DATE: January 15, 2019

Intent to Testify and Testimony Summary/Comments on Negotiating Objectives for a U.S.-U.K. trade agreement.

Federal Register Notice: 83 FR 57790
Docket Number: USTR-2018-0036

Knowledge Ecology International (KEI) requests the opportunity to testify at the hearing to be held on Tuesday, January 29, 2019 by the United States Trade Representative's Trade Policy Staff Committee regarding the negotiations on a trade agreement with the United Kingdom.

Below are KEI's written comments in regard to this hearing and request for comments.

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a. General and product-specific negotiating objectives for the proposed agreement.

KEI proposes negotiating objectives in several areas:

1. Medical technologies
    a. Promote innovation for medical technologies, including but not limited to drugs, vaccines, diagnostic tests, gene- and cell-therapies.
    b. Create more competition for medical technologies that meet appropriate standards for safety and efficacy.
    c. Increase the supply (and overcome the under-supply) of medical research as a public good.
    d. Progressively delink research and development (R&D) incentives from prices of medical products and services.
    e. Protect personal privacy, and/or make policies to promote medical innovation that is least damaging to personal privacy.
    f. Increase transparency of resource flows for research and development and of prices of medical products and services.
    g. Set targets for joint funding of market entry rewards and other R&D costs for antimicrobial drugs, with delinkage of R&D incentives from product prices, subject only to an exception for the payment of antibiotic prescription user fees to finance robust market entry rewards (MERs) or other research costs.

2. Intellectual property rights
    a. Expand access to orphaned copyrighted works.
    b. Avoid evergreening of patent protection on medicines.
    c. Protect open standards and standards-making bodies from anticompetitive and predatory licensing demands from patent holders.
    d. Ensure that legislators can set norms for damages for infringement of patents, copyrights and other intellectual property rights that can be implemented as liability rules to expand access to copyrighted works, to protect manufacturers of biosimilar drugs from litigation over undisclosed patents and for other appropriate purposes, as has been proposed by the Librarian of Congress for Orphan Works and as is currently the case in the U.S. Biologics Price Competition and Innovation act, and the Landrum Griffin Act.

3. Quality of life
    a. Establish a quality of life chapter.
    b. Set minimum standards for the size of seats and the amount of legroom on commercial airlines, in order to avoid races to the bottom that result in a decrease of quality of life and present risks to the life and productivity of travelers.
    c. Set minimum standards for paid parental leave.
    d. Set minimum standards for paid vacation time for employees.

4. Climate change
    a. Establish a chapter for measures that address the need to mitigate and slow climate change.
        i. Set norms for funding research on technologies to lower carbon emissions and otherwise mitigate and adapt to climate change.

5. Access to knowledge and culture
    a. Enhance the production and transparency of, and access to scientific research.
    b. Require public access for government-funded databases and scientific research reports and papers.
    c. Expand access to orphaned copyrighted works.

6. Control anti-competitive practices
    a. Ensure sufficient interoperability and data portability to allow the public to use different clients to share status updates, photographs and videos on the large socially important services/platforms now managed by Facebook and Twitter.

7. Public goods
    a. Enhance funding of programs to address global challenges such as the management of refugees, natural disasters, piracy on the high seas, cross-border environmental protection, global security and health and climate-related R&D supplied as a public good.
    b. Create a schedule for the supply of public goods. The schedule should have three categories of commitments: commitments that are (1) mandatory and binding, (2) voluntary but binding if placed on the schedule, and (3) soft commitments that are voluntary and non-binding.

8. Enhance cooperation on addressing tax avoidance in order to ensure fairness and sustainable funding for government programs.

9. Protect against dangerous and hostile cyber risks
    a. Enhance the transparency of software, algorithms and protocols for software, and software-enabled products, including in particular cases where software programs present risks to privacy, theft, fraud and other hostile acts.

b. Relevant barriers to trade in goods and services between the U.S. and the UK that should be addressed in the negotiations.

1. The US and the U.K. should implement measures to reduce regulatory barriers to the cross-border trade of drugs, vaccines and other similar commodities.

f. Sanitary and phytosanitary measures and technical barriers to trade that should be addressed in the negotiations.

1. Governments should eliminate regulatory exclusivity (for example for orphan drugs, pediatric testing, test data, etc), in favor in monetary incentives or expanded subsidies for clinical trials.

g. Other measures or practices that undermine fair market opportunities for U.S. businesses, workers, farmers, and ranchers that should be addressed in the negotiations.

In addition to the considerations described above, when negotiating and concluding a new US-U.K. trade agreement the USTR must take care to protect the public through undertaking certain critical objectives and avoiding other detrimental actions.

DON'Ts

1. DO NOT create a (trade agreement) norm for the years of regulatory exclusivity for drug test data;
2. DO NOT tie regulatory marketing approval of drugs, vaccines or other medical technologies to patent landscapes;
3. DO NOT create a trade agreement requirement that gene- and cell-therapies (including CAR T therapy) be defined as products, rather than procedures;
4. DO NOT create a trade agreement standard for patentable subject matter;

5. DO NOT restrict policy space to eliminate the availability of injunctions in certain intellectual property infringement cases, as currently provided under U.S. law;
6. DO NOT require more aggressive provisions on damages for infringement of patents than the core standard of “damages adequate to compensate for the infringement,” currently present in U.S. law;
7. DO NOT extend copyright terms beyond that currently required by the WTO TRIPS agreement;
8. DO NOT prohibit measures to make software code, protocols and algorithms transparent; and
9. DO NOT create post-fixation rights for broadcasting organizations.

DOs

10. DO create a pathway to enhance the cross-border trade of drugs and vaccines that have adequate regulation as regards safety and efficacy, including but not limited to off-patent medicines that lack an adequate number of competitors or any drug for which prices are excessive;
11. In the absence of delinkage of R&D incentives from prices, DO create norms against the use of parallel imports or reference pricing for drugs or vaccines under patent when importing from or referencing countries with per capita incomes less than 50 percent of a national per capita income, subject to appropriate exceptions to this policy when products are subject to shortages or excessive prices;
12. DO require transparency of the costs of each clinical trial subsidized by a government agency;
13. DO require transparency of drug prices, revenues, and quantities of products sold, by country;
14. DO make patent landscapes for medical technologies transparent:
    a. Limit remedies for infringement when the patents on drugs, vaccines or other medical technologies are not constructively disclosed;
15. DO require exceptions to test exclusivity when duplicative testing violates ethical norms for testing regarding animals or human subjects, including a reference to the World Medical Association (WMA) Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects. In this regard, take note of the EU/CA Comprehensive Economic and Trade Agreement (CETA), Article 20.30, on the Protection of data related to plant protection products as one possible model for both animal and human subjects; and
16. DO require deep transparency and technology transfer for the manufacture of biologic drugs and vaccines and cell- and gene-therapies, to remedy inadequate competition for such products and services, and to reduce risks to patients when using biosimilar products.
17. DO require full transparency of all licenses to government-funded patented inventions.

18. DO require robust exceptions to copyright to protect free expression, and the use of works in education and commentary.

KEI's concern about norms for damages from infringement of intellectual property rights were addressed in some detail in our comments to the ITC regarding the USMCA agreement, and are included here as an Annex.

ANNEX: KEI comments on the Inconsistency of USMCA norms for damages for infringement of intellectual property to U.S. law

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

December 20, 2018

ANNEX: The USMCA standard for damages

The proposed USMCA agreement has a chapter on intellectual property, which includes norms for damages when intellectual property rights are infringed. The USMCA norms are not consistent with U.S. law. The differences are important for several different industries.

The USMCA definition for intellectual property is as follows:

> *Intellectual property refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II of the TRIPS Agreement;*

The WTO describes the areas of intellectual property the TRIPS Agreement covers as:

> Copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations); trademarks including service marks; geographical indications including appellations of origin; industrial designs; patents including the protection of new varieties of plants; the layout-designs of integrated circuits; and undisclosed information including trade secrets and test data.

The general norms for damages are paragraphs 3 and 4 of Article 20.81, on the “Enforcement Practices with Respect to Intellectual Property Rights.”

USMCA Article 20.81: Enforcement Practices with Respect to Intellectual Property Rights

3. Each Party shall provide{89} that, in civil judicial proceedings, its judicial authorities have the authority at least to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person’s intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

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

{89} A Party may also provide that the right holder may not be entitled to any of the remedies set out in paragraphs 3, 5, and 7 if there is a finding of non-use of a trademark. For greater certainty, there is no obligation for a Party to provide for the possibility of any of the remedies in paragraphs 3, 5, 6, and 7 to be ordered in parallel.

In its present form, the USMCA appears to define “any legitimate measure of value” for damages to include, “lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price.”

US statutes on damages for infringement

This provision is inconsistent with numerous U.S. statutes. Note that the current USMCA text provides an exception for non-use of trademarks, but not for the many other exceptions found in U.S. law. This limited exception can be read to be the only exception allowed.

Instead, what the USMCA uses as a standard are the damages norms that some right holders apparently wish were part of U.S. law, but clearly are not.

The following are several (but not all) provisions in various U.S. statutes regarding damages for infringement of intellectual property.

Note than none of the damages norms anticipate such aggressive measures as the suggested retail price being a legitimate measure of value, and several have very specific standards which are clearly inconsistent with the USMCA.

Patents

35 U.S.C.. § 284 § 284. Damages 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.
35 U.S.C.. § 287 § 287. Limitation on damages and other remedies; marking and notice [.....] (c)(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity. . . .
The Biologics Price Competition and Innovation Act of 2009 (BPCIA) 35 U.S.C. § 271(e)(6)(B) (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. On concerns about damages norms as regards this law, see the October 20, 2015 letter from Representative Anna Eshoo (here) to USTR, requesting clarifications regarding damages language in the TPP on the norm for the ACA/BPCIA.

28 U.S.C. § 1498

§ 1498. Patent and copyright cases

(a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . . .

. . .

Copyright

17 U.S.C. § 504

§ 504. Remedies for infringement: Damages and profits

(a) In General.--Except as otherwise provided by this title, an infringer of copyright is liable for either--

(1) the copyright owner's actual damages and any additional profits of the infringer, as provided by subsection (b); or

(2) statutory damages, as provided by subsection (c).

(b) Actual Damages and Profits.--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 owner is required to present proof only of the infringer's gross revenue, and the infringer is required to prove his or her deductible expenses and the elements of profit attributable to factors other than the copyrighted work.

(c) Statutory Damages.--

(1) Except as provided by clause (2) of this subsection, the copyright owner may elect, at any time before final judgment is rendered, to recover, instead of actual damages and profits, an award of statutory damages for all infringements involved in the action, with respect to any one work, for which any one infringer is liable individually, or for which any two or more infringers are liable jointly and severally, in a sum of not less than $750 or more than $30,000 as the court considers just. For the purposes of this subsection, all the parts of a compilation or derivative work constitute one work.

(2) In a case where the copyright owner sustains the burden of proving, and the court finds, that infringement was committed willfully, the court in its discretion may increase the award of

statutory damages to a sum of not more than $150,000. In a case where the infringer sustains the burden of proving, and the court finds, that such infringer was not aware and had no reason to believe that his or her acts constituted an infringement of copyright, the court in its discretion may reduce the award of statutory damages to a sum of not less than $200. The court shall remit statutory damages in any case where an infringer believed and had reasonable grounds for believing that his or her use of the copyrighted work was a fair use under section 107, if the infringer was: (i) an employee or agent of a nonprofit educational institution, library, or archives acting within the scope of his or her employment who, or such institution, library, or archives itself, which infringed by reproducing the work in copies or phonorecords; or (ii) a public broadcasting entity which or a person who, as a regular part of the nonprofit activities of a public broadcasting entity (as defined in section 118(f)) infringed by performing a published nondramatic literary work or by reproducing a transmission program embodying a performance of such a work.

. . .

(d) Additional damages in certain cases.--In any case in which the court finds that a defendant proprietor of an establishment who claims as a defense that its activities were exempt under section 110(5) did not have reasonable grounds to believe that its use of a copyrighted work was exempt under such section, the plaintiff shall be entitled to, in addition to any award of damages under this section, an additional award of two times the amount of the license fee that the proprietor of the establishment concerned should have paid the plaintiff for such use during the preceding period of up to 3 years.

28 U.S.C. § 1498

§ 1498. Patent and copyright cases

[...]

(b) Hereafter, whenever the copyright in any work protected under the copyright laws of the United States shall be infringed by the United States, by a corporation owned or controlled by the United States, or by a contractor, subcontractor, or any person, firm, or corporation acting for the Government and with the authorization or consent of the Government, the exclusive action which may be brought for such infringement shall be an action by the copyright owner against the United States in the Court of Federal Claims for the recovery of his reasonable and entire compensation as damages for such infringement, including the minimum statutory damages as set forth in section 504(c) of title 17, United States Code . . .

. . .

(e) Subsections (b) and (c) of this section apply to exclusive rights in mask works under chapter 9 of title 17, and to exclusive rights in designs under chapter 13 of title 17, to the same extent as such subsections apply to copyrights.

17 U.S.C. § 512

§ 512. Limitations on liability relating to material online

[....]

(b) System caching.--

(1) Limitation on liability.--A service provider shall not be liable for monetary relief, or, except as provided in subsection (j), for injunctive or other equitable relief, for infringement of copyright by reason of the intermediate and temporary storage of material on a system or network controlled or operated by or for the service provider in a case in which--

(A) the material is made available online by a person other than the service provider;

(B) the material is transmitted from the person described in subparagraph (A) through the system or network to a person other than the person described in subparagraph (A) at the direction of that other person; and

(C) the storage is carried out through an automatic technical process for the purpose of making the material available to users of the system or network who, after the material is transmitted as described in subparagraph (B), request access to the material from the person described in subparagraph (A),

[....]

44 U.S. Code § 2117 - Limitation on liability

When letters and other intellectual productions (exclusive of patented material, published works under copyright protection, and unpublished works for which copyright registration has been made) come into the custody or possession of the Archivist, the United States or its agents are not liable for infringement of copyright or analogous rights arising out of use of the materials for display, inspection, research, reproduction, or other purposes.

17 U.S.C.A. § 1009

§ 1009. Civil remedies

(d) Award of Damages.--

(1) Damages for section 1002 or 1003 violations.--

(A) Actual damages.--(i) In an action brought under subsection (a), if the court finds that a

violation of section 1002 or 1003 has occurred, the court shall award to the complaining party its actual damages if the complaining party elects such damages at any time before final judgment is entered.

(ii) In the case of section 1003, actual damages shall constitute the royalty payments that should have been paid under section 1004 and deposited under section 1005. In such a case, the court, in its discretion, may award an additional amount of not to exceed 50 percent of the actual damages.

(B) Statutory damages for section 1002 violations.--

(i) Device.--A complaining party may recover an award of statutory damages for each violation of section 1002(a) or (c) in the sum of not more than $2,500 per device involved in such violation or per device on which a service prohibited by section 1002(c)has been performed, as the court considers just.

(ii) Digital musical recording.--A complaining party may recover an award of statutory damages for each violation of section 1002(d) in the sum of not more than $25 per digital musical recording involved in such violation, as the court considers just.

(iii) Transmission.--A complaining party may recover an award of damages for each transmission or communication that violates section 1002(e) in the sum of not more than $10,000, as the court considers just.

Original Designs

17 U.S. Code Chapter 13 - PROTECTION OF ORIGINAL DESIGNS

17 U.S.C. § 1323

§ 1323. Recovery for infringement

(a) Damages.--Upon a finding for the claimant in an action for infringement under this chapter, the court shall award the claimant damages adequate to compensate for the infringement. In addition, the court may increase the damages to such amount, not exceeding $50,000 or $1 per copy, whichever is greater, as the court determines to be just. The damages awarded

shall constitute compensation and not a penalty. The court may receive expert testimony as an aid to the determination of damages.

(b) Infringer's profits.--As an alternative to the remedies provided in subsection (a), the court may award the claimant the infringer's profits resulting from the sale of the copies if the court finds that the infringer's sales are reasonably related to the use of the claimant's design. In such a case, the claimant shall be required to prove only the amount of the infringer's sales and the infringer shall be required to prove its expenses against such sales.

Trademarks

15 U.S. Code § 1114 - Remedies; infringement; innocent infringement by printers and publishers

[....]

(2)Notwithstanding any other provision of this chapter, the remedies given to the owner of a right infringed under this chapter or to a person bringing an action under section 1125(a) or (d) of this title shall be limited as follows:

(A) Where an infringer or violator is engaged solely in the business of printing the mark or violating matter for others and establishes that he or she was an innocent infringer or innocent violator, the owner of the right infringed or person bringing the action under section 1125(a) of this title shall be entitled as against such infringer or violator only to an injunction against future printing.

[....]

15 U.S. Code § 1114 - Remedies; infringement; innocent infringement by printers and publishers

[....]

(B) Where the infringement or violation complained of is contained in or is part of paid advertising matter in a newspaper, magazine, or other similar periodical or in an electronic communication as defined in section 2510(12) of title 18, the remedies of the owner of the right infringed or person bringing the action under section 1125(a) of this title as against the publisher or distributor of such newspaper, magazine, or other similar periodical or electronic communication shall be limited to an injunction against the presentation of such advertising matter in future issues of such newspapers, magazines, or other similar

periodicals or in future transmissions of such electronic communications. The limitations of this subparagraph shall apply only to innocent infringers and innocent violators.

[....]

Semiconductors

Protection of Semiconductor Chip Products

17 U.S.C. § 911(b)

§ 911. Civil actions

(b) Upon finding an infringer liable, to a person entitled under section 910(b)(1) to institute a civil action, for an infringement of any exclusive right under this chapter, the court shall award such person actual damages suffered by the person as a result of the infringement. The court shall also award such person the infringer's profits that are attributable to the infringement and are not taken into account in computing the award of actual damages. In establishing the infringer's profits, such person is required to present proof only of the infringer's gross revenue, and the infringer is required to prove his or her deductible expenses and the elements of profit attributable to factors other than the mask work.

17 U.S.C. § 907

§ 907. Limitation on exclusive rights: innocent infringement

(a) Notwithstanding any other provision of this chapter, 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 chip product that the innocent purchaser imports or distributes after having notice of protection with respect to the mask work embodied in the semiconductor chip product.

(b) The amount of the royalty referred to in subsection (a)(2) shall be determined by the court in a civil action for infringement unless the parties resolve the issue by voluntary negotiation, mediation, or binding arbitration.

(c) The immunity of an innocent purchaser from liability referred to in subsection (a)(1) and the limitation of remedies with respect to an innocent purchaser referred to in subsection (a)(2) shall extend to any person who directly or indirectly purchases an infringing semiconductor chip product from an innocent purchaser.

(d) The provisions of subsections (a), (b), and (c) apply only with respect to those units of an infringing semiconductor chip product that an innocent purchaser purchased before having notice of protection with respect to the mask work embodied in the semiconductor chip product.

Plant Variety Protection

7 U.S.C.
United States Code, 2010 Edition
Title 7 - AGRICULTURE
CHAPTER 57 - PLANT VARIETY PROTECTION

§2564. Damages
(a) Upon finding an infringement the court shall award damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the variety by the infringer, together with interest and costs as fixed by the court.

(b) When the damages are not determined by the jury, the court shall determine them. In either event the court may increase the damages up to three times the amount determined.

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

(d) As to infringement prior to, or resulting from a planting prior to, issuance of a certificate for the infringed variety, a court finding the infringer to have established innocent intentions, shall have discretion as to awarding damages.

(Pub. L. 91–577, title III, §124, Dec. 24, 1970, 84 Stat. 1556.)

Pharmaceutical and Agricultural Test Data

Since the TRIPS Agreement includes norms for protection of test data for drugs and agricultural chemicals, those norms on damages appear to apply here too, but it is not obvious how. In the U.S., there are no civil damages for infringement of test data.

Damages for Government Use

Compensation for non-voluntary use of patents by the federal government is determined by judicial authorities. One precedent, often quoted is Leesona (599 F.2d at 969).

> "Because recovery is based on eminent domain, the proper measure is 'what the owner has lost, not what the taker has gained"

Going Forward

Orphan works

The U.S. Copyright Office has proposed legislation to preserve and expand access to orphaned copyrighted works. The proposal is to have significant limitations on the damages for infringement of such works. This would be contrary to the USMCA language on damages.

See: Orphan Works and Mass Digitization, a report of the register of copyrights june 2015
https://www.copyright.gov/orphan/reports/orphan-works2015.pdf

Standards Essential Patents

Under President Obama, the Department of Justice and the Federal Trade Commission (FTC) proposed limitations on damages when patent holders participated in standards organizations and had made commitments to FRAND licensing. In the future, there may be proposals to extend this obligation to parties not part of the standards bodies. These norms can be implemented as norms for damages, since this would permit more liberal exports of products or services.

Limitations on Damages and New Liability Rules

The WTO TRIPS Agreement has considerable regulation of the use of compulsory licenses or exceptions for exclusive rights for patents, copyrights and other types of intellectual property.

The TRIPS Agreement permits limits on the remedies for infringement, and these limits provide an alternative mechanism for non-voluntary use of intellectual property rights.

The United States provides the largest set of such limitations on remedies. Our government uses exceptions that are fashioned as limitations on remedies in several cases. For example, the Biologics Price Competition and Innovation Act of 2009 (BPCIA) uses a sanction of

limitations on damages to induce the disclosure of patents on biologic drugs to biosimiliar competitors. Our government use statutes (28 USC § 1498) are designed as limitations on remedies. When a judge issues a “running royalty” on a patented invention, during an infringement case, U.S. manufacturers can export even 100 percent of output, going forward, without being constrained by the limits on exports in Article 31 of TRIPS. This greater flexibility for limitations on remedies (as opposed to exceptions or limitations to rights) is why the Copyright Office wanted to limit the remedies for infringement on orphaned copyrighted works.

The term “liability rule” is used to describe cases where non-voluntary uses of patents, copyrights or other knowledge goods are allowed, subject to payments to right holders, often implemented as limitations on damages.

The USMCA should not block efforts by the Congress to create new liability rules for intellectual property.

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