Comments of KEI regarding the White House OSTP call for comments on its *Strategy for American Innovation*

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Re: *Strategy for American Innovation*

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Knowledge Ecology International is a non-profit organization. Information about KEI is available from our web page at http://keionline.org. Our comments follow:

1. The USPTO Office of the Chief Economist has yet to address some obvious questions about patent and copyright policy.

Many persons thought government policy makers needed to use more economic analysis to address controversial questions such as the costs and benefits of extended copyright or patent terms, or whether or not patents should be granted for software or business methods. So far, the Office of the Chief Economist (OCE) at the USPTO is best known for the widely ridiculed March 2012 report: *Intellectual Property and the U.S. Economy: Industries in Focus,* which used jobs in grocery stores and cut rate clothing stores to create the easily anticipated impression that millions of jobs depend upon every expanding intellectual property rights. This report, quoted endlessly by the former head of the USPTO David Kappos and hundreds of right holder public relations agents, came at a time when the United States needed to ask hard questions about copyright and patent policies. With the rise of a dynamic technology sector that dominates the global economy, the USPTO might have asked, do software patents create or hurt job growth? Does copyright fair use expand US jobs, or shrink US jobs? Instead, we have a report that makes no attempt to make any useful conclusions about the real challenges facing policy makers, and a government report that appears to have been designed largely as propaganda for a handful of right holders, including an increasingly strident motion picture

industry that uses the report to justify 95 year copyright terms, and pharmaceutical companies that excel in raising prices for life saving drugs to an aging population.

KEI recommends the USPTO OCE adopt a work program that begins to explain why we grant patents for certain activities, and attempts to evaluate the appropriate term of protection and the balance of rights and exceptions that enhance our wealth and social welfare.

2. Federal agencies that fund or subsidize clinical trials for new drugs and vaccines should publish accessible data on the costs of those trials. *Sui generis* intellectual property rights for medical inventions should be conditioned upon the disclosure of data on the economics of drug development.

Nearly all significant debates about the appropriate pricing and intellectual property rights for drugs and vaccines are influenced by highly selective and sometimes self serving studies of drug development costs, based upon closely held and/or secret industry data sets. At the same time, the United States government spends billions of dollars on clinical trials. If the public and government policy makers want to have better evidence of drug development costs, they could begin by looking at the costs of the trials that they are already funding. This would include trials subsidized or funded by the NIH, the CDC, the Department of Defense, Homeland Security, the Department of Veterans Affairs, or other federal agencies.

When KEI contacted the NIH asking for information on the costs of vaccine trials, we were told that the NIH does not collect that information in any formats remotely accessible or useable for studying the economics of vaccine development. If true, this is a troubling omission.

KEI has been unable to get GAVI to respond to requests for information on vaccine trial costs.

The Gates Foundation has not expressed a willingness to share information with the public on the costs of vaccine trials.

Among the countless government and donor funded public/private partnerships involved in drug development, there have been only a few episodic efforts to provide evidence of the costs of the trials for the public's use.

There are many extraordinary public benefits and subsidies given to drug developers, such as the Orphan Drug Tax Credit, which covers 50 percent of qualifying trial costs, the seven years of Orphan Drug market exclusivity, the six months of exclusivity for pediatric testing, FDA test data exclusivity for pharmaceutical drugs (3 and 5 years) and biologic products (12 years), and FDA and USPTO patent extensions. These benefits are worth billions of dollars to drug developers, and cost consumers and other taxpayers billions of dollars. There are no current obligation on the companies enjoying these benefits to share any data with the public on the actual economics of drug development, or the sales generated by these products.

Does anyone honestly believe the public interest is served by policies that maintain deliberate ignorance of drug development costs?

3. Information on the licensing of federally funded inventions is not well organized, or accessible.

The federal government should require that all licenses for patented inventions that have benefited from federal subsidies be made public, with minimal and time limited redactions. This should extend not only to NIH funded inventions, but to all federal agencies and to anyone who receives federal funding, including researchers associated with universities and businesses.

The NIH should end its practice of redacting the royalty rates on NIH owned patent licenses, and it should report all royalty income from specific licenses, if not immediately, after a reasonable delay.

4. Open Source Dividend programs can better align private incentives with public interests.

At present, there are strong private incentives to restrict access to research, by patenting research, or keeping information private, in order obtain the commercial benefits associating with the licensing of the knowledge, materials or technology. This often makes sense for individuals, but not necessarily for society.

Sir John Sulston was awarded the 2002 Nobel Prize in Physiology or Medicine. Sir John Sulston also played a key role in pushing for sufficient funding to ensure that the core data from the Human Genome Project entered the public domain. (See, Sulston and Ferry, The Common Thread, 2002).

In one interview, Sulston speculated that medical research in the public domain is worth nine times as much as medical research that is held privately by pharmaceutical companies, because openness accelerates scientific progress.

Innovation inducement prizes also present special issues. If an innovation inducement prize can be obtained without patents, drug developers may have incentives to rely even more on trade secrets, an issue addressed by several academic researchers.

The open source dividend is designed to create an economic incentive to share knowledge, materials and technology. As proposed in federal legislative proposals by Senator Sanders (see, for example, S.627, 113th Congress), a portion of innovation inducement prizes could be

allocated to persons who openly shared knowledge, material and technology, that were deemed useful in the development of the prize winning products.

See: James Love and Tim Hubbard, "Prizes for Innovation of New Medicines and Vaccines," Annals of Health Law, Vol. 18, No 2, pages 155-186, Summer 2009.

The open source dividend does not rely upon the use of innovation inducement prizes. Indeed, one could simply require that a percent of all drug sales (or drug sales reimbursed by Medicare and Medicaid) go into a fund to be allocated to the open source dividend. The allocation could be managed through a jury system, that would accept nominations for open sourced research that would earn a share of the open source dividend.

Drug developers would both pay and benefit from this system. They would pay by sharing the revenue from the product sales or rewards. They would benefit by the expanded access to royalty free knowledge, materials and data, and fewer transaction costs.

5. Fund the request by the National Academies to study the feasibility of delinkage in drug development.

It is now fairly obvious that there will be no serious reform of drug pricing or innovation incentives without full delinkage of R&D costs from drug prices. The National Academies has proposed a study of the feasibility of delinkage strategies, including end prizes, open source dividends and upstream prizes managed by competitive intermediaries. This should move forward.