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CSOs concerned over timing of IP policy review in India Published in SUNS #7881 dated 25 September 2014

Geneva, 24 Sep (Kanaga Raja) -- Ahead of Indian Prime Minister Narendra Modi's visit to the United States, a number of civil society organisations and prominent individuals in India have raised concerns over the timing of a Ministry-level review of the country's intellectual property rights (IPR) policy.

In a statement issued on 23 September, they warned that the proposed exercise could become "hostage to pressures of the US government and companies."

Among the notable individuals that signed the statement are Dr Nityanand, Eminent Scientist and former Director of the Central Drug Research Institute; Mr S. P. Shukla, former Ambassador to GATT and Secretary, Ministry of Health and Family Planning; Prof. Muchkund Dubey, President of the Council for Social Development and former Foreign Secretary; Mr B. L. Das, former Ambassador to GATT; Mr Anand Grover, former UN Special Rapporteur on the Right to Health and Director of the Lawyers Collective; Dr Biswajit Dhar, Professor at the Centre for Economic Studies and Planning, JNU; Prof. B. S. Chimni, Centre for International Legal Studies, JNU; and Ms Kajal Bhardwaj, an independent lawyer.

Among the organisations that signed the statement are the National Working Group in Patent Laws, Third World Network-India, Campaign for Affordable Trastuzumab, Oxfam-India, Lawyers Collective, Research Foundation for Science, Technology & Ecology, National Campaign Committee on Drug Policy, National Alliance of Peoples' Movement, All India Drug Action Network, Delhi Network of Positive People, International Treatment Preparedness Coalition South Asia, and Jan Swasthya Abhiyan.

In their statement, the CSOs and individuals noted that Commerce and Industry Minister Ms. Nirmala Sitharaman, in a press briefing on 8 September, had indicated that the government would roll out a revised policy on IPRs, and that this policy would focus on boosting innovation and tone up the overall administration, besides setting up a think tank to strengthen the country's patent regime.

The statement also quoted the Minister as having said that, "India does not have an IPR policy. This is the first time we are coming out with an IPR policy. We are very strong in IPR and we certainly want to protect our interest. IPR policy issues have been hanging for quite a long time and the new policy will give direction in terms of protecting IPRs of India. With the US we have (certain) issues. India has become a brand in terms of pharma. Because India does not have any policy, developed nations are picking holes in India's IPR laws."

The CSOs said they would like to clarify that the statement made by the minister that India does not have an IPR policy "is not true". The current Indian IP legal regime represents the policy framework on IPRs which was adopted after considerable debate inside and outside Parliament, they said.

"The strength of this IPR policy is reflected well in the successful establishment of the Indian pharmaceutical industry within three decades. Until 1995, its success was enabled by the Indian Patents Act, 1970, which limited patent protection to process innovations. After 1995, the success was ensured by Parliament's decision to take full benefit of the transition period of 10 years available under the WTO Agreement on Trade-Related Aspects of Intellectual Property [Rights] (TRIPS)," said the statement.

India delayed the implementation of product patent and chose to limit the scope of patent protection through the introduction of Section 3 (d) of the Indian Patents Act.

According to the statement, it also added article 3 (j) on biological processes not being inventions to protect its biotechnological innovations in the sector of agriculture and health.

"Section 3 (d) rejects patents that do not involve real innovation, an issue that foreign pharmaceutical companies are not in agreement with. Similarly, compulsory licensing provisions in the Indian Patents Act aim to ensure that patent holders do not abuse patents to develop monopolies and thereby charge exorbitant prices which would result in denial of access to medicine at affordable prices to the people of India."

The groups underlined that India's IPR policy is TRIPS-compliant, and that India chose to use the health safeguards available in the TRIPS Agreement, to protect the interests of Indian patients as well as millions of people living in other developing countries.

The law requires that patented inventions are available to the public at affordable prices as well as obligates the patent holders to work their patents in India. By making use of flexibilities in the TRIPS agreement, the Indian Patents Act and policy reduce options to pharmaceutical companies, be they Indian or foreign, to profit from diseases or those suffering from them.

"The Indian law has stood the test of time and judicial scrutiny. It is also increasingly serving as model legislation for many developing countries including Brazil," the statement stressed.

The CSOs are concerned about the implications of the Minister's statement, linking innovation with strengthened IP protection.

Globally, they argued, there is no conclusive proof that strengthened IP protection promotes innovation and "we should be under no illusion that strong IP protection can boost innovative activities in India. Instead of seeking to strengthen IP protection, the government needs to enhance public investment in drug discovery and development research, to promote innovations that can lead to new drug discovery in India."

"We are worried about the implications of the statement by the minister that the country's IPR policy will 'not be restrictive or regressive' but will 'only give clarity and consistency without any overlap or contradictions.' We believe that the problem is not with the lack of clarity and consistency in the existing IPR policy but rather with the lack of its implementation by the political leadership."

The CSOs were also of the view that the continued efforts by transnational corporations on linking strong IPR as a precondition to attracting foreign direct investment (FDI) are misplaced.

"There is no evidence to link IPR with inflow of FDI. We urge the government not to fall prey to such organised propaganda. While the US administration has been hostile towards India's sovereign laws because they run contrary to the interests of US-based pharmaceutical companies, it has not prevented US-based pharmaceutical companies from operating in India. They are also able to patent products that are patentable under the Indian Act," said the statement.

Meanwhile, the statement noted, the US continues to target India's patent system and has amplified its pressure on India.

For example, the Global Intellectual Property Centre of the US Chamber of Commerce accused India of harbouring the "weakest" IP environment among countries that it studied.

Further, the US International Trade Commission (ITC) has initiated an investigation on India's industrial policy, which is primarily focused on India's intellectual property regime and its impact on the US economy.

Similarly, said the CSOs, the United States Trade Representative (USTR) "continues to make illegitimate threats (inconsistent with the principles of the multilateral decision-making and dispute settlement processes of the WTO) of unilateral trade sanctions against India through the Special 301 process. It is to undertake an out-of-cycle review of India's intellectual property protection and enforcement standards in the coming months."

"We would like to convey strong reservation on the unrelenting pressure mounted by the US to weaken public health safeguards in the Indian Patents Act. These pressures would further intensify through the mechanism of negotiations for a bilateral investment treaty," said the CSOs.

The groups understand that during the forthcoming visit to the US by the Prime Minister, there will be tremendous pressure exerted to modify India's Patents Act in the following ways:

- * Dilution of patentability criteria, including those enshrined in Section 3(d) of the Indian Patents Act;
- * Limitations to the use of compulsory licensing for access to patented medicines through generic production;
- * Prohibition of the use of pre- and post-grant oppositions that are currently being used to challenge fraudulent patent claims by foreign TNCs;

- * Strengthening of IP enforcement, so that the Indian judicial system would police and secure the patent rights of foreign entities; and
- * Introduction of 'data exclusivity', thus extending patent monopolies and delaying the entry of generics.
- "India needs an IP regime, especially a patent regime, which can facilitate technology catchup and that aids industrialisation. An IP regime that favours transnational companies would act contrary to the Prime Minister's efforts to revive the manufacturing sector in India," said the statement.

"We underline our demand that the Government of India should not carry out any amendment to the Indian Patents Act to increase patent protection. We strongly urge the Government to proactively use the flexibilities in the Patents Act such as government use and compulsory license. In fact, smaller developing countries, with much less bargaining power, have issued more compulsory licenses than just the one that India has granted."

The CSOs called upon the Prime Minister, during his visit to the US, not to make any legal or political commitment that compromises flexibilities in the Indian Patents Act for facilitating access to medicines and safeguarding public health, which is based on policies and principles approved by the Indian Parliament and is fully consistent with international laws. +