United Nations Development Programme

POVERTY REDUCTION AND HIV/AIDS

FIVE YEARS INTO THE PRODUCT PATENT REGIME: INDIA'S RESPONSE

FIVE YEARS INTO THE PRODUCT PATENT REGIME: INDIA'S RESPONSE

Sudip Chaudhuri, Chan Park and K. M. Gopakumar

December 2010

United Nations Development Programme
One United Nations Plaza
New York, NY 10017
U.S.A.

Website: *www.undp.org/poverty*

UNDP is the UN's global development network, advocating for change and connecting countries to knowledge, experience, and resources to help people build a better life.

Cover Photo: Mohammad Moniruzzaman / UNDP Picture This.

Design: Alex Majumder.

Printing: Consolidated Graphics, New York, USA.

Disclaimer:

The views expressed in this publication are those of the authors and do not necessarily represent those of the United Nations, including UNDP, or their Member States.

This study was commissioned by the United Nations Development Programme (UNDP) under the auspices of the Intellectual Property and Access to Medicines Capacity Building Initiative, a cross-practice project between UNDP's Poverty Group and the HIV/AIDS Group. The project initiated in 2004 seeks to support the building of developing country and broader Southern capacity to sustainably access affordable HIV/AIDS drugs in the context of the implementation of the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) and intellectual property provisions in other trade agreements (e.g. bilateral and regional trade arrangements). Since 2009, the project has broadened its focus in understanding various dimensions and policy interventions to direct health innovation towards meeting long term public health goals, including sustainable access to affordable medicines. In terms of the Millennium Development Goals (MDGs), the project aims to contribute directly to the achievement of MDGs 6 and 8 (and indirectly to MDG 1) by seeking to facilitate a policy environment in which generic drugs will be more accessible to those who need them, in particular poor and vulnerable populations.

The tension between the need to promote innovation and development of new healthcare technologies (which some parties argue require higher standards of patent protection) and the promotion of sustainable access to affordable medicines is not new — it has come to the fore in many developing countries as a result of their implementation of certain provisions of the TRIPS Agreement. Developments in India have impacts well beyond its borders, given the reliance thus far of much of the global market, especially in developing and least developed countries (LDCs), on the supply of low-cost, quality Indian generic pharmaceutical products. This study is intended to be a contribution towards understanding the continued role of India as a supplier of affordable medicines five years after having complied with the TRIPS Agreement. The study analyses the role of both the Indian pharmaceutical industry and the Indian legal system in building a post-TRIPS scenario that continue to be conducive to sourcing affordable medicines.

Chapter 1 of this study (written by Sudip Chaudhuri) looks at the changes in the Indian pharmaceutical industry and the strategies adopted by surviving generic companies as well as the emergence of new originator companies and how this could impact availability of affordable medicines. Chaudhuri further analyses and presents options available and makes recommendations for policy makers including using flexibilities under the Patent law to the fullest which may be critical to promote the revival of a robust generic industry.

Chapter 2 of this study comprises two sections and analyses the response of the Indian legal system. The first section (written by Chan Park) analyses whether Indian patent offices and courts of law have made full use of flexibilities within the new patent act as well as whether they have interpreted provisions in favor of public health. Focusing on the strict patentability criteria in the Indian law, Chan additionally analyses applications that have been granted patents in all of the patent offices in the country foreseeing possible trends and establishes the need for continued strict interpretation of patentability criteria. In his recommendations, Chan also urges for more transparency by the Patent Offices.

The second section (written by K. M. Gopakumar) takes a closer look at the pharmaceutical patent applications in India's 'mailbox'. The mailbox was a transitional mechanism required under TRIPS that was established to accept patent applications between 1995 and 2004. Based on databases of the mailbox applications, medicines approved during this period for marketing both in India and the US and their patent history, Gopakumar examines the potential of some of the safeguards in India's patent law to keep space for generic competition open. He urges the strict application of the safeguards in the Indian law as well as institutional

reforms and capacity building for the safeguards to be truly effective and finds that the Indian experience has some important lessons for LDCs seeking to implement the TRIPS Agreement in the coming years.

The study has benefitted from several inputs and comments from various experts including through a national validation meeting organized by UNDP which was attended by various stakeholders including from the government, private sector, national experts and civil society. Initial drafts of the study benefitted from inputs and comments provided by Tenu Avafia, Luisa Bernal, Biplove Choudhary, Kamal Malhotra, Luciana Mermet, Savita Mullapudi Narasimhan, Cecilia Oh and Yumiko Yamamoto.

During the national validation and technical consultation meeting comments and inputs were provided by Tenu Avafia (UNDP); Jayant Dasgupta (Economic Advisory Council, India); Arun Jha (Department of Pharmaceuticals, India); K S Kardam (Deputy Controller of Patents and Design, India); Yogendra Kumar (Ministry of External Affairs, India); Dinesh Abrol (NISTADS, India); Kajal Bharadwaj (national expert); Reji Joseph (RIS); Radhika Lal (UNDP); M. Santhosh (CENTAD); Leena Menghaney (MSF); Savita Mullapudi Narasimhan (UNDP); Yogesh Pai (CENTAD); Rathin Roy (UNDP); D G Shah (IPA); Madhukar Sinha (Center for WTO Studies) and Juliana Vallini, (ANVISA, Brazil). Support from UNDP India Country Office in the organization of the workshop is gratefully acknowledged, including from Deepti Handa, Alka Narang and Shashi Sudhir.

UNDP hopes that the findings of this study will be used to design appropriate policy approaches for the consideration of different stakeholders in India, including the ministry of health, patent offices, ministry of trade, department of industrial policy, pharmaceuticals, agrochemicals, the justice department, national policy experts and civil society. Outside India, the findings may provide useful policy lessons for policy makers in other developing countries seeking to balance similar tensions in policy objectives. It is hoped that this study shall provide much needed insight into India's continued role as a supplier of affordable medicines to the developing world. Additionally, it can be used as an entry point towards exploring strategic south-south cooperation mechanisms on seeking solutions for health innovation to meet human development goals.

The study was edited by Kajal Bharadwaj and Savita Mullapudi Narasimhan, and the overall coordination was facilitated by Savita Mullapudi Narasimhan.

TABLE OF CONTENTS

List of Acronyms and Abbreviations

ACTA	Anti Counterfeiting Trade Agreement
AGE	Advanced Glycation End product
ANDA	Abbreviated New Drug Application
ANVISA	Agência Nacional de Vigilância Sanitária (Brazil)
API	Active Pharmaceutical Ingredient
ARIPO	African Regional Intellectual Property Organization
ARV	Anti Retroviral
AZT	zidovudine (ARV drug)
CARG	Compound Annual Rate of Growth
CDRI	Central Drug Research Institute
CDSCO	Central Drug Standards Control Organization (India)
CENTAD	Centre for Trade and Development
CIPI	Confederation of Indian Pharmaceutical Industries
CIPIH	Commission on Intellectual Property Rights, Innovation and Health (WHO)
CMIE	Centre for Monitoring Indian Economy
CRAMS	Contract Research and Manufacturing Services
CRO	Contract Research Companies
CSIR	Council of Scientific and Industrial Research (India)
DCGI	Drug Controller General of India
DGCI&S	Directorate General of Commercial Intelligence and Statistics
DMF	drug master file
EC	European Commission
EFTA	European Free Trade Association
EMR	exclusive marketing rights
INN	International Non-proprietary Name
IPAB	Intellectual Property Appellate Board (India)
LDCs	Least Developed Countries
MMV	Medicines for Malaria Venture (MMV)
MNC	Multi National Corporation
MRP	Maximum Retail Price
MSF	Médecins Sans Frontières
NCE	New Chemical Entity
NDA	New Drug Application
NME	New Molecular Entity
NDDS	Normal Drug Delivery System
NISTADS	National Institute of Science Technology and Development Studies (India)
NIPO	National Intellectual Property Organization (India)
NME	New Molecular Entity
OAPI	Organisation Africaine de la Propriété Intellectuelle
OSDD	Indian Government's Open Source Drug Discovery
PAT	Profit After Tax
PCT	Patent Co-operation Treaty
R&D	Research and Development
TDF	Tenofovir Disoproxil Fumarate
TEG	Technical Expert Group on Patent Law Issues (India)
TNMSC	Tamil Nadu Medical Services Corporation
TRIPS	Agreement on Trade Related Intellectual Property Rights (WTO)
UK	United Kingdom
UNDP	United Nations Development Program