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February 14, 2018

Ambassador Robert E. Lighthizer
U.S. Trade Representative
Executive Office of the President
600 17th Street, NW
Washington, DC 20508

Re: NAFTA Renegotiation: ABA IPL Section Comments

Dear Mr. Ambassador:

On behalf of the American Bar Association ("ABA") Section of Intellectual Property Law (the "Section"), we respectfully submit our comments on the renegotiation of the North American Free Trade Agreement ("NAFTA") for your consideration. The views expressed herein are presented on behalf of the Section of Intellectual Property Law. They have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the position of the Association. We respectfully request that our concerns be raised with your Canadian and Mexican counterparts, to the extent you have not already done so in the negotiation rounds to date. On behalf of the Section, I would be pleased to answer any questions that USTR has regarding these comments, as well as to testify at any future hearings or other public fora that the USTR or U.S. Government might hold pertaining to the issues addressed by these comments.

I. EXECUTIVE SUMMARY

Given the importance of adequate and effective trade secret and IPR protection and enforcement to so many U.S. companies and to the U.S. economy as a whole, and the many current gaps in such protection and enforcement in Canada and Mexico, a modernized NAFTA must address as many of those deficiencies as possible. A modernized NAFTA should also take account of best-practice international norms of protection and enforcement and avoid overly prescriptive solutions specified in previous FTAs that have not stood the test of time, with the goal of opening these important trading-partner markets to U.S. intellectual property materials. A modernized NAFTA should retain the current NAFTA's Investor-State Dispute Settlement Systems (ISDS). A modernized NAFTA should also ensure that Parties are not "free to adopt" an interpretation of the conditions for patentability set out in Article 1709(1) that obviates, compromises or otherwise lowers the minimum standards of patent protection. Finally, a modernized NAFTA should include robust digital trade protections to ensure that US-based digital products and services have full and fair access to Canadian and Mexican digital markets, given the importance of digital trade to U.S. intellectual property rightsholders and the historic trade surpluses that these goods and services produce.

The Section’s specific recommendations for each area, and the reasoning behind them, are set forth in detail below but can be summarized as follows:

Trade secrets: With respect to trade secret protection, the Section’s key recommendations for a renegotiated NAFTA are as follows:

- It should prohibit any Party from requiring that trade secrets be reduced to a tangible form. Unfortunately, Article 1711(2) of the current NAFTA expressly permits parties to impose such an additional requirement, and Mexico does so in Article 83 of its Industrial Property Law.

- It should require that all Parties enact national laws regarding protection of trade secrets, as the U.S. recently did by enacting the Defend Trade Secrets Act.

- It should require that all the Parties have criminal penalties and procedures for trade secret violations, as contained in the U.S. Economic Espionage Act (“EEA”) and in the text originally negotiated for the Trans-Pacific Partnership Agreement ("TPP").

Trademarks: With respect to trademark protection, the Section’s key recommendations for a renegotiated NAFTA are as follows:

- It should require repeal of the amendments relating to the Canadian Trademarks Act that allow an applicant for a trademark to obtain a registration without showing or alleging use.

- It should require amendment of the provisions of Mexican law which require the visibility of a trademark.

- It should require each Party to provide adequate financial and other resources to customs officials to deal with all aspects of IP enforcement.

- It should require each Party to ensure that customs enforcement officers receive additional training to identify counterfeits.

- It should require each Party to provide a simplified procedure for destruction of uncontested counterfeit goods without any requirement to initiate court proceedings.

- It should require each Party to implement the method of proceeding set out in article 18.76 of the TPP, including the alternative option of disclosure of information, to allow for sharing of information relating to uncontested counterfeit goods and in-transit goods.

- It should require each Party to give its customs officials the authority to detain, seize and destroy uncontested counterfeit goods in transit or transhipment to other countries.

Copyright: With respect to copyright protection, the Section’s key recommendations for a renegotiated NAFTA are as follows:

- Its copyright provisions should be based upon the copyright provisions in the U.S.-Korea

Free Trade Agreement (KORUS), updated as described below.

- For the reasons explained below, it should not include KORUS's requirement that each Party adopt the equivalent of Section 512 of the U.S. Digital Millennium Copyright Act (DMCA), nor should it include the specific language in the original TPP (in Section 18.66) calling for each Party to have "balance" in copyright systems. Instead, it should use high-level language, still consistent with U.S. law, requiring each Party to establish intermediary liability and appropriate limitations on such liability consistent with effective protections for each Party's rightsholders. If a more specific approach is required, it should require each Party to have an ISP liability framework that provides "best practice" legal incentives for ISPs to cooperate with rightsholders (and specifically, to require ISPs to take action when they become aware of infringing activity on their services), and that confines limitations on damages liability to ISPs that truly assist rightsholders in fighting infringements and do not control, initiate or direct infringements.

- It should explicitly require that each Party's exceptions and limitations to exclusive rights comply with the internationally recognized three-step test.

- It should include a requirement that each Party provide aiding and abetting liability for all criminal copyright offenses and meaningful injunctive relief in civil cases.

- It should ensure that all Parties take immediate steps to implement and ratify their obligations under the WIPO Digital Treaties and that they complete the process of harmonizing the duration of protection for copyright in accordance with the modern-day international standard of the life of the author plus 70 years.

- It should, at a minimum, review the existing NAFTA's "cultural exception" for Canada with a view to improving U.S. rightsholders' access to the Canadian market for copyrighted works.

Patents: With respect to patent protection, the Section's key recommendations for a renegotiated NAFTA are as follows:

- It should not cede or enable a Party to lower the minimum standards of patentability. The conditions for patentability set out in Article 1709(1) provide that patents shall be available "for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step (to be non-obvious) and are capable of industrial application." These conditions must be understood to set a minimum, commonly understood threshold. Parties cannot self-define the conditions to lower the minimum standards of patent protection.

- It should protect medicinal innovation during the regulatory review process through a mandate that all Parties adopt periods of patent term restoration that are at least equivalent to those provided under U.S. law.

Regulatory Exclusivity: With respect to regulatory exclusivity, the Section's key recommendation for a renegotiated NAFTA is as follows:

- It should establish periods of protection for regulatory data ("data exclusivity") for small and large molecule drugs, drugs for the treatment of certain rare diseases, and new indications that are at least equivalent to those periods provided for in the United States.

ISDS: With respect to the investor-state dispute settlement system ("ISDS") issue, the Section's key recommendation for a renegotiated NAFTA is as follows:

- It should preserve ISDS provisions of the existing NAFTA so as to maintain accountability and an adequate enforcement mechanism for investors.

Digital Trade: With respect to digital trade issues, the Section's key recommendations for a renegotiated NAFTA are as follows:

- The Parties should not be permitted to impose customs duties on digital products and services (e.g., software, music, video, e-books).

- The Parties should be required to provide non-discriminatory treatment of digital products and services transmitted electronically and to guarantee that these products and services will not face government-sanctioned discrimination based on the nationality or territory in which such products and services are produced.

- No Party should be permitted to impose measures that restrict cross-border data flows, to require the use or installation of local computing facilities, nor to require the disclosure of a company's proprietary algorithms as a prerequisite for trade opportunities.

II. DETAILED DISCUSSION--TRADE SECRET ISSUES

The Section believes that a renegotiated NAFTA should reflect the growing recognition globally of the importance of trade secret protection, as reflected in the recent passage of the U.S. Defend Trade Secrets Act ("DTSA"), the EU's Trade Secret Directive, and reforms to the trade secret laws of several countries. Several research studies have shown that trade secrecy is the form of intellectual property that is most widely and strongly relied upon by businesses to protect their assets. As this Administration has recognized, trade secrets are also increasingly vulnerable to state-sponsored economic espionage as well as misappropriation by unscrupulous competitors and departing employees.

The Section urges that trade secret protection in NAFTA be consistent with trade secret protection available under U.S. law under the DTSA. U.S. businesses and investors need to be assured that their investments in R&D, innovative processes and formulas, and other valuable confidential business information are just as safe across the borders with our closest trading partners as they are in the United States. As a matter of global competitiveness, the members of NAFTA should look to the example of the EU, where the Trade Secret Directive was motivated by the economic benefits of consistent, reliable trade secret protection among trading partners.

The Section recommends focusing on three significant improvements to NAFTA and national laws, as applicable, that would lead to more effective, reliable, and consistent trade secret protection within the NAFTA territories.

First, the Parties should amend NAFTA to prohibit parties from imposing additional requirements for trade secret protection, such as a requirement that trade secrets be reduced to a tangible form. Unfortunately, Article 1711(2) of the current NAFTA expressly permits parties to impose this additional requirement by stating that a "Party may require that to qualify for protection a trade secret must be evidenced in documents, electronic or magnetic means, optical discs, microfilms,

films or other similar instruments." This provision essentially adopted the language of Article 83 of Mexico's Industrial Property Law, which remains the law in Mexico today.

This additional qualification on trade secret protection is a significant and outdated exception to trade secret protection. As recent OECD research shows, trade secret laws have significantly strengthened around the world in the decades since the adoption of NAFTA.[1] What once may have been a tolerable exception now represents a large deviation from the norm. Mexico stands alone among OECD members in imposing an explicit requirement for documentary evidence. In fact, of the nearly 40 countries studied by the OECD, only Russia and China, which the OECD found to have some of the least effective trade secret laws, maintain such a requirement in fact or law.

The difficulty with a documentary evidence requirement is that it misunderstands the nature of trade secrets and thus presents a potential obstacle to protecting the rights of trade secret owners. A trade secret does not arise when it is embodied in a tangible medium of expression, as in the case of a copyrighted work, nor is it defined by claims in an application reviewed and granted by an intellectual property office, as in the case of a patented invention. Rather, a trade secret is first truly defined when the owner goes to court to enforce it. While the trade secret owner will need to describe the trade secret with sufficient clarity in its pleadings and establish its existence in court, it is a mistake to require it to be evidenced in a particular tangible form. For example, for reasons of security, a trade secret owner may divide a formula or process into multiple parts, some or all of which may be known only to particular individuals and only retained in their memories. Similarly, an employee doing research for their employer may make specific, valuable discoveries that should be proprietary to the employer, rather than part of the employee's general skills and knowledge, without reducing them to writing. A trade secret owner should be able to establish the existence of such trade secrets through all available means, rather than through the existence of a particular tangible embodiment. Indeed, maintaining such documentation may threaten the security of a trade secret.

Second, the lack of a national law in Canada represents a weakness that could well be remedied. While the U.S. might be seen as a recent convert on this point, given the very recent adoption of the DTSA, the DTSA was adopted for good reasons. Congress was motivated by the business community's need for certainty and uniformity provided by codification in a single Federal statute. Indeed, USTR has noted the value of such a statute for other countries in its own annual Special 301 Reports. Given the growing recognition of the importance of trade secrets, it would be helpful to have such a single statute.

Third, revising NAFTA to add text providing for criminal penalties and procedures for trade secret violations, as contained in the U.S. Economic Espionage Act ("EEA"), would provide an essential tool for trade secret owners to protect their trade secrets. The Section notes that the text negotiated in the TPP providing for criminal penalties and procedures to protect trade secrets would serve this purpose well. While criminal trade secret laws such as the EEA are typically used sparingly, they are truly needed when they are used. Governments have powers and expertise not available to private parties to investigate and prosecute trade secret misappropriation. A trade secret owner that finds itself the victim of sophisticated economic

[1] Mark Schultz & Douglas Lippoldt, Approaches to Protection of Undisclosed Information (Trade Secrets), (OECD 2014), available at http://bit.ly/1Dk6ONp; Douglas Lippoldt & Mark Schultz, Uncovering Trade Secrets - An Empirical Assessment of Economic Implications of Protection for Undisclosed Data (OECD 2014), available at http://bit.ly/1ale8gD.

espionage, particularly where it is state-sponsored, often finds itself vastly outmatched. The assistance of law enforcement in conducting searches, surveillance, and sting operations, as well as making arrests, levels the playing field in such cases.

III. DETAILED DISCUSSION--IP ISSUES

A. Trademark Issues

Canada

As we said in our letter of October 6, 2017 to Elizabeth Kendall, the Acting Assistant U.S. Trade Representative for Innovation & Intellectual Property (copy attached), the amendments relating to the Canadian Trademarks Act that allow an applicant for a trademark to obtain a registration without showing or alleging use (Sections 330, 339, and 345) should be repealed or not brought into force for the reasons set out in that letter.

Mexico

The provisions of Mexican law which require the visibility of a trademark should be amended to allow for the registration of non-traditional marks including marks relating to a particular color, sound, animated image or a taste or a smell. This is consistent with article 18-2, paragraph 1 of KORUS.

Border Measures

Adequate financial and other resources should be provided to custom officials to deal with IP enforcement including investigation, prosecution and hiring and training of an adequate number of custom officers so the public can be protected. We believe this is important on a practical basis and is consistent with the obligations contained in ACTA Chapter II, article 28

Custom enforcement officers should receive additional training to identify counterfeits. Many rights holders and industry associations are prepared to provide training at no charge but officials have not accepted these offers. Once again we believe this is consistent with the obligations contained in ACTA Chapter II, article 28 and 29.

There should be a simplified procedure to permit the destruction of uncontested counterfeit goods without the requirement of initiating court proceedings. This is important since without such procedures a rights holder is faced with the costs of initiating proceedings in the courts in all cases and in addition to bearing the costs of storage and destruction of the goods.

The method of proceeding set out in article 18.76 of the TPP should be implemented, including the alternative option of disclosure of information to allow for sharing of information relating to uncontested counterfeit goods and in-transit goods. This is consistent with the requirements set out in KORUS Chapter 18, articles 19-25.

Finally, customs officials should be given the authority to detain, seize and destroy uncontested counterfeit goods in transit or transshipment to other countries. This is also consistent with the requirements set out in KORUS Chapter 18, articles 19-25.

B. Copyright Issues

As has been repeatedly pointed out, NAFTA's copyright provisions were negotiated in the early 1990s, prior to the development of national and international digital distribution networks for copyrighted works and prior to a host of more recent multilateral and bilateral treaties and FTAs reflecting the current international norms of protection and enforcement in the digital age. The renegotiation of NAFTA provides the U.S. with the opportunity not merely to update NAFTA's antiquated copyright provisions to reflect these more recent multilateral and bilateral treaties and FTAs but also to improve upon those more recent agreements to reflect the latest learning on what works and what doesn't to protect copyrighted materials in foreign markets.

With respect to specific provisions for a modernized NAFTA, the Section believes that USTR would do well to build upon--but not adopt wholesale--the copyright provisions in the U.S.-Korea Free Trade Agreement (KORUS).

- Provisions to build upon include KORUS's requirement to criminalize unauthorized camcording in theaters (as the U.S. and Canada have already done, but not Mexico, one of the largest sources of these illegal camcords), requirements for strong civil and criminal remedies for infringements including satellite and cable signal theft, and the treatment of Technological Protection Measures (TPMs).

- The one KORUS copyright provision we do not recommend adopting is its rote recitation of Section 512 of the U.S. Digital Millennium Copyright Act (DMCA), which was intended by Congress to incentivize effective cooperation between copyright owners and service providers to combat online infringement, but in a number of recent U.S. court decisions has instead been treated as a "get-out-of-jail-free card" for service providers instead.[2] In addition, technological developments including near-instantaneous re-posting of infringements taken down pursuant to Section 512's notice-and-takedown process have rendered the process much less effective than Congress intended.[3] The resulting need to reconsider the adequacy of Section 512 has been reflected in several U.S. legislative and regulatory initiatives.[4] Taken together, these developments indicate that what was contemplated when Section 512 was enacted in 1998 has, unfortunately, not worked as intended for copyright creators and producers. This is particularly

[2] *See, e.g., UMG Recordings, Inc. v. Shelter Capital Partners LLC*, 718 F.3rd 1006 (9th Cir, 2013) (holding that, *inter alia*, a service does not have "red flag" knowledge sufficient to disqualify it from Section 512's "safe harbor" even if it knows it is hosting a category of infringing content); and *Viacom Int'l, Inc. v. YouTube, Inc*., 676 F.3rd 19 (2nd Cir. 2012) (same).

[3] Just to take one example, content owners must send thousands of such notices to the same sites, regarding the same works, because U.S. courts have held that service providers have no obligation to remove all copies of an identified work—only the copy located at the specific URL identified in the takedown notice. As a result, as one copy of a work is removed from the Internet, another appears almost immediately thereafter. Indeed, in some cases, content is never actually removed at all, because, once a content owner identifies an infringing URL, that URL is taken down, but another URL linking to the same infringing work, on the same site, simultaneously replaces the original link. It should be noted that Canada's "notice and notice" infringement notice-sending system (which does not require that even the specific URL identified in the notice be taken down) is even less effective than the Section 512 system, and certainly much less effective than a best-practice "takedown/staydown" regime would be, and should certainly not become a "model" for Mexico to adopt.

[4] Indeed, Section 512 has been the subject of intense study by the U.S. House Judiciary Committee, the U.S. Patent and Trademark Office, and others with a view towards possible amendments even in the U.S., which is why adopting that prescriptive language in NAFTA would tie Congress' hands for future improvements.

disheartening in light of the far more positive legal developments in other countries outside North America, who have adopted more robust shared-responsibility schemes that include site-blocking,[5] notice-and-staydown, and effective injunctive relief.

In light of these developments, the Section recommends a new approach to this important trade policy by moving to high-level language that requires each Party to establish intermediary liability and appropriate limitations on such liability consistent with effective protections for each party's rightsholders. Such an approach would be fully consistent with U.S. law while discouraging the misinterpretation of Sec. 512-like limitations of liability by policymakers and courts outside the US.

If a more specific approach is required, the ISP liability framework should be amended to provide "best practice" legal incentives for ISPs to cooperate with rightsholders (and specifically, to require ISPs to take action when they become aware of infringing activity on their services), and confine limitations on damages liability to ISPs that truly assist rightsholders in fighting infringements and do not control, initiate or direct infringements.

- In addition, a renegotiated NAFTA should avoid what we believe was an even larger mistake, in the now-abrogated Trans-Pacific Partnership[6], which diverged both from KORUS and other FTAs by including specific language (in Section 18.66) calling for "balance" in copyright systems. The Section supports a copyright system in all countries that balances the exclusive rights of authors and producers with prescribed exceptions and limitations to such rights, consistent with international treaties and norms. But some countries have pushed their exceptions and limitations in the digital world beyond that which the treaties or other bilateral agreements permit via the so-called three-step test (treated with virtually identical language in Berne Art. 9.2; WTO TRIPS Art. 13; WCT Art. 10; WPPT Art. 16). For example, Canada's attempt at "balance", by permitting its "fair dealing" exception to cover very broad educational exceptions to copyright, has resulted in the loss of millions of dollars in existing contracts by U.S. (and Canadian) educational publishers and authors, as the USTR itself noted in its 2017 Special 301 Report, which placed Canada on its Priority Watch List. As with Section 512 of the DMCA, the concept of "balance" can be and has been twisted and used as a vehicle for weakening copyright protections and expanding exceptions beyond the scope of the well-established, and well-implemented, three-step "balancing" test already found in the Berne Convention, the TRIPS Agreement and the WIPO Internet Treaties. In this regard, the current NAFTA's clean recitation of the three-step test is preferable and should just be left alone. Further, the Section urges the USTR to use the opportunity presented by the renegotiation of NAFTA to examine each Party's current exceptions and limitations to the exclusive rights, ensuring not only that all Parties are and remain in compliance with the three-step test but also that existing provisions do not have unduly detrimental market effects. A renegotiated NAFTA should, in any case, reaffirm that all such exceptions and limitations must comply with the three-step test.

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[5] See Hugh Stephens, "Why the Time Has Come to Block Offshore Pirate Websites in Canada", Jan. 22, 2017, available at https://hughstephensblog.net/2018/01/22/why-the-time-has-come-to-block-offshore-pirate-websites-in-canada/.

[6] The Section looks forward to reviewing and commenting upon the copyright provisions of the 11-country replacement treaty now called the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP).

- A salutary provision missing from KORUS but found in subsequent trade negotiations is a provision requiring aiding and abetting liability for all criminal copyright offenses. Another improvement would be to ensure that rightsholders have fully effective injunctive relief, as provided by Rule 65 of the U.S. Code of Civil Procedure.

- A renegotiated NAFTA should ensure that all parties take immediate steps to implement and ratify their obligations under the WIPO Digital Treaties and that they complete the process of harmonizing the duration of protection for copyright in accordance with the modern-day international standard of the life of the author plus 70 years.

- A renegotiated NAFTA should also address the market access barriers that remain in both countries, one of which is contained in NAFTA itself—Canada's "cultural exception", which prevents U.S. rightsholders from full access to Canada's market for copyrighted works. The efficacy and appropriateness of market access barriers should, at minimum, be reviewed as part of any renegotiation of NAFTA.

C. Patent Issues

The Section agrees with the recommendations of the USTR's Summary of Objectives for the NAFTA Renegotiation ("*Summary of Objectives*"), dated November 2017, regarding securing for U.S. investors important rights consistent with U.S. legal principles and practice. *Summary of Objectives*, p. 9, Investment. An increasing share of U.S. output is in the form of inventions and technological improvement. Intellectual property industries support millions of jobs, producing trillions of dollars of value added output. The protection of intellectual property rights continues to be essential to encourage further technological breakthroughs and innovation. We support continued inclusion of sections for national treatment (current Section 1102), most-favored nation treatment (current Section 1103), and a minimum standard of treatment under customary international law (current Section 1105). With respect to intellectual property rights, these standards must apply to all sectors non-discriminatorily, including pharmaceuticals and medical devices, ensuring an environment fostering innovation.

The Section urges the USTR to address the following specific concerns on the Patent provisions of NAFTA, including:

(a) Minimum Standards of Patentability

The Section strongly recommends not ceding or enabling a Party through "self-definition" to lower the minimum standards of patentability. The conditions for patentability set out in Article 1709(1) provide that patents shall be available "for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step (to be non-obvious) and are capable of industrial application." These conditions must be understood to set a minimum, commonly understood threshold.[7] Parties cannot self-define the conditions to lower the minimum standards of patent protection.

[7] The minimum requirements for patentability are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 27(1) and Patent Cooperation Treaty's Article 33—"the

claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable."

For example, the government of Canada advanced a troubling position when arbitrating the Chapter 17 patent provision of NAFTA[8] (emphasis added):

> The plain and ordinary meaning of patent criteria such as "utility", when stated but left undefined in a treaty, is that the ***Parties are free to adopt at their election one of the range of national technical approaches to this specialised criterion, in accordance with the requirements and policies of their respective patent laws***.[9]

The requirements for patentability of new, non-obviousness and useful are baseline requirements with well-understood meaning. While member states are free to adopt their approach in assessing compliance with these requirements (*e.g.*, NAFTA should not mandate *how* obviousness is assessed), the Section strongly supports a position that the Parties cannot self-define the conditions of patentability to drop below minimum standards of patent protection.

(b) Patent term restoration and Patent term extension

Furthermore, this Section encourages a renegotiated NAFTA to mandate the establishment in Mexico and Canada of periods of patent term restoration that are at least equivalent to those provided under U.S. law. In the United States in 1984, Congress enacted Title II of the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417) to extend patent life to compensate patent holders for the marketing time lost while developing a drug product and awaiting the necessary government review and approval of safety and efficacy required to market such a product. Specifically, Title II of the Act created a program whereby patent holders whose patents claim a human drug product, medical device, food additive or color additive could recoup some of the lost patent time. A maximum of five years can be restored to the patent. In all cases, the total patent life for a product with the patent extension cannot exceed fourteen years from the product's approval date, or in other words, fourteen years of potential marketing time. Canada recently enacted a law that will provide a maximum of two years of restoration to a patent in limited situations. Unfortunately, Mexican law does not provide any period of patent term restoration. Therefore, in order to adequately compensate patent holders for their lost marketing time while awaiting the necessary government approval to market their products, Canada and Mexico should provide patent term restoration that is at least equivalent to the period provided for and based upon similar criteria as under U.S. law.

IV. DETAILED DISCUSSION—REGULATORY EXCLUSIVITY ISSUES

The Section encourages USTR to mandate through NAFTA the establishment in Mexico and Canada of periods of protection for regulatory data ("data exclusivity") for small and large molecule drugs, drugs for the treatment of certain rare diseases, and new indications that are at least equivalent to those periods provided for in the United States. Data exclusivity protection ensures that a subsequent drug manufacturer cannot rely on an innovator's undisclosed test and other research data for approval of its application for a specified period from the date of marketing approval to the innovator. This period of

[8] *Eli Lilly and Company v. The Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2.

[9] *Eli Lilly and Company v. The Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2, GOVERNMENT OF CANADA COUNTER MEMORIAL at p. 7.

exclusivity is critical in protecting the investments of time, talent, and financial resources typically in excess of $2 Billion U.S. dollars to develop and gain market approval required to establish a new therapy as safe and effective[10].

U.S. law currently provides five years of data exclusivity for new small molecule drugs (new chemical entities), twelve years of data exclusivity for new large molecule drugs (biologics) and three years of data exclusivity for new indications of a previously approved small molecule drugs. Additionally, the U.S. also provides seven years of data exclusivity for certain rare disease ("orphan drug" exclusivity).

Canadian law provides eight years of data exclusivity for both small and large molecule drugs but provides no new use or orphan drug exclusivity. Moreover, Mexico does not have any specific legislation providing for data exclusivity of any kind and the protection of such data is uncertain at best. The Federal Commission for Protection against Sanitary Risks (COFEPRIS), which is part of the Ministry of Health provided guidance in 2012, in an attempt to provide guidance on data exclusivity. The guidelines provided a five year term of data protection for new small molecule drugs. Unfortunately, the guidelines did not address data protection for large molecules or new indications. The guidelines are unclear and ambiguous in sections and remain subject to litigation.

V. DETAILED DISCUSSION—INVESTOR-STATE DISPUTE SETTLEMENT ISSUES

As noted in the prior letter from the ABA's Section of International Law (attached), the Section supports that all investor-state dispute settlement system ("ISDS") provisions be preserved to maintain accountability and an enforcement mechanism for investors.

The Section encourages the continuation all ISDS provisions for individuals who make investments in one of the member states, similar to that of current Chapter 11 of NAFTA. Such a system has proven essential as an alternative mechanism to raise attention to patent issues and spur resolution when such issues are not receiving appropriate attention between Member States. [11]

The ISDS system is critically important to hold Member States accountable to the treaty terms in the interest of all investors, whether the investor is U.S., Canadian, or Mexican. The current NAFTA provisions have been in place more than twenty years, with demonstrated accountability benefits amply justifying any burden associated with ISDS arbitration.

V1. DETAILED DISCUSSION—DIGITAL TRADE ISSUES

The Section agrees with the recommendations of the USTR's *Summary of Objectives*, regarding securing commitments not to impose customs duties on digital products and services (e.g., software, music, video, e-books). Imposition of such extra charges will impede the flow of music,

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[10] http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published

[11] For example, Chapter 11 investor-state dispute settlement based on violations under Chapter 17 of NAFTA were arbitrated in Eli Lilly and Company v. The Government of Canada, UNCITRAL, ICSID Case No. UNCT/14/2.

video, software and games throughout the region and will be particularly harmful to the creators, artists, and entrepreneurs who depend on such online sales for their livelihood.

This Section also supports the non-discriminatory treatment of digital products and services transmitted electronically and the guarantee that these products and services will not face government-sanctioned discrimination based on the nationality or territory in which such products and services are produced. The ability to transfer and access information across borders is critical to all U.S. economic sectors, and if such information is restricted based on the nationality or territory in which the product or service is produced, the U.S. economy and exports are impacted. Moreover, Canada and Mexico should not be permitted to impose measures that restrict cross-border data flows and require the use or installation of local computing facilities. Requirements that force U.S. companies to manage, store, or otherwise process data locally or other policies that link market access or commercial benefits to investment or use of the local infrastructure hurt U.S. businesses and consumers and threaten the open transnational nature of the internet. For similar reasons, governments should not be able to require the disclosure of a company's proprietary algorithms as a prerequisite for trade opportunities.

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Once again, the Section appreciates the opportunity to provide these comments to you. If you have any questions regarding the above comments, please feel free to contact me.

Very truly yours,

Scott F. Partridge

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cc:

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