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Ms. Pratibha M Singh, Sr.Advocate, Singh & Singh Law Firm, Member;
Ms. Punita Bhargava, Advocate, Inventure IP, Member;
Dr. Unnat Pandit, Cadila Pharmaceuticals Limited, Member;
Mr. Rajeev Srinivasan, Director, Asian School of Business, Thiruvananthapuram, Member;
Mr. Narendra K. Sabarwal, Chair IPR Committee, FICCI and Retired DDG, WIPO, Member and Convener

Re: intellectual property and access to medicines

We write to the newly constituted IPR Think Tank as patient groups, public interest organisations, treatment providers and academia world-wide to raise critical issues around the intellectual property system in India. We hope that the Think Tank will work to deepen India's contribution to international dialogues around intellectual property and access to medicines.

A particular area of concern has been in pharmaceuticals, as India is the world's supplier of affordable generic versions of drugs that otherwise would be out of reach for public health programmes, treatment providers and millions of people.

We are writing to request that the Think Tank not revisit or challenge democratically-determined and legally-consistent intellectual property rules introduced under India's Patent Act. We call upon the Think Tank to invest its expertise, time and resources to focus its mandate upon the proper implementation and operationalisation of public health safeguards in India's patent law.

India has played a pivotal role in supplying affordable generic versions of drugs used throughout the developing world. The availability of 'fixed-dose combination' HIV/AIDS therapy (or three-in-one pills) at affordable prices – 1 USD per day – in 2001 revolutionised AIDS treatment, a fact we collectively have witnessed firsthand in many developing countries. Providing this form of treatment adapted to resource-poor settings has only been possible because there were no patent constraints in India on putting these medicines together in one tablet. Currently, over 80% of people living with HIV on treatment in low- and middle-income countries use generic antiretrovirals manufactured in India. As a result of generic competition from India, the cost of first-line HIV treatment has come down by 99%, from over 10,000 USD to approximately a 100 USD per patient per year. HIV/AIDS is just one example. India supplies affordable generic drugs for a variety of medical problems that affect patients, including both communicable and non-communicable diseases.

In 2005, faced with the TRIPS agreement deadline, India once again developed a patent system that protects the need of patients to access life-saving medicines at affordable prices and is consistent with WTO rules. Specifically, while India has been granting patents on new pharmaceutical compounds since the onset of the a product patent system in 2005, India's Patents Act also allows patient groups and other interested parties to oppose frivolous or abusive patenting through pre- or post-grant oppositions. India has also been the first country to clearly define strict patentability criteria that prevents a practice known as ever-greening, where market monopolies can be wrongfully granted or endlessly extended.

In 2008, the launch of the Open Source Drug Discovery (OSDD) project by the Ministry of Science & Technology for the first time outlined India's focus on neglected areas of medical R&D – new TB drugs - long ignored by the pharmaceutical industry. It represented a sincere effort to view innovation outside the narrow prism of intellectual property monopolies through open innovation, open source drug development models and the 'de-linkage' of R&D costs from pharmaceutical product prices.

In 2011, the Indian government rejected unnecessary attempts by developed countries and their pharmaceutical sector to agree to additional intellectual property rules in India that would only serve to limit access to affordable medicines without improving innovation on behalf of the public health needs of India. At the height of the EU-India Free Trade Agreement (FTA) negotiations, Indian negotiators from the Commerce Ministry rejected patent term extensions and data exclusivity as being "well beyond" international trade rule obligations. In doing so, the government stated its position on the issue clearly – "On [the] intellectual property rights issue, whatever is discussed has to be in compliance with the TRIPS commitment," and made an assurance publicly that instead, India will ensure that the high-quality generic drugs it produces continue to be accessible for all countries[1].

[1] Anand Sharma Chairs Consultative Committee of Parliament on Challenges in IPR-International and Domestic, Press Release by Ministry of Commerce & Industry, 29 March 2011
http://pib.nic.in/newsite/erelease.aspx?relid=71341
India against inclusion of data exclusivity in any FTA, PTI, 6 April 2011
http://articles.economictimes.indiatimes.com/2011-04-06/news/29388653_1_data-exclusivity-drug-seizure-issue-data-protection.
India—EU free-trade pact could stifle generics industry, The Lancet, Volume 377, Issue 9774, Pages 1305 – 1306, 16 April 2011

In the last decade India has established a balanced position on the patent system. While India does grant patent monopolies to a number of new pharmaceutical products, it is trying to strike a balance between providing IP protection and having the legal flexibility to protect the right to health. It does so in at least four ways: first, the Indian Patent Office applies strict patentability criteria; second, when deemed necessary in the interest of public health the Indian government grants compulsory licenses; third, Indian courts maintain a balanced approach to IP enforcement; and fourth, Indian trade negotiators reject any IP proposals in FTA negotiations that go beyond the requirements of the TRIPS Agreement. All four approaches are available in the TRIPS Agreement as legal flexibilities.

Public health activists and others have been watching closely in recent months as the pharmaceutical industry and United States Trade Representative's office steadily and intensively try and press change in India's patent system towards one that that would dismantle the careful balance established under India's patent law. Multinational pharmaceutical companies in hand with US Trade Representative (USTR) continue to lobby against: India's stricter patentability criteria that makes it tougher to get a patent on new forms of existing medicines, any refusal to grant excessive and unwarranted injunctions on claims of patent infringement and discretion of the Patent Controller to grant a compulsory license to a competitor to bring down the prices of medicines that are patented.

In the present context of heightened US pressure on the Department of Industrial Policy and Promotion (DIPP) and the Indian government, we believe that any re-opening of the discussion on patentability criteria, interpretation of Indian patent law and introduction of TRIPS plus standards[2] will be extremely contentious and provide an opportunity for multinational pharmaceutical companies and USTR to take forward their agenda to undermine generic competition from India at the expense of public health safeguards in India's patent law and its negotiating position in various bilateral and international forums.

We strongly urge you to not allow the use of the Think Tank to revisit decisions made democratically by the Indian Parliament, the Government of India and Indian courts, which could have an incalculable impact upon the lives and access to treatment for millions of people in India and across the developing world.

Any examination of IP issues by the Think Tank must not further undermine access to medicines and India's standing as the pharmacy of the developing world, on which millions around the world rely.

Signatories:

Access Campaign - Médecins Sans Frontières
ABIA (Brazilian Interdisciplinary Aids Association)
Asia Pacific Network of People Living With HIV (APN+)
Africa Japan Forum
AIDS Access Foundation, Thailand
All India Drug Action Network (AIDAN), India
ABGLT (Brazilian Association of Gays, Lesbians, bisexuals, travesties and Transexuals)
Conectas Human Rights, Brazil
Cancer Association of South Africa
Community Network for Empowerment (CoNE), India
Consumer Association the Quality of Life (EKPIZO), Greece
Campaign for Affordable Trastuzumab, India
Diverse Women for Diversity
Drug Study Group, Thailand
Dr. Amit Sengupta, Delhi Science Forum
Delhi Network of Positive People (DNP+)
Foundation for AIDS Rights (FAR), Thailand
Foundation for Consumers (FFC), Thailand
FTA Watch, Thailand
GIV (Group of Incentive to Life), Brazil
GRAB (Group of Resistance Asa Branca), Brazil
GESTOS, Brazil
IBASE (Brazilian Institute of Socio-Economic Analysis)
International Treatment Preparedness Coalition (ITPC) – South Asia
INESC (National Institute of socio-economic studies), Brazil
Initiative for Health & Equity in Society, India

FTA: India fights back over its generics, Alliance Sud News No. 70, Winter 2011/12
http://www.alliancesud.ch/en/policy/trade/fta-india-fights-back-over-its-generics

[2] Briefing note, Data Exclusivity and Other "TRIPS Plus" Measures, WHO, Regional Office for South East Asia, March 2006
http://www.searo.who.int/entity/intellectual_property/data-exclusively-and-others-measures-briefing-note-on-access-to-medicines-who-2006.pdf

ISP (International Public Services), Brazil
Mr. T.C. James (former Director, IPRs Division, DIPP, Ministry of Commerce & Industry), India
Michelle Childs, IP, Medicine and Law, Brazil
National coalition of people living with HIV in India (NCPI+)
Oxfam, India
People's Health System Movement, Thailand
Prabir Purkayastha, Knowledge Commons, India
RNP+ São Luis (National Network of Positive People), Brazil
Rebrip (National Network for the Integration of Peoples), Brazil
Stop Stockouts Project, South Africa
Section 27, South Africa
Sunitha Srinivas (Associate Professor, Faculty of Pharmacy, Rhodes University) South Africa
The Rural Pharmacist Association, Thailand
The Southern African HIV Clinicians Society
Thai Network of People living with HIV/AIDS (TNP+), Thailand
The Southern African HIV Clinicians Society
Thai NGO Coalition on AIDS (TNCA), Thailand
The Network of Maharashtra People with HIV (NMP+)
Thai Holistic Health Foundation
The Rural Pharmacist Foundation, Thailand
Universities Allied for Essential Medicines (UAEM)

C.c.:

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Mr. J.P Nadda, *Honourable Minister for Health & Family Welfare*
Shri Nripendra Mishra, *Principal Secretary, Prime Minister's Secretariat*
Ms. Anu Garg, *Joint Secretary, Prime Minister's Secretariat*
Shri Amitabh Kant, *Secretary, Department of Industrial Policy and Promotion, Ministry of Commerce & Industry*
Shri Rajeev Kher, *Secretary, Department of Commerce, Ministry of Commerce & Industry*
Shri Lov Verma, *Secretary, Department of Health & Family Welfare, Ministry of Health and Family Welfare*
Mr V.V. Subburaj, *Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers*
Mr. Amit Singla, *Deputy Secretary (TPD) Department of Commerce, Ministry of Commerce & Industry*
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Mr. Amal Pusp, *Director (IH), Department of Health & Family Welfare*
Mr. Shailendra Kumar, *Director (Drugs), Department of Health & Family Welfare*
Mr. Injeti Srinivas, Chairman, NPPA