

Using Intellectual Property Rights to
Stimulate Pharmaceutical Production
in Developing Countries:
A REFERENCE GUIDE



UNITED NATIONS

United Nations Conference on Trade and Development

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Preface

Over the past few years, intellectual property rights (IPRs) have become a major economic, trade and investment issue, as illustrated by considerable increases in royalty payments and licensing fees in most areas of the world and the inclusion of intellectual property (IP) provisions in regional and bilateral trade and investment agreements. At the same time, concerns have been raised in many countries as to whether the IP system still serves its original purpose, i.e. the promotion of innovation and the transfer and dissemination of technology to the benefit of society, or whether exclusive rights are increasingly being used to defend selective private interests and prevent effective competition.

This debate has been particularly intense in the context of countries' public health policies. Patents and the protection of pharmaceutical test data are frequently mentioned in discussions regarding access to medicines in developing countries. The United Nations Millennium Development Goals (MDGs) put considerable emphasis on access to medicines. Based on its expertise in the interrelated areas of investment, IP and technology transfer, the United Nations Conference on Trade and Development is committed to making its contribution to this important issue.

The present Guide has been prepared by the UNCTAD secretariat (Division on Investment and Enterprise (DIAE)) as part of its technical assistance activities in the area of IPRs and the promotion of pharmaceutical production and supply capacities in developing countries.

These activities respond to a 2005 recommendation by UNCTAD's Commission on Investment, Technology and Related Financial Issues that:

“UNCTAD should, within its work programme on investment, technology transfer and intellectual property, assess ways in which developing countries can develop their domestic productive capability in the supply of essential drugs in cooperation with pharmaceutical companies.”¹

In the pursuit of this mandate, UNCTAD established in 2006 a pilot programme on local pharmaceutical production and the implementation of regulatory frameworks for access to medicines with the financial support of Germany and the United Kingdom. The overall objective of the programme, implemented by the UNCTAD/DIAE Intellectual Property Unit, is to assist developing countries, and least developed countries (LDCs) in particular, to (a) establish domestic intellectual property regimes that facilitate increased access to affordable medicines; and (b) where feasible, create local or regional pharmaceutical production and supply capacities, with the possibility of cooperative arrangements with investors.

¹ See http://www.unctad.org/en/docs/c2l22_en.pdf (paragraph 9(c) of the 2005 Agreed Recommendations).

The objective of the present Guide is to provide concise and practical information on ways to promote local pharmaceutical production and improve access to medicines through a variety of policy tools, focusing on the flexibilities provided under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the interfaces between IP, investment, drugs regulation and procurement strategies. The Guide will be an important tool for training activities for stakeholders from selected developing countries, in an effort to build capacities for the creation of domestic legal frameworks conducive to the promotion of pharmaceutical production and supply capacities.

A handwritten signature in black ink, appearing to read 'S. Panitchpakdi'.

Supachai Panitchpakdi
Secretary-General of UNCTAD

Acknowledgments

This Guide was prepared by Christoph Spennemann of UNCTAD's Intellectual Property Unit, Investment Capacity-Building Branch of the Division on Investment and Enterprise, and Professor Jerome H. Reichman, Bunyan S. Womble Professor of Law, Duke University School of Law, under the supervision of Kiyoshi Adachi. James Zhan provided overall guidance. Important inputs were provided by Dr. Sandy Harnisch and Ermias Biadgleng. The preparation of this Guide has been supported by the Ministry of Economic Cooperation and Development (BMZ) of Germany and the Department for International Development (DFID) of the United Kingdom.

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