

Pre-Hearing Statement of Knowledge Ecology International (KEI)

On the United States-Mexico-Canada Agreement: Likely Impact on the U.S. Economy and on Specific Industry Sectors Investigation (No.TPA-105-003)

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Introduction

Knowledge Ecology International (KEI) is a non-profit organization with offices in Washington, DC and Geneva, Switzerland, that focuses on the management of knowledge goods. KEI is focused on improving innovation for and access to new medical technologies. KEI is concerned about the impact of high prices on the affordability of and access to medical treatments, both in the United States and for vulnerable populations in developing countries.

KEI welcomes the opportunity to present a pre-hearing statement to the U.S. International Trade Commission (ITC) related to its investigation, “United States-Mexico-Canada Agreement: Likely Impact on the U.S. Economy and on Specific Industry Sectors” (Investigation No. TPA-105-003). Our statement addresses some of the intellectual property aspects of the United States-Mexico-Canada Agreement (USMCA).

Patentable subject matter for medical or surgical procedures

Mirroring the exception for patentable subject matter in the WTO TRIPS Agreement Article 27.3.a, the proposed USMCA agreement includes the following text:

Article 20.F.1: Patentable Subject Matter

...

3. . . . A Party may also exclude from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

...

We support this exception but also note that in the United States, in addition to certain limits on patentable subject matter, the United States also uses limitations on remedies for infringement to accomplish the same purpose as a limit on patentable subject matter. For example, in 35 U.S. Code § 287(c), a patent may be granted but not enforced against “the performance of a medical or surgical procedure on a body.” This means the exception in 20.F.1 is not by itself sufficient to protect the current U.S. exception applying to medical or surgical procedures.

Exclusivity for biologics test data, including the application to certain cell and gene therapies

The USMCA proposes obligations to provide exclusive rights in test data, including the following provisions:

Article 20.F.14: Biologics

1. With regard to protecting new biologics, a Party shall, with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, fn. 45, fn. 46 provide effective market protection through the implementation of Article 20.F.13.1 (Protection of Undisclosed Test or Other Data) and Article 20.F.13.3 (Protection of Undisclosed Test or Other Data), mutatis mutandis, for a period of at least ten years from the date of first marketing approval of that product in that Party.

2. Each Party shall apply this Article to, at a minimum fn. 47, a product that is produced using biotechnology processes and that is, or, alternatively, contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, for use in human beings for the prevention, treatment, or cure of a disease or condition.

Footnotes

45. Nothing requires a Party to extend the protection of this paragraph to:

- (a) any second or subsequent marketing approval of such a pharmaceutical product; or
- (b) a pharmaceutical product that is or contains a previously approved biologic.

46. Each Party may provide that an applicant may request approval of a pharmaceutical product that is or contains a biologic under the procedures set forth in Article 20.F.13.1(a) (Protection of Undisclosed Test or Other Data subparagraph 1(a)) and Article 20.F.13.1(b) (Protection of Undisclosed Test or Other Data subparagraph 1(b)) on or before March 23, 2020, provided that other pharmaceutical products in the same class of products have been approved by that Party under the procedures set forth in in Article 20.F.13.1(a) (Protection of Undisclosed Test or Other Data subparagraph 1(a)) and Article 20.F.13.1(b) (Protection of Undisclosed Test or Other Data subparagraph 1(b)) before the date of entry into force of this Agreement for that Party.

47. For greater certainty, for the purposes of this Article, the Parties understand that “at a minimum” means that a Party may limit the application to the scope specified in this paragraph.

KEI objects to the 10 year term in 20.F.14.1, because it will restrict the ability of the U.S. Congress to amend the U.S. law to a term shorter than 10 years, in order to lower drug prices in the United States.

KEI objects to 20.F.14.2, which appears to extend test data protection obligations to certain gene and cell therapies, including those where patents cannot be enforced under U.S. patent law under 35 U.S. Code § 287(c). This provision can effectively create a monopoly when Congress has specifically sought to avoid monopolies for patented inventions by limiting remedies for infringement of a patent. KEI is of the opinion that this provision was inserted into the agreement at the request of companies currently charging or intending in the future to charge excessive and access-denying prices for important new medical therapies that are not considered drugs, and for which the NIH has often funded the science and development.

The USMCA provisions on injunctions¹

One topic KEI has followed closely throughout the ACTA and TPP negotiations concerns injunctions, and here the agreement seems to track the WTO requirements in Article 44 of the TRIPS, which is good, particularly since the United States and Canada both have areas where injunctions are not available by statute. For example, the United States eliminates the availability of injunctions in certain cases involving biologic drugs, use of patents, copyrights and other intellectual property rights for use by or for the federal government, and in several specialized statutes, such as for nuclear energy, semiconductor chips, certain uses of trademarks, etc. In Canada, “when the construction of a building or other structure that infringes or that, if completed, would infringe the copyright in some other work has been commenced, the owner of the copyright is not entitled to obtain an injunction in respect of the construction of that building or structure or to order its demolition.” (40.1) These exceptions are allowed in the new agreement.

The USMCA provisions on damages²

The damages provisions in the new trade agreement are dangerous, and create a norm that is in conflict with national laws, including in particular, several in the United States. Among the provisions on damages are the following:

Section J: Enforcement

Article 20.J.4: Civil and Administrative Procedures and Remedies

1. Each Party shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered in this Chapter.87

...

3. Each Party shall provide 88 that, in civil judicial proceedings, its judicial authorities have the authority at least to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person’s intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity

¹ Based on <https://www.keionline.org/29006>

² Based on <https://www.keionline.org/29006>

4. In determining the amount of damages under paragraph 3, each Party's judicial authorities shall have the authority to consider, among other things, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price.

5. At least in cases of copyright or related rights infringement and trademark counterfeiting, each Party shall provide that, in civil judicial proceedings, its judicial authorities have the authority to order the infringer, at least in cases described in paragraph 3, to pay the right holder the infringer's profits that are attributable to the infringement.⁸⁹

6. In civil judicial proceedings with respect to the infringement of copyright or related rights protecting works, phonograms or performances, each Party shall establish or maintain a system that provides for one or more of the following:

(a) pre-established damages, which shall be available on the election of the right holder;
or

(b) additional damages.⁹⁰

(a) pre-established damages, which shall be available on the election of the right holder; or

(b) additional damages.⁹¹

8. Pre-established damages under paragraphs 6 and 7 shall be in an amount sufficient to constitute a deterrent to future infringements and to compensate fully the right holder for the harm caused by the infringement.

9. In awarding additional damages under paragraphs 6 and 7, judicial authorities shall have the authority to award such additional damages as they consider appropriate, having regard to all relevant matters, including the nature of the infringing conduct and the need to deter similar infringements in the future.

—Footnotes

87. For the purposes of this Article, the term "right holders" shall include those authorized licensees, federations and associations that have the legal standing and authority to assert such rights. The term "authorized licensee" shall include the exclusive licensee of any one or more of the exclusive intellectual property rights encompassed in a given intellectual property.

88. A Party may also provide that the right holder may not be entitled to any of the remedies set out in paragraphs 3, 5, and 7 if there is a finding of non-use of a trademark.

For greater certainty, there is no obligation for a Party to provide for the possibility of any of the remedies in paragraphs 3, 5, 6, and 7 to be ordered in parallel.

89. A Party may comply with this paragraph through presuming those profits to be the damages referred to in paragraph 3.

90. For greater certainty, additional damages may include exemplary or punitive damages.

91. For greater certainty, additional damages may include exemplary or punitive damages.

There is a lot to unpack on this text, but I'll focus here on a few (of several) examples where the requirements of the agreement are in conflict with U.S. law, starting with patents.

Damages for patent infringement in the United States are set out in 35 USC § 284, which is for the general standard, as well as in other statutes dealing with narrower cases, where there are exceptions to the general rule.

35 USC § 284 reads, in full, as follows:

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d).

The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

The core standard is “damages adequate to compensate for the infringement” which can be “in no event less than a reasonable royalty for the use made of the invention by the infringer.”

The text of the new agreement would require that in a patent infringement case, a court have the authority to consider damages based upon a value that is “measured by the market price, or the suggested retail price” of the infringed goods.

In determining the amount of damages under paragraph 3, each Party's judicial authorities shall have the authority to consider, among other things, any legitimate

measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price. [24.J.4(4)].

The most aggressive part of the text is the suggested retail price, which rarely is the same as “damages adequate to compensate for the infringement,” the general requirement of 35 USC § 284.

Even more problematic are provisions in U.S. law where there are specific limitations on damages for patent infringement, such as in the Biologics Price Competition and Innovation Act of 2009 (BPCIA) which provides that in some circumstances, damages for infringement are limited to a reasonable royalty. Consider 5 USC § 271(e)(6)(B), which reads as follows:

‘(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

When a similar provision was proposed in the TPP, Representative Eshoo wrote to the USTR to register an objection in a October 20, 2015 letter. Eshoo cited the BPCIA provision, which she described as, “an important mechanism to increase timely transparency of relevant patents for biologic drugs, and to decrease the risks of expensive litigation for biosimilar manufacturers.” Eshoo also noted that the provision would leave the U.S. exposed to acts brought under the investment provisions of the agreement, and “also limit the ability of Congress to provide statutory limitations on damages for other important intellectual property infringement problems.”

There are other areas where patent damages are limited by statute, for example, the “measure of damages” in 42 USC § 2184/2187 for certain patents used for the production of nuclear power, where a court is required to consider “the extent to which, if any, such patent was developed through federally financed research.”

In cases where the infringement of a patent is by a medical practitioner, the damages are zero, according to 35 USC § 271(c).

Even more problematic for copyright

The provisions in the new agreement on copyright are even more aggressive than in the case of patents or other types of intellectual property, and they create similar problems for the United States, both for existing laws and areas where legislation has been proposed, such as for orphaned copyrighted works. The issues regarding trade agreement standards for damages and U.S. law were the subject of a July 22, 2015 letter to the head of the U.S. Copyright Office,

Maria A. Pallante. Pallante ignored these warnings during the TPP negotiations. She is now a lobbyist for book publishers.

Among the areas where the United States will face challenges are cases where state universities are protected under the doctrine of state sovereign immunity from damages for patent or copyright infringement. State sovereign immunity, which was addressed in a series of court cases including *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank* in 1999, eliminated the ability of patent, copyright or trademark owners to obtain damages for infringement by state governments and state universities. This decision has provided an important safeguard for many academic researchers, since the U.S. does not have a statutory research exception for use of patented inventions. The exemption from damages has also made it easier for universities to digitize book collections.

The USMCA agreement provisions on test data for biologic products³

The United States-Mexico-Canada Agreement (USMCA) provisions on the term of protection of test data for new pharmaceutical products has received considerable attention, and in some cases, some inaccurate reports on the agreement have conflated the term for test data protection with the term of a patent.

The key provisions are **Article 20.F.13: Protection of Undisclosed Test or Other Data**, and **Article 20.F.14: Biologics**, from the intellectual property chapter of the agreement. These Articles, taken together, require the parties to withhold marketing approval for “a new pharmaceutical product that is or contains a biologic” that relies upon “undisclosed test or other data concerning the safety and efficacy of the product” without the consent of the person that previously submitted such information, in order to market the same or a similar product on the basis of (i) that information; or (ii) the marketing approval granted to the person that submitted such information, for a period of at least ten years from the date of first marketing approval of that product in the territory of the Party.

The term “undisclosed or other data” is understood to include the evidence from clinical trials used to establish the safety and efficacy of a drug in humans. These trials which can be expensive, and depending upon the drug, take years to complete, constituting a significant barrier to entry for generic or biosimilar products.

While it is generally understood that this provision will apply to drugs, it is important to note that **Article 20.F.14.2** extends this right in test data more broadly to products “produced using biotechnology processes” as well as products that “alternatively, contains, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product,

³ Based on <https://www.keionline.org/29101>

protein, or analogous product, for use in human beings for the prevention, treatment, or cure of a disease or condition.” Here it appears as though some gene and cell therapies may be included, so long as they are defined as a “product” as opposed to a procedure or service, something that may be consequential for new therapies such as CAR T, which involves modifying one’s own T-cells with a virus.

The most common issue in reporting in the text is the 10 years of the exclusive right and what impact if any it will have on prices of biologic drugs. This is a sufficiently complex topic to make it hard to quantify. The issues are as follows.

1. The 10 year period for marketing approval based upon third party test data is shorter than the current 12 years in the U.S., but longer than the terms in the TPP or national laws in Mexico and Canada, so at least for Mexico and Canada, it extends the term, as compared to current law. For the United States, it also is a barrier to the U.S. reforming the U.S. law. When the ACA was considered the FTC recommended a term of zero years, the drug companies lobbied for 14 to 16 years, and officially President Obama wanted 7 years.
2. Note that at least three bills pending before the current Congress propose reducing the U.S. term from 12 to 7 years (HR 6577, HR 1776 and S.3411).
3. Not all or even most biologic drugs will be constrained by the test data provisions, because the terms of patent protection are often longer, at 20 years from the filing of the application plus up to five years of additional patent extensions, on what in some cases are fairly large numbers of patents, some of which are filed even after drugs are approved. The 10 year terms resulting from this agreement will primarily benefit products with weak patent protection, or companies marketing products in countries where patents were not filed or granted (a principal factor for several TPP member states for the term in that agreement). Note that Canada and Mexico are typically countries where drug companies file patents.
4. Even though the 10 years is less than the 12 year period in the U.S., it will still have a negative impact on the U.S. by delaying entry in foreign markets that otherwise would encourage earlier entry for biosimilars.
5. One overlooked aspect of the text is the language that appears to lock the United States and other countries in to providing test data rights for therapies such as CAR T, which are more like services or procedures than drugs, and in some countries (including the United States), patents are not granted or enforced against medical procedures.
6. Another overlooked issue concerns the lack of clear language on exceptions to the exclusive rights. This topic is addressed below.

Exceptions

The ability of governments to provide exceptions to exclusive rights, for example, in order to remedy shortages, excessive or unreasonable prices, or other concerns, seems poorly worded.

In **Article 20.F.13.3**, “a Party may take measures to protect public health in accordance with the [WTO] [Declaration on TRIPS and Public Health](#),” and any waiver or amendment to the TRIPS related to that declaration.

Among the exceptions referred to in the Doha Declaration (used here to describe the WTO Declaration on TRIPS and Public Health) is the agreement in paragraph 5.b that “Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted,” and more generally in paragraph 4, that “the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all,” and that WTO members have the “right . . . to use to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.” This may be read to mean that the required “consent” to rely upon third party test data can be acquired through a compulsory license, in the same way exclusive patent rights can be subject to compulsory licenses. A narrower reading would be that exceptions to exclusive rights in test data would only apply to the special TRIPS cases involving countries that lack manufacturing capacity, either as importers and exporters, under [31bis](#) of the TRIPS, a complex and so far unused provision in the TRIPS for exporting products to countries lacking domestic manufacturing capacity. Not only is this a significantly narrow and complex procedure, the United States and Canada have indicated to the WTO they are not eligible to import under 31bis, as set out in *footnote 3* to the *Annex and Appendix to the TRIPS Agreement*.

The decision by the United States to opt-out of the right to import under the WTO mechanism that became *31.bis* has been criticized, including, for example, in this 2005 Congressional hearing, where then-Representative Tom Allen questioned HHS Secretary Michael Leavitt in the context of shortages of drugs to treat a possible influenza pandemic. (Link [here](#)). At one point the European Commission wrote to the TransAtlantic Consumer Dialogue (TACD) to indicate the European Union would not use the *31.bis* mechanism even if the European Union was facing a pandemic that could kill millions of its citizens, and that this would also extend to the domestic test data exclusivities, because there was no possibility of an exception in the EU regulation. Also, at various times, the European Commission and the United States Trade Representative have argued the Doha Declaration only applies to a limited scope of diseases, a view that has been expressed as recent as this year during negotiations over a non-communicable disease political declaration at the UN.

The ambiguity over the role of exceptions for test data protection is not a new issue, although it is often overlooked. One area for concern is the current lack of exceptions to exclusive rights for data in the countries where such rights are granted. There is no explicit exception in the European Union regulations or U.S. law, and countries that have been forced to implement such law due to trade pressures from the European Union, Japan or the United States have generally done so without exceptions, making this regulatory monopoly even more problematic than a patent, when dealing with abuses or health problems.

It is worth noting that the treatment of test data is different for pharmaceutical products that treat humans than for agricultural chemicals that protect plants, both in national law and in trade agreements. The European Union, in particular, has a striking mandatory exception to exclusive rights for agricultural plant protection products “to avoid duplicative testing on vertebrate animals,” which is considered unethical. In such cases, governments have a mandate to force licensing of the data, with binding arbitration to determine compensation, which is limited to *sharing* the costs of testing, and then only “to share in the costs of information that the applicant is required to submit to meet the authorisation requirements.” (The Comprehensive and Economic Trade Agreement, or CETA, between the EU and Canada; ARTICLE 20.30: Protection of data related to plant protection products).

The mandatory cost sharing approaches embraced and promoted by the European Union were adopted after lobbying by animal rights groups.

Unfortunately, the protections afforded to laboratory animals like mice or rabbits in regards to tests involving agricultural chemicals are not extended to clinical trials for new drugs that involve human subjects.

The leading international standard for ethical treatment of humans in medical research is the World Medical Association Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects. The Declaration of Helsinki is referenced by professional societies, several governments and by the World Health Organization's *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (WHA61.21), which requires WHO members to:

“promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines” [6.2.g]

The 2013 revision of the Declaration of Helsinki, like earlier versions, places restrictions on the testing of humans when the risks of the tests are unnecessarily risky, excessively risky relative to benefits, or when there is conclusive proof of the outcomes. As is the case for vertebrate animals in connection with agricultural plant production products, replicating previous studies (duplicative testing) involving human subjects is discouraged if not prohibited.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

The earlier versions of the Declaration of Helsinki were even more strict. For example, the 2008 version required physicians to stop studies when conclusive proof of the results was known, which was stronger than the above language to “assess whether to continue, modify or immediately stop...”

“Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.”

The change from 2008 to 2013 occurred after the WHO formally embraced the Declaration of Helsinki in WHA61.21, and several countries sought to create biosimilar pathways for biologic drugs.

The EU/Canada CETA makes an exception for duplicative testing mandatory for plant protection products, but mentions no exceptions for drugs to treat humans. The USMCA text provides for possible exceptions for biologic drugs, but not for agricultural chemicals, creating conflict for Canada, which is required to provide exemptions for agricultural products by the EU/CA CETA, but apparently not permitted to by the USMCA.

Congress should ask USTR to clarify the practical scope of the exception for biologic drugs test data in the USMCA text (20.F.13.3)

The exceptions issue is quite important, and more important than the term for most products where even the 12 years is shorter than the patent terms. When a compulsory license (march-in) was proposed for Fabrazyme in 2010, one rationale given for its rejection was the lack of an exception in the test data regime for the biologic product. The recent bill introduced with more than 100 cosponsors in the House would provide for compulsory licenses on drugs when Medicare price negotiations fail includes exceptions to test data rights, a topic addressed, but unclear, in the USMCA.

Finally, the Trump Administration should be reminded we have farmers, and Bayer is buying Monsanto. The US may have need, and should therefore ensure that there is room for exceptions in the agricultural chemical test data provisions of **Article 20.F.10: Protection of Undisclosed Test or Other Data for Agricultural Chemical Products**.

Copyright term

In Article 20.H.7, the proposed USMCA text would lock members into excessive and harmful terms of protection for copyright.

Article 20.H.7: Term of Protection for Copyright and Related Rights

Each Party shall provide that in cases in which the term of protection of a work, performance or phonogram is to be calculated:

(a) on the basis of the life of a natural person, the term shall be not less than the life of the author and 70 years after the author's death; fn.59 and

(b) on a basis other than the life of a natural person, the term shall be:

(i) not less than 75 years from the end of the calendar year of the first authorized publication fn.60 of the work, performance or phonogram;

or (ii) failing such authorized publication within 25 years from the creation of the work, performance or phonogram, not less than 70 years from the end of the calendar year of the creation of the work, performance or phonogram.

Footnote 59: The Parties understand that if a Party provides its nationals a term of copyright protection that exceeds life of the author plus 70 years, nothing in this Article or Article 20.A.8 (National Treatment) shall preclude that Party from applying Article 7(8) of the Berne Convention with respect to the term in excess of the term provided in this subparagraph of protection for works of another Party.

Footnote 60: For greater certainty, for the purposes of subparagraph (b), if a Party's law provides for the calculation of term from fixation rather than from the first authorized publication that Party may continue to calculate the term from fixation.

KEI continues to object to any provision in a trade agreement that creates an obligation to extend copyright protection beyond that currently required by the WTO TRIPS agreement. Extended copyright terms do not benefit authors, and there is no policy reason to provide income to heirs of authors for more than 50 years after the death of authors. Those people can get jobs like the rest of us. The extended term is also a tax on performers, who then have to share their incomes with persons who did not write works or perhaps even know the authors, more than a half century after the death of an author.

The extended copyright term also creates extensive damage to society by creating millions of orphaned copyrighted works, an issue discussed in endless academic articles and government policy papers, that USTR officials should have read and taken into consideration, instead of doing the bidding of lobbyists representing heirs of dead authors or corporations seeking to extend protections over works more than a half century beyond anyone was paid to create them.

The agreement could be improved by a provision that ensures that governments can impose formalities for terms in excess of the Berne copyright term, for works subject to Berne protection, or for any work protected by a related right.

Limits on source code disclosure requirements

The USMCA repeats errors in earlier secretive trade negotiations, including those in the TPP and the TISA, which created a prohibition on government obligations to make software code transparent or subject to access, and in the USMCA text, has even expanded the provision to cover algorithms expressed in source code.

Article 19.16. Source Code 1. No Party shall require the transfer of, or access to, source code of software owned by a person of another Party, or to an algorithm expressed in that source code, as a condition for the import, distribution, sale or use of that software, or of products containing that software, in its territory.

2. Nothing in this Article shall preclude a regulatory body or judicial authority of a Party from requiring a person of another Party to preserve and make available the source code of software, or an algorithm expressed in that source code, to the regulatory body for a specific investigation, inspection, examination enforcement action or judicial proceeding fn7, subject to safeguards against unauthorized disclosure.

Footnote 7. Such disclosure shall not be construed to negatively affect the software source code's status as a trade secret, if such status is claimed by the trade secret owner.

These provisions in trade agreements were negotiated in secret, but influenced by lobbyists for the Business Software Alliance and other well connected commercial interests, without giving the public an opportunity to weigh in, so that trade negotiators could be apprised of the unintended consequences of such provisions.

We are just beginning to appreciate the extent to which our lives are controlled by secret software code and software enabled algorithms. Software and software-enabled algorithms are used for a vast range of purposes, from manipulating medical records, to making recommendations on criminal sentencing and parole, to influencing what news is read and shared, what music we listen to, videos we watch, people we date, how we heat our homes, how automobiles determine who lives and dies in crash, which businesses are found in search engines and social media, and a million other purposes.

There are ample examples of computer security risks in Wi-Fi networks, mobile phone apps, and home internet-enabled devices that put personal and even national security at risk.

Companies like Volkswagen have used software code to cheat on emissions standards, and medical devices now often include software code.

USTR has ignored every opportunity to reflect on the vast risks to security, privacy, health, corporate crime, and anticompetitive conduct that this provision will enable.