

Inconsistencies between the U.S. Proposal for the IP Chapter of the TPPA and U.S. Law

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Table of Contents

Introduction.....	1
Article 4: Copyright and Related Rights.....	2
Parallel Importation	2
Technological Protection Measures.....	6
Article 8: Patents.....	10
Surgical methods.....	10
Second Use Patents.....	12
Article 9: Measures Related to Certain Regulated Products.....	13
Data Protection for Pharmaceutical Products.....	13
Article 12: Civil and Administrative Procedures and Remedies.....	13
Injunctions.....	13
Damages.....	14
Suggested Retail Price/Actual Damages.....	15
Innocent Infringements.....	16
Secondary Transmission by Satellite Carrier.....	17
Disclosure of Biological Product Patent	17
Non-Military Atomic Power.....	18
Technological Protection Measures.....	19
Court Costs and Attorney's Fees.....	19
Destruction of goods.....	20
Article 14: Special Requirements Related to Border Enforcement.....	21
Article 16: Special Measures Relating to Enforcement in the Digital Environment.....	25
Definition of “service provider”.....	25
Limitations on monetary damages.....	25
Privacy Safeguards.....	26
Pharmaceutical Pricing.....	27
Areas where the U.S. TPPA proposal could limit current and future legislative reform efforts.....	28
Orphan Works.....	28
Data Protection.....	33

Introduction

The U.S. has proposed aggressive intellectual property norms in the currently negotiated Trans-Pacific Partnership Agreement (TPPA). While some of its proposals are replicas of U.S. law, others go beyond current U.S. law. Still others would impede the ability of Congress to take action on various areas of reform that are currently being considered. U.S. norms are not always appropriate for the contexts of other countries, particularly in the developing world. It is even more inappropriate for the U.S. to propose provisions that would effectively create backdoor changes to its own laws or block current

legislative reform efforts. The following comments on the U.S. proposal for the IP chapter of the TPPA¹ highlight some areas which could be inconsistent with its domestic laws and USTR should carefully consider the implications for pushing these norms.

Article 4: Copyright and Related Rights

Parallel Importation

Article 4.2 of the U.S. proposal on the TPPA would prohibit parallel importation of copyrighted goods including books, journals, sheet music, sound recordings, computer programs, and audio and visual works. This provision reads:

Each Party shall provide to authors, performers, and producer of phonograms the right to authorize or prohibit the importation into that Party's territory of copies of the work, performance, or phonogram made without authorization, or made outside that Party's territory with the authorization of the author, performer, or producer of the phonogram.[11]

n.11: With respect to copies of works and phonograms that have been placed on the market by the relevant right holder, the obligations described in Article [4.2] apply only to books, journals, sheet music, sound recordings, computer programs, and audio and visual works (i.e., categories of products in which the value of the copyrighted material represents substantially all of the value of the product). Notwithstanding the foregoing, each Party may provide the protection described in Article [4.2] to a broader range of goods.

As the footnote clarifies, this text applies to works where the value of the copyrighted material substantially represents the value of the product, Parties to the TPPA may apply such protection to other copyrighted goods, as well.

The U.S. Copyright Act provides for specific rights in copyrighted works, subject to limitations and exceptions. These rights include the exclusive rights to reproduction, preparation of derivative works, distribution of copies, public performance rights, and public display.² Rights of attribution and integrity exist, as well.³ Under U.S. law, distribution rights have limitations including, for example, the first sale doctrine, codified by 17 U.S.C. Section 109(a), provides that once a physical copy of the work has been lawfully distributed, subsequent distributions of that copy do not require permission from the copyright holder.⁴

While the Copyright Act does prohibit “infringing importation of copies or phonorecords,” it is unsettled as to whether a right to prohibit parallel importation exists. 17 U.S.C. Section 602 provides:

1 References to the U.S. proposal are based of the draft text dated February 10, 2011, *available at* <http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>.

2 17. U.S.C. §106.

3 17. U.S.C. §106A.

4 “Notwithstanding the provisions of section 106(3), the owner of a particular copy or phonorecord lawfully made under this title, or any person authorized by such owner, is entitled, without the authority of the copyright owner, to sell or otherwise dispose of the possession of that copy or phonorecord . . .”

(a) Importation into the United States, without the authority of the owner of copyright under this title, of copies or phonorecords of a work that have been acquired outside the United States is an infringement of the exclusive right to distribute copies or phonorecords under section 106 [17 USCS §106], actionable under section 501 [17 USCS §501]. This subsection does not apply to--

(1) importation of copies or phonorecords under the authority or for the use of the Government of the United States or of any State or political subdivision of a State, but not including copies or phonorecords for use in schools, or copies of any audiovisual work imported for purposes other than archival use;

(2) importation, for the private use of the importer and not for distribution, by any person with respect to no more than one copy or phonorecord of any one work at any one time, or by any person arriving from outside the United States with respect to copies or phonorecords forming part of such person's personal baggage; or

(3) importation by or for an organization operated for scholarly, educational, or religious purposes and not for private gain, with respect to no more than one copy of an audiovisual work solely for its archival purposes, and no more than five copies or phonorecords of any other work for its library lending or archival purposes, unless the importation of such copies or phonorecord is part of an activity consisting of systematic reproduction or distribution, engaged in by such organization in violation of the provisions of section 108(g)(2) [17 USCS §108(g)(2)].

(b) In a case where the making of the copies or phonorecords would have constituted an infringement of copyright if this title had been applicable, their importation is prohibited. In a case where the copies or phonorecords were lawfully made, the United States Customs Service has no authority to prevent their importation unless the provisions of section 601 [17 USCS §601] are applicable. IN either case, the Secretary of the Treasury is authorized to prescribe, by regulation, a procedure under which any person claiming an interest in the copyright in a particular work may, upon payment of a specified fee, be entitled to notification by the Customs Service of the importation of articles that appear to be copies or phonorecords of the work.

It is uncertain under current U.S. case law whether a right holder may prohibit the importation of copyrighted works lawfully acquired. In 1998, the Supreme Court in *Quality King Distributors* examined the interplay between the exclusive rights granted under 17 U.S.C. Section 106 and the provision governing importation of works ultimately concluding that the copyright holder could not ban importation of salon products which had copyrighted labels affixed to its packaging. There, the salon products were created in the United States, exported to a foreign distributor, sold to third parties abroad, then re-imported back into the United States without authorization. Quoting 17 U.S.C. §602, the Court noted:

It is significant that this provision does not categorically prohibit the unauthorized importation of copyrighted materials. Instead, it provides that such importation is an infringement of the exclusive right to distribute copies “under section 106.” Like the exclusive right to “vend” that was construed in *Bobs-Merrill*, the exclusive right to

distribute is a limited right. The introductory language in §106 expressly states that all of the exclusive rights granted by that section—including, of course, the distribution right granted by subsection (3) are limited by the provisions of §§107 through 120. One of those limitations, as we have noted, is provided by the terms of §109(a), which expressly permit the owner of a lawfully made copy to sell that copy “[n]otwithstanding the provisions of section 106(3).”

After the first sale of a copyrighted item “lawfully made under this title,” any subsequent purchaser, whether from a domestic or from a foreign reseller, is obviously an “owner” of that item. Moreover, since §602(a) merely provides that unauthorized importation is an infringement of an exclusive right “under section 106,” and since that limited right does not encompass resales by lawful owners, the literal text of §602(a) is simply inapplicable to both domestic and foreign owners of L'anza's products who decide to import them and resell them in the United States.⁵

Additionally, the court noted that the exclusive rights granted to copyright holders by 17 U.S.C. §106 are limited not only by the first sale doctrine, but also by the other exceptions contained in Sections 107 through 120. Thus:

If §602(a) functioned independently, none of those sections would limit its coverage. For example, the “fair use” defense embodied in §107 would be unavailable to importers if §602(a) created a separate right not subject to the limitations on the §106(3) distribution right. Under L'anza's interpretation of the Act, it presumably would be unlawful for a distributor to import copies of a British newspaper that contained a book review quoting excerpts from an American novel protected by a United States copyright. Given the importance of the fair use defense to publishers of scholarly works, as well as to publishers of periodicals, it is difficult to believe that Congress intended to impose an absolute ban on the importation of all such works containing any copying of material protected by a United States copyright.

In the context of this case, involving copyrighted labels, it seems unlikely that an importer could defend an infringement as a “fair use” of the label. In construing the statute, however, we must remember that its principal purpose was to promote the progress of the “useful Arts,” U.S. Const., Art. 1, §8, cl. 8, by rewarding creativity, and its principal function is the protection of original works, rather than ordinary commercial products that use copyrighted material as a marketing aid. It is therefore appropriate to take into account the impact of the denial of the fair use defense for the importer of foreign publications. As applied to such publications, L'anza's construction of §602 ‘would merely inhibit access to ideas without any countervailing benefit.’ *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 450-51 (1984).

In light of the first sale doctrine and other limitations to exclusive rights, such as fair use, the Supreme Court determined that a right holder could not affix copyrightable subject matter to a product's packaging way as a method of preventing parallel importation of salon products into the United States if they were originally manufactured in the United States. However, while the reasoning in *Quality*

⁵ *Quality King Distributors, Inc. v. L'anza Research Int'l, Inc.*, 523 U.S. 135 (1998) (citations omitted).

King may in fact be applicable to cases involving unauthorized importation of copies manufactured abroad, the Court carefully noted that this issue was not before the Court and therefore not resolved.

More recently, this issue has been considered by the federal courts of appeals and the Supreme Court, but remains unresolved. In 2008, the Ninth Circuit considered whether the first sale doctrine applies to copies made outside the United States.⁶ In the *Costco* case, Costco had legitimately purchased Omega watches that had a small copyrighted design on the back, then imported these watches into the United States. The district court granted summary judgment in favor of Costco accepting the first sale doctrine as a valid defense. The Ninth Circuit reversed, holding that the first sale doctrine applies to copies manufactured abroad only after a lawful domestic sale has occurred. Costco appealed and the Supreme Court agreed to hear the case.

Ultimately, in 2010 the Supreme Court ended up divided 4-4 in its opinion, with Justice Kagan recusing herself from the case.⁷ This evenly divided split means that the issue is still unresolved and leaves the Ninth Circuit ruling intact without actually creating any binding Supreme Court precedent. No analysis was provided and the opinion, in its entirety, simply stated “The judgment is affirmed by an equally divided Court.”

Although the above cases involve goods where the value of the copyrighted material does not substantially represent the value of the good, this issue was recently considered in a case involving textbooks. In August 2011, the Second Circuit, in hearing a case to determine whether the first sale doctrine applied in a case involving the importation of textbooks, affirmed a lower court ruling that “lawfully made” requires physical manufacture within the United States.⁸ However, this case was narrowly decided by a 2-1 where the majority noted that the *Costco* holding “relied on Ninth Circuit precedents not adopted by other courts of appeals” and that the case before it was a “close call.” The dissent, agreeing that the case presented a “close call” would have reversed the district court's decision and concluded that the first sale defense should apply regardless of place of manufacture.⁹

Given that only the Ninth and Second Circuits have weighed in on parallel importation, the Supreme Court has yet to decide this issue and judges are clearly divided over the “close” interpretation of 17 U.S.C. §602, it is an unsettled area of law.

As a general policy matter, for goods for which the intellectual property represents most of the value of the product, such as for patented pharmaceutical drugs, and the type of copyrighted goods described in

6 *Omega SA v. Costco Wholesale Corp.*, 541 F.3d 982 (9th Cir. 2008).

7 *Costco Wholesale Corp. v. Omega, S.A.*, 131 S.Ct. 565 (2010), *aff'd by an equally divided court*, 541 F.3d 982 (9th Cir. 2008).

8 *John Wiley & Sons Inc., v. Supap Kirtsaeng*, ___ F.3d ___ (2d Cir. 2011).

9 The dissent, interpreting *Quality King* found that U.S. Copyright Law “does not refer to a place of manufacture: It focuses on whether a particular copy was manufactured lawfully under title 17 of the United States Code. The United States law of copyrights is contained in title 17. Accordingly, the lawfulness of the manufacture of a particular copy should be judged by U.S. copyright law. A U.S. copyright owner may make her own copies or authorize another to do so. Thus, regardless of place of manufacture, a copy authorized by the U.S. rightholder is lawful under U.S. copyright law. Here, Wiley, the U.S. copyright holder, authorized its subsidiary to manufacture the copies abroad which were purchased and then imported into the United States . . . If Congress intended §109(a) to apply only to copies manufactured in the United States, it could have stated 'lawfully manufactured in the United States under this title.' As Congress did not include 'manufactured in the United States' in §109(a) though it was clearly capable of doing so as demonstrated by §601(a), the omission supports the conclusion that Congress did not intend the language 'lawfully manufactured under this title' to limit application of §109(a) to only copies manufactured in the United States.”

footnote 11 of the US proposal on IPR, KEI takes the position that it may be appropriate and useful to have trade rules that limit parallel importation in cases where price discrimination between countries of much different incomes is appropriate. In other cases, parallel trade would be permitted from countries of similar or higher income levels. High income countries would be permitted to engage in parallel trade with other high income countries and low income countries would be permitted to parallel trade with both low and high income countries. USTR has yet to explain why US consumers should pay higher prices than consumers in other high income countries, when justifying restrictions on all parallel trade for copyrighted goods.

Furthermore, as will be discussed in greater detail in the section discussing border measures, *infra*, certain circumstances exist under U.S. law where a right holder cannot prevent the importation of even infringing goods, such as where the goods are imported by or for the use of the U.S. government. Thus, providing copyright holders with an exclusive right to control importation of their works would be inconsistent with current U.S. law.

Technological Protection Measures

Article 4.9(c) provides that a violation of a measure contained within Article 4 is “a separate cause of action, independent of any infringement that might occur under the Party's law on copyright and related rights.” This provision essentially allows a person to be found liable for circumventing a TPM even where such conduct is legitimate and considered to be fair use under copyright law.

For example, under U.S. copyright law, there are specific exceptions that exempt from infringement the reproduction or distribution of accessible format works for those who are blind or otherwise disabled. It is therefore non-infringing to reproduce a work into an accessible work format. Due to our digital age, many persons who are blind utilize new technologies, such as the “text-to-speech” feature on Kindle, which may employ TPMs. Although it is non-infringing to provide and distribute accessible format works to persons who are blind, anyone who manufactures or distributes a device to overcome this TPM could be held liable under a separate cause of action under the TPPA.¹⁰

Essentially, this provision undermines existing copyright limitations and exceptions. Even where a work is produced or accessed under a legitimate copyright exception, if that product circumvents a TPM, the person creating such a work could be found liable and subject to criminal penalties for the sole reason that he violated a TPM.

Article 4.9(c) of the U.S. template could be considered as going beyond what is required in the U.S. under the Digital Millennium Copyright Act (DMCA) as it is currently unsettled as to whether the TPM provisions contained under U.S. law would require a person to also be found liable for copyright infringement in order to be found liable for circumvention of a TPM.

¹⁰ This scenario is used by way of example. We note that under the DMCA's exemption to prohibition on circumvention of TPMs rule-making procedure, the Library of Congress does currently provide for an exemption to circumvent a TPM for a visually impaired person where “literary works distributed in ebook format when all existing ebook editions of the work (including digital text editions made available by authorized entities) contain access controls that prevent the enabling either of the book's read-aloud function or of screen readers that render the text into a specialized format.” See 37 C.F.R. §201.40(b)(6). However, reliance on this exemption applies only for a three-year period and the exemption must be re-examined at the end of the three-year period. As will be discussed in greater detail, *infra*, the analogous provision in the TPPA could be read as more restrictive as what is contained within the DMCA.

The Court of Appeals for the Federal Circuit, for example, held in *Chamberlain Group Inc., v. Skyling Technologies*, that a “critical nexus” must exist between an underlying copyright infringement and DMCA liability for circumvention of a TPM. There, the Federal Circuit noted, “17 U.S.C. §1201 prohibits only forms of access that bear a reasonable relationship to the protection that the Copyright Act otherwise affords copyright owners . . . it is the only meaningful reading of the statute.”¹¹ In denying Chamberlain's DMCA claim, the Federal Circuit laid out a six-prong test to determine whether a violation under 17 U.S.C. §1201 exists:

A plaintiff alleging a violation of §1201(a)(2) must prove: (1) ownership of a valid copyright on a work, (2) effectively controlled by a technological measure, which has been circumvented, (3) that third parties can now access (4) without authorization, in a manner that (5) infringes or facilitates infringing a right protected by the Copyright Act, because of a product that (6) the defendant either (i) designed or produced primarily for circumvention; (ii) made available despite only limited commercial significance other than circumvention; or (iii) marketed for use in circumvention of the controlling technological measure. A plaintiff incapable of establishing any one of elements (1) through (5) will have failed to prove a prima facie case. A plaintiff capable of proving elements (1) through (5) need prove only one of (6)(i), (ii), or (iii) to shift the burden back to the defendant. At that point, the various affirmative defenses enumerated throughout §1201 become relevant.¹²

The Federal Circuit affirmed the nexus requirement in *Storage Tech Corp. v. Custom Hardware Eng'g & Consulting, Inc.*¹³ Under the standard set forth by the Federal Circuit, the U.S. proposal for the TPPA is clearly inconsistent with U.S. law by permitting circumvention of a TPM to be a separate cause of action independent of any copyright infringement.

In contrast to the Federal Circuit's test, the Ninth Circuit has held that the DMCA creates liability for the very act of circumvention of a TPM, even absent a nexus to an underlying copyright violation.¹⁴ The Supreme Court has yet to resolve this issue and the circuit split in interpretation of 17 U.S.C. §1201(a) demonstrates the uncertainty of U.S. law in this area. Thus, the U.S. proposal for the IP chapter of the TPPA could potentially be inconsistent with U.S. law, providing for a separate cause of action for TPM violations, even absent any underlying copyright infringement.

Enforcement of TPM

Article 12.12 of the U.S. template provides for civil enforcement of Article 4.9 regarding TPMs. This provision states that:

In civil judicial proceedings concerning the acts described in Article 4.[9] (TPMs) and Article 4.[10] (RMI), each Party shall provide that its judicial authorities shall, at the least, have the authority to:

(a) impose provisional measures, including seizure of devices and products suspected of being involved in the prohibited activity;

11 381 F.3d 1178, 1203 (Fed. Cir. 2004), *rehearing and rehearing en banc denied* (Oct. 22, 2004)

12 *Id.* (emphasis in original).

13 421 F.3d 1307 (Fed. Cir. 20005)

14 *MDY Industries LLC v. Blizzard Entertainment*, 629 F.3d 928 (9th Cir. 2010).

(b) provide an opportunity for the right holder to elect between actual damages it suffered (plus any profits attributable to the prohibited activity not taken into account in computing those damages) or pre-established damages;

(c) order payment to the prevailing right holder at the conclusion of civil judicial proceedings of court costs and fees, and reasonable attorney's fees, by the party engaged in the prohibited conduct; and

(d) order the destruction of devices and products found to be involved in the prohibited activity.

No party shall make damages available under this paragraph against a nonprofit library, archives, educational institution, or public noncommercial broadcasting entity that sustains the burden of proving that such entity was not aware and had no reason to believe that its acts constituted a prohibited activity.

Although the DMCA provides for similar civil remedies, 17 U.S.C. §1203(c)(5) permits the reduction or remittance of damages for “innocent violations.”¹⁵ Other than the exception for “nonprofit library, archives, educational institution, or public noncommercial broadcasting entity,” the TPPA does not provide for reduction or remittance in the amount of damages awarded for innocent circumvention of TPMs. The aggressive language of the U.S. TPPA proposal with regard to civil enforcement of TPMs would impose high damages—including election of pre-established damages—for even innocent violations of anti-circumvention provisions.

Article 4.9(a) of the U.S. proposal requires parties to the TPPA to “provide for criminal procedures and penalties to be applied when any person, other than a nonprofit library, archive, educational institution, or public noncommercial broadcasting entity, is found to have engaged willfully and for purposes of commercial advantage or private financial gain in any of the foregoing activities.” However, as discussed above, it is currently unclear under U.S. law whether an underlying copyright infringement is needed in order to find an alleged infringer liable for circumvention of a TPM under the DMCA.

Limitations and exceptions for TPM

Articles 4.9(d) and (e) are drawn very narrowly. Article 4.9(d), for example, provides that “Each Party shall confine exceptions and limitations . . . to the following activities,” thereby completely limiting the exceptions that it may provide with regard to circumvention of TPMs. Additionally, subparagraph (e) states that exceptions and limitations “may only be applied as follows, and only to the extent that they do not impair the adequacy of legal protection or the effectiveness of legal remedies against the circumvention of effective technological measures . . .”.¹⁶ This chapeau, using the phrase “do not impair the adequacy of legal protection,” is unclear and could be interpreted to render the exceptions contained within Article 4.9(d) meaningless.

¹⁵ 17 U.S.C. §1203(c)(5)(A) reads “In general.--The court in its discretion may reduce or remit the total award of damages in any case in which the violator sustains the burden of proving, and the court finds, that the violator was not aware and had no reason to believe that its acts constituted a violation.” Subsection (B) provides for innocent violations by nonprofit libraries, archives and educational institutions.

¹⁶ Emphasis added.

In comparison, the exemptions provided for under the DMCA, codified by 17 U.S.C. §1201(d)-(j) do not use similar language. For example, the exemption for nonprofit libraries¹⁷ lays out the exemption unencumbered by a directive that the provision may only be applied “to the extent that they do not impair the adequacy of legal protection or the effectiveness of legal remedies . . .”. Depending on the interpretation, the U.S. proposal for the TPPA regarding limitations and exceptions related to the TPM could be seen as restricting the exceptions currently provided for under the DMCA.

Similarly, the language of the specific exemption proposed under Article 4.9(d)(viii) of the IP chapter places a heavier burden on users of copyrighted works applying for an exception to anti-circumvention measures than the DMCA requires. Under Article 4.9(d), parties may provide an exception or limitation for:

(viii) noninfringing uses of a work, performance, or phonogram in a particular class of works, performances, or phonograms when an actual or likely adverse impact on those noninfringing uses is demonstrated in a legislative or administrative proceeding by substantial evidence, provided that any limitation or exception adopted in reliance upon this clause shall have effect for a renewable period of not more than three years from the date of conclusion of such proceeding.

Although the DMCA provides for a similar procedure for an exemption,¹⁸ it is less restrictive:

(C) During the 2-year period described in subparagraph (A), and during each succeeding 3-year period, the Librarian of Congress, upon the recommendation of the Register of Copyrights, who shall consult with the Assistant Secretary for Communications and

¹⁷ 17 U.S.C. §1201(d).

¹⁸ We note that in addition to the exception listed in footnote 10, *supra*, other exceptions currently exist as part of the most recent three-year rulemaking process by the Library of Congress. The Library Congress announced that “persons making noninfringing uses of the following six classes of works will not be subjected to the anticircumvention of TPMs until the next rulemaking: 1) Motion pictures on DVDs lawfully made and acquired and that are protected by the Content Scrambling System when circumvention is accomplished solely in order to accomplish the incorporation of short portions of motion pictures into new works for the purpose of criticism or comment, and where the person engaging in circumvention believes and has reasonable grounds for believing that circumvention is necessary to fulfill the purpose of the use in the following instances: (i) Educational uses by college and university professors and by college and university film and media studies students; (ii) Documentary filmmaking; (iii) Noncommercial videos. . (2) Computer programs that enable wireless telephone handsets to execute software applications, where circumvention is accomplished for the sole purpose of enabling interoperability of such applications, when they have been lawfully obtained, with computer programs on the telephone handset. (3) Computer programs, in the form of firmware or software, that enable used wireless telephone handsets to connect to a wireless telecommunications network, when circumvention is initiated by the owner of the copy of the computer program solely in order to connect to a wireless telecommunications network and access to the network is authorized by the operator of the network. (4) Video games accessible on personal computers and protected by technological protection measures that control access to lawfully obtained works, when circumvention is accomplished solely for the purpose of good faith testing for, investigating, or correcting security flaws or vulnerabilities, if: (i) The information derived from the security testing is used primarily to promote the security of the owner or operator of a computer, computer system, or computer network; and (ii) The information derived from the security testing is used or maintained in a manner that does not facilitate copyright infringement or a violation of applicable law. (5) Computer programs protected by dongles that prevent access due to malfunction or damage and which are obsolete. A dongle shall be considered obsolete if it is no longer manufactured or if a replacement or repair is no longer reasonably available in the commercial marketplace; and (6) Literary works distributed in ebook format when all existing ebook editions of the work (including digital text editions made available by authorized entities) contain access controls that prevent the enabling either of the book’s read-aloud function or of screen readers that render the text into a specialized format.”

Information of the Department of Commerce and report and comment on his or her views in making such recommendation, shall make the determination in a rulemaking proceeding on the record for purposes of subparagraph (B) of whether persons who are users of a copyrighted work are, or are likely to be in the succeeding 3-year period, adversely affected by the prohibition under subparagraph (A) in their ability to make noninfringing uses under this title of a particular class of copyrighted works. In conducting such rulemaking, the Librarian shall examine--

- (i) the availability for use of copyrighted works;
- (ii) the availability for use of works for nonprofit archival, preservation, and educational purposes
- (iii) the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research;
- (iv) the effect of circumvention of technological measures on the market for or value of copyrighted works; and
- (v) such other factors as the Librarian considers appropriate

(D) The Librarian shall publish any class of copyrighted works for which the Librarian has determined, pursuant to the rulemaking conducted under subparagraph (C), that noninfringing uses by persons who are users of a copyrighted work are, or are likely to be, adversely affected, and the prohibition contained in subparagraph (A) shall not apply to such users with respect to such class of works for the ensuing 3-year period.¹⁹

The DMCA, unlike the proposed language of the TPPA, does not explicitly place a “substantial evidence” burden on persons wishing to make use of this exemption. Furthermore, while the DMCA provides that the Librarian of Congress shall consider these exemptions “during *each* succeeding 3-year period,” the TPPA states that “any limitation or exception adopted in reliance upon this clause shall have effect for a renewable period of *not more than three years*.” It is unclear whether the language of the TPPA seeks to limit exceptions that fall under this provision to a mere three-years, or whether such an exemption might be available for a renewable period every three years.

Article 8: Patents

Surgical methods

The U.S. template would require that patents be provided, specifically, for surgical methods, with no limitations on enforcement of these patents. Article 8.2 states that

Each Party shall make patents available for inventions for the following:

¹⁹ 17 U.S.C. §1201(a)(1)(C)-(D).

(a) plants and animals, and

(b) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.

This provision goes beyond U.S. law and previous U.S. free trade agreements. Under U.S. patent law, limitations exist regarding the enforcement of particular patents. 35 U.S.C. 287(c) reads:

(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

(2) For the purposes of this subsection:

(A) the term “medical activity” means the performance of a medical or surgical procedure on a body, but shall not include (I) the use of a patented machine, manufacture, or composition of such matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.

(B) the term “medical practitioner” means any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.

(C) the term “Related health care entity” shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.

(D) the term “professional affiliation” shall mean staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity.

(E) the term “body” shall mean a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans.

(F) the term “patented use of a composition of matter” does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method.

Although the U.S. does not provide an exception for the patent eligibility of a surgical method, patent law does limit enforcement of these patents.²⁰ A patent owner may not enforce its patents against medical practitioners who perform patented medical or surgical procedures. As a practical matter, this limit on enforcement of surgical method patents allows medical practitioners to essentially ignore these patents. However, a similar carve-out does not exist in the U.S. template for the TPPA

Prior U.S. free trade agreements, including those with TPPA negotiating partners, such as the Australia-United States FTA and United-States-Peru FTA, specifically allows for parties to exclude “diagnostic, therapeutic, and surgical methods for the treatment of humans and animals” from patentability. It also exceeds the scope of the United States-Chile FTA which does not explicitly require for parties to provide patents for surgical methods.

While U.S. law and prior U.S. FTAs have contained provisions which allow exceptions from patentability or patent infringement for surgical methods, a similar exception does not exist in the U.S. TPPA proposal. This lack of exception not only exceeds U.S. law, but also creates very real practical and ethical problems for medical practitioners. Surgeons may not be able to treat patients who are best served by a patented technology for fear of patent infringement.

Second Use Patents

Article 8.1 of the U.S. proposal for the IP Chapter of the TPPA provides that

Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application. In addition, the Parties confirm that: patents shall be available for any new forms, uses, or methods of using a known product; and a new form, use or method of using a known product may satisfy the criteria for patentability, even if such invention does not result in the enhancement of the known efficacy of that product.

This language specifically requires that parties to the TPPA provide patents for “any new forms, uses or methods of using a known product” even where there is no “enhancement of the known efficacy of that product.” The language of the U.S. proposal allows more expansive patenting than what is currently required under the plain language of U.S. law. 35 U.S.C. §101 lays out subject matter eligibility for patents:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

20 The US previously allowed enforcement of surgical method patents, but a “blizzard of lawsuits followed” creating serious ethical problems and endangering the lives of patients in need of the most recent surgical advances. As a result, the American Medical Association (AMA) successfully lobbied Congress to enact 35 USC §287 (c) to prohibit the enforcement of surgical patents against other doctors. See <http://www.nytimes.com/2006/03/19/opinion/19crichton.html?ex=1172379600&en=66dcde5df677af77&ei=5070>. See also *Pallin v. Singer*, 1995 WL 274407 at *1 (D. Vt. March 28, 1996) (invalidating Pallin's patented method of making self-sealing incisions during eye surgery and ordering that the plaintiff “take no [further] action to enforce any feature of the patent against the parties, any physician, health care provider, hospital, clinic, teaching institution.”

The plain language of the patent statute permits second use patents, but only for “new *and* useful improvement[s]” therefore requiring enhancement to the product. The TPPA which would require second-use patents even absent any improvement to the efficacy of a product.

Additionally, U.S. case law has suggested that the requirements that patents for new uses are available, but only where the claim has utility, novelty as to its use, and is non-obvious. With regard to novelty, for example, the Court of Appeals for the Federal Circuit rejected a claimed method of inhibiting serotonin uptake using fluoxetine hydrochloride because it was a “natural result” of the use of fluoxetine hydrochloride.²¹ The Federal Circuit has also rejected second-use patents that are obvious where the claimant had a reasonable expectation of success.²² New uses of a patented property alone, therefore, may be an insufficient basis to provide patent eligibility.²³ Article 8.1 of the U.S. template might therefore be inconsistent with U.S. law, requiring greater patenting for new uses of patented inventions.

Article 9: Measures Related to Certain Regulated Products

Data Protection for Pharmaceutical Products

Article 9.2 contains placeholder text or “provisions related to data protection for pharmaceutical products” and Article 9.4 provides a “placeholder for provisions related to patent term/data protection relationship.” As will be discussed in further detail in the section on areas in which the U.S. proposal could limit reform efforts, depending on what provisions are put forth by USTR, it is possible that they will conflict with the 2012 budget proposed by President Obama and impede current and future legislative efforts to reform this area of U.S. law.

Article 12: Civil and Administrative Procedures and Remedies

Injunctions

Article 12.2 of the U.S. proposal provides for injunctive relief stating that:

Each Party shall provide for injunctive relief consistent with Article 44 of the TRIPS Agreement, and shall also make injunctions available to prevent the exportation of infringing goods.

If Article 12.2 is read to require parties to provide injunctions in all cases of infringement, then it is clearly inconsistent with the provisions in several U.S. Laws that eliminate the availability of injunctions, even when there is infringement. Examples of exclusions of injunctions in cases of infringement including the following U.S. Statutes:

21 *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 971-72 (Fed. Cir. 2001) (prior art treatment for anxiety)

22 *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). O'Farrell claimed a method of using a fused gene to produce foreign protein in a bacteria. Although O'Farrell argued that there was no basis for predicting RNA from his method, the Federal Circuit found that a reasonable expectation of success existed and that his method was not eligible for a patent.

23 *See, e.g., In re Spada*, 911 F.2d 705, 708-09 (Fed. Cir. 1990) (holding that the “discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, cannot impart patentability to claims to the known composition”).

Trademarks:

5 USC 1114 Remedies; infringement; innocent infringement by printers and publishers.

Copyrights:

17 USC 512. Limitations on liability relating to material online

28 USC 1498 (b) Use by or for the government

As will be discussed in further detail, infra, it would also be inconsistent with proposals for expanding access to orphaned copyrighted works.

Patents:

35 USC 271 (e) (3) The Safe Harbour exception for uses of patents related to the development and submission of information concerning the sale of drugs or veterinary biologic products

35 USC 271(e)(6)(B-C) Non-disclosed biological product patents

35 USC 272 Temporary presence in the United States (meeting obligations under Chicago and Paris conventions).

35 U.S.C. 287 Limitation on damages and other remedies; marking and notice. No injunctions for patent infringement by medical practitioners

42 USC 2184. Injunctions; measure of damages. Nuclear energy

28 USC 1498 (a) Use by or for the government

Semiconductor chip design:

17 USC 907 Limitation on exclusive rights: innocent infringement

Plant Breeder Rights :

28 USC 1498 (d) Use by or for the government

Designs, including designs of a vessel hull or deck:

28 USC 1498 (e) Use by or for the government

Mask work fixed in a semiconductor chip product:

28 USC 1498 (e) Use by or for the government

Damages

The U.S. template for the TPPA provides for aggressive enforcement measures of intellectual property rights, including election of pre-established damages, using the suggested retail price as a measure of value, providing for attorney's fees and court costs to be paid by the losing party of an infringement action, and permitting seizure of allegedly infringing goods and destruction of the goods. The manner in which the U.S. proposal is drafted in this area conflicts with numerous provisions in current U.S. law

that limit the availability of damages. Article 12.3 of the U.S. proposal for the TPPA sets forth the damages for intellectual property infringement and reads:

Each Party shall provide that:

(a) in civil judicial proceedings, its judicial authorities shall have the authority to order the infringer to pay the right holder:

(i) damages adequate to compensate for the injury the right holder has suffered as a result of infringement,[18] and

(ii) at least²⁴ in the case of copyright or related right infringement and trademark counterfeiting, the profits of the infringer that are attributable to the infringement and that are not taken into account in computing the amount of damages referred to in clause (i)

(b) in determining damages for infringement of intellectual property rights its judicial authorities shall consider, inter alia, the value of the infringed good or service, measured by the suggested retail price or other legitimate measure of value submitted by the right holder.

n.18: In the case of patent infringement, damages adequate to compensate for the infringement shall not be less than a reasonable royalty.

This language (“shall consider”) would *require* judicial authorities to take into account the suggested retail price of an infringing product. In addition to providing for a methodology that anticipates using the suggested retail price as an appropriate measure of damages, the U.S. proposal would create high statutory damages and an infringer can be found liable for treble damages. Article 12.4 permits the right holder, in cases of works, phonograms and performances protected by copyright or in cases of trademark counterfeiting, to elect:

Pre-established damages . . . in an amount sufficiently high to constitute a deterrent to future infringements and to compensate fully the right holder for the harm caused by infringement. In civil judicial proceedings concerning patent infringement, each Party shall provide that its judicial authorities shall have the authority to increase damages to an amount that is up to three times the amount of the injury found or assessed.[19]

n.19: No Party shall be required to apply this paragraph to actions for infringement against a Party or a third party acting with authorization or consent of a Party.

24 We note that the CRS Report on ACTA took issue with the phrase “at least.” Article 2.18(2) of the October 2010 ACTA draft provides that “Each Party’s enforcement procedures shall apply to infringement of *at least trademark and copyright* or related rights over digital networks, including the unlawful use of means of widespread distribution for infringing purposes.” The CRS Report goes on to say, “It is unclear what the phrase ‘at least’ refers to in the above article; it appears to envision IP rights beyond traditional trademark and copyright rights (or related rights), but nowhere in ACTA provides an explanation of this potential expansion.”

The losing party in civil judicial proceedings for intellectual property infringement may also be liable for court costs and fees and/or “reasonable attorneys' fees” except in cases of “exceptional circumstances.”²⁵

Suggested Retail Price/Actual Damages

The provision of Article 12.3 of the U.S. template which would require authorities to consider the “suggested retail price” of an infringed good or service in determining damages is inconsistent with aspects of U.S. law. The “suggested retail price” is often not an appropriate measure of damages and, under U.S. law, this language appears only in reference to importation of goods bearing an infringing trademark under the Tariff Act of 1930. With respect to copyright, U.S. law uses “actual damages” as the appropriate measure:

The copyright owner is entitled to recover the actual damages suffered by him or her as a result of the infringement, and any profits of the infringer that are attributable to the infringement and are not taken into account in computing the actual damages. In establishing the infringer's profits, the copyright owners is required to present proof only of the infringer's gross revenue, and the infringer is is required to prove his or her deductible expenses and the elements of profit attributable to factors other than the copyrighted work.

²⁶

Similarly, U.S. patent law uses the term “damages adequate to compensate for the infringement” as the appropriate measure of damages. 35 U.S.C. §284 provides:

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.

Neither U.S. copyright law nor patent law uses “suggested retail price” as a measure for determining damages. Providing for “suggested retail price” as an appropriate measure of damages goes beyond U.S. copyright and patent law and fails to take into account the fact that right holders often do not receive the “retail” price for goods or services. Often times, right holders will sell to intermediaries, such as wholesalers and distributors, and will therefore receive substantially less than the “suggested retail price.” Actual damages, which is the language used under current U.S. copyright law is a more appropriate measure of damages and is often lower than what would be considered under the U.S. proposal for the TPPA.

Innocent Infringements

Under U.S. copyright and trademark laws, a number of limitations and exceptions exist, particularly in the area of “innocent infringements” where an infringer does not incur liability or is liable only for a reasonable royalty, yet these limitations do not appear under the TPPA. One “innocent infringement” exception currently codified by U.S. law exists for semiconductor chip products under 17 U.S.C. §907:

Limitation on exclusive rights: innocent infringements

²⁵ See Article 12.5 of the U.S. Proposal for the Intellectual Property Chapter of the TPPA.

²⁶ 17 U.S.C. §504(b)

(a) Notwithstanding any other provision of this chapter [17 U.S.C. §901 et. seq.], an innocent purchaser of an infringing semiconductor chip product--

(1) shall incur no liability under this chapter with respect to the importation or distribution of units of the infringing semiconductor chip product that occurs before the innocent purchaser has notice of protection with respect to the mask work embodied in the semiconductor chip product; and

(2) shall be liable only for a reasonable royalty on each unit of the infringing semiconductor that the innocent purchaser imports or distributes after having notice of protection with respect to the mask work embodied in the semiconductor chip product.

The U.S. proposed IP chapter for the TPPA fails to provide similar limitations for innocent infringements and could be considered inconsistent with current U.S. law.

Secondary Transmission by Satellite Carrier

Another provision of the Copyright Act provides for exceptions to damages in cases of willful secondary transmissions that are actionable as acts of infringement. As the CRS Report on ACTA noted:

The following provision of the Copyright Act provides a limited exception to the availability of damages for willful infringement of a copyrighted work (in the phrase “no damages shall be awarded for such act of infringement . . .”), which could be considered to be in conflict with the first sentence of the above ACTA article:

The willful or repeated secondary transmission to the public by a satellite carrier of a primary transmission embodying a performance or display of a work made by a television broadcast station to a subscriber who does not reside in that station's local market, and is not subject to statutory licensing under section 119 . . . or subject to a private licensing agreement, is actionable as an act of infringement . . . and is fully subject to the remedies provided by section 502 through 506 [17 U.S.C. §§ 502-506], except that--(A) no damages shall be awarded for such act of infringement if the satellite carrier took corrective action by promptly withdrawing service from the ineligible subscriber . . .²⁷

Given the similar language on damages contained in the U.S. TPPA proposal, this portion of the CRS Report on ACTA is applicable. The statute quoted in the CRS Report, 17 U.S.C. Section 122(f)(1), provides for zero damages for this particular act of infringement and would therefore conflict with the TPPA's aggressive damages provisions.

27 Brian T. Yeh, American Law Division, Congressional Research Service, *Memorandum to The Honorable Ron Wyden on Potential Implications for Federal Law Raised by the October 2010 Draft of the Anti-Counterfeiting Trade Agreement (ACTA)* (October 29, 2010), available at <http://keionline.org/sites/default/files/RedactedACTACRSMemotoSenWyden.pdf> (quoting 17 U.S.C. §122(f)(1); see also a similar provision in 17 U.S.C. §119(a)(6)(A).).

Disclosure of Biological Product Patent

In addition to the limitations on damages that exist under U.S. copyright law, similar limits exist in other areas. Under U.S. patent law, including recent health care reform, limits exist on the remedies for infringement of patents where the patents are not properly disclosed by the innovators of biologic drugs. Failure to properly disclose biological product patents may result in a limitation of damages to a reasonable royalty or may prohibit a patent holder from bringing an infringement action.

Where infringement is found under 35 U.S.C. §271(e)(2), for example, a court may award:

damages or other monetary relief may be awarded against an infringer *only if* there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product. . .²⁸

thereby limiting the circumstances under which a patent holder can seek damages. Furthermore, the Affordable Care Act would amend U.S. law to limit the amount of damages recoverable on non-disclosed patents on biological products:

(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.

(C) The owner of a patent that should have been included in the list described in section 351(I)(3)(A) of the Public Health Service Act, including as provided under section 351(I)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.²⁹

These limits on damages are not mirrored in the U.S. proposal for the TPPA and the proposals on damages are thus inconsistent with numerous areas of current U.S. law.

Non-Military Atomic Power

Similar to the limits on damages noted above, another exception is provided for in cases involving infringement of patents used for non-military atomic power. For infringement of these patents, U.S. law provides that a right holder is limited to recovering only a “reasonable” royalty:

. . . the measure of damages shall be the royalty fee determined pursuant to section 2187(c) of this title, together with such costs, interest, and reasonable attorney's fees as may be fixed by the court.

42 U.S.C. §2187(c) sets forth the standards for determining a reasonable royalty fee:

²⁸ 35 U.S.C. §271(e)(4)(C) (emphasis added).

²⁹ 35 U.S.C. §271(e)(6)(B)-(C).

(1) In determining a reasonable royalty fee as provided for in section 2183(b) or 2183(e) of this title, the commission shall take into consideration

(A) the advice of the Patent Compensation Board;

(B) any defense, general or special, that might be pleaded by a defendant in an action for infringement;

(C) the extent to which, if any, such patent was developed through federally financed research; and

(D) the degree of utility, novelty, and importance of the invention or discovery, and may consider the cost to the owner of the patent of developing such invention or discovery or acquiring such patent.

(2) In determining what constitutes just compensation as provided for in section 2181 of this title, or in determining the amount of any award under subsection (b)(3) of this section, the Commission shall take into account the considerations set forth in paragraph (1) of this subsection and the actual use of such invention or discovery. Such compensation may be paid by the Commission in periodic payments or in a lump sum.

Thus, like the areas discussed above, including innocent infringements, secondary transmissions by satellite carriers, and where disclosure of biologic products have not been properly disclosed, limits on the amount of damages that a right holder may receive are limited. These areas of limitations preclude high statutory damages and the right holder is, instead, entitled only to a “reasonable” royalty or in some case, to zero damages. The U.S. proposal for the TPPA does not seem to take into account these existing limits to damages and therefore exceed that which is currently required under U.S. law.

Technological Protection Measures

Article 12.12 of the U.S. proposal provides for civil remedies for circumvention of TPMs including actual damages or pre-established damages plus court and attorney fees. As discussed in the comments on TPMs, *supra*, this proposal does not provide for any limitations on damages for “innocent violations” of anti-circumvention laws despite the fact that the DMCA permits a court to reduce or remit the total award of damages and is inconsistent with U.S. law.

Court Costs and Attorney's Fees

Under Article 12.5 of the U.S. proposal, attorney's fees would be made available “except in exceptional circumstances”:

Each Party shall provide that its judicial authorities, except in exceptional circumstances, have the authority to order, at the conclusion of civil judicial proceedings concerning copyright or related rights infringement, trademark, infringement, or patent infringement, that the prevailing party shall be awarded payment by the losing party of court costs or fees and, at least in proceedings concerning copyright or related rights infringement or willful trademark counterfeiting, reasonable attorney's fees. Further, each Party shall provide that its judicial authorities, at least in exceptional circumstances, shall have the authority to

order, at the conclusion of civil judicial proceedings concerning patent infringement, that the prevailing party shall be awarded payment by the losing party of reasonable attorney's fees.

The language used in the U.S. proposal would flip the granting of attorney's fees in trademark cases to favor the prevailing party's ability to recover attorney's fees. While the U.S. proposal for the TPPA would allow require ("shall provide") the losing party to pay attorney's fees "except in exceptional circumstances," U.S. trademark law generally does not permit the award of attorney's fees and allows these fees *only* "in exceptional cases":

The court shall assess such profits and damages or cause the same to be assessed under its direction. In assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction claimed. In assessing damages the court may enter judgment, according to the circumstances of the case, for any sum above the amount found as actual damages, not exceeding three times such amount. If the court shall find that the amount of the recovery based on profits is either inadequate or excessive the court may in its discretion enter judgment for such sum as the court shall find to be just, according to the circumstances of the case. Such sum in either of the above circumstances shall constitute compensation and not a penalty. The court *in exceptional cases* may award reasonable attorney fees to the prevailing party.³⁰

The U.S. proposal reverses the presumption of attorney's fees, providing that only in exceptional cases can a court refuse attorney's fees for trademark cases under the TPPA despite the fact that U.S. law generally does not permit a prevailing party to recover attorney's fees. The language of Article 12.5 on its face contradicts U.S. law and presumes greater damages to be recovered by a trademark right holder.

Additionally, under U.S. copyright law, the grant of reasonable attorney's fees is discretionary rather than mandatory. 17 U.S.C. §505 provides only that:

In any civil action under this title, the court *in its discretion may allow* the recovery of full costs by or against any party other than the United States or any officer thereof. Except as otherwise provided by this title, the court *may also award* a reasonable attorney's fee to the prevailing party as part of the costs.³¹

Although current U.S. law provides for discretionary awards of court costs and attorney's fees in copyright cases ("in its discretion may allow" and "may also award"), the TPPA would provide for mandatory awards of both court costs and attorney's fees ("shall be awarded"). The U.S.-proposed language on court costs and attorney's fees is therefore inconsistent with U.S. trademark and copyright law.

Destruction of goods

In addition to high damage provisions and court costs and attorney's fees, the U.S. proposal would allow for the destruction of goods that have been found to be infringing. Article 12.7(a) requires:

³⁰ 15 U.S.C. §1117(a)(3) (emphasis added).

³¹ Emphasis added.

Each Party shall provide that in civil judicial proceedings:

(a) at the right holder's request, goods that have been found to be pirated or counterfeit shall be destroyed, except in exceptional circumstances.

The only exception provided for in this provision occurs in “exceptional circumstances.” By contrast, under U.S. trademark law, for cases of infringing trademarks which involve “dilution by blurring” or “dilution by tarnishment,” such measures are only available for *willful* infringements:

In any action arising under this chapter, in which a violation of any right of the registrant of a mark registered in the Patent and Trademark Office, a violation under section 1125(a) of this title, or a *willful violation* under section 1125(c) of this title, shall have been established, the court may order that all labels, signs, prints, packages, wrappers, receptacles, and advertisements in the possession of the defendant, bearing the registered mark, or, in the case of a violation of section 1125(a) of this title or a *willful violation* under section 1125(c) of this title, the word, term, name, symbol, device, combination thereof, designation, description, or representation that is the subject of the violation, or any reproduction, counterfeit, copy, or colorable imitation thereof, and all plates, molds, matrices, and other means of making the same, shall be delivered up and destroyed.³²

The fact that willful infringement is necessary in this case in order to trigger the provision permitting destruction of infringing goods provides at least one limit to this provision that exists under U.S. law but is not replicated in USTR's proposal for the TPPA.

Article 14: Special Requirements Related to Border Enforcement

Article 14 of the U.S. proposal provides for a number of provisions related to the enforcement of intellectual property rights by customs or border authorities. These provisions provide for border measures, including those initiated *ex officio*, for the detention of goods suspected of infringing trademarks or copyright:

1. Each Party shall provide that any right holder initiating procedures for its competent authorities to suspend release of suspected counterfeit or confusingly similar trademarked goods, or pirated copyright goods[20] into free circulation is required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement of the right holder's intellectual property right and to supply sufficient information that may reasonably be expected to be within the right holder's knowledge to make the suspected goods reasonably recognizable by its competent authorities. The requirement to provide sufficient information shall not unreasonably deter recourse to these products. Each Party shall provide that the application to suspend the release of goods apply to all points of entry to its territory and remain in force for a period of not less than one year from the date of application, or the period that the good is protected by copyright or the relevant trademarked registration is valid, whichever is shorter.

³² 15 U.S.C. §1118 (emphasis added).

[. . .]

4. Each Party shall provide that its competent authorities may initiate border measures *ex officio*[22] with respect to imported, exported, or in-transit merchandise, [23] or merchandise in free trade zones, that is suspected of being counterfeit or confusing similar trademarked goods, or pirated copyright goods.

5. Each Party shall adopt or maintain a procedure by which its competent authorities shall determine, within a reasonable period of time after the initiation of the procedures described under Article 14.1 whether the suspected goods infringe an intellectual property right. Where a Party provides administrative procedures for the determination of an infringement, it shall also provide its authorities with the authority to impose administrative penalties following a determination that the goods are infringing.

6. Each Party shall provide that goods that have been determined by its competent authorities to be pirated or counterfeit shall be destroyed, except in exceptional circumstances. In regard to counterfeit trademarked goods, the simple removal of the trademark unlawfully affixed shall not be sufficient to permit the release of the goods into the channels of commerce. In no event shall the competent authorities be authorized, except in exceptional circumstances, to permit the exportation of counterfeit or pirated goods or to permit such goods to be subject to other customs procedures.

n.20: For purposes of Article 14: (a) **counterfeit trademarked goods** means any goods, including packaging, bearing without authorization a trademark that is identical to the trademark validly registered in respect of such goods, or that cannot be distinguished in its essential aspects from such a trademark, and that thereby infringes the rights of the owner of the trademark in question under the law of the country of importation; and (b) **pirated copyright goods** means any goods that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and that are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or related right under the law of the country of importation.

n.22: For greater certainty, the parties understand that *ex officio* action does not require a formal complaint from a private party or right holder.

n.23: For purposes of Article 14.4, **in-transit merchandise** means goods under “Customs transit” and goods “Transhipped,” as defined in the *International Convention on the Simplification and Harmonization of Customs Procedures (Kyoto Convention)*³³

Under these articles, a right holder could request the detention of allegedly infringing goods or detention can be initiated by customs authority even absent a formal complaint by a right holder. Although we recognize that the U.S. proposal provides that customs authorities shall have the authority, the text would not require such officials to exercise this authority, permitting ex-officio border measures could still be problematic. We note that the only clear exception to these detention and

33 Articles 12.1, 12.4-12.6.

border measures appears in Article 14.8 which provides that a “Party may exclude from the application of this Article . . . small quantities of goods of a non-commercial nature contained in traveler's personal baggage.” The language of the U.S. proposal does not specifically envision any other exceptions.

Under U.S. law, additional exceptions exist clearly exist and customs authorities cannot prevent the importation of infringing goods if they fall under a general public health and welfare exception or are being imported by or for the use of the U.S. government under 19 U.S.C. §1337:

(a) Unlawful activities; covered industries; definitions

(1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provisions of law, as provided in this section:

[. . .]

(B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee of articles that--

(i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17; or

(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

(C) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that infringe a valid and enforceable United States trademark registered under the Trademark Act of 1946 [15 U.S.C. §1051, et. seq.]

(D) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of a semiconductor chip product in a manner that constitutes infringement of a mask work registered under chapter 9 of title 17.

(E) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consigner, of an article that constitutes infringement of the exclusive rights in a design protected under chapter 13 of title 17

(2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright,

trademark, mask work, or design concerned, exists or is in the process of being established.

(3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned--

(A) significant investment in plant and equipment;

(B) significant employment of labor or capital; or

(C) substantial investment in its exploitation, including engineering, research and development, or licensing

[. . .]

(d) Exclusion of articles from entry

(1) If the Commission determines, as a result of an investigation under this section, that there is a violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry. The Commission shall notify the Secretary of the Treasury of its action under this subsection directing such exclusion from entry, and upon receipt of such notice, the Secretary shall, through the proper officers, refuse such entry.

[. . .]

(l) Importation by or for United States

Any exclusion from entry or order under subsection (d), (e), (f), (g), or (i) of this section, in cases based on a proceeding involving a patent, copyright, mask work, or design under subsection (a)(1) of this section, shall not apply to any articles imported by and for the use of the United States, or imported for, and to be used for, the United States with the authorization or consent of the Government. Whenever any article would have been excluded from entry or would not have entered pursuant to the provisions of such subsections but for the operation of this subsection, an owner of the patent, copyright, mask work, or design adversely affected shall be entitled to reasonable and entire compensation in an action before the United States Court of Federal Claims pursuant to the procedures of section 1498 of title 28.

Article 14 of the TPPA, providing customs authorities with the authority to detain goods suspected of infringing copyright or trademarks could therefore be inconsistent with the above portion of 19 U.S.C.

§1337 which permits a clear exception to the detention of goods. Importation of even infringing copyright, trademark and patented goods are permitted under certain circumstances under current U.S. law. It is possible that the U.S. proposal for the TPPA might preclude customs authority from determining whether prohibiting importation of goods would harm public or consumer interests, but customs officials might also prohibit infringing goods from entering the United States where such importation occurs by or for the use of the U.S. government.

Article 16: Special Measures Relating to Enforcement in the Digital Environment

Definition of “service provider”

Article 16.3(b)(xii) of the U.S. proposal sets forth the definition of “service provider,” expanding the definition to cover any provider of online materials which goes beyond the DMCA:

For purposes of the function referred to in clause (i)(A), **service provider** means a provider of transmission, routing, or connections for digital online communications without modification of their content between or among points specified by the user of material of the user's choosing, and for purposes of the functions referred to in clauses (i)(B) through (D) **service provider** means a provider operator of facilities for online services or network access.³⁴

The text of the DMCA, however, provides two different definitions of service provider. For purposes of transmission, the definition of service provider is more narrowly defined:

As used in subsection(a), the term “service provider” means an entity offering the transmission, routing, or providing of connections for digital online communications, between or among points specified by a user, of material of the user's choosing, without modification to the content of the material as sent or received.³⁵

The U.S. proposal therefore seeks to create greater liability with regard to transmission of online material than is currently provided for by U.S. law. While the TPPA would provide that any “provider” of transmission could be liable, the DMCA limits the definition to “an entity.” Thus, while current U.S. law makes a distinction between an entity and an individual person for purposes of transmission or routing, the TPPA would eliminate this distinction and open up liability to an individual person for purposes of transmission, routing or connections for digital online communications.

Limitations on monetary damages

Article 16.3(b)(i) provides for limitations on monetary damages and “reasonable restrictions on court-ordered relief to compel or restrain” that might otherwise be available against internet service providers (ISPs). These limitations are confined to:

³⁴ Emphasis in original.

³⁵ 17 U.S.C. §512(k)(1)(A).

- (A) transmitting routing, or providing connections for material without modification of its content, or the intermediate and transient storage of such material in the course thereof;
- (B) caching carried out through an automatic process;
- (C) storage, at the direction of a user, of material residing on a system or network controlled or operated by or for the service provider; and
- (D) referring or linking users to an online location by using information location tools, including hyperlinks and directories.

This list of limitations mirrors the first four exceptions to liability contained in the DMCA. However, the DMCA also provides for one additional limitation on liability relating to online material for nonprofit educational institutions:

- (1) When a public or other nonprofit institution of higher education is a service provider, and when a faculty member or graduate student who is an employee of such institution is performing a teaching or research function, for the purposes of subsections (a) and (b) such faculty member or graduate student shall be considered to be a person other than the institution and for purposes of subsections (c) and (d) such faculty member's or graduate student's knowledge or awareness of his or her infringing activities shall not be attributed to the institution, if—
 - (A) such faculty member's or graduate student's infringing activities do not involve the provision of online access to instructional materials that are or were required or recommended, within the preceding 3-year period, for a course taught at the institution by such faculty member or graduate student;
 - (B) the institution has not, within the preceding 3-year period, received more than two notifications described in subsection(c)(3) of claimed infringement by such faculty member or graduate student, and such notification of claimed infringement were not actionable under subsection (f); and
 - (C) the institution provides to all users of its system or network informational materials that accurately describe, and promote compliance with, the laws of the United States relating to copyright.

This provision, contained within the DMCA, does not appear in the U.S. proposal for the TPPA. It could therefore be possible for a nonprofit institution of higher education to be found liable under the provisions of the TPPA.

Privacy Safeguards

The U.S. proposal would require a service provider to disclose information identifying an alleged infringer, but in providing this enforcement mechanism, fails to provide safeguards for the user. Article 16.3(b)(xi) states:

Each Party shall establish an administrative or judicial procedure enabling copyright owners who have given effective notification of claimed infringement to obtain expeditiously from a service provider information in its possession identifying the alleged infringer.”

This language does not appear to conceive of privacy protections for the alleged infringer that currently appear under the DMCA. Under 17 U.S.C. §512(h), a copyright owner can request for a subpoena to be issued directing a service provider to expeditiously disclose information sufficient to identify an alleged infringer. However, this request must include:

a sworn declaration to the effect that the purpose for which the subpoena is sought is to obtain the identity of an alleged infringer and that such information will only be used for the purpose of protecting rights under this title.³⁶

This provision provides at least some protection for the user, requiring a copyright holder to legally swear that the information obtained regarding the identity of an alleged infringer will only be used to protect his copyright. The failure to include similar safeguards for privacy in the TPPA could therefore be another area which is inconsistent with current U.S. law.

Pharmaceutical Pricing

The U.S. is reportedly seeking to introduce text on pharmaceutical pricing, as a separate chapter titled “transparency and due process”, modeled after Chapter 5 of the Korea-US (KORUS) FTA and Annex 2(c) of the Australia-United States (AUSFTA) FTA. Provisions in both KORUS and AUSFTA require that government reimbursement formularies “recognize the value” of patented medicines.

In the U.S., drug reimbursement programs such as Medicaid, have price restraining formularies and achieve prices on par with, and often lower than, those operated by foreign country reimbursement programs. However, the language USTR reportedly seeks to introduce into the TPPA would prohibit an agency from referencing prices in other countries when determining reimbursement rates.³⁷

Furthermore, in the KORUS FTA, the U.S. was careful to carve out U.S. pharmaceutical pricing programs from those provisions. Most federal pharmaceutical programs are direct purchase programs and would not fall under the “reimbursements” of KORUS. Even the drug reimbursement programs in the U.S. are carved out in a footnote to the KORUS text, clarifying that the language does not cover “regional level” government programs, essentially exempting Medicaid from the restraints. Despite these carve outs, the KORUS language still may not cover all reimbursements as it does not specifically exempt the federal 340(b) program of providing discounts for pharmaceutical reimbursements by health facilities that serve poor and disabled persons in the U.S.

Depending on whether the U.S. proposal would include similar carveouts in the TPPA, provisions on pharmaceutical pricing may be inconsistent with U.S. law. Even if the U.S. does negotiate similar double standards into the agreement, the U.S. should not “promote policies abroad that it is not prepared to require governments to abide by at home.”³⁸

36 15 U.S.C. §512(h)(2)(C).

37 *U.S. Circulates Draft TPP Proposal on Drug Pricing & Reimbursement*, Inside U.S. Trade (July 15, 2011)

38 Letter from Governor of Vermont, James H. Douglas to The Honorable Kathleen Sebellius, U.S. Department of Health

Areas where the U.S. TPPA proposal could limit current and future legislative reform efforts

Orphan Works

The U.S. proposal for the TPPA could eliminate the possibility of changes to U.S. law to address the problem of “orphan works,” copyrighted works where it is difficult or impossible to locate the owner of the copyright. The U.S. Congress has considered legislation to expand access to orphaned works and limits on injunctions and damages are central to these proposals.

As noted above, the U.S. proposed IP chapter for the TPPA would create a system that would calculate high damages (as measured, for example, by the “suggested retail price”) or provides large statutory damages. However, as Marybeth Peters, former Register of Copyrights, testified before the House of Representatives in 2008, statutory damages may be inappropriate for certain uses of orphan works:

Some who oppose orphan works legislation have also objected to the removal of statutory damages, which are available under Title 17 in certain instances. A few have even asserted that statutory damages are an entitlement under the law that cannot be rescinded. We disagree. Statutory damages are an alternative means by which a copyright owner may recover against an infringer in lieu of proving actual damages and lost profits. However, they are only available if the owner has registered the work prior to the infringement or within three months of publication. (While it is possible that a registered work could be an orphan work within the proposed legislative framework, we think this is unlikely to be a common situation, not because the registration is guaranteed to be found, but because an owner who has taken steps to register his work has likely taken other steps to make himself available outside the registration system.) Statutory damages are not an absolute entitlement any more than copyright ownership itself is an absolute right. Just as there are exceptions to, and limitations on, the exclusive rights of copyright owners (for example, fair use), there are exceptions to statutory damage awards. In cases of “innocent infringement,” the court may reduce statutory damages to \$200; for certain infringements by nonprofit educational institutions, libraries, archives, and public broadcasters, the court may reduce the award to zero. The fact remains that the possibility of statutory damages, however remote, is the single biggest obstacle preventing use in orphan works situations. In case of non-willful infringement, statutory damages may be as high as \$30,000 for each infringed work. In case of willful infringement, they may be as high as \$150,000 per infringed work.

We are not suggesting, in general, that the scheme of statutory damages is unjust. On the contrary, statutory damages fulfill legitimate and necessary purposes. That said, we do believe that in the case of orphan works, the rationale for statutory damages is weak. By

and Human Services (May 3, 2010), available at http://www.wcl.american.edu/pijip/download.cfm%3Fdownloadfile%3DF81CC0C9-D7AD-7E79-93F4FB6F2B430EF6%26typename%3DdmFile%26fieldname%3Dfilename+james+douglas+sebelius+abroad+policies+abide&hl=en&gl=us&pid=bl&srcid=ADGEESjwYgfAtiuk9M5gDLYC_Kb3U3ruKz54_r1Ht1MgmBXr6a7jM1SZuscAUF6CydkT1NSd1DVd9AOkZoD-CIkksfbEPb_tcHKaX_lInlV1fpt5nMZQHPJB2-osQv5svHtSIEmm2NnT&sig=AHIEtbSiE_xQP8xjqFFAMZhpU7BjSYYr7w

definition, in the orphan work situation, the user is acting in good faith and diligently searching for the owner, and the owner is absent. The purposes of statutory damages, i.e. making the owner's evidentiary burden lighter and deterring infringement, weigh less heavily here. If the copyright owner is not identifiable and cannot be located through a diligent, good faith search, we believe the appropriate recovery is reasonable compensation. If orphan works legislation does not remove statutory damages from the equation, it will not motivate users to go forward with important, productive uses. On the other hand, the prospect of orphan works legislation may motivate some owners to participate more actively in the copyright system by making themselves available.³⁹

A January 2006 Library of Congress report elaborated upon consideration of damages for uses of orphaned works, stating that large monetary damages substantially deterred use of orphaned works and concluded that a “reasonable compensation” was a more appropriate measure of damages in these cases. The report stated:

A vast majority of the commenters in this proceeding agreed that the prospect of a large monetary award from an infringement claim, such as an award of statutory damages and attorneys' fees, was a substantial deterrent to users who wanted to make use of an orphan work, even where the likelihood of a claim being brought was extremely low. Most of the proposals for addressing the orphan works problem called for clear limitations on the statutory damages and attorneys' fees remedies in cases involving orphan works. Our recommendation follows this suggestion by limiting the possible monetary relief in these cases to only 'reasonable compensation,' which is intended to represent the amount the user would have paid to the owner had they engaged in negotiations before the infringing use commenced. In most cases it would equal a reasonable license fee, as that concept is discussed in recent copyright case law.

While many commenters supported a general remedy like 'reasonable compensation,' some expressed concern about the impact that any monetary remedy at all might have on their ability to go forward and use orphan works. For example, museum representatives explained that they would like to use hundreds or even thousands of orphan works in their collections, so the potential of even a minimal monetary award for each work, would, in their view, be prohibitive. Libraries and archives made similar observations, given their desire to make large collections of orphan works accessible.

In our view, a general standard of reasonable compensation is the right solution to this problem, for several reasons. First, with respect to the concern about a chilling effect of any monetary remedy, it must be noted that in nearly all cases where a diligent search has been performed, the likelihood of a copyright owner resurfacing should be very low, so that no claim for compensation is ever made. Second, it should be clear that 'reasonable compensation' may, in appropriate circumstances be found to be zero, or a royalty-free license, if the comparable transactions in the marketplace support such a finding. Our

³⁹ Statement of Marybeth Peters, Registrar of Copyrights, before the Subcommittee on Courts, the Internet, and Intellectual Property, Committee on the Judiciary, United States House of Representatives, 110th Congress, 2nd Session, March 13, 2008, *The “Orphan Works” Problem and Proposed Legislation*, available at <http://www.copyright.gov/docs/registrar031308.html>; see also pages 115-119.

discussions with museums, universities and libraries indicated that in many orphan works situations a low or zero royalty is likely to be the reasonable compensation.

In addition, to make absolutely sure that the concerns of nonprofit institutions like libraries, museums and universities about monetary relief are assuaged, we recommend an additional limitation on monetary relief where the user is making a non-commercial use of the work and expeditiously ceases the infringement after receiving notice of the infringement claim. In that case, there should be no monetary relief at all. Libraries, archives and museums indicated that posting material on the Internet was a primary use they would like to make of orphan works, and that they would take down any material if a copyright owner resurfaced. This additional provision provides certainty about their exposure in that circumstance. If the organization wishes to continue making use of the work, it would have to pay reasonable compensation for its past use, and, as described below, for future use of the work.⁴⁰

In the 110th Congress, the U.S. Senate approved the Shawn Bentley Orphan Works Act of 2008, but the bill did not pass in the House of Representatives. The Shawn Bentley Orphan Works Act of 2008 would have limited remedies on uses of orphan works:

S.2913. Shawn Bentley Orphan Works Act of 2008 (Engrossed as Agreed to or Passed by Senate)

(a) Definitions—In this section, the following definitions shall apply:

[. . .]

(3) REASONABLE COMPENSATION—The term “reasonable compensation” means, with respect to a claim of infringement, the amount on which a willing buyer and willing seller in the positions of the infringer and the owner of the infringed copyright would have agreed with respect to the infringing use of the work immediately before the infringement began.

Sec. 514. Limitation on remedies in cases involving orphan works

[. . .]

(c) Limitations on Remedies—The limitations on remedies in an action for infringement of copyright to which this section applies are the following:

(1) MONETARY RELIEF--

(A) GENERAL RULE—Subject to subparagraph (B), an award for monetary relief (including actual damages, statutory damages, costs, and attorney's fees) may not be made other than an order requiring the infringer to pay reasonable

40 Library Congress, Report of the Register of Copyrights, *Report on Orphan Works* (January 2006), at 12-13, available at <http://www.copyright.gov/orphan/orphan-report-full.pdf>; see also pages 115-119.

compensation to the owner of the exclusive right under the infringed copyright for the use of the infringed work.

(B) FURTHER LIMITATIONS—An order requiring the infringer to pay reasonable compensation for the use of the infringed work may not be made under subparagraph (A) if the infringer is a nonprofit educational institution, museum, library, archives, or a public broadcasting entity (as defined in subsection (f) of section 118), or any of such entities' employees acting within the scope of their employment, and the infringer proves by a preponderance of the evidence that--

(i) the infringement was performed without any purpose of direct or indirect commercial advantage;

(ii) the infringement was primarily educational, religious, or charitable in nature; and

(iii) after receiving a notice of claim of infringement, and having an opportunity to conduct an expeditious good faith investigation of the claim, the infringer promptly ceased the infringement.

(C) LIMITATIONS—The limitations on injunctive relief under subparagraphs (A) and (B) shall not be available to an infringer or a representative the infringer acting in an official capacity if the infringer asserts that neither the infringer nor any representative of the infringer acting in an official capacity is subject to suit in the courts of the United States for an award of damages for the infringement, unless the court finds that the infringer

(i) has complied with the requirements of subsection (b); and

(ii) pays reasonable compensation to the owner of the exclusive right under the infringed copyright in a reasonably timely manner after the amount of reasonable compensation has been agreed upon with the owner or determined by the court.

(D) RULE OF CONSTRUCTION—Nothing in subparagraph (C) shall be construed to authorize or require, and no action taken under such subparagraph shall be deemed to constitute, either an award of damages by the court against the infringer or an authorization to sue a State.

(E) RIGHTS AND PRIVILEGES NOT WAIVED—No action taken by an infringer under subparagraph (C) shall be deemed to waive any right or privilege that, as a matter of law, protects the infringer from being subject to suit in the courts of the United States for an award of damages.

An October 29, 2010 Congressional Research Service (CRS) report, requested by Senator Wyden, evaluated the Anti-Counterfeiting Trade Agreement (ACTA) and areas in which the agreement could

require changes to federal law.⁴¹ It should be noted that many of the provisions of ACTA, or of the U.S. proposed language to ACTA, has been replicated and proposed in the TPPA. This CRS report covered, among other areas, the problems that ACTA would create for efforts to reform copyright law and improve access to orphaned works:

Congress could continue to consider legislation in the area of reform to damages in patent litigation or access to orphaned copyrighted works that resemble approaches in the 110th and 111th Congresses. Such approaches specify methods of calculating monetary damages in patent cases and call for limitations on damages and injunctive relief in cases involving orphan works. ACTA, as an executive agreement that reportedly will not be submitted to Congress for approval, does not reduce, constrain, or otherwise impact the authority and prerogative of Congress to enact such measures that change federal law. Further, Congress may not be compelled to take into account the requirements of an agreement that it had no formal role in approving. On the other hand, it may well be that Members of Congress might be reluctant to consider legislative approaches that would alter federal law in a manner that might make the United States in default of its ACTA obligations. The seriousness of such a concern may turn on the extent to which the United States may be held accountable for ignoring its ACTA obligations, or how successful the United States is in convincing other ACTA Parties of its compliance with the ACTA commitments even with such legislation.⁴²

Like ACTA, the U.S. proposal on the TPPA contains aggressive methods for calculating monetary damages.⁴³ This excerpt from the CRS Report on ACTA is therefore applicable to the language proposed in the TPPA. The language of the U.S. proposal for the TPPA as it currently stands would be inconsistent with the efforts to reform copyright law, such as the Shawn Bentley Orphan Works Act of 2008. Notably, the Shawn Bentley Orphan Works Act of 2008 does not provide for costs and attorney's fees for infringement of orphan works, while both may be available under Article 12.4 of the TPPA. Additionally, damages under the orphan works legislation would be based upon a reasonable compensation as opposed to actual damages, the suggested retail price or statutory damages as USTR proposes for the TPPA.⁴⁴

The U.S. TPPA language fails to include any limitations on damages for cases involving orphaned works and could constrain Congress' ability to reform copyright law in a manner that would increase access to orphan works.

Congressional action on the issue of orphaned works is extremely important in light of the fact that the Southern District of New York denied final settlement approval in the Google Book Search Copyright Class Action Settlement which would have allowed Google to provide access to orphaned works while

41 See <http://keionline.org/node/1123>

42 Brian T. Yeh, American Law Division, Congressional Research Service, *Memorandum to The Honorable Ron Wyden on Potential Implications for Federal Law Raised by the October 2010 Draft of the Anti-Counterfeiting Trade Agreement (ACTA)* (October 29, 2010), available at <http://keionline.org/sites/default/files/RedactedACTACRSMemotoSenWyden.pdf> (internal citations omitted).

43 SEE SECTION XXX, *supra*.

44 For additional and information on how trade agreements with poorly drawn sections on enforcement and damages for infringement of copyrighted works can impede legislative efforts at resolving the orphan works problem, see James Love, *Access to Orphan Works, and ACTA provisions on damages*, Oct. 20 2010, available at <http://keionline.org/node/980>

creating a books registry for authors to identify themselves and receive compensation for Google's use of their works.⁴⁵ Additionally, even if the settlement had been approved, legislative action may have been necessary to address orphaned works not covered by the Google Books Settlement. The TPPA would constrain legislative reform in this area and its provisions governing damages would be inconsistent with previous Congressional proposals to address orphaned works. USTR should not seek to prejudice a solution in line with the recommendations of the U.S. Copyright Office or proposals considered by the 110th Congress.

Data Protection

Although the U.S. has reportedly not yet introduced its proposal on data protection, its template for the IP chapter contains placeholder text “for provisions related to data protection for pharmaceutical products.”⁴⁶ Depending on the language ultimately proposed, the TPPA could limit the flexibility of Congress to limit exclusive rights to data protection.

In the Second Session of the 111th Congress, S.3921, the Ethical Pathway Act of 2010 was introduced to eliminate exclusive rights on test data where repetition of the clinical trial would violate medical ethics.⁴⁷ The Ethical Pathway Act of 2010 sought to ensure that an applicant seeking regulatory approval of a pharmaceutical or biological product would not be forced to repeat clinical trials of the product in violation of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.

(b) ETHICAL PATHWAY.--As soon as practicable after the date of enactment of this Act, the Secretary, acting through the Commissioner, shall establish a mechanism by which an applicant may request a cost-sharing arrangement described in subsection (c). Such an applicant may request such an arrangement if, but for the arrangement--

(1) such applicant would be required to conduct clinical investigations involving human subjects that violate Article 20 of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects in order to obtain approval or licensure from the Secretary of the application described in subsection (a)(2) submitted by the applicant; or

(2) the duplication of the clinical investigations required for such application would violate other applicable ethical standards concerning the testing of products on humans or other vertebrate animals.⁴⁸

In relying upon existing test data used for regulatory approval of pharmaceutical products, the applicant would engage in cost sharing to pay the entity that produced such data a reasonable fee that can be agreed upon voluntarily by the parties involved or determined through arbitration or by the FDA Commissioner.

45 *Authors Guild, Inc., et. al. v. Google Inc.*, Case No. 05-CV-8136 (S.D.N.Y. 2009). For updated information on the Google Book Settlement case, visit www.googlebooksettlement.com

46 Article 9.2.

47 S.3291, Ethical Pathway Act of 2010, 11th Cong., 2d Sess. (2010).

48 *Id.*

Depending on the exact proposal tabled by the U.S., its language on protection of test data could impede legislative areas to reform existing law in a manner that would comply with the Helsinki Declaration.

Furthermore, the period of data protection for pharmaceutical products is a subject of contention in the U.S. and the eventual proposal by USTR could conflict with efforts to modify existing law. Some members of Congress have pushed for USTR to require twelve years of data protection in the TPPA,⁴⁹ stating, “we urge you to support current U.S. law on biologics, which provides for 12 years of protection.” By contrast, other members of the House of Representatives argued against the negotiation of “any provisions” relating to exclusivity in data protection:

The United States only recently established its biosimilars pathway when it enacted the Patient Protection and Affordable Care Act (PPACA) (Pub. L. No. 111-148) last year. Therefore, the consequences of PPACA's mandated 12 years of biologics exclusivity are not yet known. Additionally, the Food and Drug Administration has not yet promulgated any regulations to implement the biosimilars provisions of the new law, nor has the Agency approved any biosimilars in the United States.

Proposing 12 years of exclusivity in the context of TPP negotiations would also conflict with stated Administration policy, as reflected in the FY 2012 budget proposal, recommending the exclusivity period of biologics be reduced to 7 years. According to the Administration's budget, a term of 7 years of exclusivity, instead of 12 years would achieve an estimated \$2.34 billion in savings over the next decade.

Were the TPP ultimately to contain a 12 year biologics exclusivity provision, it would impede the ability of Congress to achieve the Administration's proposed 7 year change without running afoul of U.S. trade obligations. We see no reason for the United States to agree to such provision, much less to propose it.⁵⁰

If USTR does, in fact, propose a 12 year period of protection for pharmaceutical test data, this period of exclusivity would exceed what the President's own budget proposes. It is unclear why a 12 year period is reportedly being considered and would not only be inconsistent with the President's budget proposal, but would hinder the flexibility of Congress to reduce the length of exclusivity or to create limitations to these exclusive rights.⁵¹

49 Letter to President Barack Obama from Members of the House of Representatives, July 27, 2011, *available at* <http://infojustice.org/wp-content/uploads/2011/07/40-Members-of-Congress-07272011.pdf>.

50 Letter to President Barack Obama from Members of the House of Representatives, August 4, 2011, *available at* http://www.henrywaxman.house.gov/UploadedFiles/TPP_Biologics_Letter_08-04-11.pdf.

51 In addition to potentially being inconsistent with U.S. law or limiting the ability of Congress to reform this area, exclusive rights to test data for pharmaceutical products without the possibility of exceptions would also override the May 10, 2007 agreement between President George W. Bush and the leadership of the then-Democratic controlled House of Representatives on “Provisions on Patents/IPR and Access to Medicines.” A portion of that agreement included “an exception to the data exclusivity obligation for measures to protect public health in accordance with the Doha Declaration and subsequent protocols for its implementation.”