[3] Equipped with some remnants of the previous 1989 bilateral trade agreement between the U.S. and Canada, called the Canadian-U.S. Free Trade Agreement ("CFTA")[4], NAFTA sought to progressively eliminate tariffs between the U.S., Canada, and Mexico; and reduce other duties and restrictions that had previously prevented the free flow of goods and services across their international borders.[5] Economic in nature, NAFTA's main objectives included the "liberalization of trade between [the signatories]" through "stimulat[ing] economic growth and giv[ing] the NAFTA countries equal access to each other's markets."[6] Notably, NAFTA's patent protections, including those related to pharmaceutical drugs, have caused some controversy over the last two decades. Although this controversy springs from a preexisting debate about the value and use of patent law in society,[7] NAFTA's protections have further highlighted this tension and its effects.

1. *USTR: Trump Administration Announces Intent to Renegotiate the North American Free Trade Agreement*, OFF. U.S. TRADE REPRESENTATIVE (May 18, 2017), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2017/may/ustr-trump-administration-announces [https://perma.cc/A2QA-HYUM]; North American Free Trade Agreement, Can.-Mex.-U.S., Dec. 17, 1992, 32 I.L.M. 289 (1993) [hereinafter NAFTA].

2. OFFICE OF THE U.S. TRADE REPRESENTATIVE, SUMMARY OF OBJECTIVES FOR THE NAFTA RENEGOTIATION 9 (2017), https://ustr.gov/sites/default/files/files/Press/Releases/NAFTAObjectives.pdf [https://perma.cc/UT6R-LMTS].

3. *North American Free Trade Agreement (NAFTA)*, OFF. U. S. TRADE REPRESENTATIVE, https://ustr.gov/trade-agreements/free-trade-agreements/north-american-free-trade-agreement-nafta [https://perma.cc/98HZ-9DJP] (last visited Oct. 8, 2017).

4. U.S. INT'L TRADE COMM'N, THE YEAR IN TRADE 2001: OPERATION OF THE TRADE AGREEMENTS PROGRAM 1–9 (2002), https://www.usitc.gov/publications/332/pub3510.pdf [https://perma.cc/33Z6-24QX].

5. *North American Free Trade Agreement (NAFTA)*, *supra* note 3.

6. *North American Free Trade Agreement (NAFTA)*, U.S. CUSTOMS & BORDER PROTECTION, https://www.cbp.gov/trade/nafta-old [https://perma.cc/N3QB-DH3X] (last visited Feb. 8, 2019).

7. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989).

The preexisting debate has two primary camps of thought. From the perspective of countries like the U.S., pharmaceutical patents are essential to their technology-driven economies.[8] Thus, their theory of patent law creates an incentive to invent while minimizing free-riding, thereby enabling inventors to continue to develop new products despite the high costs of innovation.[9] Providing proof for this theory, a study titled *The Economic Impact of the Patent System* found that "patent protection had a strong influence on the willingness of pharmaceutical firms to invest in research and development," likely because of the high monetary and time-related costs of developing new drugs.[10]

By contrast, from the perspective of other countries, including those that produce fewer medical innovations, the high cost of pharmaceutical patents from countries such as the U.S. creates a barrier that leads to a lack of access to new pharmaceuticals. Nevertheless, without effective patent protection, a major issue that companies in the developed world face from bad actors in the developing world is the piracy of pharmaceutical patents.[11] Additionally, and important to the discussion in this Note, competition from generic pharmaceutical drug manufacturers often drives up the cost of producing new medicine, which potentially stifles new innovation.

The provisions of the original NAFTA that are particularly significant to the role of medical patent rights across international borders are found in Chapter 17, which outlines NAFTA's robust intellectual property standards; and Chapter 11, which lays out the framework for foreign investment under NAFTA and introduces the highly controversial investor-state dispute settlement mechanism ("ISDS").[12] While controversy over NAFTA's current medical patent protections primarily resides with conventional pharmaceutical drugs, this controversy highlights the increasing importance of strengthening the original NAFTA's provisions to encompass the unique needs of biologics and personalized medicine.

Biologics are increasingly being used by medical professionals to treat patients based on their specific genetic makeup.[13] Because biologics are patentable for their process and not their molecular formula, they are more difficult to replicate in generic form than con-

8. *See* Frank J. Garcia, *Protection of Intellectual Property Rights in the North American Free Trade Agreement: A Successful Case of Regional Trade Regulation*, 8 AM. U. J. INT'L L. & POL'Y 817, 818–19 (1993).

9. *See* Eisenberg, *supra* note 7, at 1025–26.

10. *Id.* at 1032; *see* C.T. TAYLOR & Z.A. SILBERSTON, THE ECONOMIC IMPACT OF THE PATENT SYSTEM: A STUDY OF THE BRITISH EXPERIENCE 331–50 (1973).

11. Garcia, *supra* note 8, at 819.

12. *See* NAFTA, *supra* note 1, at 296.

13. *See What Are "Biologics" Questions and Answers*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm [https://perma.cc/5JCW-KDGZ] (last visited Sept. 11, 2017).

ventional pharmaceutical drugs and, thus, are more costly to produce.[14] For these reasons, it is imperative that free trade agreements like the new NAFTA address the current issues with both Chapters 17 and 11. By addressing these issues, NAFTA signatories can preemptively resolve issues that were articulated in cases like *Eli Lilly v. Government of Canada*, in which the U.S. pharmaceutical company Eli Lilly sued the Canadian government for invalidating two of the company's patents prior to their patent expiration dates, despite Eli Lilly's reasonable expectation that its significant investment in the two patents would be protected against generic manufacturing.[15]

In Section II, this Note will outline the basics of biologics. This discussion will focus on how biologics differ from conventional pharmaceutical drugs, and how the current U.S. law's biologics patenting process slightly differs from the process for patenting conventional pharmaceutical drugs. Additionally, the introduction to biologics will include a brief overview of the vast and increasing monetary investments that pharmaceutical companies are making in this new area of medicine. Next, this Note will provide an in-depth examination of the previously mentioned relevant provisions of the original NAFTA, including Chapters 17, which focuses on intellectual property; and Chapter 11, which outlines the treaty's foreign investment provisions. The intellectual property and investment provisions will be outlined as two distinct lines of defense for medical-patent rights holders to protect their intellectual property under the original NAFTA. Although this Note will describe how Chapters 17 and 11 relate to conventional pharmaceutical drugs, the discussion will focus primarily on how these provisions relate to new forms of medicine such as biologics and personalized medicine. Finally, this Note will examine proposals to update the original NAFTA to accommodate advancements in medicine, such as biologics. These proposals will highlight the *sick* nature of the intellectual property and investment provisions of the original NAFTA, as well as effective means of curing them under a new and reconfigured NAFTA.

II. BIOLOGICS AND PERSONALIZED MEDICINE: THE FUTURE OF PHARMACEUTICAL MEDICINE

A. *The Basics of Biologics*

Unlike conventional pharmaceutical drugs of the past, which generally have well-defined chemical structures and "can usually be analyzed to determine all its various components," biologics are produced

14. *How Do Drugs and Biologics Differ?*, BIOTECHNOLOGY INNOVATION ORG., https://www.bio.org/articles/how-do-drugs-and-biologics-differ [https://perma.cc/94X2-R5EP] (last visited Sept. 11, 2017).

15. Eli Lilly & Co. v. Government of Can., ICSID Case No. UNCT/14/2, ¶ 5 (Sept. 12, 2013).

by using recombinant DNA technology of individual patients and are personalized to the patient's specific genetic makeup.[16] Biologics come in a wide variety of forms, which include the following: vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.[17] These unique products are used to treat several conditions, including cancer, rheumatoid arthritis, psoriasis, and other autoimmune diseases like inflammatory bowel disease.[18]

Biologics are typically stronger than conventional pharmaceutical drugs, and are used when patients require a more escalated therapy, often due to failure of the first line of treatment.[19] Thus, a physician may be more inclined to prescribe a biologic to help bring a patient into remission, if the physician suspects that the patient's treatment will fail under the weaker pharmaceutical medication.[20] Indeed, this new form of personalized medicine seems to be shifting the direction of health care "by providing physicians with a more precise tool to evaluate, diagnose, and treat patients."[21]

B. *Biologics and the Patenting Process*

Because, unlike conventional pharmaceutical products with known and distinct chemical structures, most biologics come from living matter and "are complex mixtures that are not easily identified or characterized,"[22] patenting these products raises a variety of issues.

First, unlike conventional pharmaceuticals, it is difficult "to characterize a complex biologic by testing methods available in the laboratory," and many of the components of a finished biologic are often unknown because they are personalized to a specific group of patients.[23] Thus, the patentability of the product lies in the process of developing it and not in the drug's molecular formula, as is the case with most conventional pharmaceutical drugs.[24] Additionally, even when the general process of creating biologics is known, patenting the process remains difficult because of the variability of the number of unknown components in the biologic.

Second, the aforementioned difficulty of variability in chemical formula increases costs in the production of biologics because testing

16. BIOTECHNOLOGY INNOVATION ORG., *supra* note 14.
17. FDA, *supra* note 13.
18. *See id.*
19. *See id.*
20. *See id.*
21. Kristin L. Burge, *Personalized Medicine, Genetic Exceptionalism, and the Rule of Law: An Analysis of the Prevailing Justification for Invalidating BRCA1/2 Patents in Association of Molecular Pathology v. USPTO*, 8 WASH. J.L. TECH. & ARTS 501, 505 (2013).
22. FDA, *supra* note 13.
23. BIOTECHNOLOGY INNOVATION ORG., *supra* note 14.
24. *Id.*

the product for effectiveness and safety is only done through clinical trials.[25] Additionally, because the finished product cannot be fully characterized in the laboratory, manufacturers of biologics "must ensure product consistency, quality, and purity by ensuring that the manufacturing process remains substantially the same over time," which further adds to the cost of production.[26] Critics of gene patents argue that *patent thickets*, which are multiple patents on various components of a gene, potentially increase the cost of researching gene therapy by stifling "innovations further downstream in the course of research and product development."[27]

Third, there is a rising controversy over whether genetic material can be patented. In recent years, several U.S. federal court decisions have "reinvigorated the longstanding debate of whether genes qualify for patent protection and whether granting such protection does more harm to patients than good for innovation."[28] The primary argument against allowing the patenting of these new forms of personalized medicine is that while such progress comes with "the desire to protect the intellectual property associated with such advancements,"[29] allowing these genetic patents "may substantially impede necessary scientific research and block access to therapeutic treatments" for individuals who simply cannot afford the high cost of such personalized treatment.[30] Those in favor of stronger patent protection of biologics and other forms of personalized medicine suggest that such a potential setback to genetic innovation would cause more harm to patients by stifling research initiatives.[31]

Thus far, the U.S. Food and Drug Administration ("FDA")'s solution to the third issue is to grant a twelve-year right to data exclusivity for biologic drugs to supplement the traditional twenty-year patent.[32] Data exclusivity pertains to the data that its originator must submit to regulatory authorities to demonstrate both the safety and efficacy of its product in order to obtain marketing approval.[33] In particular, data exclusivity "concerns the extent to which a generic competitor, a 'follower,' may rely on the originator's data in its own application for

25. FDA, *supra* note 13.
26. BIOTECHNOLOGY INNOVATION ORG., *supra* note 14.
27. Burge, *supra* note 21, at 512.
28. *Id.* at 503.
29. *Id.* at 510.
30. *Id.* at 511.
31. *Id.* at 503.
32. *Health Policy 101: How the Trans-Pacific Partnership Will Impact Prescription Drugs*, BROOKINGS INST., https://www.brookings.edu/blog/health360/2015/05/19/health-policy-101-how-the-trans-pacific-partnership-will-impact-prescription-drugs/ [https://perma.cc/UWN3-K84S] (last visited Jan. 12, 2018).
33. Lisa Diependaele et al., *Raising the Barriers to Access to Medicines in the Developing World – The Relentless Push for Data Exclusivity*, 17 DEVELOPING WORLD BIOETHICS 11 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/ [https://perma.cc/D2DN-EDDW] (last visited Jan. 27, 2018).

marketing approval."[34] During the twelve-year period of data exclusivity, the FDA may not approve a biosimilar or generic application that "relies on the data submitted as part of the original biologic application."[35] Thus, the producers of biologic drugs are granted a temporary monopoly; however, this data exclusivity does not prevent another company from generating the data independently.[36]

Indeed, despite the aforementioned high cost of clinical trials in generating biologic data independently, biosimilars of personalized drugs have appeared on the market in recent years. For example, Celltrion produces and sells Inflectra (infliximab-dyyb), a biosimilar to one of the most common biologics, Remicade (infliximab), sold by Janssen.[37] Generic producers argue that the current "restrictions on competition keep drug prices unnecessarily high, inevitably putting a strain on the health system and keeping potentially life-saving drugs out of reach for many patients." To counter that point, supporters of the current data exclusivity measures argue that "given the greater cost and difficulty of bringing a biologic to market, a longer period of exclusivity is necessary to incentivize innovation."[38] Either way, if the twelve-year data exclusivity was shortened, a generic maker could "petition the FDA for abbreviated clinical trials, . . . saving them millions of dollars" and "shortening the time needed to get the biosimilar to the market as a competing product with the original biologic agent."[39]

C. *Biologics as a Growing Investment Opportunity*

Because of the high costs associated with developing and patenting biologics (and other forms of personalized medicine), pharmaceutical companies have a significant incentive to protect not only the finished patented product but also their investment in the development of these unique drugs. Indeed, research and development ("R&D") in biologics has significantly increased in recent years, likely due to the similar increase in sales revenue from biologics.

In 2014, the top five biologics companies by sales included the following: (1) Roche, with $30 billion in revenue; (2) Amgen, with $17.6 billion in revenue; (3) Novo Nordisk, with $14.5 billion; (4) AbbVie, with $13.9 billion; and (5) Sanofi, with $13.9 billion in revenue.[40] By 2016, Transparency Market Research ("TMR") valued the global bio-

34. *Id.* at 12.

35. BROOKINGS INST., *supra* note 32.

36. *Id.*

37. *Inflectra*, FDA, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/125544s000lbl.pdf [https://perma.cc/5GDM-W8CB] (last visited Oct. 14, 2017).

38. BROOKINGS INST., *supra* note 32.

39. Michael Fuller, *Data Exclusivity, Medications, and the Trans-Pacific Partnership*, DataInformed, http://data-informed.com/data-exculsivity-medications-and-trans-pacific-partnership/ (last visited Jan. 27, 2018).

40. *Id.*

logic drugs market at $209.8 billion.[41] Additionally, TMR forecasts that the market will enjoy a compound annual growth rate of 10.1% between 2016 and 2020, reaching $287.2 billion; and 10.9% between 2016 and 2024, reaching $479.8 billion. These estimates are very similar to those from entities such as BCC research.[42] In response to this growth, individual pharmaceutical companies have increased their investment in biologics. For example, in June 2017, Sanofi pharmaceuticals announced plans to invest $673 million annually over the next two to three years in the field of biologics production.[43]

Not surprisingly, North America remains "the largest single regional market," with a 44.9% share of the total, and is expected to grow at a compound annual growth rate of 9.6% from 2016 to 2024.[44] TMR submits that while heavy R&D investment has been occurring in the U.S., these figures are expected to continue to accelerate in the near future.[45] Thus, pharmaceutical companies and biologics producers have much more at stake than mere data exclusivity. Their investments in this new form of medicine are equally, if not more, important to protect both domestically and globally if they are to recoup their development costs and continue to produce new products, particularly in the U.S.

III. THE PROBLEM FOR BIOLOGICS UNDER NAFTA

It is hard to imagine that the original NAFTA's drafters could have foreseen all of the twenty-first century developments in modern medicine. Thus, it is not surprising that the growth of biologics and personalized medicine poses a challenge to the provisions of the original Agreement with respect to intellectual property and investment protection. While its patent protections were innovative, NAFTA's robust measures, as written, are insufficient to grant biologics patent holders the protections that they seek. As regards the investment protections, the provisions of the original NAFTA are now insufficient to guarantee patent rights holders that their large investments in biologics will be adequately protected.

41. Nigel Walker, *Biologics: Driving Force in Pharma*, PHARMA'S ALMANAC, (June 5, 2017; 12:31 PM), https://www.pharmasalmanac.com/articles/biologics-driving-force-in-pharma [https://perma.cc/7SMC-XGLH].

42. *Id.*

43. Matthias Blamont, *Sanofi to Invest Further in Biologics*, REUTERS, (June 14, 2017; 6:51 AM), https://www.reuters.com/article/us-sanofi-biologics/sanofi-to-invest-further-in-biologics-idUSKBN1951IV [https://perma.cc/73TY-QPWQ].

44. Walker, *supra* note 41.

45. *Id.*

A. *First-Line Protection: Intellectual Property*

1. NAFTA Chapter 17

NAFTA's intellectual property provisions begin in Chapter 17. Article 1701 stipulates that "each Party shall provide in its territory to [all signatories] adequate and effective protection and enforcement of intellectual property rights," so long as barriers to legitimate trade are not created,[46] as doing so would defeat the objectives of NAFTA. Thus, Chapter 17 creates a minimum standard to which all signatories must adhere.

While Article 1701 establishes the minimum standards for signatories,[47] the Agreement also allows contracting countries to create even higher standards, so long as such protections are extended to other NAFTA signatories. Article 1702 allows a signatory to "implement in its domestic law more extensive protection of intellectual property rights than is required under [NAFTA]," so long as said protection is not inconsistent with the Agreement;[48] and under Article 1703, "each party shall accord to nationals of another party treatment no less favorable than that it accords to its own nationals with regard to the protection and enforcement of all intellectual property rights."[49]

Provisions specific to patent protection are found in Article 1709. This article makes patents available "for any inventions," including both products and processes, "in all fields of technology, provided that such inventions are new, result from an inventive step, and are capable of industrial application."[50] Additionally, Article 1709.3 specifically provides for pharmaceutical patents.[51] Among its other advantages, this provision resolved an existing and "key problem" for the pharmaceutical industry in the area of "pipeline production," as pharmaceutical patents had previously been vulnerable to piracy during the testing and development stages of production.[52] As a result of this additional provision, NAFTA ensured that a conventional pharmaceutical patent that was in the domestic pipeline at the time NAFTA was enacted could "be protected when introduced in the foreign market for the remainder of its patent term."[53]

With regard to patent life, Article 1709.12 states that the patent life between NAFTA signatories runs for either twenty years from when the patent application was filed or seventeen years after granting the

46. NAFTA, *supra* note 1, art. 1701.
47. Garcia, *supra* note 8, at 830.
48. NAFTA, *supra* note 1, art. 1702.
49. *Id.* art. 1703.
50. *Id.* art. 1709.
51. *Id.* art. 1709.3.
52. Garcia, *supra* note 8, at 831.
53. *Id.*

patent rights,[54] which was the traditional U.S. standard until the 1995 amendments introduced following the Uruguay Round of Multilateral Trade Negotiations and the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS").[55] For pharmaceutical patents specifically, five years of protection from generic competition can be achieved under NAFTA's five-year exclusivity requirement for product approval test data, which begins after the pharmaceutical patent is registered.[56]

Article 1709.10 of NAFTA introduces a provision that allows for compulsory licensing of patents by the governments of the NAFTA signatories.[57] However, NAFTA only permits such compulsory licensing if "the proposed user has made efforts to obtain authorization from the right holder," except in emergency circumstances.[58] Notably, after Canada significantly changed its compulsory licensing of pharmaceuticals in 1993, some pharmaceutical prices in Canada rose as a result.[59] Some experts believe that Article 1709.10 was probably meant to address the concerns of the U.S. pharmaceutical industry regarding Canada's use of compulsory licensing prior to the 1993 change in the law.[60]

2. Shortcomings for Biologics

The introduction of biologics into the market has created some uncertainty about its treatment under international trade agreements such as NAFTA, which predates these recent advances in modern medicine. As a result, while Chapter 17 of NAFTA has advanced international patent rights, biologics developers will likely not be able to secure patent protection like the developers of conventional pharmaceutical products.

While certain provisions of NAFTA, such as Article 1709.3, seek to protect conventional pharmaceutical drugs from piracy and generic manufacturing in the production pipeline, these same protections are not afforded to biologics. This is perhaps the most compelling issue for personalized medicine under a new NAFTA, as the proposition of allowing stronger patent protections for biologics under future free trade agreements sparks criticism of the current timeline of gene-based patents. Specifically, critics argue that while a high "level of patent protection is necessary for incentivizing research," the patent system for these products offers "protection at the wrong stage in the

54. NAFTA, *supra* note 1, art. 1709.12.
55. *See* Uruguay Round Agreements Act, Pub. L. No. 103–465, 108 Stat. 4809 (1994).
56. *See* NAFTA, *supra* note 1 at 1711.5–.7.
57. Garcia, *supra* note 8, at 831–32.
58. NAFTA, *supra* note 1, art. 1709.10(b).
59. *See* Garcia, *supra* note 8, at 832.
60. *Id.*

development process."[61] In other words, much like the Canadian government's argument for invalidating U.S. pharmaceutical company Eli Lilly's patents for lack of shown utility, some critics argue that the current patent system grants personalized medicine producers "a 'hunting license' . . . rewarding the search without compensating later discoveries that result in useful application."[62]

Additionally, while Article 1709.12 of NAFTA may provide an additional five-year exclusivity requirement in addition to the basic twenty-year patent protection for conventional pharmaceutical drugs,[63] no such provision exists to supplement the data exclusivity protections for biologics. Most data exclusivity provisions are written for chemical-based or conventional pharmaceuticals, as *new chemical entities* is the keyword in these provisions for data exclusivity. Because biologics contain mostly biological materials, biologics do not fit nicely under the definition of new chemical entities. Thus, biologics are not protected under these provisions. This lack of data exclusivity protection exacerbates the issue that many pharmaceutical companies face in recouping the cost of their investments in new medical technologies. Because the original NAFTA does not specifically grant biologics patent holders an extended data exclusivity provision, pharmaceutical companies are disadvantaged in the market, potentially stifling innovation.

Despite NAFTA's lack of special provisions for biologics, biologics represent the future of medical developments and pose an important challenge for a new version of NAFTA. Not only is the cost of personalized medicine likely higher than the cost of producing conventional pharmaceutical drugs, but because of the higher costs, there will likely be a greater demand for generic versions of personalized medical products such as biologics. Thus, it is imperative that a new NAFTA contemplate the continuing development of biologics and other forms of personalized medicine.

B. *Second-Line Protection: Investment*

1. NAFTA Chapter 11

Although Chapter 17 of NAFTA created robust intellectual property protections, Chapter 11 has also generated interest in the world of intellectual property rights. Specifically, Chapter 11 covers all things related to foreign investments, with Article 1105 establishing a minimum standard of treatment for NAFTA investors. This standard is defined as "treatment in accordance with international law, including fair and equitable treatment and full protection and security."[64]

61. Burge, *supra* note 21, at 512.
62. *Id.* at 512–13.
63. NAFTA, *supra* note 1, art. 1709.12.
64. *Id.* art. 1105.

Beyond the minimum standards established by Article 1105, Article 1103 grants NAFTA investors most-favored-nation treatment "with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments."[65] This provision allows investors from a NAFTA signatory to enjoy the privileges that the other signatories accord one another under similar circumstances.[66]

While Chapter 11 covers a wide array of protections and prohibitions, no article has been as innovative or as controversial as Article 1117, which relates to NAFTA's investor-state dispute settlement mechanism ("ISDS"). In practice, the ISDS allows private investors to sue foreign governments without consulting their home governments.[67] Notably, investors may assert claims both as individuals and on behalf of NAFTA enterprises that they either own or control, both directly and indirectly.[68] Therefore, this mechanism grants an investor standing to sue a foreign government in circumstances in which the investor's only injury is to its investments abroad if the appropriate ninety-day notice is given to the host country, as outlined in Article 1119.[69]

According to Article 1120, once the claim is submitted, the investor chooses between one of the following three arbitration rules: the International Center for Settlement of International Disputes ("ICSID") Convention, the Additional Facility Rules of ICSID, or the UNCITRAL Arbitration Rules.[70] Article 1123 states that the claim is heard by a tribunal made up of three panelists, one who is chosen by the investor and one who is chosen by the state.[71] The remaining panelist is chosen by agreement if possible.[72] Under Article 1136, an investor may seek enforcement of a judgment if a NAFTA signatory government fails to honor it.[73]

Despite its innovative addition to NAFTA, Chapter 11's ISDS has been criticized for a variety of reasons. First, throughout the development of bilateral investment treaties, a huge motivator of U.S. support for the ISDS is the "U.S. government's desire to afford greater protection for U.S. investors in developing countries," which goes against some beliefs about the role of intellectual property in society.[74] In ef-

65. *Id.* art. 1103.
66. *Most Favored Nation*, BLACK'S LAW DICTIONARY (5th pocket ed. 2016).
67. *See* Peter K. Yu, *The Investment-Related Aspects of Intellectual Property Rights*, 66 AM. U. L. REV. 829 (2017).
68. NAFTA, *supra* note 2, art. 1117.
69. *Id.* art. 1119.
70. *Id.* art. 1120.
71. *Id.* art. 1123.
72. *Id.*
73. *Id.* art. 1136.
74. David A. Gantz, *Increasing Host State Regulatory Flexibility in Defending Investor-State Disputes: The Evolution of U.S. Approached from NAFTA to TPP*, 50 INT'L LAW. 231, 232 (2017).

fect, the ISDS grants private investors from developed countries, like the U.S., a second chance to protect their intellectual property related to conventional pharmaceutical drugs and other medical developments with arbitration panels under the investment protection provisions in Chapter 11. Thus, the ISDS may grant large multinational corporations the right to challenge laws that they oppose through arbitration, which tends to be more industry-friendly.[75]

Second, there is a "renewed and growing concern about the shift of intellectual property norm-setting activities from the trade regime to the investment regime."[76] One key issue with this shift is its potential to "eliminate the traditional limitations, safeguards, and flexibilities that have been built into the international intellectual property regime," which developed over many years of compromise.[77]

Third, the ISDS creates the potential for parties to arbitrate intellectual property disputes behind closed doors in secret proceedings, which attract less public attention. Contrasted against the Chapter 17 intellectual property terms, which direct parties to litigate claims in open court,[78] these secret proceedings potentially grant terms to a party that fall below the minimum intellectual property standards established by the TRIPS Agreement of the World Trade Organization. For some critics, this outcome appears to contradict NAFTA's objectives.

In practice, some experts believe NAFTA has "acted as the catalyst for an explosion of investment claims."[79] Over the last twenty-two years, NAFTA has generated more than 50 ISDS claims.[80] However, the U.S. "has yet to be required to pay an award to a foreign claimant."[81] Indeed, more than half of the claims filed, and in some cases litigated, have occurred between the two more-developed nations of NAFTA, the U.S. and Canada.[82] This result is striking in light of Mexico's general lack of intellectual property standards prior to NAFTA,[83] which could have led to more intellectual property and investment claims after NAFTA came into force. However, the data indicates that this assumption has yet to materialize.

Based on actual litigation arising under Chapter 11 investment provisions, "the most significant and controversial investor's protections" include the right to national treatment; the right to fair and equitable treatment; and the right to fair compensation in the event of expropri-

75. Yu, *supra* note 67, at 832.
76. *Id.* at 835.
77. *Id.*
78. *See generally* NAFTA, *supra* note 1, ch. 17.
79. Todd Weiler, *NAFTA Article 1105 and the Principles of International Economic Law*, 42 COLUM. J. TRANSNAT'L L. 35, 67 (2003).
80. Gantz, *supra* note 74, at 237.
81. *Id.*
82. *Id.*
83. Garcia, *supra* note 8, at 825.

ation or nationalization.[84] Additionally, the primary concerns surrounding medical patents have surfaced "over the lack of transparency" in secret, behind-closed-doors ISDS proceedings.[85] These central claims highlight the potential for a lack of consistent and predictable intellectual property enforcement in a time of emerging and expensive technological advancements in medicine.

2. The Shortcomings of Chapter 11 for Biologics

Unfortunately, the investment involved in the developing biologics may face difficulty receiving protection under NAFTA. However, although NAFTA grants conventional pharmaceutical drugs stronger protection than biologics, the NAFTA investment chapter seems to create difficulty for both conventional and newer forms of pharmaceutical drugs.

In the previously mentioned *Eli Lilly* case, Eli Lilly utilized Chapter 11 of NAFTA to sue the Canadian government for invalidating the patents of two of Ely Lilly's primary drugs, Strattera and Zyprexa.[86] Between 2005 and 2015, Canadian courts invalidated eighteen patents for prescription drugs produced by several U.S. pharmaceutical companies.[87] Then the Canadian government invalidated two of Eli Lilly's patents under the "promise of the patent" doctrine of utility of the Canadian Patent Act, which "seeks to ensure that firms do not obtain a legal monopoly on the basis of speculative claims about increased utility . . . that were unsubstantiated at the time of filing."[88] Although Canadian courts previously interpreted this doctrine favorably for U.S. pharmaceutical companies, when the Canadian court invalidated Eli Lilly's patents prior to their expiration, based on the grounds that their utility was not shown, the pharmaceutical company sued Canada under Chapter 11 ISDS provisions due to the company's belief that the court exercised a new and inconsistent interpretation of the Act.[89]

One key issue in the case was that Eli Lilly reasonably expected its patents to be valid for the standard twenty-year period established by years of global intellectual property doctrine.[90] Despite this expectation, the Canadian courts retroactively invalidated Eli Lilly's patents potentially to support public policy and to prevent pharmaceutical companies from trying "to evergreen prior patents by claiming that a

84. Gantz, *supra* note 74, at 238.

85. *Id.* at 239.

86. Eli Lilly & Co. v. Government of Can., ICSID Case No. UNCT/14/2, Notice of Arbitration, ¶¶ 3, 4 (Sept. 12, 2013), http://icsidfiles.worldbank.org/icsid/icsidblobs/onlineawards/c3544/dc4612_En.pdf [https://perma.cc/2FQS-BQQQ].

87. Yu, *supra* note 67, at 834.

88. Jerome H. Reichman, *Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection*, 108 AM. SOC'Y INT'L PROC. 313, 313 (2015).

89. *Eli Lilly*, ICSID Case No. UNCT/14/2 at ¶¶4–5.

90. *Id.* ¶ 5.

small selection of a number of previously patented compounds provides a 'substantial advantage' that merits new patent protection."[91] The basis of Eli Lilly's claims was that, under this promise doctrine, Canadian courts invalidated the patents of successful pharmaceutical companies, such as Eli Lilly, which was inconsistent with Canada's obligations under NAFTA, the TRIPS Agreement, and other treaties.[92] However, Eli Lilly was unsuccessful in using Chapter 11 as a second-line attempt to protect its patents and its investments when its claims under Chapter 17 of NAFTA failed.

Although Eli Lilly ultimately lost its NAFTA complaint,[93] the suit generated a great deal of discussion about the difference between intellectual property in the trade regime and intellectual property in the investment regime—particularly with respect to newer pharmaceutical products like biologics. If the producers of conventional pharmaceutical drugs cannot successfully utilize Chapter 11 to protect their investments against intellectual property violations by the NAFTA signatories, it is unlikely that more advanced pharmaceuticals, such as biologics, will enjoy a better outcome.

A key issue with this likely outcome under the original NAFTA is that the investment in conventional pharmaceuticals and biologics is continuing to grow in the global market and particularly in the U.S. despite the inadequate Chapter 11 protections. While it is important that investment in conventional pharmaceutical drugs, like those produced by Eli Lilly, is reasonably protected under NAFTA, it may become an increasingly contentious issue as investment in biologics becomes the largest share of growth in the pharmaceutical industry.[94] Thus, while a new NAFTA should contain updated intellectual property provisions, it is also imperative that the Agreement's investment chapters be updated, affording intellectual property holders an opportunity to challenge foreign governments and protect their already robust and continuously growing investments in biologics.

IV. PROPOSAL: USING THE TPP AS A MODEL FOR INTELLECTUAL PROPERTY BUT NOT FOR INVESTMENT

When evaluating the future of NAFTA and its potential revisions, many experts look to the language of the TPP Agreement as a guide.[95] The TPP Agreement was signed in 2016 under U.S. President Barack

91. Reichman, *supra* note 88, at 313.

92. Yu, *supra* note 67, at 834.

93. *Eli Lilly*, ICSID Case No. UNCT/14/2 at ¶480.

94. *World Preview 2017, Outlook to 2022*, EVALUATEPHARMA (June, 2017), http://info.evaluategroup.com/rs/607-YGS-364/images/WP17.pdf [https://perma.cc/62PW-Q43R].

95. Trans-Pacific Partnership Agreement, OFF. U.S. TRADE REPRESENTATIVE, https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text [https://perma.cc/J7N6-RQ46] (last visited Feb. 8, 2019).

Obama.[96] Originally including twelve diverse countries, the TPP Agreement attempted to resolve key issues that arose under previous free-trade agreements.[97] In addition to updating traditional approaches to issues covered by previous free trade agreements like NAFTA, the TPP Agreement incorporates new and emerging trade issues, including those related to intellectual property and investment.[98] Of particular importance to biologics and other forms of personalized medicine, while the TPP Agreement's intellectual property provisions fix the previously described issues with patent rights under the original NAFTA, the TPP Agreement's investment provisions should likely be scrutinized more heavily.

A. *Fixing NAFTA*

1. Chapter 17 Patent and Data Exclusivity Provisions

The TPP Agreement offers a model for new advances in intellectual property protections that the NAFTA renegotiations should consider, including those related to biologics and personalized medicine. Of special importance for these new forms of pharmaceuticals, the initial TPP Agreement proposals required participating signatories to either increase their individual, mismatched data exclusivity provisions for biologic drugs to match the U.S. standard of twelve years; or to actually create data exclusivity standards where none had previously existed.[99] This advancement surprised many experts, as the proposal was different from the expected changes to free trade agreements under the Obama Administration. However, this significant change represents an attempt by the TPP Agreement's drafters to standardize the period of data exclusivity to which biologics drug makers are entitled "as a way of recouping the high costs of discovering and proving effectiveness of biologic therapeutics."[100]

2. Chapter 11 Investment Provisions

When President Obama entered the U.S. into the TPP Agreement in 2016,[101] over two decades after NAFTA was signed, the TPP Agreement's investment provisions were the latest in the evolution of

96. *Summary of the Trans-Pacific Partnership Agreement*, OFF. U.S. TRADE REP. (Oct. 04, 2015), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/summary-trans-pacific-partnership [https://perma.cc/M3WR-RV66] [hereinafter OFF. U.S. TRADE REP. 4].

97. *Id.*

98. *Id.*

99. BROOKINGS INST., *supra* note 32.

100. Fuller, *supra* note 39.

101. *Statement by the President on the Signing of the Trans-Pacific Partnership*, OFF. PRESS SECRETARY, https://obamawhitehouse.archives.gov/the-press-office/2016/02/03/statement-president-signing-trans-pacific-partnership [https://perma.cc/8EF5-GXUZ] (last visited Jan. 12, 2018).

investor protection.[102] Among its various changes, section 1(c) of the TPP Agreement continued to evolve the definition of the NAFTA Chapter 11 term "customary international obligation" as "resulting from"[103] a "general and consistent practice of States that they follow from a sense of legal obligation," which is consistent with current free-trade agreement practices and resolved many confusing definitions in NAFTA.[104] Importantly, several TPP Agreement provisions also changed the investment landscape in previous free trade agreements like NAFTA, as well as their relationship to intellectual property rights. However, the earlier NAFTA's investment provisions are perhaps more useful for U.S. pharmaceutical companies than the newer TPP provisions, particularly with respect to biologics and new forms of personalized medicine.

Two primary significant changes were made to investment provisions under the TPP Agreement. First, the TPP Agreement requires "transparency" with respect to the arbitral tribunals in its Chapter 9 provisions.[105] Under the TPP Agreement, "arbitral proceedings will remain open and publicly accessible."[106] Under Article 9.24.1, the TPP Agreement "requires the respondent to make publicly available" several important documents,[107] including "notice of intent;" "notice of arbitration;" and "orders, awards and decisions of the tribunal."[108] According to experts in trade and investment, "such transparency will ensure high-quality decision making while promoting democratic values, public participation, accountability, and legitimacy,"[109] all of which were concerns voiced about the *Eli Lilly* arbitration with Canada.

Importantly, the TPP Agreement also establishes a code of conduct for arbitrators using the ISDS to ensure "independence and impartiality"[110] under Article 28.10(d),[111] which was a voiced concern of the pharmaceutical company Eli Lilly.[112] Additionally, Article 28.17.7 specifically grants disputing parties the opportunity to "submit written comments to the panel on its initial report,"[113] opening the dialogue between the discontent party and the host state.

Second, the TPP Agreement supposedly improves the *tunnel-vision* of the arbitrators using the ISDS under Chapter 11 of NAFTA, as well

102. Gantz, *supra* note 80, at 259.
103. *Id.* at 254.
104. OFF. U.S. TRADE REPRESENTATIVE, *supra* note 95, at Annex 9-A.
105. Gantz, *supra* note 80, at 254.
106. Yu, *supra* note 67, at 870.
107. *Id.*
108. OFF. U.S. TRADE REPRESENTATIVE, *supra* note 95, art. 9.24.1.
109. Yu, *supra* note 67, at 871.
110. *Id.*
111. OFF. U.S. TRADE REPRESENTATIVE, *supra* note 95, art. 28.2.10.
112. *Eli Lilly*, ICSID Case No. UNCT/14/2.
113. OFF. U.S. TRADE REPRESENTATIVE, *supra* note 95, art. 28.17.7.

as "their over-emphasis [on] intellectual property rights as investor's rights."[114] Specifically, Article 9.23.3 of the TPP Agreement states that "the tribunal may accept and consider written *amicus curiae* submissions" from non-disputing parties that may have an interest in the proceedings "regarding a matter of fact or law within the scope of the dispute that may assist the tribunal."[115] This provision allows stakeholders outside of the dispute to provide insight about the proceedings that allow the tribunal to consider non-intellectual property related issues that could be affected by the outcome of the proceedings. Additionally, under Article 28.14,[116] the TPP Agreement allows the "investor's home states" to "make submissions to arbitral tribunals,"[117] furthering the stakeholder's input in the process.

Despite the TPP Agreements' advancements, a few experts believe that the investment provisions, including the ISDS, under the original NAFTA have been overly criticized. These experts contend that the older provisions are not as in need of update as some critics suggest. After all, despite the pervasive notion that arbitration through the ISDS lacks transparency and gives arbitrators tunnel vision, Eli Lilly still lost its claim under Chapter 11.

The experts in favor of keeping the investment arbitration system under the original NAFTA posit that criticism of NAFTA's current ISDS provisions focuses too intently on a perceived lack of transparency, unpredictability, incoherence, and unfair bias toward industry.[118] Specifically, experts in favor of the original NAFTA provisions disagree that investment treaties and investment-treaty arbitration "institutionalize a pro-investor bias that casts the legitimacy of the entire system of international investment law and arbitration into doubt."[119] These experts argue that, "while aspects of the system should be critically observed and evaluated," the overall system design as such "faces fewer fundamental concerns than critical voices purport."[120] In particular, these experts look to the current system's ability to stabilize and enable "economic exchange in the investment context,"[121] as well as the fact that the current ISDS actually contains several checks and balances against unfair bias towards industry, including a host-state's ability to appoint arbitrators[122] and the informal control mechanism of public scrutiny through instantaneous online ac-

114. Yu, *supra* note 69, at 870–871.

115. OFF. U.S. TRADE REPRESENTATIVE, *supra* note 95, art. 9.23.3.

116. *Id.* art. 28.14.

117. Yu, *supra* note 69, at 873.

118. Charles N. Brower & Stephan W. Schill, *Is Arbitration a Threat of a Boon to the Legitimacy of International Investment Law?*, 9 CHI. J. INT'L L. 427, 474-75 (2009).

119. *Id.* at 474–75.

120. *Id.* at 477.

121. *Id.* at 497.

122. *Id.* at 491.

cess.[123] All told, advocates of the ISDS under the original NAFTA believe that arbitration has long served as "an accepted system of dispute resolution in public international law" and has been tested over time.[124] Thus, instead of focusing on the perceived bias in the system, some experts advocate that "critics should look to the outcomes of proceedings in order to evaluate the legitimacy of protection and the capacity to live up to the standards of independence, impartiality, and judicial judgment."[125]

This observation is particularly important in light of the outcome of several cases, including *Eli Lilly*, that show how well the current system works despite the perception that arbitration proceedings favor the pharmaceutical industry. In fact, in light of these outcomes, the ISDS in the original NAFTA is likely equipped with enough checks and balances to be a viable mechanism for international investor disputes against the governments of the NAFTA signatories. Thus, despite popular opinion that the ISDS is in desperate need of revision, the results indicate that the system is fine in its current form under the original NAFTA. Therefore, newer developments under the TPP Agreement should not be weighed as heavily in the renegotiation of the Chapter 11 investment provisions under a new and improved NAFTA.

V. CONCLUSION

President Donald Trump's May 2017 announcement that NAFTA will be renegotiated has reenergized the treatment of intellectual property-based investments under the respective chapters of the original NAFTA. This discussion has been historically controversial because there are two vastly different opinions on the issue of intellectual property rights protections in a global economy. On the one hand, countries like the U.S tend to believe that pharmaceutical patents are essential to their technology-driven economies. These countries often focus on a theory of patent law that awards innovation and minimizes free-riding, thereby enabling inventors to develop new products in the face of high costs. On the other hand, other countries—particularly developing countries—believe that pharmaceutical patents are an expensive barrier to economic development, as these developing countries are more likely to pay royalties than receive them. However, without effective patent protection, pharmaceutical companies in the U.S. face the possibility of piracy and premature generic competition. Both pose a problem for the producers of conventional pharmaceutical drugs that invest large sums of money into the research and development of new drugs.

123. *Id.* at 492.
124. Brower & Schill, *supra* note 118, at 493.
125. *Id.* at 497.

This disagreement has been exasperated by new developments in medical technology, including the introduction of biologics and personalized medicine in the pharmaceutical drugs market. As was previously mentioned, without effective patent protection for these new forms of pharmaceutical drugs, pharmaceutical companies will struggle when generic manufacturers begin producing new forms of biosimilars at a greatly reduced price. Although the producers of conventional pharmaceutical drugs have encountered this problem in the past, the introduction of biosimilar drugs will pose an even greater threat to biologics than generic drugs have previously posed for conventional pharmaceutical drugs, as the cost of producing biologics is significantly greater than the cost of producing conventional pharmaceutical drugs. These increased costs will put a strain on biologics producers, as they attempt to recoup their hefty investments in this new form of medicine. Unfortunately, under the original NAFTA's intellectual property and investment provisions, biologics producers are not sufficiently armed to combat these significant losses in new medical technology.

Although the Trump Administration announced its decision to withdraw from the TPP Agreement on January 23, 2017,[126] the innovations of the Agreement are likely to remain— particularly with respect to the TPP Agreement's intellectual property advancements, including those related to extending data exclusivity.[127] This is illustrated by the fact that the investment chapter of the TPP has been incorporated by reference into international agreements, such as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership.

The TPP Agreement provisions related to intellectual property represent a substantial improvement to the older provisions of the original NAFTA that will likely increase patent protections for biologics and personalized medicine rights holders. Thus, the TPP protections offer a strong first-line defense of protection for patent-rights holders, and a new version of NAFTA should adopt them. However, criticism of the old NAFTA Chapter 11 investment provisions may be overstated, as the original investment provisions likely provide a good second-line defense for patent-rights holders, as they strengthen transparency, which is ultimately good for business.

126. *Regarding Withdrawal of the United States from the Trans-Pacific Partnership Negotiations and Agreement*, OFF. U.S. TRADE REP., https://www.whitehouse.gov/presidential-actions/presidential-memorandum-regarding-withdrawal-united-states-trans-pacific-partnership-negotiations-agreement/ [https://perma.cc/2J3B-5VPW] (last visited Jan. 12, 2018).

127. *See* Gantz, *supra* note 80, at 259.