NAFTA Negotiations, intent to testify

June 14, 2017

Knowledge Ecology International requests the opportunity to testify on the negotiating objectives for the moderation of NAFTA, docket USTR-2017-0006.¹

Our testimony will address the following points:

- Any re-negotiation of NAFTA should not create a mandatory term for copyright.
 Copyright terms are already addressed in the Berne Convention, the WIPO Copyright
 Treaty (WCT), the WIPO Performances and Phonograms Treaty (WPPT), the Beijing
 Treaty on Audiovisual Performances, and the WTO TRIPS Agreement. The United
 States should retain as much flexibility as possible to reduce copyright terms for works
 out of print, no longer being commercialized, and where the authors and performers
 have alienated all rights.
- 2. Any re-negotiation of NAFTA should not give drug companies stronger monopoly protections for pharmaceutical drugs, vaccines or medical devices, or any other measure making it more difficult to address pricing abuses in the United States. The President promised to cut \$300 billion annual on U.S. drug costs², and USTR should not make that task harder than it already is. Note that high prices for drugs are among the most pressing public policy challenges today. Consider that some 15 years ago, a \$30,000 cancer drug was considered an expensive drug, for a rare disease. Today a new drug for a common disease, such as breast cancer, may have price five times as high, for a chronic rather than a curative treatment. Prices on the newest drugs for cancer are even more expensive. For example, Takeda Oncology's recent drug for lung cancer (the second most common type of cancer in the United States) was introduced at an annual cost of \$170,000.3 Prices for new treatments for HIV are so expensive patients4 have to threaten to litigate to obtain reimbursements for newer and more expensive drugs, such as combination treatments that include Gilead's expensive Tenofovir Alafenamide (TAF). Among the mechanisms that should be protected in the negotiations is the ability of governments and courts to permit third parties to use patents without permission of right

¹ The Register Notice is here. https://www.federalregister.gov/documents/2017/05/23/2017-10603/request-for-comments-on-negotiating-objectives-regarding-modernization-of-the-north-american-free

² For example, Donald Trump, remarks at Plymouth State University, Holderness, N.H., Feb. 7, 2016; Donald Trump, remarks in Manchester, N.H.; and Associated Press, Donald Trump says Medicare should negotiate drug prices, Published in Stat News on January 26, 2016. https://www.statnews.com/2016/01/26/trump-negotiate-drug-prices/

³ Robert Weisman, "Takeda's lung cancer drug OK'd for sale," *the Boston Globe*. April 28, 2017. https://www.bostonglobe.com/business/2017/04/28/takeda-lung-cancer-drug-for-sale/JjMMbUo9DYmw25 rHzCKKVJ/story.html

⁴ Including one of our board members.

- holders, a crucial mechanism to protect patients when there are pricing abuses that threaten access and create strains on household and reimbursement entity budgets.
- 3. Investor-state arbitrations should be eliminated. Investors in all three countries have and can continue to rely upon the national court systems to protect their interests. If a country has inadequate protections for investors, one consequence would be to drive investments to countries that have better protections, like the United States. If investor-state arbitration is included, it should only address a very narrow set of topics where there is a compelling reason for the mechanism. Investor-state arbitration definitely should not be used to regulate intellectual property rights regimes or drug prices, or to prevent states from protecting the environment, health, worker or consumer safety or other areas of public interest.
- 4. USTR should not adopt the TPP proposals negotiated under the previous President regarding remedies for infringement of patents, copyrights or other intellectual property rights. The TPP remedies provisions as they relate to damages and related costs are contrary to US law, including but not limited to (1) liability for non-voluntary use of patents and copyrights, (2) the limits on damages relating to biologic drug patents, and (3) proposals by the Library of Congress to limit the damages and other remedies for the infringement of orphaned copyrighted works.
- 5. Ensure that no provisions in NAFTA prevent our government from making software source code transparent, since transparency in some cases is needed to address concerns over spying and malicious code, such as for Internet routers and wifi devices⁵, cheating on regulatory standards such as those relating to fuel efficiency in automobiles⁶, auditing software algorithms that determine if prisoners deserve parole⁷, and to promote interoperability, including but not limited to medical records.⁸
- 6. Create a chapter on the supply of public goods. Require our trading partners to publish the results of taxpayer-funded research in at least as open a manner as is required by the NIH. Require our trading partners to implement the WIPO Marrakesh Treaty on copyright exceptions in a manner that facilitates access for persons with disabilities.

https://www.healthit.gov/providers-professionals/faqs/what-ehr-interoperability-and-why-it-important, accessed June 11, 2017; Patel, Aman et al. "Interoperability of Open Source Medical Record Systems: For AMIA 2003 Open Source Expo." AMIA Annual Symposium Proceedings 2003 (2003): 965.; Michael J. Doyle, Open Source Will Help Drive EHR Costs Down, Medsphere.

http://www.medsphere.com/resources/news/medsphere-in-the-news/3091-open-source-will-help-drive-ehr-costs-down, Accessed June 11, 2017.

⁵ Klint Finley. Trade Pact Could Bar Governments From Auditing Source Code. *Wired.* November 5, 2015. https://www.wired.com/2015/11/trade-pact-could-bar-governments-from-auditing-source-code/. ⁶ *Ibid.*

⁷ Rebecca Wexler. When a Computer Program Keeps You in Jail, *New York Times*. June 13, 2017 https://mobile.nytimes.com/2017/06/13/opinion/how-computers-are-harming-criminal-justice.html.

⁸ What is EHR Interoperability and why is it important?

Create pooled rights in patents funded by all three governments, with a mechanism for exercising public interest rights in the patents when appropriate.

- 7. Consider a chapter on the quality of life. It might be useful to explore an agreement on minimum quality of life issues, such as an ongoing mechanism to ensure that employers provide minimum maternity leave for fathers and mothers, mechanisms to save toward retirement, minimum standards for comfort for people flying in commercial airlines, including in particular, minimum width of seats and legroom. Some of these measures involving workers could be applied to certain sectors where goods and services are traded between borders, in order to avoid a race to the bottom in terms of worker quality of life. In the case of retirement plans, note that in some sectors, global competition has driven down both wages and benefits, including retirement plans, and this while the life expectancy of populations is growing. The dependency ratio, measuring the percentage of persons working compared to persons not in the labor force, is becoming less and less sustainable.
- 8. Any chapter on transparency should address activities by corporations to influence governments and professionals, outlays on R&D costs and revenues for new drugs and vaccines, scientific data from clinical trials, and other items of public interest.

⁹ For a discussion in the trend toward worse and worse seating on airlines, see: Scott McCartney "The Best and Worst Coach Seats on U.S. Airlines: The space between seats on planes has never been tighter, though some carriers are resisting taking more legroom away." *WSJ*, June 14, 2017. https://www.wsj.com/articles/the-best-and-worst-coach-seats-on-u-s-airlines-1497452020

¹⁰ See: William J. Wiatrowski, "Changing Landscape of Employment-based Retirement Benefits," Bureau

of Labor Statistics. Originally Posted: September 29, 2011

https://www.bls.gov/opub/mlr/cwc/changing-landscape-of-employment-based-retirement-benefits.pdf.

¹¹ See: Ana Maria Santacreu, "Long-Run Economic Effects of Changes in the Age Dependency Ratio, A decrease in the labor force and an increase in the elderly population could slow economic growth." *Economic Synopses*, 2016, NO. 17 (Posted 2016-09-02) Federal Reserve Bank of Saint Louis. https://research.stlouisfed.org/publications/economic-synopses/2016/09/02/long-run-economic-effects-of-changes-in-the-age-dependency-ratio/