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# *PRESS RELEASE*

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**South Centre[1] Calls on WTO Members to Respect the Legitimacy of the Use of TRIPS Flexibilities for Public Health in light of New Threats of Unilateral Trade Measures by the United States against India over its Intellectual Property Laws and Regulations**

***The South Centre is deeply concerned that developing countries, and more recently the government of India, are facing increasing pressure from the United States of America to reform their intellectual property (IP) laws. The Indian IP laws include balanced provisions to ensure that IP rights do not hinder the ability of the government to adopt measures for promoting development priorities, particularly in the area of public health. These are fully in line with the TRIPS Agreement and reaffirmed by the Doha Declaration on TRIPS and Public Health.***

The United States International Trade Commission (USITC) has initiated investigations against India on trade, investment and industrial policies in India particularly on intellectual property protection and enforcement. Moreover, the United States Trade Representative (USTR) is being asked to include India as a priority foreign country in the Special 301 review for 2014, at the request of US industry associations including Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Industry Organization (BIO), the National Manufacturers Association (NAM), the National Foreign Trade Council (NFTC), the US Chamber of Commerce's Global Intellectual Property Centre, and the Alliance for Fair Trade with India (AFTI), alleging lack of adequate and effective protection of intellectual property rights (IPRs).

The South Centre views these recent developments as most inappropriate, as it is against the spirit of the landmark Ministerial Declaration on TRIPS Agreement and Public Health. India and other developing and least developed countries have the right to use the flexibilities in the TRIPS Agreement to the fullest extent for advancing public health needs and other development priorities. The legal and regulatory measures that India has used for protecting public health are fully consistent with the WTO TRIPS Agreement. The continued threat of unilateral trade sanctions by the US to developing countries through USITC investigations and the Special 301 review undermines the legitimacy of the WTO , particularly the TRIPS Agreement and the WTO's dispute settlement system.

[1] The South Centre is an intergovernmental organization of developing countries supporting their efforts and providing expertise to promote their common interests in the international arena. The South Centre was established by an Intergovernmental Agreement which came into force on 31 July 1995. Its headquarters are in Geneva, Switzerland.

It is regrettable that India or any other developing countries may be designated as a "priority foreign country" under the "Special 301" provisions of the US Trade Act of 1974. Designation as a "priority foreign country" starts a 30-day period during which targeted countries must engage in good faith negotiations or make significant progress in bilateral or multilateral negotiations or face sanctions under the section 301 process. Priority foreign country determinations are reserved for countries "that have the most onerous or egregious acts, policies, or practices," that "have the greatest adverse impact (actual or potential) on the relevant US products," and for which "there is a factual basis for the denial of fair and equitable market access as a result." The USTR investigation may lead to unilateral trade sanctions that would be illegitimate under the WTO rules.

The mere threat of sanctions by placing a country in any specific category in the US watch list would appear to violate the WTO Dispute Settlement Understanding. A WTO panel noted, in a dispute brought in 1999 by the EU against Section 301 of the US law, that "the threat alone of conduct prohibited by the WTO would enable the Member concerned to exert undue leverage on other Members. It would disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster and consequently establish, namely equal protection of both large and small, powerful and less powerful Members through the consistent application of a set of rules and procedures."

Separately, the USITC has launched an investigation, requested by the US Senate Committee on Finance and the House Committee on Ways and Means with the backing from various US industry associations including PhRMA.

The establishment by the government of a country of its criteria to grant patents (as provided for in section 3 (d) of the Indian Patent Act and interpreted by the Indian Supreme Court in the Novartis case[2]), the right to issue compulsory licenses, and the use of patent pre-grant and post-grant opposition proceedings are, among others, important flexibilities that serve to protect public health, consistent with the TRIPS Agreement. None of the recent decisions in India to reject patents on known medicines or to issue compulsory licenses on anti-cancer medicines have been challenged before the WTO dispute settlement mechanism. In fact, the recent actions taken by India are not unique. Many other developing countries have issued compulsory licenses for ensuring access to affordable medicines to meet their public health needs, including Brazil, Ecuador, Eritrea, Ghana, Indonesia, Malaysia, Mozambique, Thailand and Zambia.[3]

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[2] See Carlos Correa, *The Novartis Decision by the Indian Supreme Court : A Good Outcome for Public Health*, South Bulletin, 7 October 2013, Issue 75, pp.13.15, available at http://www.southcentre.int/wp-content/uploads/2013/10/SB75_EN.pdf

[3] See Carlos Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing*, South Centre Research Paper 41, pp.17-19, available at http://www.southcentre.int/wp-content/uploads/2013/05/RP41_Pharmaceutical-Innovation_EN.pdf

The TRIPS Agreement also does not preclude that countries include in their patent laws a requirement to disclose the source and geographical origin of biological materials used in an invention that is the subject of a patent application. The disclosure requirement is conducive to the mutually supportive implementation of the TRIPS Agreement and the Convention on Biological Diversity and the Nagoya Protocol on Access and Benefit sharing.

Continued pressures by the United States on India and other developing countries to adopt an IPRs regime that would go beyond the minimum standards in the TRIPS Agreement and that does not make use of the flexibilities that are part of TRIPS would have adverse social and developmental effects, including on the public's access to medicines.

***The South Centre encourages India and other developing countries to continue to make full use of the TRIPS flexibilities for public health and other public policy objectives, consistent with their rights and obligations under the WTO rules.***

***The US administration should also stop putting pressures on developing countries to prevent them from making use of their rights under the TRIPS Agreement to make use of policy measures to promote access to medicines, public health and other development objectives.***

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