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Re: Draft National IPR Policy (India)

Knowledge Ecology International (KEI) has reviewed the document entitled "National IPR Policy" prepared by the IPR Think Tank. The document is surprisingly lacking in several key areas. In particular:

1. There is almost no data presented in the document to support the proposed actions and policies.

2. There is a lack of sophistication and nuance in its overall evaluation of intellectual property rights, and a tendency to present complex issues as over simplified choices.

To illustrate these shortcomings, consider just a couple of issues.

A. Patents on new uses of existing drugs

The granting of patents for new uses of old drugs is just one of many issues considered controversial globally as regards India's intellectual property policy. India is among countries that decline to grant patent monopolies for new uses of old drugs.

The United States government and many large pharmaceutical companies are among those asking India to reverse its position on this topic, on the grounds that the granting of patents for new uses creates useful incentives to invest in research that can expand the benefits of the older drugs.

The answers to the questions below might inform policy makers as they seek to defend or change the current policy in India:

1. Is the discovery of new uses of older drugs important, as regards medicine? The answer to that question is yes, as evidenced by the large number of regulatory approvals for new indications for existing drugs, following the initial registration of a new molecular entity for its lead indication.

2. How many of these new approvals take place during the initial period of monopoly for the patent relating to the compound and the lead indication?

3. How much do companies spend on R&D to provide regulators with the evidence that the drug is safe and has efficacy for the new use?

4. Are the expanded sales of the drugs for those new uses sufficient to induce investments by the originator of the drug on said regulatory approvals?

5. After patents on the original use of a drug expire, how often are patents on new uses an ineffective way of inducing R&D for new uses, because the product is available off patent for the older uses?

6. In order to induce investments in R&D, what alternatives exist to the granting of a patent on a new use? For example, would innovation inducement prizes, regulatory obligations for follow up testing, grants or other non-patent alternatives be preferred?

   See attachment: *Alternatives to the Patent System that are used to Support R&D Efforts, Including both Push and Pull Mechanisms, with a Special Focus on Innovation-Inducement Prizes and Open Source Development Models,* World Intellectual Property Organization, CDIP/14/INF/12, September 19, 2014.

7. What are the costs to consumers and reimbursement entities of granting patents on new uses of drugs? If the patent on the new use actually extends the monopoly, that must impose costs on consumers. Does this lead to access barriers, financial hardships, or some combination of both in India?

8. Given India represents a small fraction of the global market for pharmaceutical drug, does the decision to grant patents on new uses of drugs have a significant impact on the inducement investments in R&D?

B. Granting compulsory licenses on drug patents.

Some of the same issues described above are relevant to any policy analysis relating to the granting of compulsory licenses on drug patents. On the one hand, a compulsory license can be used to expand access to medicines, lower the costs to consumers, and to stimulate employment in the generic drug manufacturing sector. On the other hand, there can be a negative impact on global R&D. But how much does India benefit from the compulsory license, and how small is the impact on global R&D? In the Natco case, Bayer acknowledged in a widely reported conference organized by the Financial Times (FT) that it never expected to see the drug provided to India cancer patients. (Transcript of Bayer CEO Marjin Dekkers quote at the December 3, 2013 FT Event, regarding India compulsory license of Nexavar, http://keionline.org/node/1924).

If the positive benefit of the compulsory license is large in India, and the negative impact on global R&D is small, as Bayer suggests, there is a compelling reason to grant the compulsory license. India would also have the option to address the small impact on R&D by other means, such as by funding R&D through research grants and contracts, and even including provisions in those grants and contracts that protect India national interests, such

as by requiring national manufacturing, or providing royalty free licenses to the government, such as is done in the United States under the Bayh-Dole Act.

C. Copyright exceptions

The United States is now dominating the rapidly expanding market for sharing information over computer networks, including through social media. This industry depends upon robust copyright exceptions. The United States benefits also by having a more informed population, including the many businesses using information. The importance of distributing, finding, sharing, visualizing and using information is growing, leading many scholars and experts to advocate new approaches to copyright laws that expand the freedom to use information without permission from right holders, with or without compensation, depending upon the use and the context.

This has now become a far more import source of wealth and employment than the traditional publishing sector.

D. Free software

The United States Patent and Trademark Office and the European Commision have both published deeply flawed studies on the relationship between employment and intellectual property. Both studies imply that work involving the development of software depends upon copyright protection. However, employment for traditional software publishers represents only a small fraction of the total employment for software programmers and engineers. The far greater employment base is for work that uses free software platforms to build customized applications for businesses, governments and personal use.

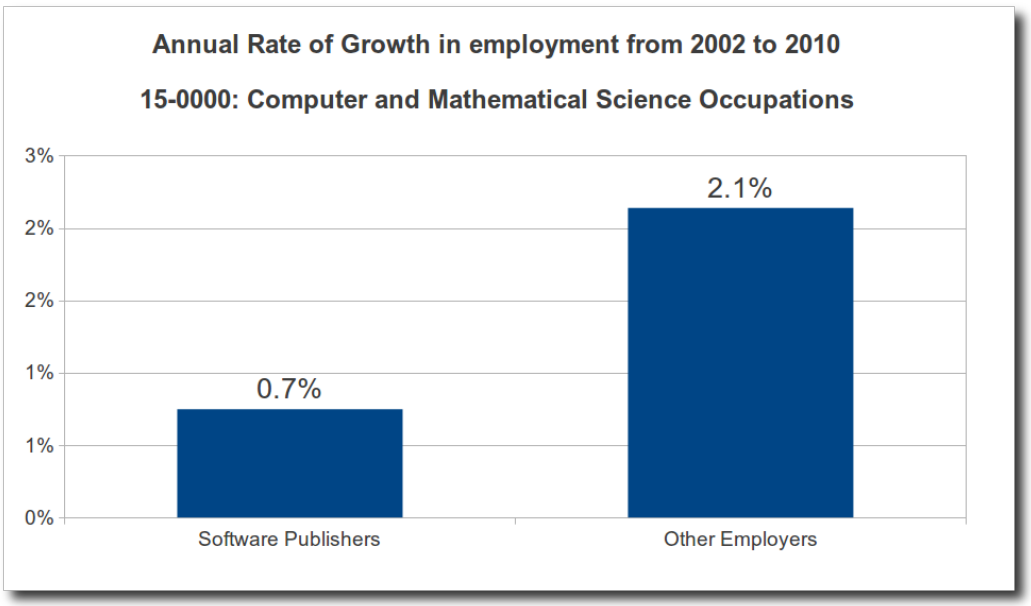
Linux based servers, open source content management systems, and data manipulation programs like Python or R are examples of the widely used free software programs that have been critical to the innovation sector. While it is true that these programs are subject to copyright, and often licensed under the GNU/GPL, to say that copyright is important is to miss the point. So too is the freedom to use and modify the code. It is surprising that government policy makes are relatively timid in identifying ways that these platforms can be protected or enhanced.

As regards employment, consider that in the United States, in 2010, software publishers employed only 4 percent of the BLS defined category for “Computer and Mathematical Occupations,” and just 4.9 percent of occupation code for computer programmers. In the BLS category for “Software Developers, Applications,” just 8.1 percent worked in the “Software Publishing” sector. This suggests the role of commercial software applications is only a relatively small element of value added work involving software.

United States Occupational Employment and Wages, May 2010

BLS Occupation Code	Software Publishers	Other Employers	Total Employment	Percent working for Software Publishers
15-0000 Computer and Mathematical Occupations (Major Group)	129940	3154010	3283950	4.0%
15-1131 Computer Programmers	16420	317200	333620	4.9%
15-1132 Software Developers, Applications	40300	458980	499280	8.1%
15-1133 Software Developers, Systems Software	25240	353680	378920	6.7%
15-1111 Computer and Information Research Scientists	1470	23430	24900	5.9%
15-1121 Computer Systems Analysts	8330	487470	495800	1.7%

The rate of growth of employment for computer related jobs was also much higher for non-software publishers.



E. Software and mobile computing patents

The United States and Europe are both taking steps to grant fewer software patents, and to grant fewer injunctions for the patents that are granted and infringed. It is now practically impossible to manufacture a mobile computing device or develop a major software application without infringing a large numbers of patents granted in the United States or Europe. The US has used limitations on injunctions to mitigate the damage from the patent system, and Europe is headed in the same direction. India should be asking, if it granted more or fewer software and computing related patents, would it be better or worse off? And for granted and infringed patents, what should the remedies be?

F. Trade Secrets and confidential business information

Several big global companies are seeking to protect their markets by making new and sometimes novel claims for trade secrets and confidential business information. This is a rich topic and extends to diverse areas of policy, such as the conflict with the transparency of clinical trial data, to information about the costs of research and development of a new drug, or information on the interface information to make software interoperable.

Striking the right balance in these debates is important. Excessive protections of confidential business information can become a barrier to legitimate and welfare improving competition, and reduced accountability.

For example, in 2010, the US Environmental Protection Agency (EPA) Inspector General found that the agency's procedures for handling confidential business information (CBI) request "are predisposed to protect industry information rather than to provide public access to health and safety studies." (EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities, Report No. 10-P-0066, February 17, 2010)

We take leave to submit further detailed comments on the draft National IPR Policy.