

## **FICCI's rebuttal to arguments made during the USTR's public hearing on 24 February 2014 on designating India as "Priority Foreign Country" in the USTR's 2014 Special 301 report**

**New Delhi, 6 March, 2014:** FICCI and Indian industry is of the view that the investigation is a manifestation of a broader tension between a handful of disgruntled US companies and the Indian government, which has now spread to Capitol Hill. **Dr. A Didar Singh, Secretary General, FICCI** opines that "although India has a social and constitutional responsibility of providing health care and better standard of life to its people, the policy drive is geared to meet the country's obligations under TRIPS'.

**During the United States Trade Representative (USTR) office hearing on the USTR's 2014 Special 301 Hearing on 24 February 2014, Alliance for Fair Trade with India (AFTI), Biotechnology Industry Organization (BIO), Global Intellectual Property Center (GIPC) of the US Chamber, Pharmaceutical Research and Manufacturers of America (PhRMA) and National Association of Manufacturers (NAM) recommended to the USTR to designate India as "Priority Foreign Country" in its 2014 Special 301 report.**

The effort being made to declare India as "Priority Foreign Country" under the Special 301 under US Trade Act of 1974, is a unilateral action to create pressure on India to increase IPR protection beyond the TRIPS Agreement and aims to protect private corporate interests over national interests. The US advocacy groups have leveled charges against India's business environment, arguing that it is restrictive and discriminatory, with weak protections for intellectual property due to a number of patent invalidations and issuance of compulsory licenses. **Dr. A Didar Singh lays stress** that the "Indian policy is not protective towards its domestic industry, but is protective of the interests and welfare of its citizens."

India has a well-established legislative, administrative and judicial framework to safeguard IPRs which meets its obligations under TRIPS, and has withstood the test of severe international scrutiny. The two Trade Policy Reviews conducted by WTO in respect of India in 2007 and 2011 have found the Indian IPR regime to be adequate and there has been no mention to the contrary. India has an independent authority and appellate board and courts to decide on due processes. The fact that a number of cases are being appealed or being invalidated by the Indian courts only show the robustness of the Indian IP eco-system. There has been no concerted effort by the Indian system discriminating foreign companies and there have been a number of Indian patents also being invalidated. Similarly there is increasing number of cases being decided by the US Supreme Court relating to patents and infringements, revocation and other disputes relating to IPRs and the US Federal courts have upheld only 39 patents in 283 cases between 2007 and 2011.

With regard to Compulsory Licensing in the pharma sector, there has only been one case - Natco where a Compulsory License was granted in India. The decision was taken by an independent, quasi-judicial authority, the Controller General of Patent Designs and Trademark, after fully examining the facts of the case as per the provisions of Indian law. The grant of Compulsory License was permitted both under the Indian law and TRIPS. In fact, Compulsory Licenses have also been invoked in the US in past, through use of executive powers of President, to ensure availability of certain products. The US used CL in the past to curb anti competitive activities and has also used it for providing to its citizen availability of commodities at an affordable price. While allowing Apple to import devices into the US that

infringed a patent held by Samsung, the USTR signaled that it would not enforce exclusive rights in patents at the cost of public interest or other domestic concerns

The US Government has wide powers under several legislations to exercise Compulsory License for reasons such as government use (USC 28§1498), public purpose or anti-competitive remedies. Besides this, CL provisions exist under the **Clean Energy Act, Atomic Energy Act and the Federal Insecticide, Fungicide and Rodenticide Act**. The US through Executive orders in the last 2 years has taken decisions in the apparent best interest of US consumers. The US Government allowed the import of 'Lipodox', a replacement drug for 'Doxil' from India (M/s Sun Pharmaceuticals). Thereafter, in February, 2013 the USFDA approved the first generic version of the cancer drug 'DOXIL' from Sun Pharmaceuticals. Similarly, the USTR decided in favour of Apple Incorporation in the Apple Vs. Samsung case where infringement action had been initiated by Samsung Electronics for infringement of their US patent by Apple. This decision now allows the company to continue selling cheaper versions of iPhone4 and iPad2 in US.

FICCI supports the Govt. of India policy on public health and affordable healthcare and works with in the international framework and in genuine interest of Indian public. India has a robust IPR system and FICCI is working with all relevant stakeholders for effective enforcement and capacity building and training in industry and enforcement agencies, including the police and customs departments and judiciary.

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**FICCI MEDIA DIVISION**