

Knowledge Ecology International (KEI) Request to Testify at Hearing and Comments Regarding the 2017 Special 301 Review

February 9, 2017

Request to Testify

James Love, Director of Knowledge Ecology International (KEI), requests the opportunity to testify at the hearing on Special 301.

His contact information is:

James Love
Knowledge Ecology International
1621 Connecticut Ave NW Suite 500
Washington, DC 20009
Phone: +1 (202) 332-2670
Fax: +1 (202) 332-2673
Email: james.love@keionline.org

Our written comments and hearing statement follow:

Table of Contents

Introduction	2
About Knowledge Ecology International	3
The USPTO Studies on IP and Employment	3
The Role of Trademarks in Providingto Provide Misleading Data on IP-Intensive Industry Employment	4
Figure 1: USTPO/ESA estimate of employment in IP-Intensive industries, 2014	5
Table 1: Employment in Top 10 IP-Intensive Industries, ranked by number of jobs	5
Copyright-Intensive Industries	6
Table 2: Employment in Copyright Intensive Industries	6
Table 3: Components of NAICS Code 5419, Other Professional, Scientific, and Technical Services	7
Table 4: Components of NAICS Code 5111, Newspaper, periodical, book, and directory publishers	8
Motion Picture and Sound Recording Industries	9
Software publishers	9
Open Source Software	10

Foreign Ownership in Copyright Industries	11
The U.S. information technology sector is important	12
Table 5: Selected U.S. technology firms	12
Patent-Intensive Industries	12
Pharmaceuticals and Medicine	13
Copyright Term	13
Attacks on Copyright Exceptions	13
Hague Convention on the Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters	14
Patent Trolls Target US Businesses	15
Patents in China and the United States	15
Table 6: China, patent applications (Source: WIPO)	15
Table 7: China, patent grants (Source: WIPO)	16
Figure 2: China, Patent Applications	17
Figure 3: China, Patent Grants	17
Table 8: U.S., Patent Applications (Source: WIPO)	17
Table 9: U.S. Patent Grants (Source: WIPO)	18
Figure 4: U.S., Patent Applications	19
Figure 5: U.S., Patent Grants	19
The United States' Aging Population, the Price of Medicines, and Healthcare Costs	20
Trade Policies Concerning Pharmaceuticals and Medicine	20
Delinkage of R&D Costs from Product Prices	21
Parallel Trade	22
Transparency	23
Open Access and Other Public Goods	23
Concluding Comments	24

Introduction

This year's Special 301 hearing is the first for the new administration of President Donald Trump and provides an opportunity to review USTR policies on intellectual property rights, and, in particular, to reassert the interests of American citizens when it comes to global norms and practices.

In the past, the notion that the United States automatically benefited from greater and greater levels of protection for patents and copyrights was assumed, not as a consequence of any nuanced and useful analysis but by the force of rightsholders' lobbying. Our comments review some of the common talking points by rightsholders, and offer suggestions on how to refashion trade policy to enhance the welfare of the majority of U.S. citizens.

About Knowledge Ecology International

Knowledge Ecology International (KEI) is a non-profit non-governmental organization based in Washington, D.C., with an office in Geneva, Switzerland. Information about our activities are available on the KEI website at <http://keionline.org>.

The USPTO Studies on IP and Employment

U.S. industry groups and government officials use misleading employment statistics to justify intellectual property policies for patents, copyrights, and related rights that benefit rightsholders, particularly in the context of Special 301.

In 2012, the U.S. Patent and Trademark Office (USPTO) and the Economics and Statistics Administration (ESA) issued a report titled "[Intellectual Property and the U.S. Economy: Industries in Focus](#)," which claimed that "intellectual property (IP)-intensive industries support at least 40 million jobs and contribute more than \$5 trillion dollars to, or 34.8-percent of U.S. gross domestic product (GDP)," based upon 2010 employment data. A second study, titled "[Intellectual Property and the U.S. Economy: 2016 Update](#)," found that "IP-intensive industries continue to be an important and integral part of the U.S. economy and account for more jobs and a larger share of U.S. gross domestic product (GDP) in 2014 compared to what we observed for 2010."

Both studies have been quoted extensively by government officials and rightsholders' groups to justify policies that expand the scope, rights, and effective terms of patents, copyrights, and a host of *sui generis* rights that protect pharmaceutical products from competition from generic companies.¹ While seemingly designed to be used as advocacy tools and to promote

¹ For industry sources that cite the 2012 study, see, for example: Renee C. Quinn, "IP Contributes \$5 Trillion and 40 Million Jobs to US Economy," *IPWatchdog*, Apr. 11, 2012, <https://goo.gl/CRSC1b>; Patrick Kilbride, U.S. Chamber of Commerce's Global Intellectual Property Center Submission to the United Nations Secretary-General's High-Level Panel on Access to Medicines, Feb. 26, 2016, <https://goo.gl/ltQfPW>; National Association of Manufacturers, Submission to USTR 2016 Special 301 Review, Feb. 5, 2016, <https://goo.gl/TJ1eeM>; and PhRMA, Submission to USTR 2014 Special 301 Review, <https://goo.gl/F1NENE>. For industry sources that cite the 2016 study, see, for example: National Association of Manufacturers, Submission to USTR 2017 National Trade Estimate Report on Foreign Trade Barriers, Oct. 27, 2016, <https://goo.gl/S1fRe0>; American Intellectual Property Law Association, Letter to President-Elect Donald J. Trump Re: Recommendations on Intellectual Property Priorities for the Trump Administration, Jan. 4, 2017, <https://goo.gl/uAuM2U>; and Copyright Alliance, "Here's how much copyright contributes to the US economy," *Medium*, Sept. 30, 2016, <https://goo.gl/qF613A>.

rightsholders' interests, the data sometimes misses or makes the opposite point, if people take the time to examine the employment numbers.

Here are some of the issues:

The Role of Trademarks to Provide Misleading Data on IP-Intensive Industry Employment

Even though the policies rightsholders promote largely concern copyrights and patents, the number of jobs described as IP-intensive mostly concern trademarks, and industries with almost no stake in Special 301 proceedings.

Figure 1 (see below) of the 2016 USPTO and ESA study reports an estimate of 27.877 million as the total number of jobs in "IP-intensive" industries, based upon data collected on 2013 employment.

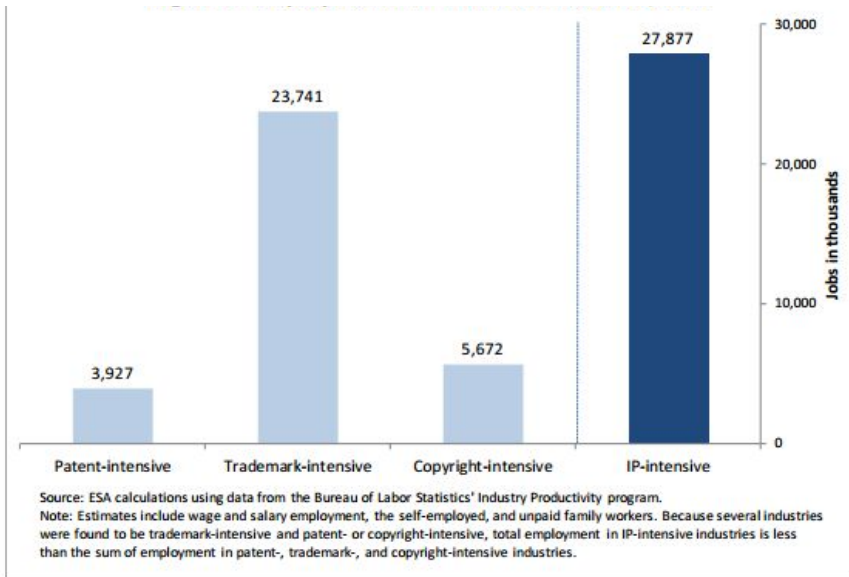
Rightsholders for both patent and copyright industries frequently refer to 27.9 million jobs, but this number misleading.

Most of the jobs, 23.741 million, or 85-percent of the "IP-intensive" total, are in industries that USPTO and ESA consider to be trademark-intensive.

Many of those industries comprise retail sales and fashion. The USPTO estimated that the copyright-intensive industries had 5.672 million jobs, or 20-percent of the IP-intensive total.

For the patent-intensive industries, the number of jobs was 3.927 million, or 14-percent of the IP-intensive total.

Figure 1: USTPO/ESA estimate of employment in IP-Intensive industries, 2014



The USPTO study designated 81 four digit NAICS Code industries as IP-intensive. The sector with the largest number of jobs was “grocery stores” (NAICS code 4451). **Table 1** lists the top 10 IP-intensive industry sectors, which account for 47-percent of all of jobs in the IP-intensive industries. They include industries such as management consulting, insurance carriers, department stores, residential building construction, lessors of real estate, outpatient care centers, and in addition to grocery stores, grocery products. None of the top 10 IP-intensive industry sectors are from patent-intensive industries.

We do not doubt that grocery stores, department stores, and lessors of real estate value and benefit from trademark protection — nearly all industries do. However, there is almost nothing covered in the Special 301 process that concerns most of these industries.

Table 1: Employment in Top 10 IP-Intensive Industries, ranked by number of jobs

NAICS Code	Industry title	Employment in 2013 (1000 jobs)	Patent	Trademark	Copyright
4451	Grocery stores	2600.0		X	
5415	Computer systems design and related services	1848.4			X
5416	Management and technical consulting services	1443.0		X	
5241	Insurance carriers	1433.9		X	
4521	Department stores	1348.3		X	
2361	Residential building construction	975.0		X	

5311	Lessors of real estate	883.7		X	
5419	Other professional and technical services	790.6		X	X
4244	Grocery and related products	725.5		X	
6214	Outpatient care centers	719.4		X	

Copyright-Intensive Industries

The USPTO has designated 12 industry sectors as copyright-intensive, and **Table 2** ranks those sectors by the number of jobs reported in 2013.

Table 2: Employment in Copyright Intensive Industries

NAICS Code	Industry title	Employment in 2013 (1000 jobs)	Patent	Trademark	Copyright
5415	Computer systems design and related services	1848.4			X
5419	Other professional and technical services	790.6		X	X
5418	Advertising and related services	503.9		X	X
5111	Newspaper, periodical, book, and directory publishers	464.0		X	X
5121	Motion picture and video industries	413.9		X	X
7115	Independent artists, writers, and performers	338.6			X
5112	Software publishers	300.6		X	X
5414	Specialized design services	265.6			X
5151	Radio and television broadcasting	223.6		X	X
5191	Other information services	201.3		X	X
7111	Performing arts companies	138.6			X
5152	Cable and other subscription programming	71.3		X	X
5122	Sound recording Industries	23.5			X

Note that while copyright is relevant to each of these sectors, many of the jobs have nothing to do with publishing, and in some cases, the interests of employers diverge from the interests of rightsholders.

The largest industry sector in Table 2, by far, is NAICS Code 5415, “Computer systems design and related services,” with 1.848 million jobs. Most of these jobs are in service, support, and customization of software and systems, where open interfaces, the ability to modify, and the use of free software are often important. Issues like the term of copyright in software are largely

irrelevant, given the relatively short usable life of software code, which is regularly updated or replaced as technologies change.

The second largest industry sector is NAICS Code 5419, “Other Professional, Scientific, and Technical Services,” which USPTO reported had 790.6 thousand jobs in 2013. This appears to overstate employment, since the U.S. Census estimated employment in that industry sector at 590.8 thousand jobs in 2014. This is where those jobs are:

Table 3: Components of NAICS Code 5419, Other Professional, Scientific, and Technical Services

NAICS Code	Industry title	Employment in 2014
5419	Other professional and technical services	590,759
541910	Marketing Research and Public Opinion Polling	101,909
541921	Photography Studios, Portrait	44,571
541922	Commercial Photography	10,856
541930	Translation and Interpretation Services	27,884
541940	Veterinary Services	323,197
541990	All Other Professional, Scientific, and Technical Services	82,342

Note that more than half of the jobs in NAICS Code 5419 are in veterinary services, about as far away from publishing as one can imagine.

The U.S. Census gives these illustrative examples of jobs in the “All other professional, scientific, and technical services” sector (NAICS 541990):

- Appraisal (except real estate) services
- Marine surveyor (i.e., appraiser) services
- Arbitration and conciliation services (except by lawyer, attorney, or paralegal offices)
- Patent broker services (i.e., patent marketing services)
- Commodity inspector services
- Pipeline or power line inspection (i.e., visual) services
- Consumer credit counseling services
- Weather forecasting services
- Handwriting analysis services

The closest elements of NAICS 5419 to copyright-intensive are the two photographic sectors, which collectively employ 55.4 thousand, only 10.8 thousand of which are in commercial photography. If you include all 55.4 thousand persons working in portrait studies and commercial photography, you only reach 7-percent of the jobs in NAICS 5419 that USPTO claims are copyright-intensive.

It is important to take a critical look at what the USPTO is doing: it is using jobs in the veterinary sector, consumer credit counseling services, weather forecasting, and public opinion marketing to inflate jobs numbers for sectors that are supposed to depend on copyright protection.

The third largest copyright intensive industry is “Advertising and related services.” While it is true that advertisements are protected by copyright, the whole point of most advertising is to be seen. Companies pay to have advertisements seen.

The fourth largest sector of the copyright intensive industries is NAICS Code 5111, “Newspaper, periodical, book, and directory publishers.” Again, the U.S. Census numbers for employment in 2014 for this sector are somewhat lower than reported by USPTO. This is the breakdown in jobs for this sector:

Table 4: Components of NAICS Code 5111, Newspaper, periodical, book, and directory publishers

NAICS Code	Industry title	Employment in 2014
5111	Newspaper, Periodical, Book, and Directory Publishers	431,427
511110	Newspaper Publishers	209,464
511120	Periodical Publishers	110,036
511130	Book Publishers	65,189
511140	Directory and Mailing List Publishers	24,794
511191	Greeting Card Publishers	15,687
511199	All Other Publishers	6,257

Within NAICS Code 5111, nearly half of the jobs are in the newspaper sector, an area where copyright is relevant, but copyright terms are not, given the perishable nature of news. The newspaper sector also depends to a large extent upon the mandatory exceptions in the Berne Convention for quotations and news of the day, because much of what is reported is borrowed and copied from other news reports.

Book publishers are the most dependent upon copyright protection, and they have about 15-percent of the jobs in NAICS Code 5111. Very little of the revenue in the book publishing sector comes from very old titles.² Moreover, copyright terms greater than life plus 50 are actually a negative for some book publishers because with shorter copyright terms they can use and repurpose older works, including photographs, letters, etc., without clearing rights from copyright owners, many of whom cannot be identified.³

² For a discussion of the declining value of older copyrighted works, see: Landes, W. and R. Posner, *The Economic Structure of Intellectual Property Law*, Belknap Press, Cambridge, US, 2003.

³ *Orphan Works and Mass Digitization: a Report of the Register of Copyrights*. June 2015.

Motion Picture and Sound Recording Industries

The fifth largest sector for the copyright-intensive industries is NAICS Code 5121, “Motion picture and video industries.” According to the U.S. Census, there were 377,987 jobs in this sector in 2014, down slightly from the USPTO estimates. Of these jobs, 133,555 were in “Motion Picture and Video Exhibition” (including theaters and drive-ins), which includes such jobs as selling popcorn and candy. The payroll per employee was just under \$12,000 per year for these jobs.

Related to the motion picture industry is the sound recording industry, which is much smaller — the U.S. Census estimates just 25.5 thousand jobs, or less than 0.4-percent of the jobs USPTO assigns to the copyright-intensive sector.

The motion picture industry is economically significant, and culturally important, and both the motion picture and the sound recording industries have legitimate interests in fighting piracy of films and recorded music. That said, collectively, their share of jobs in the so called copyright-intensive sector is small, and their legitimate concerns extend only to piracy, and not the terms of protection or exceptions to copyright in areas such as quotations, news of the day, public affairs, or education.

For both the motion picture and the sound recording industries, the ability to provide legal offers for works streamed over the Internet, via services such as Netflix, Amazon, Hulu, HBO GO, Showtime Anytime, Spotify, and Pandora, have greatly reduced the threats of piracy. The challenges to expanding these efforts are largely related to the complexity and high translation costs associated with licensing content across borders. There are also important concerns amongst performers and authors that the distribution of revenues from streaming is unfair, and that the new publishing platforms are highly concentrated, creating the risk of anticompetitive actions.

Software publishers

The next largest copyright intensive industry is NAICS Code 5112, software publishers, with 442,246 jobs in 2014 and an average payroll expense of \$146,600 per employee, 3.5 times greater than the average payroll expense for the motion picture and sound recording industries.

The software publishing industry, which includes a variety of products ranging from office productivity, tax preparation, bookkeeping, and computer games, plays an important role in increasing productivity, conducting commerce, expanding access to knowledge and having fun, and historically has faced considerable challenges regarding piracy. None of these challenges have been related to the term of copyright protection, as each version of software rapidly becomes less useful and secure over time, and often is virtually unuseable without access to updates.

Increasingly, publishers are shifting from ownership to service models, including in particular cloud-based services.

Copyright exceptions are often necessary to promote interoperability of products, and to protect users and their data from lock-in by publishers.

As important as the software publishing industry is, one should not overstate its importance, even in the area of software and computers. For example, the Bureau of Labor Statistics (BLS) publishes data on the employment by occupation.

The BLS Standard Occupational Classification (SOC) code 15-1131 is for Computer Programmers. In that occupation, there were 289,420 jobs in May 2015. Of these, just 21,260, or 7-percent, were working for software publishers.⁴ Similarly, for SOC code 15-1133, software developers, systems software, there were 390,750 jobs, but only 23,000, or 6-percent, were working for software publishers.⁵

Open Source Software

Much of the work for computer programmers and software developers is in creating and maintaining software and services for businesses, including applications that rely upon various open source software platforms and tools.

O'Reilly Media publishes an annual "Data Science Salary Survey." The 2016 edition singles out proficiency in Python and Spark as "among the tools that contribute most to salary."⁶ Both are open source. The 2016 Dice Tech Salary Survey found proficiency in these open source tools among the highest paid: Cassandra, Chef, CloudStack, Docker, Hadoop, HIVE, MapReduce, Netezza, NoSQL, OpenStack, PIG, Puppet, R, Scoop, TcL.⁷

On the server side, Linux, which is free and open software, is the dominant operating system. February 8, 2017, W3Tech estimated that 66.5-percent of all servers on the public internet were running Linux or some other type of Unix software, as compared to 33.5-percent for Windows.⁸ W3Tech estimated that Apache (50.6-percent) and Ngix (32.4-percent), both open source, were used to run 83-percent of all web pages,⁹ and that the open source PHP scripting language is used by 82.5-percent of all websites.¹⁰

Many new start-up technology firms rely extensively upon open source software to create and maintain new applications and services.

⁴ <https://www.bls.gov/oes/current/oes151131.htm>

⁵ <https://www.bls.gov/oes/current/oes151133.htm>

⁶ <https://www.oreilly.com/ideas/2016-data-science-salary-survey-results>

⁷ http://marketing.dice.com/pdf/Dice_TechSalarySurvey_2016.pdf

⁸ https://w3techs.com/technologies/overview/operating_system/all

⁹ https://w3techs.com/technologies/overview/web_server/all

¹⁰ https://w3techs.com/technologies/overview/programming_language/all

Foreign Ownership in Copyright Industries

In 2013, Jonathan Band and Jonathan Gerafi published a paper on “Foreign Ownership Of Firms in IP-Intensive Industries.”¹¹ Among their findings are the following points:

- Four of the “Big Six” publishers, the largest English language trade publishers, are foreign-owned. More than 80-percent of the global revenue of the Big Six is generated by these foreign-owned companies. These foreign-owned companies publish more than two thirds of the trade books in the U.S.
- Four of the five largest STM (science, technical and medical)/Professional publishers are foreign-owned. More than 90-percent of the revenue of the five largest STM/Professional publishers was generated by foreign-owned firms.
- Only seven of the world’s 50 largest publishers of all categories are U.S.-owned.
- The book publishing industry in Europe has approximately twice as many employees as in the United States.
- Two of the three major record labels are foreign-owned. These two labels have a market share of 59-percent.
- Thirteen of the twenty best-selling recording artists are foreign.
- Of the 50 most popular motion pictures in the United States in 2012, 50-percent were filmed partly or entirely outside of the United States.
- In 2013, the Oscar winners in 13 of 24 categories were foreign.
- In 2012, the Oscar winners in 11 of 24 categories were foreign.
- 70-percent of the most recent generation of game consoles were manufactured by Japanese companies. Japanese companies have manufactured 92-percent of all game consoles ever sold.

¹¹ Band, Jonathan and Gerafi, Jonathan, Foreign Ownership of Firms in IP Intensive Industries (March 13, 2013). Available at SSRN: <https://ssrn.com/abstract=2333839> or <http://dx.doi.org/10.2139/ssrn.2333839>

The U.S. information technology sector is important

The U.S. technology sector is important economically, and valuable largely because it facilitates *access to information*. **Table 5** provides the market capitalization for twelve selected U.S. technology firms, as of February 8, 2017, with a market capitalization of \$3.3 trillion.

Table 5: Selected U.S. technology firms

Firm	Market Cap, Feb 8, 2017 (billions of USD)
Apple	\$697.65
Alphabet	\$572.64
Microsoft	\$490.39
Facebook	\$386.81
AT&T	\$253.69
Verizon	\$197.41
Intel	\$172.98
IBM	\$170.02
Oracle	\$164.30
Cisco	\$157.92
Linkedin	\$26.65
Red Hat	\$14.09
Twitter	\$13.58
Total	\$3,318.13

Many of these companies have lobbied against restrictive copyright provisions in trade agreements, and several have lobbied Congress to increase the standards for granting patents (to make it more difficult to get a patent).

Patent-Intensive Industries

The USPTO study identifies 25 industry sectors as “patent-intensive.” The 25 industry sectors employ 3.9 million persons.

Pharmaceuticals and Medicine

Pharmaceuticals and medicine (NAICS Code 3254) rank 5th in the patent-intensive sectors, and account for 276.7 thousand jobs, less than 7-percent of the patent-intensive industry jobs, and 1-percent of all IP-intensive jobs.

Copyright Term

USTR has pressured foreign governments to extend copyright terms beyond the years required by the Berne Convention or the WTO TRIPS Agreement. There is no cogent argument for doing this. Longer copyright terms create devastating barriers to access to older copyrighted works, for the vast majority of which it is difficult, if not impossible, to identify the owners. Some book publishers prefer shorter copyright terms and better access to older out of commerce works, and many publishers of all types support legislative efforts to expand access to Orphan Works. One of the proposed legislative approaches to expand access to Orphan Works are limitations on the remedies to infringement, a mechanism that does not conflict with the 3-step test in copyright. Another helpful approach is to introduce formalities for certain types of works. All of these measures are impacted negatively by the IP chapter in the TPP.

Performers and producers of new works would not have to clear rights and pay authors to use works in the public domain. Documentary film makers would not face so many challenges if copyright terms were shorter. The primary beneficiary of copyright terms longer than life plus 50 years are a handful of rent seeking estates and corporate investors, not the working authors, editors, producers, directors, or performers.

Attacks on Copyright Exceptions

Several states in the European Union are currently seeking to undermine the exceptions to copyright mandated in the Berne Convention and by the WTO for quotations (Berne Article 10.1) and news of the day (Berne Article 2.8). These policies are efforts by EU members to indirectly tax certain U.S. technology firms that have an enormous global presence. KEI's position is that governments need to do a better job of taxing global corporations, curbing anticompetitive practices, promoting interoperability, and reducing consumer lock-in to services, but that efforts to impose fees on the use of hypertext links, snippets, or quotations are a dangerous threat to the growth of the Internet and to access to knowledge. USTR should consider bringing a case against the European Union in the WTO for imposing trade restricting neighboring rights that undermine the Berne Convention mandatory exceptions for quotations and news of the day.

Hague Convention on the Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters

In June 2016, the Hague Conference on Private International Law (“The Hague Conference”), an international organization in the Netherlands, published a Preliminary Draft Convention that contains general and specific provisions that would apply to the recognition and enforcement of judgments arising from transnational intellectual property disputes.

The United States Patent and Trademark Office (USPTO) held a public meeting on this convention, days before the inauguration. On February 16-24, 2017, negotiations on this proposed treaty will take place in the Hague.

The draft treaty is here:

<https://assets.hcch.net/docs/42a96b27-11fa-49f9-8e48-a82245aff1a6.pdf>

One purpose of this convention is to enable patent and copyright holders to enforce foreign judgements.

Article 5 of the draft convention says that:

A judgment is eligible for recognition and enforcement if one of the following requirements is met –

. . .

k) the judgment ruled on an infringement of a patent, trademark, design, [plant breeders’ right,] or other similar right required to be [deposited or] registered and it was given by a court in the State in which the [deposit or] registration of the right concerned has taken place, or is deemed to have taken place under the terms of an international or regional instrument;

l) the judgment ruled on the validity, [ownership, subsistence] or infringement of copyright or related rights [or other intellectual property rights not required to be [deposited or] registered] and the right arose under the law of the State of origin;

Under the Convention, the United States would have new obligations to enforce foreign judgements against U.S. residents. Given the very significant differences in international laws regarding copyright, patents, and trademarks, not to mention various *sui generis rights*, this creates risks for U.S. residents and businesses.

In general, this Convention, as was the case with the Convention of 30 June 2005 on Choice of Court Agreements (which the U.S. signed but did not ratify), is designed to promote European Union legal norms on the cross border enforcement of judgements. In KEI’s view, these types of

instruments are problematic when treaty members' countries have very significantly different legal norms and standards.

We suggest that USTR work with other federal agencies and a wide range of stakeholders to do a full risk assessment of such an instrument.

Patent Trolls Target US Businesses

In the debates before the US Congress on patent reform, the companies seeking to curb litigation from non-practicing entities (NPEs) and to make it easier to reject questionable patents include many of the best known companies in the United States. For example, the lobbying group "United for Patent Reform" has 188 company and trade association members (<http://www.unitedforpatentreform.com/members>), including companies that themselves are major holders of patents. This further illustrates the complex and nuanced interests that U.S. businesses have when it comes to patents.

Patents in China and the United States

The assumption that more patents with stronger rights favors U.S. economic interests needs to be reassessed, particularly in light of the evidence that other countries, including most importantly China, have dramatically increased the use of patents to block market entry by U.S. companies and to use patents to require royalty payments.

The following are time-series data from WIPO regarding patent applications and patent grants in the United States and in China, from 2001 to 2015.

Since 2010, China has ranked first in resident patent applications, and in 2015, China was ranked first in resident patent grants. The ratio of resident to non-resident patent application in China was 0.9 in 2001. In 2015, the ratio of resident to non-resident patent applications was 7.2, a dramatic and consequential change in a short amount of time.

In **Table 9**, note that since 2008, the USPTO has granted more patents to non-residents than residents.

Table 6: China, patent applications (Source: WIPO)

Year	Resident	Rank	Non- Resident	Rank	Abroad	Rank
2001	30,038	5	33,412	5	1,194	20
2002	39,806	5	40,426	4	1,612	19
2003	56,769	5	48,548	4	1,988	19
2004	65,786	5	64,598	2	3,231	18
2005	93,485	4	79,842	2	4,463	17

2006	122,318	4	88,183	2	6,972	16
2007	153,060	3	92,101	2	8,248	16
2008	194,579	3	95,259	2	9,689	13
2009	229,096	2	85,508	2	12,338	12
2010	293,066	1	98,111	2	15,260	11
2011	415,829	1	110,583	2	20,341	9
2012	535,313	1	117,464	2	26,095	8
2013	704,936	1	120,200	2	29,160	8
2014	801,135	1	127,042	2	36,682	6
2015	968,252	1	133,612	2	42,154	6

Table 7: China, patent grants (Source: WIPO)

Year	Resident	Rank	Non-Resident	Rank	Abroad	Rank
2001	5,395	8	10,901	6	327	25
2002	5,868	8	15,389	3	480	21
2003	11,404	7	25,750	3	580	23
2004	18,241	6	31,119	2	726	22
2005	20,705	5	32,600	2	870	22
2006	25,077	5	32,709	2	1,279	20
2007	31,945	4	36,003	2	1,557	19
2008	46,590	4	47,116	2	2,329	18
2009	65,391	3	62,998	2	3,110	15
2010	79,767	3	55,343	2	5,047	13
2011	112,347	2	59,766	2	5,783	12
2012	143,808	2	73,297	2	8,289	12
2013	143,535	2	64,153	2	10,965	9
2014	162,680	2	70,548	2	13,702	8
2015	263,436	1	95,880	2	16,065	8

Figure 2: China, Patent Applications

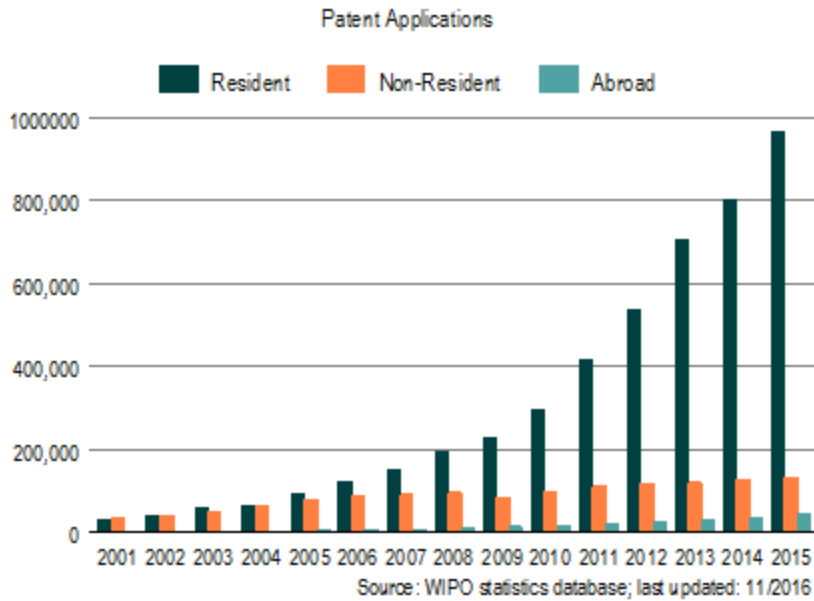


Figure 3: China, Patent Grants

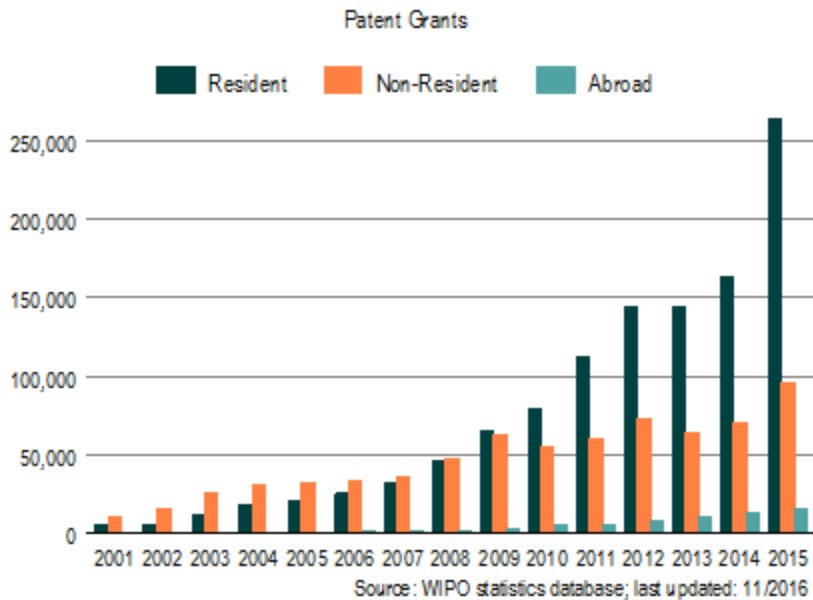


Table 8: U.S., Patent Applications (Source: WIPO)

Year	Resident	Rank	Non-Resident	Rank	Abroad	Rank
------	----------	------	--------------	------	--------	------

2001	177,513	2	148,958	1	113,256	2
2002	184,245	2	150,200	1	107,561	2
2003	188,941	2	153,500	1	112,796	2
2004	189,536	2	167,407	1	141,319	2
2005	207,867	2	182,866	1	175,375	1
2006	221,784	2	204,182	1	182,476	1
2007	241,347	2	214,807	1	196,006	1
2008	231,588	2	224,733	1	197,293	1
2009	224,912	3	231,194	1	173,007	1
2010	241,977	3	248,249	1	191,222	1
2011	247,750	3	255,832	1	192,882	1
2012	268,782	3	274,033	1	204,707	1
2013	287,831	2	283,781	1	213,331	1
2014	285,096	2	293,706	1	224,425	1
2015	288,335	2	301,075	1	237,961	1

Table 9: U.S. Patent Grants (Source: WIPO)

Year	Resident	Rank	Non-Resident	Rank	Abroad	Rank
2001	87,606	2	78,432	1	51,983	2
2002	86,976	2	76,542	1	56,873	2
2003	87,901	2	81,134	1	64,212	2
2004	84,271	2	80,020	1	63,360	2
2005	74,637	2	69,169	1	64,848	2
2006	89,823	2	83,947	1	69,073	2
2007	79,527	3	77,756	1	70,605	2
2008	77,501	2	80,271	1	72,482	2
2009	82,382	2	84,967	1	75,613	2
2010	107,792	2	111,822	1	83,050	2
2011	108,626	3	115,879	1	93,431	2
2012	121,026	3	132,129	1	108,090	2
2013	133,593	3	144,242	1	111,831	2
2014	144,621	3	156,057	1	111,313	2
2015	140,969	3	157,438	1	114,843	2

Figure 4: U.S., Patent Applications

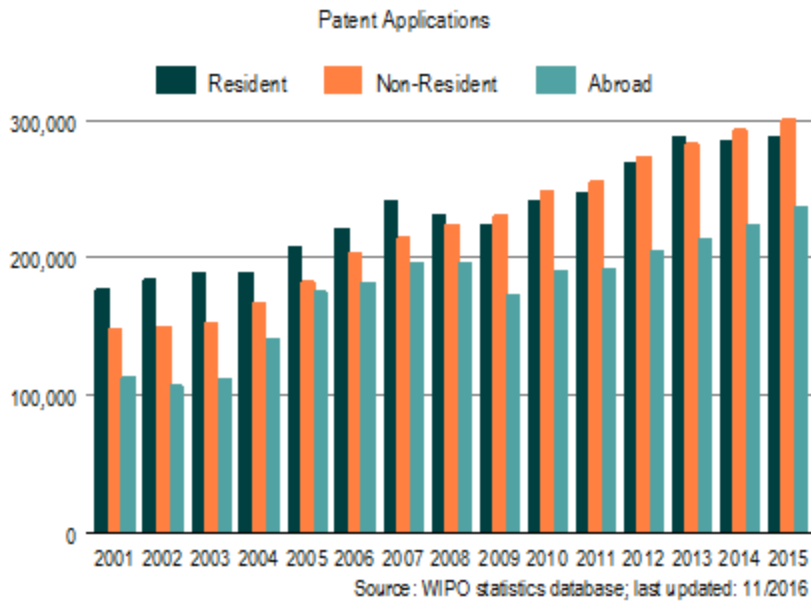
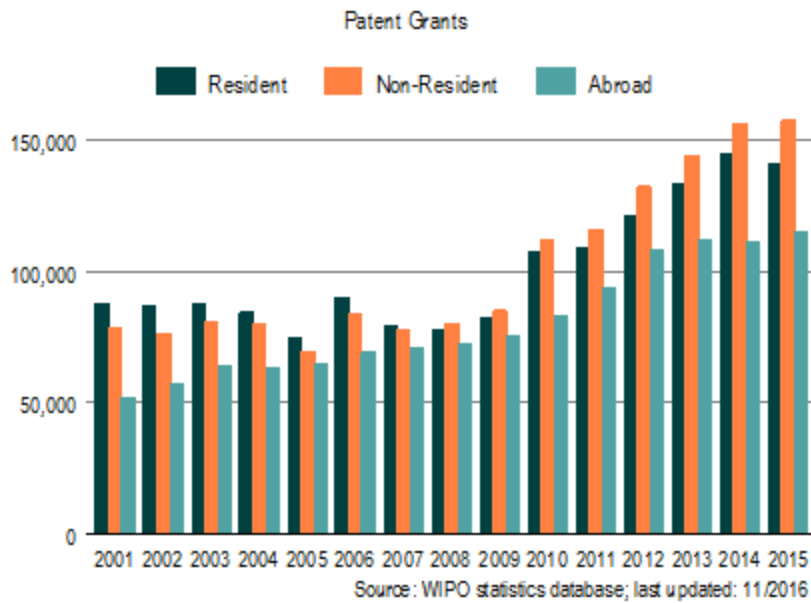


Figure 5: U.S., Patent Grants



The United States' Aging Population, the Price of Medicines, and Healthcare Costs

KEI is concerned about the prices of medicines in the United States. We do not believe the United States can have universal access to new medicines unless measures are taken to limit the legal monopoly protections for new drugs, vaccines, and diagnostic tests.

For diseases such as cancer, the challenges of providing access to affordable medicines will get worse as the U.S. population ages. In a June 20, 2016 blog titled, "Why Does Cancer Risk Increase As We Get Older?"¹² The Dana Farber Institute wrote:

Age is the biggest single risk factor for cancer. Risk increases significantly after age 50, and half of all cancers occur at age 66 and above. According to the National Cancer Institute, one quarter of new cancer diagnoses are in people aged 65 to 74.

As a nation, we are getting older, in terms of our average ages. According to the United States Administration on Aging (AoA):

The older population—persons 65 years or older—numbered 46.2 million in 2014 (the latest year for which data is available). They represented 14.5% of the U.S. population, about one in every seven Americans. By 2060, there will be about 98 million older persons, more than twice their number in 2014. People 65+ represented 14.5% of the population in the year 2014 but are expected to grow to be 21.7% of the population by 2040.

Over time, the United States will have workers entering the labor force later, and living longer after retirement. The ratio of dependency will grow. Unless the United States can curb higher drug prices, the costs of health care will be a growing burden on businesses and wage earners, and/or we will have less and less equal access to new drugs and vaccines.

Trade Policies Concerning Pharmaceuticals and Medicine

Most of the patent-related trade disputes that USTR focuses on concern medical patents, and in particular patents on drugs and *sui generis* rights in test data.

In order to expand, extend, and amplify the intellectual property rights for drug companies, the United States has to give its trading partners something they want. Typically, USTR trades away jobs in non-pharmaceutical industry sectors for policies that raise drug prices in foreign countries. This is good for the owners of the drug companies, but is this good for the United States? Policies at USTR are generally lobbyist driven. No one in the government has seriously

¹² <http://blog.dana-farber.org/insight/2016/06/why-does-cancer-risk-increase-as-we-get-older/>

tried to evaluate this basic and consequential question, despite the considerable effort, political capital, and priority USTR gives to promoting the interests of drug companies.

A significant number of the jobs in the pharmaceutical sector are in sales and marketing, by persons who seek to influence prescribing decisions by doctors. Some of the drug detailing work is valuable education for physicians, but much of the marketing efforts have little if any positive social value.

The pharmaceutical industry does have jobs that are engaged in the research and development of new drugs, although these jobs are distributed around the world, and there is little transparency of the distribution of jobs in the U.S. and in non-U.S. locations.

Much of the employment in the United States in biomedical research and development is due to the considerable public investments by the NIH, the CDC, the U.S. Department of Defense, and other federal agencies.

In addition to the massive public sector funding for biomedical R&D, the United States provides a number of subsidies and incentives that no other country offers for drug development, including, for example, the U.S. Orphan Drug Tax Credit, which provides a subsidy of 50-percent for qualifying clinical trial costs. A large majority of new cancer drugs benefit from Orphan Drug Act programs, including the tax credits.

Rather than press countries to increase drug prices, a policy that would only increase access barriers in foreign countries,¹³ our trading partners could be pressed to match our direct funding and subsidies research and development. An “R&D+” policy (as opposed to TRIPS+) would lower the net costs of drug development, and would be consistent with the objective of progressively delinking R&D costs from drug prices.¹⁴

Delinkage of R&D Costs from Product Prices

There is considerable interest in new approaches to financing drug development that eliminate the negative impact of high drug prices on access, while preserving robust incentives and other financing for R&D.

In 2016, KEI authored or co-authored four submissions to the UN Secretary-General’s High-Level Panel on Access to Medicines that addressed the mechanics and benefits of delinkage and the transparency of pharmaceutical markets. They are available here:

<http://keionline.org/node/2431>

¹³ See: *Ann Oncol.* 2016;27(8):1423-1443. doi:10.1093/annonc/mdw213.

¹⁴ See: *The Role of R&D Subsidies for Clinical Trials in Progressive Delinkage of R&D Costs from Product Prices.* <http://keionline.org/sites/default/files/Subsidize-trials-UN-HLP-A2M-28Feb2016-final.pdf>.

1. "The Need for Global Negotiations on Agreements to Fund R&D within the Context of a Progressive De-linking of R&D Costs from Product Prices". Supported by 12 organizations; 1 individual; 3 Members of European Parliament.
2. "Increasing the Transparency of Markets for Drugs, Vaccines, Diagnostics and other Medical Technologies". Supported by 17 organizations; 2 individuals; 3 Members of European Parliament.
3. "The Role of R&D Subsidies for Clinical Trials in Progressive Delinkage of R&D Costs from Product Prices"
4. "Trade Agreements and the Supply of Public Goods"

KEI is among those disappointed by the attacks on the High-Level Panel by the Obama Administration, and we urge the Trump Administration to look at these issues with an open mind, considering the sobering alternatives facing U.S. taxpayers, employers, and consumers in paying for new drugs. There is no reason to treat the current business model for drug development as sacred because it is (1) insanely expensive and (2) based upon policy-induced and logically unnecessary rationing of access, two big flaws.

To this end, the World Health Assembly in May will consider a proposal by India, supported by Brazil, to progressively delink R&D costs from the prices of cancer drugs:¹⁵

(OP2.5ter) [to conduct a [preliminary] (Brazil) feasibility study of creating a multi-country push and pull fund for cancer R&D, as an alternative to incentives-based intellectual property rights and/or regulatory monopolies and to progressively delink cancer R&D costs from product prices;]India

USTR should engage in this delinkage discussion and provide constructive suggestions regarding the trade related issues (of which there are many) that policy makers should consider when evaluating delinkage proposals.

Parallel Trade

One of the areas where KEI's views are aligned with drug companies and publishers concerns certain cases of parallel trade. For certain copyrighted works, such as those involving entertainment (including computer games) or textbooks, and for certain patented goods, including most importantly medicine, when the development is financed through the product prices (as opposed to more forward looking delinkage models), parallel trade should not be allowed from lower income countries to higher income countries. USTR should explore the benefits of norms or agreements that would allow parallel trade in certain socially important goods (like medicines and textbooks), where some types of price discrimination is appropriate, between countries of roughly equal or higher incomes, but not allow (subject to appropriate exceptions) parallel imports from countries that have significantly lower incomes. A possible rule

¹⁵ Catherine Saez, Confidential Draft Of WHO Cancer Resolution Shows Remaining Issues IP-Related, IP-Watch, February 7, 2017.

would be to limit parallel imports for such goods from countries that have per capita incomes less than 50 percent of the importing country.

Such restrictions on parallel trade would not be appropriate for all goods. For example, It is particularly important that goods that are used to manufacture other goods be available in the United States at the best world prices.

Transparency

Globally, society has interests in transparency. Locally, a decision to be transparent can put a country at a disadvantage, for example, by making it more difficult to negotiate a discount on the price of a patented medicine or an academic journal. For some areas of public policy, global cooperation on transparency can be beneficial, including, for example, to gather better understanding of the costs of research and development, measuring both the access to and impact of medicines, and evaluating the fairness of the copyright system in rewarding authors and performers (as opposed to distributors). Government negotiations of new trade agreements also present important challenges for democracies. Negotiators want some space and secrecy to consider the contours of a possible agreement, but the public wants to have the opportunity to monitor and influence agreements before they are too far along to make changes. In the past, USTR has promoted transparency of drug reimbursement policies, for the benefit of drug manufacturers, but in other ways, sought to reduce the transparency for the public, for example, by not giving the public the same type of access to negotiating texts, and including provisions in the TPP that prohibits regulators from asking for data on drug prices and other relevant economic information. We suggest the USTR hold a series of meetings to consider a broad set of issues about transparency, trade-related transparency, and trade policy making.

Open Access and Other Public Goods

The United States has been progressively imposing obligations on federally funded researchers to make copies of their research papers available to the public for free over the Internet. USTR could press our trading partners to make similar obligations, so that U.S. citizens would have better access to research funded by foreign governments.

Beyond open access policies for published research papers, USTR could develop initiatives to address a much wider range of public goods that have a cross border dimensions, such as the funding of the Global Fund for AIDS, TB and Malaria, or funding the development of new antibiotic drugs or a vaccine for the Zika virus. The United States is often a major funder of global health programs, and by inducing other countries to contribute more, will amplify the impact of our own contributions, and/or reduce burdens on taxpayers.

Concluding Comments

USTR should use the Special 301 process to reevaluate the goals and objectives of the United States as regards intellectual property rights in general, and topics such as copyright exceptions or pharmaceutical drug pricing and R&D funding mechanisms in particular.

The simplistic notion that more IP is better for the United States ignores the domestic and global realities of both the copyright and the pharmaceutical industries.