

## KEI COMMENT AND REQUEST TO TESTIFY AT PUBLIC HEARING, REGARDING

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE 2012 Special 301 Review:  
Identification of Countries Under Section 182 of the Trade Act of 1974:

February 10, 2012

Knowledge Ecology International (KEI) is a not for profit non governmental organization that was created to continue work undertaken earlier by the Consumer Project on Technology (CPTech). KEI and CPTech have monitored the Special 301 list since 1994. Background on KEI is available on the web at <http://keionline.org>.<sup>1</sup>

Knowledge Ecology International (KEI) requests the opportunity to testify at the Special 301 hearing.

KEI also offers these initial comments on the 2012 Special 301 list:

### **1. It is time to eliminate the annual 301 Review.**

Even if you support all of the goals and objectives of the Special 301 list as it is currently implemented, the notion that this should be an annual review needs to be questioned. The annual review is excessively time consuming, repetitive, and an unnecessary waste of time for most of us. The Special 301 list is published around April 1, and by December USTR is already asking people to nominate countries for the next list. Since the Obama Administration has proposed abolishing USTR and reorganizing the trade office, if you can't get rid of the Special 301 process altogether, perhaps it should consider making the 301 process something that happens less frequently, such as every three year or so. If this was not such an ongoing exercise, maybe people would put more thought into the report.

### **2. The norms promoted via the Special 301 Review should be subject to better analysis, independence evidence and scrutiny.**

The norms promoted via the Special 301 Review should be more than an edited version of the PhRMA, the International Intellectual Property Alliance and other trade association submissions. USTR is trying to create global norms for copyright, patents, trademarks and other types of intellectual property, not to mention drug pricing, and they do it in an environment that seems to have been largely captured by lobbyists for industry, many of them who used to work for USTR, the USPTO, the Copyright Office or other government offices. In many respects, this is something not unique to the United States government – it is a larger problem of intellectual property policy making, and was one of the focuses of the UK recent Independent Review of how the Intellectual Property framework supports growth and innovation, undertaken by Ian Hargreaves. This was a high level project, that was announced by Prime Minister David Cameron. Recommendation 2 of the Hargreaves review was on the topic of evidence:

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1 KEI searches for better outcomes, including new solutions, to the management of knowledge resources. KEI is focused on social justice, particularly for the most vulnerable populations, including low-income persons and marginalized groups. There are probably 5 billion people who live in the margins of the global economy, and an entire planet that depends upon knowledge for economic and personal development, education and health, political power and freedom, culture and fun. We are just now learning about the opportunities to manage knowledge resources in ways that are more efficient, more fair, and responsive to human needs.

### **Recommendation: Evidence.**

Government should ensure that development of the IP System is driven as far as possible by objective evidence. Policy should balance measurable economic objectives against social goals and potential benefits for rights holders against impacts on consumers and other interests. These concerns will be of particular importance in assessing future claims to extend rights or in determining desirable limits to rights.

The following are excerpts from Chapter 2 of the Hargreaves review

2.13 There are three main practical obstacles to using evidence on the economic impacts of IP:

- There are areas of IPRs on which data is simply difficult to assemble. While patents are well documented, and traceable to their owners, unregistered design rights and copyright use are not.
- The most controversial policy questions usually arise in areas (such as computer programs, digital communication and biosciences) which are new and inherently uncertain because they involve new technologies or new markets whose characteristics are not well understood or measured.
- Much of the data needed to develop empirical evidence on copyright and designs is privately held. It enters the public domain chiefly in the form of “evidence” supporting the arguments of lobbyists (“lobbynamics”) rather than as independently verified research conclusions.

2.14 Dealing with these obstacles requires an approach to evidence which: makes the most of the available research where data can be developed; applies the lessons learned in those areas where we do have data to areas where we don't, in ways which make credible use of economic theory; demands standards of transparency and openness in both methodology and data.

2.15 It also presupposes an institutional environment which encourages the relevant public authorities to build, present and act upon the evidence. This cannot be achieved if relevant institutions of Government lack access to the data upon which corporate lobbying and other positions are constructed. We return to this point later in the Review.

2.16 The Review has found that IP policy has not always been developed in a way consistent with the economic evidence. We give two examples below.

#### *The EU Database Directive*

An EU Directive to harmonise and increase protection for databases was adopted in 1996. Its aims were to a) harmonise laws between Member States to aid the functioning of the single market and b) increase protection for databases in those Member States where they were “not sufficiently protected”.

The hope was that by introducing such protection throughout the EU, database producers would be incentivised to invest in databases and information processing systems, and thereby reduce the “very great imbalance” in the level of investment in the database sector between the EU and third countries – notably the US, which has no such right. The aim was to ensure the EU got a foothold in this growing sector at an early stage. The European Commission carried out an evaluation of the Directive in 2006.<sup>13</sup> This found that EU database creation had declined since introduction of the Directive, whilst it had continued to rise in the US, undermining the rationale for the right in the first place. The EU Database Directive remains unchanged.

#### *Copyright Term Extension*

Economic evidence is clear that the likely deadweight loss to the economy exceeds any additional incentivising effect which might result from the extension of copyright term beyond its present levels.<sup>14</sup> This is doubly clear for retrospective extension to copyright term, given the impossibility of incentivising the creation of already existing works, or work from artists already dead. Despite this, there are frequent proposals to increase term, such as the current proposal to extend protection for sound recordings in Europe from 50 to 70 or even 95 years. The UK Government assessment found it to be economically detrimental.<sup>15</sup> An international study found term extension to have no impact on output

[...]

#### *Recommendations*

1. Evidence. Government should ensure that development of the IP System is driven as far as possible by objective evidence. Policy should balance measurable economic objectives against social goals and potential benefits for rights holders against impacts on consumers and other interests. These concerns will be of particular importance in assessing future claims to extend rights or in determining desirable limits to rights.
2. International priorities. The UK should resolutely pursue its international interests in IP, particularly with respect to emerging economies such as China and India, based upon positions grounded in economic evidence. . . .

The concerns expressed by Ian Hargreaves are shared by many persons. We are reaching a point where policy makers need to admit that intellectual property policy is more complicated than simply pushing for more and more rights and ever harsher penalties for infringements. We also need to acknowledge that we barely know how the world works. Here are just a few areas where evidence is lacking.

1. Given the huge emphasis on test data protection in the Special 301 reports, does the Special 301 Committee know how much money drug companies spend on clinical trials?
2. Does the Special 301 Committee have knowledge of the minimum economies of scale to efficiently manufacture active pharmaceutical ingredients?
3. Given the huge emphasis on forcing countries to grant patents on new uses of old medicines and for relatively obvious tweaks in drug delivery mechanisms, and to link drug registration to

patent status, does the Special 301 Committee know if developing countries have the capacity to evaluate low quality patents on pharmaceutical drugs, or how much it costs to litigate patents in different countries?

4. What will be the impact of higher IPR norms on PEPFAR budgets?
5. Does the Special 301 Committee know how much of the publishing industry is owned by foreign owned companies?
6. How much of publisher revenues go to authors or performers?
7. How do the wages and growth rates in employment compare between old content industries and new Internet and information technology firms?
8. Are the promotion of open royalty free standards for information technologies likely to be a positive or a negative in terms of economic growth in the United States?
9. Do low quality patents in the United States and China benefit the US?
10. Do developing country patents on heat stable formulations of drugs induce much investment into such technologies? To what extent do such patents create ethical dilemmas and public health risks as poor patients use heat damaged drugs and develop more drug resistance?
11. Does the United States gain more from global norms that create liberal access to knowledge than we do from norms that restrict access to knowledge? Is access to knowledge in the United States important for our economic growth? Do we benefit or suffer from higher levels of education in developing countries?
12. Would the United States benefit or suffer if there was more liberal parallel trade with other high income countries. (Note to Special 301 committee – President Obama campaigned in favor of such parallel trade for pharmaceutical drugs.)

Some Intellectual Property organizations are beginning to create the capacity to evaluate intellectual property policy in the same way they evaluate other government policies, such as the regulation of environmental pollution – another activity that imposes both benefits and costs. Both WIPO and the USPTO have created offices for economists to contribute to policy discussions. USTR might want to do the same.

The Special 301 Committee could also begin to organize its work in ways that allow various stakeholders and experts to engage each other in transparent debates over the evidence that supports various policy norms promoted in the Special 301 reports. For example, if the Special 301 Committee could get out from underneath its annual review work load, it might have time to open an inquiry into the best policy for dealing with test data protection, given the complex ethical and economic issue at stake, and attempt to explain what objectives we are trying to achieve, and debate how best those objectives can be achieved.

### **3. Least Developed Countries Should Not be Required to Grant or Enforce Patents on Medicines.**

For a number of years, the Special 301 Report has indicated it expects Least Developed Countries to comply with TRIPS obligations, including the granting of patents on pharmaceutical drugs. This year the Special 301 Report should express a new policy, that supports indefinite extensions of that deadline.

### **4. The Protection of Consumers**

KEI, like many other public health groups, objects to efforts in the Special 301 list to bully countries to adopt patent extensions, gut price controls, implement TRIPS plus standards for patentable subject matter, grant exclusive rights in test data, link drug registration to patent status and otherwise push for measures that drive up drug prices. While this is a general concern, we continue to be particularly concerned about the impact of such policies on developing countries.

KEI, like many other consumer and digital rights groups, objects to efforts in the Special 301 list to promote long copyright terms and larger damages for copyright and patent infringements. The extended copyright terms in the United States are an embarrassing episode of special interest lobbying and we should not impose this mistake on the rest of the world, undermining our own opportunities to reform our own laws.

Special 301 norms should not undermine efforts to liberalize access to orphaned copyrighted works.