UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

Workshop on Developing Local Productive and Supply Capacity in the Pharmaceutical Sector – the Role of Intellectual Property Rights

Addis Ababa, 19-23 March 2007

FINAL REPORT

Organized by the United Nations Conference on Trade and Development and co-sponsored by Ethiopia Engineering and Capacity Building Programme (GTZ) and the Commonwealth Secretariat

Financing for this workshop is made possible by the German Federal Ministry for Economic Cooperation and Development (BMZ) and the United Kingdom's Department for International Development (DFID)

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Outcome

This workshop was designed to familiarize and sensitize stakeholders (i.e, relevant officials of the Ministries of Health and Trade/Investment, intellectual property offices, lawmakers, drug regulatory authorities, senior executives of local pharmaceutical manufacturers, civil society and academia) of the full range of intellectual property (IP) tools to encourage the development of local productive and supply capacity in the pharmaceutical sector. Particular attention was paid to the obligations and flexibilities available under the TRIPS Agreement. The participants of this regional workshop were from Botswana, Ethiopia, Kenya and Tanzania, as the beneficiary countries of UNCTAD's joint technical cooperation activities with the Governments of Germany (BMZ and GTZ) and the United Kingdom (DFID) in this area. UNCTAD organized this workshop in collaboration with the Engineering and Capacity Building Programme (ECBP) of Ethiopia and the Commonwealth Secretariat.

The workshop consisted of three main parts (see the workshop programme), i.e. (1) lectures on public health-related TRIPS flexibilities and their strategic use; (2) a role play on these flexibilities; and (3) presentations of UNCTAD's analyses of the national patent laws of Ethiopia and Tanzania.

The **lectures**, which were designed to allow time for questions and answers, covered the following issue areas: overviews of IP implications for local pharmaceutical production and of related TRIPS flexibilities; pre- and post-patent grant TRIPS flexibilities; regional approaches; non-IP aspects of pharmaceutical production and the role of civil society. The lectures were given by the following resource persons: Mr. Kiyoshi Adachi (UNCTAD); Mr. Christoph Spennemann (UNCTAD); Dr. Sandy Harnisch (GTZ); Mr. Achal Prabhala (Alternative Law Forum); Mr. Jonathan Berger (AIDS Law Project); Ms. Kathy-Ann Brown (Commonwealth Secretariat); and Mr. Frank Schmiedchen (BMZ). All presentations were made available to the participants in electronic form. In order to ensure sustainability of the capacity building process, UNCTAD staff selected a number of participants from each of the beneficiary countries to act as domestic trainers on TRIPS flexibilities. In a separate working session for the Training of Trainers (TOT), the selected individuals received information on the effective use of the presentations for domestic training purposes.

The **role play** was designed to help the participants understand the operation of some of the TRIPS flexibilities in practice. All participants were assigned to a particular group playing a particular role in the context of local pharmaceutical production or supply. The main task of each group was to identify their main objectives and priorities and pursue these through negotiations with the other groups. The exercise lasted for one entire day, providing time for each group for internal strategizing and planning, as well as meetings and negotiations with other groups. A debriefing session on the next day provided the groups with the opportunity to present the results of their negotiations as well as to review the main lessons and challenges of the exercise. The role play was run by Professors Lichia Yiu and Raymond Saner (Centre for Socio-Eco-Nomic Development/CSEND).

Upon request by BMZ/GTZ, UNCTAD and GTZ staff had prepared **analyses of national patent legislation** of Ethiopia and Tanzania, which were discussed with the participants from these countries. The objective was to receive feedback from the participants for the finalization of the country studies. Resource persons involved in the presentations of the country studies were Dr. Sandy Harnisch (GTZ) and Mr. Kiyoshi Adachi (UNCTAD) for Ethiopia; and Mr. Christoph Spennemann (UNCTAD) for Tanzania.

The workshop will in several ways feed into UNCTAD's activities on IP and local pharmaceutical production and supply (BMZ/GTZ)/regulatory frameworks for ATM (DFID). Feedback from the participants will help the TOT-IP team finalize both the draft on A Stakeholders' Reference Guide to IP and Related Policies and the Ethiopia and Tanzania country studies. In addition, the experiences made at this workshop will provide important guidance for the design of UNCTAD's future training courses on IP and local pharmaceutical production and supply capacity. Finally, UNCTAD is prepared to provide follow-up advisory services to the participants and their respective agencies, based upon the course materials made available at the workshop.

Results of the Evaluation Questionnaire

Of the 42 participants, all beneficiary participants and observers were asked to complete the Evaluation Questionnaire, a copy of which is attached. 27 evaluation forms were returned, and constitute the basis for this analysis.

The evaluation forms unanimously indicated that the workshop had achieved its objective in familiarizing and sensitizing stakeholders of the full range of intellectual property tools to encourage the development of local productive and supply capacity in the pharmaceutical sector, with particular attention to the obligations and flexibilities available under the TRIPS Agreement.

Participants were asked to rate on a scale of 1 to 5 various aspects of the workshop, with a score of 1 indicating "very poor", a score of 2 indicating "poor", a score of 3 indicating "good", a score of 4 indicating "very good" and a score of 5 indicating "excellent". The average score for the organization of the workshop, audio-visual equipment, quality of trainers/lecturers and documentary materials all scored averages of 4 or above (4.00, 4.08, 4.25 and 4.22, respectively), indicating a very high degree of satisfaction with these aspects. The conference facilities at UN Economic Commission for Africa were rated, on average, slightly lower at 3.96. With respect to the workshop materials disseminated, average responses for presentation and technical expertise were 4.15 and 4.02, respectively, with a slightly lower average response of 3.89 for both clarity and comprehensiveness.

Of the 27 respondents, two-thirds (18) stated that the workshop was long enough to cover the topics presented fully, while one third (9) stated that the workshop was too short. No one indicated that the workshop was too long.

With respect to the curriculum, all 27 participants found the module on patentable subject matter to be very useful to their work. This was followed by the modules on parallel imports (26 participants), patentability criteria and exceptions to patent rights (25 participants, respectively), strategic perspectives (24 participants), restrictive business practices (23 participants) and compulsory licenses (22 participants). Respondents generally were generally of the opinion that sufficient time was allocated to covering these topics (more than 20 of the respondents stated this for all the modules except strategic perspectives, for which 13 participants felt that there was sufficient time spent on this topic and 10 participants felt that more time could have been spent on this topic).

The participants unanimously found the role-play to be an effective way to deepen understanding of the legal concepts introduced in the workshop (26 responses – one respondent missed the role play and did not fill out this section of the evaluation questionnaire). The participants also unanimously felt that the simulation exercise was an effective way to help grasp how the obligations and flexibilities under the TRIPS Agreement interact with various business and other decision-making processes. The overwhelming majority also felt that they benefited from the simulation in becoming more effective in policy related negotiations on this topic (25 of 26 respondents).

Respondents were asked to assess whether they benefited substantially, sufficiently or insufficiently in the introduction of new topics, understanding problems and issues, introducing new concepts, facilitating exchange of experiences and facilitating transfer of skills. According to the participants, the workshop was particularly effective in getting the participants to better understand problems and issues and facilitating the exchange of experiences (25 participants answered substantially or sufficiently for the former, 24 participants answered substantially or sufficiently for the latter). This was followed by introduction of new concepts (22 participants answered substantially or sufficiently), transfer of skills (21 participants answered substantially or sufficiently) and the introduction of new topics (19 participants answered substantially or sufficiently).

The results of the evaluation questionnaire appear to validate the course curriculum. The role play seems to effectively bring together the concepts introduced in the first three days of the workshop. The materials could be considered ready for deployment in any region or country, given a measure of tailoring.

Potential areas for improvement include: 1) better time management, in particular, where there are invited speakers such as for the strategic perspectives session; and 2) ensuring better facilities (consider holding at a

hotel where there are a full-range of business support services and lodgings already available, as opposed to the significantly less expensive, but somewhat spartan, UN premises). Consideration may also be given to extending the workshop to five full days, as opposed to 4.5 days, if time permits (in this case, mini-workshops for Ethiopia and Tanzania were held on the afternoon of the last day to discuss the preliminary findings of our analysis of their patent laws). On the other hand, two-thirds of the participants felt the workshop to be the right length of time.

EVALUATION QUESTIONNAIRE

Workshop on Developing Local Productive and Supply Capacity in the Pharmaceutical Sector – the Role of Intellectual Property Rights
Addis Ababa, 19-23 March 2007

You have been participating in the above-mentioned workshop. The organizers of the workshop are conducting an evaluation of the workshop with a view to improving similar training activities. Your assistance in completing this questionnaire will be of great benefit for that purpose. Your answers to the questions will be treated on a confidential basis and will be for internal use only. It would be appreciated if you could draw on your personal knowledge and records and be as specific as possible in your response. You may also wish to extend your response beyond the space allocated in the questionnaire or provide supplementary material as relevant.

1. Please rate the following aspects of the workshop using the following scale:
5 = Excellent, 4 = Very Good, 3 = Good, 2 = Poor, 1 = Very Poor, NA = Not Applicable

Organization: ___ Facilities: ___
Audio/visual equipment: ___ Overall quality of documentary material: ___
Overall quality of trainers/lecturers: ___

2. If you have given a rating of 2 or less, please give a brief comment or the reasons for the rating:

3. Did you think the workshop was: (Please underline the appropriate expression)

Too long Long enough to cover topics fully Too short

4. Using the same scale as in item 1 above, please rate the workshop materials:

Presentation: ___ Clarity: ___
Technical/analytical expertise: ___ Comprehensiveness: ___

5. Please check the appropriate value for each topic covered in the workshop:

	Usefulness to your work		**Time allocated**		
	Very useful	Not very useful	Too much	Sufficient	Too little
Patentable Subject Matter	___	___	___	___	____
Patentability Criteria	___	___	___	___	____
Exceptions to Patent Rights	___	___	___	___	____
Restrictive Business Practices in Licensing	___	___	___	___	____
Parallel Imports	___	___	___	___	____

	Usefulness to your work		Time allocated		
	Very useful	Not very useful	Too much	Sufficient	Too little
Compulsory Licensing	___	___	___	___	____
Strategic Perspectives	___	___	___	___	____

Please list any topics that you would have liked to see covered in this workshop:

6. The objective of the workshop was to familiarize and sensitize stakeholders of the full range of intellectual property tools to encourage the development of local productive and supply capacity in the pharmaceutical sector, with particular attention to the obligations and flexibilities available under the TRIPS Agreement. In your opinion, did the workshop achieve its objective as stated? (Please circle the appropriate answer)

YES NO

Please comment if you checked NO:

7. a) Did you feel that the Simulation Exercise was an effective way to deepen your understanding of the legal concepts introduced in the workshop?

YES NO

b) Did you feel that the Simulation Exercise was an effective way to help you grasp how the obligations and flexibility under the TRIPS Agreement interact with various business and other decision making processes in the context of ensure access to essential drugs?

YES NO

c) Did you feel that you have benefited from the Simulation Exercise in becoming more effective in policy related negotiations?

YES NO

Please comment if you checked NO to any of the above.

8. If you benefited from the workshop, was it because of the following? (Please check the appropriate answer)

	Substantially	Sufficiently	Insufficiently
Introduction of topics new to you	____	____	____
Understanding of problems and issues	____	____	____
Introduction of new concepts	____	____	____
Exchange of experiences	____	____	____
Transfer of skills	____	____	____

9. Please provide any additional comments and/or suggestions the organizers should take into account for future similar events:

PROGRAMME

UNCTAD REGIONAL WORKSHOP ON DEVELOPING LOCAL PRODUCTIVE AND SUPPLY CAPACITY IN THE PHARMACEUTICAL SECTOR – THE ROLE OF INTELLECTUAL PROPERTY RIGHTS
19-23 March 2007
United Nations Conference Center UNECA
Addis Ababa, Ethiopia

Objective: This workshop is designed to familiarize and sensitize stakeholders (i.e, relevant officials of the Ministries of Health and Trade/Investment, drug regulatory authorities, senior executives of local pharmaceutical manufacturers, civil society and academia) of the full range of intellectual property tools to encourage the development of local productive and supply capacity in the pharmaceutical sector. Particular attention will be paid to the obligations and flexibilities available under the TRIPS Agreement. The intended participants of this regional workshop are from Botswana, Ethiopia, Kenya and Tanzania, as the beneficiary countries of UNCTAD's joint technical cooperation activities with the Governments of Germany (BMZ and GTZ) and the United Kingdom (DFID) in this area. UNCTAD is organizing this workshop in collaboration with the Engineering and Capacity Building Programme and the Commonwealth Secretariat.

Sunday, 18 March 2007

Arrival of participants

Monday, 19 March 2007

Morning Session

10:00 Registration of participants

I. Welcome and Introduction

11:00 Welcome Remarks
- Mr. Kiyoshi Adachi, Legal Officer, Technology Transfer & Intellectual Property, UNCTAD
- Mr. Michael Nebelung, Deputy Programme Director, ECBP
- Mr. Andreas Edele, Trade Policy, Trade and Investment Promotion, Economic Development and Employment Division, GTZ

11:45 Introduction to the Workshop/Setting the Scene: Intellectual Property Rights and the Local Production & Supply of Pharmaceutical Products
Mr. Kiyoshi Adachi, UNCTAD

13:00-14:30 Lunch

Commonwealth Secretariat

Afternoon Session

II. Intellectual Property Regime under TRIPS: Obligations and Flexibilities

14:30 Overview: The TRIPS Agreement Flexibilities in the Context of Public Health Policies
Mr. Christoph Spennemann, UNCTAD
15:15 Questions & Answers

15:45 Coffee break

16:00 Pre-Grant Flexibilities: Patentable Subject Matter
Mr. Christoph Spennemann, UNCTAD
16:30-17:00 Questions & Answers

19:30 Welcome Dinner

Tuesday, 20 March 2007

Morning Session

II. Intellectual Property Regime under TRIPS: Obligations and Flexibilities (con't.)

09:00 Pre-Grant Flexibilities: Patentability Criteria
Mr. Christoph Spennemann, UNCTAD
10:00 Questions & Answers

10:30 Post-Grant Flexibilities: Exceptions to Patent Rights
Mr. Christoph Spennemann, UNCTAD
11:15 Questions & Answers

11:45 Coffee Break

12:15 Overview: The Control of Restrictive Business Practices in IP Licensing: TRIPS minimum standards
Mr. Christoph Spennemann, UNCTAD
12:45 Questions & Answers

13:00-14:30 Lunch

Afternoon Session

II. Intellectual Property Regime under TRIPS: Obligations and Flexibilities (con't.)

14:30 Parallel Imports
Mr. Achal Prabhala, Alternative Law Forum
15:15 Questions & Answers

15:45 The Protection of Clinical Test Data
Mr. Achal Prabhala, Alternative Law Forum
16:30-17:00 Questions & Answers

Wednesday, 21 March 2007

Morning Session

II. Intellectual Property Regime under TRIPS: Obligations and Flexibilities (con't.)

9:00 Post-Grant Flexibilities: Compulsory Licensing of Patented Inventions
Dr. Sandy Harnisch, GTZ

10:30 Coffee Break

11:00 Post-Grant Flexibilities: Compulsory Licensing of Patented Inventions (con't.)
Dr. Sandy Harnisch, GTZ
11:30 Questions & Answers

12:15 Wrap-up Session: TRIPS Flexibilities
Mr. Christoph Spennemann, UNCTAD

12:30-14:00 Lunch

Afternoon Session

III. IPR Frameworks - Strategic Perspectives

14:00 Using TRIPS Flexibilities: The Regional Approach
Mr. Kiyoshi Adachi, UNCTAD

14:35 The Role of Civil Society in the Use of TRIPS Flexibilities
Mr. Jonathan Berger, AIDS Law Project

15:10 Beyond IPRs: Strategies for the Promotion of Local Production Capacities in Developing Countries
Mr. Frank Schmiedchen, Senior Officer, BMZ

15:45 Beyond IPRs: Trade and Fiscal Frameworks for Pharmaceutical Products
Ms. Kathy-Ann Brown, Commonwealth Secretariat

16:20 Questions & Answers

IV. Introduction to Role Play Exercise

17:00-18:00 Modalities & Objectives of the Role Play Exercise
Prof. Lichia Yiu, Prof. Raymond Saner, CSEND

Thursday, 22 March 2007

IV. Role Play Exercise

Prof. Lichia Yiu, Prof. Raymond Saner, CSEND
Resource Persons: Adachi, Brown, Edele, Harnisch, Prabhala, Schmiedchen, Spennemann

12:00-13:30 Lunch

16:00 Coffee break

Working Dinner w/ Academia – Training of Trainers

Friday, 23 March 2007

Morning Session

9:00 V. Debriefing – Role Play Exercise
Prof. Lichia Yiu, Prof. Raymond Saner, CSEND
Resource Persons: Adachi, Brown, Edele, Harnisch, Prabhala, Schmiedchen, Spennemann

11:00 Coffee break

11:15 VI. Closing Remarks, Workshop Evaluation and Certificate Presentations
Mr. Kiyoshi Adachi, UNCTAD
Mr. Frank Schmiedchen, BMZ
Mr. Michael Nebelung, Deputy Programme Director, ECBP

12:00-13.30 Lunch

Afternoon Session (participants from Tanzania and Ethiopia only; parallel sessions)

13:30 VII A . UNCTAD Analysis of Country Patent Law – Tanzania
Mr. Christoph Spennemann

13:30 VII B. UNCTAD Analysis of Country Patent Law – Ethiopia
Mr. Kiyoshi Adachi, Dr. Sandy Harnisch

15:30 Questions & Answers

LIST OF PARTICIPANTS, FACILITATORS AND RESOURCE PERSONS

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BIONOTES: RESOURCE PERSONS AND FACILITATORS

Kiyoshi Adachi

Kiyoshi Adachi is a lawyer with the International Arrangements Section, part of the Investment Policies and Capacity Building Branch, Division on Investment, Technology and Enterprise Development at the Geneva-based United Nations Conference on Trade and Development (UNCTAD). Mr. Adachi leads a team at UNCTAD looking into the integrated treatment of investment, intellectual property and transfer of technology issues in multilateral, regional and bilateral treaties. Before this, he managed technical assistance projects in investment promotion that involved, *inter alia*, the elaboration of draft foreign investment legislation for a number of developing countries; benchmarking countries in their foreign worker entry regulations and practices; and designing and delivering a training programme in policy advocacy for investment promotion agencies. Prior to joining UNCTAD in April 2002, he worked with the United Nations in both New York and Vienna, and as a corporate lawyer with the international law firm of Baker & McKenzie in Tokyo. Mr. Adachi holds a *Juris Doctor* from the UCLA School of Law in Los Angeles (1991) and is admitted to the bars of Pennsylvania and the District of Columbia, USA. He also has a Master of Public Administration from the American University in Washington, D.C. (1995) and a Bachelor's degree from Dartmouth College (1988).

Jonathan Berger

Jonathan Berger is a senior researcher and the head of policy and research at the AIDS Law Project, South Africa. After serving as the legal education and advice officer at the National Coalition for Gay and Lesbian Equality, Jonathan clerked for Justice Kate O'Regan of the Constitutional Court of South Africa. He holds degrees in architecture and law from the University of the Witwatersrand, Johannesburg, as well as a Master of Laws from the University of Toronto. His recent publications include *Health & Democracy: a guide to human rights, health law and policy in post-apartheid South Africa* (co-edited with Adila Hassim and Mark Heywood) (SiberInk, Cape Town: 2007); "Resexualising the epidemic: desire, risk and HIV prevention", (2005) 5 *Development Update* 45; "Patents and Public Health: Principle, Politics and Paradox" (with Edwin Cameron), (2005) 131 *Proceedings of the British Academy* 339 (also published in David Vaver (ed), *Intellectual Property Rights* (Routledge, London: 2005)); and "Advancing Public Health by Other Means: Using Competition Policy" with Pedro Roffe in *Negotiating Health: Intellectual Property and Access to Medicines* (Earthscan, London: 2005)

Kathy-Ann Brown

Dr. Kathy-Ann Brown is a Legal Adviser with the Special Advisory Services Division of the Commonwealth Secretariat. She is attached to the Economic and Legal Section (ELS) which brings together international lawyers and economists who work on trade and investment issues, providing technical assistance to vulnerable developing countries on, *inter alia*, sequencing trade-related policy reforms consistent with their strategic development objectives and WTO rules. The implementation of WTO flexibility measures is a key element of ELS program work; a particularly prominent area concerns TRIPS and access to medicines. Prior to working in-house with the Commonwealth Secretariat, Dr. Brown was engaged by the Commonwealth as an external consultant to provide support to the ACP Secretariat in Brussels. Previously, she spent four years with the Caribbean Regional Negotiating Machinery (London & Geneva offices) as Senior Technical Adviser (Legal – International Trade) – during that time she worked on WTO issues and closely followed the ACP-EU negotiations; she also held the position of Lead Negotiator for the Caribbean Community (CARICOM) in the FTAA Negotiating Group on Subsidies, Antidumping and Countervailing Duty Measures.

Dr. Brown has served as a panelist in WTO dispute settlement proceedings and as a representative of Saint Lucia to the WTO. Formerly, she lectured in the field of international economic and development law at both graduate and undergraduate levels at the Faculty of Law, University of the West Indies, Barbados. Prior to joining the Faculty of Law, she worked briefly with the Attorney Generals' Office, Jamaica. Dr. Brown is an Attorney-at-Law. She is a graduate of Trinity Hall, Cambridge University, England, where she gained a Masters degree in Law, before obtaining a PhD on a Commonwealth Scholarship at Osgoode Hall Law School, York University, Canada.

CSEND (Raymond Saner and Lichia Yiu)

The Centre for Socio-Eco-Nomic Development (CSEND) is an independent, project-financed, non-profit foundation, registered with the Geneva Chamber of Commerce. CSEND specializes in the various fields of organizational reform and institutional development, project start-up and team building, management development and training seminars, international negotiations and mediation, quality management (ISO10015), and cultural exchanges. CSEND works to strengthen public administrations and public-sector enterprises through the use of an interdisciplinary, socio-economic approach. In the field of international negotiations, CSEND designs and conducts seminars for government officials, diplomats and others on international trade, diplomatic and environmental negotiations. Participants are provided with concepts and techniques needed for an effective mastery of diverse negotiation situations with different contexts. CSEND designs and develops live case simulations as part of the learning process tailored for specific international negotiations.

Raymond Saner is the Director of Diplomacy Dialogue, Centre for Socio-Economic Development, Geneva and professor of Organization and International Management at the Economic Sciences and Business Administration Centre, University of Basel, Switzerland. His current research focuses on multi-stakeholder economic diplomacy and multilateral trade. He gained his Ph.D. in social psychology from UGS University, Ohio.

Lichia Yiu is a senior partner of Organizational Consultants Ltd. in Hong Kong and a visiting professor at the Business School, National Chengchi University, Taipei. Her current research focuses on global leadership, learning and development management and HR governance. She gained her Ed.D. in counseling psychology from Indiana University, Bloomington and did her post-doctoral fellowship in organizational psychology at Teachers College, Columbia University, New York.

Andreas Edele

Andreas Edele has been working at the German Agency for Technical Cooperation (GTZ) in the area of trade policy as well as trade and investment promotion since January 2007. He studies international relations, economics and pulbic law at the University of Tübingen and the University of California at Berkeley. Prio to joining GTZ, he worked as a consultant for the Centre for Applied Studies in International Negotiations in Geneva, and as a research and teaching assistant at the University of Tübingen.

Sandy Harnisch

Dr. Sandy Harnisch studied law at the University of Goettingen (Germany). After her first examination, she did her doctoral research on intellectual property law at the Universities of Cape Town (South Africa) and Berlin. As part of her legal traineeship, Dr. Harnisch is working for the German Technical Cooperation (GTZ) in Arusha, Tanzania on legal aspects of pharmaceutical production in East Africa.

Achal Prabhala

Achal Prabhala was educated in economics and public policy management at Middlebury College and Yale University. He researches intellectual property from Bangalore, India. Previously, he was based in Johannesburg, South Africa where he coordinated a regional project on access to learning materials. Relevant research, including co-authored work, consists of the World Bank's "Battling HIV/AIDS – A Decision Maker's Guide to the Procurement of Medicines and Related Supplies" (2004), an analysis of the US-SACU FTA (2005), a needs assessment around access to medicines in Botswana (2006), and a position paper on pharmaceutical data protection in India (ongoing, 2007).

Frank Schmiedchen

Frank Schmiedchen is Senior Officer at the Department of Globalization, Trade and Investment of the German Federal Ministry for Economic Cooperation and Development (BMZ). He is responsible for intellectual property rights (WTO-TRIPS, WIPO) as well as for Germany's seat at the UN Industrial Development Organization (UNIDO). From 1999 to 2001, he worked in the area of biotechnology and biological diversity at the Ministry. From 2001 to 2004, he was responsible for trade and

development issues as well as for the relations between the EU and ACP countries at Germany's Permanent Mission at the European Union.

Christoph Spennemann

Christoph Spennemann, LL.M, holds a master's degree in international economic law and European law of the Universities of Lausanne and Geneva (Switzerland). He also studied law at the universities of Passau and Freiburg (Germany) and Grenoble (France). After his bar examination, Mr. Spennemann practised law in a Berlin firm and joined UNCTAD's Division on Investment, Technology and Enterprise Development (DITE) in 2001 to work as a Legal Expert on intellectual property rights, technology transfer and development.

List of Documents Distributed

I. Publications

- UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, Cambridge University Press 2005
- UNCTAD-ICTSD, *Exceptions to Patent Rights in Developing Countries*, Issue Paper No. 17, by Christopher Garrison, Geneva, 2006
- UNCTAD-ICTSD, *Guidelines for the Examination of Pharmaceutical Patents: Developing A Public Health Perspective*, Working Paper, by Carlos Correa, Geneva, January 2007
- Adila Hassim/Mark Heywood/Jonathan Berger (eds.), *Health & Democracy. A Guide to Human Rights, Health Law and Policy in Post-apartheid South Africa*, Siber Ink, Cape Town, 2007.

II. Official documents

- Marrakesh Agreement Establishing the World Trade Organization [WTO Agreement], Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994 [TRIPS Agreement], 33 I.L.M. 81 (1994) (http://www.wto.org/english/docs_e/legal_e/27-trips.pdf)
- Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf)
- Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr.1, Decision of the WTO General Council of 30 August 2003 (http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)

General Background

BigPharma Corp (BPC) is a major pharmaceutical TNC with headquarters located in the United Kingdom. Last year, after significant investments in R&D, BPC researchers received a patent from the European Patent Office for algoterine, considered a revolutionary new second line medication used in treating HIV/AIDS. The IP Department at BPC simultaneously filed patent applications in a number of countries, including the Sotowa Republic, a least developed country in sub-Saharan Africa with a population of 25 million. In January 2007, the application in Sotowa was approved by the country's patent office, for the statutory period of 20 years from the date of filing (two years ago).

Due to its rich mineral resources, Sotowa Republic generates a sizeable amount of income and has in the past few years enjoyed a relatively strong growth rate. Accession talks were successfully concluded permitting Sotowa Republic to join the World Trade Organization in 2002. Sotowa is also a member of the Arunga Economic Community (a regional intergovernmental organization and customs union made up of five least developed countries in the region), and is contemplating entering into a bilateral investment treaty (BIT) with the United Kingdom. Representatives of the African empowerment movement within Sotowa and some elements of civil society have voiced concern on the issue of entering into BIT negotiations with the UK, however. Sotowa has to date used a significant portion of its development assistance to build human capital. For instance, the country established a medical and pharmaceutical university ten years ago, which is relatively well respected and is attended by students from Sotowa and neighboring countries.

As with many sub-Saharan African countries, Sotowa Republic has a major health crisis with close to 20% of their population between 18 and 35 being HIV positive. Life expectancy has dropped significantly over the past decade to 47 years. The Sotowa Ministry of Health (SMH) has therefore, in addition to other measures (including fundraising for donations of ARVs from donor governments or cash to purchase them), prioritized access to affordable medicines as an important means to address this problem. After a recent review, the SMH decided to add algoterine to their list of essential medicines.

Founded by graduates of the national medical and pharmaceutical university, GeneRex Corp. (GR) is a local firm that has to date manufactured selected over-the-counter drugs for the Sotowa population. Its initial success has enabled it to invest in production capacity, and they are currently producing seven different over-the-counter (OTC) drugs. Most of the inputs are imported. GR is also a distributor in the region for a number of generic drugs made by a fast-growing Indian generic manufacturer, International Pharmaceutical Enterprise (IPE).

The Kingdom of Kando borders Sotowa Republic to the south, with which it enjoys good relations. Kando is a landlocked LDC. Its sole industry is to manufacture cheap garments for export that enjoy preferential tariff treatment in developed markets. Many of these manufacturers are Chinese and Indian, and have pulled out of Kando in recent years leaving behind empty factories and warehouses. Kando has to date never manufactured any medicines. Almost half of its workforce remains unemployed. While it harbors intentions of one day becoming a WTO member, it has not yet been able to conclude, let alone seriously start, accession talks. Kando is, however, also a member of the Arunga Economic Community.

The health crisis in Kando is even more serious than the one in Sotowa. The population relies on donations for a large proportion of their essential medicines. These medicaments are distributed either through aid agencies or through KandoPharmacies (KP), the only notable retailer of medicaments in

the country. The majority of shares of KP are owned by GR. The Kando Ministry of Health (KMH) also has recently included algoterine on their list of essential medicines. BPC has not applied for a patent in Kando.

Both Sotowa and Kando have laws which permit the issuance of a compulsory license upon the failure to agree on terms for the manufacture and sale of a pharmaceutical product that is the subject of a registered patent, with the requirement that the owner of the patent must receive fair payment therefore. Neither country has so far issued such a compulsory license, however. Both Sotowa and Kando laws permit the parallel importation of pharmaceutical products, a situation where a local producer may consider selling its cheaper products to richer countries, for example, South Africa or Thailand. Further, both Sotowa and Kando permit the issuance of government use licenses of pharmaceutical products. Neither the laws of Sotowa or Kando provide for clinical test data exclusivity, though owners may file claims under the respective unfair competition laws.

The guarantee of quality is an important issue. Even when medicines and other products get to infected people, they may not always be of good or adequate quality. Sometimes the best available medicine can have substantial side-effects, be toxic or can even be counterfeit. Exactly how regulatory authorities can guarantee quality or what methods and methodologies are appropriate in regulating medicines depends on a range of circumstances and case-by-case judgments about risks and benefits. Issues of quality include both the production of algoterine as well as proper storage and labeling techniques. Methods to insure proper quality must be discussed and can potentially include, among other options, government regulation, third party audits or direct regulation by either BPC or IPE. Issues with respect to the Sotowa or Kando government's ability to effectively regulate the domestic production and marketing of algoterine will also be relevant.

Executives at GR have succeeded in inviting a team of representatives from BPC to explore the possibility of negotiating a license for the manufacture, use and distribution of algoterine. Concerned about ensuring a price for the drug that is affordable for the population, officials from the SMH have summoned GR executives to its offices for a meeting ahead of their negotiations. At the same time, representatives of IPE are in town to assess the possibility of relocating some of its manufacturing operations to an LDC, with a view to taking advantage of extensions in TRIPS Agreement implementation phases for LDCs. Additionally, IPE is interested in TRIPS flexibilities which give each TRIPS Member the right to develop their own methods to bring themselves into conformance with TRIPS obligations. According to the Doha Declaration, TRIPS flexibilities also give each Member the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

Meanwhile, the regional office of AIDS Watch, an international NGO, has received significant press coverage of late, especially due to its criticism of how the governments of the region have lagged behind in responding to the AIDS crisis, and are paying particular attention to the negotiations between GR and BPC. NGOs such as AIDS Watch have proven instrumental in ensuring social interests and essential human rights are considered and protected during negotiation processes. It is also known that AIDS Watch has contact with International Dispensary Association (IDA) whose mission is to ensure affordable prices of essential drugs around the world.

Confidential Information for each of the teams is provided herewith. Copies of the relevant provisions of the laws of Sotowa Republic and of the Kingdom of Kando are also made available as background materials to the participants. All participants should also have a copy of a sample license agreement as part of the guide and training materials (annex I).

Demographic Information

Sotowa	
Population	24,707,817
Median Age	18.2 years
Population Growth Rate	2.57%
Birth Rate	39.72 births/1,000 population
Death Rate	14.02 deaths/1,000 population
Net Migration Rate	0 migrant(s)/1,000 population
Life Expectancy	46.93 years
HIV/AIDS Prevalence Rate	7.7%
Literacy Rate	85.1%
GDP Purchasing Power	$37,890,000,000
GDP Per Capita (real)	$530
Population Below Poverty Line	50%

Kando	
Population	6,005,250
Median Age	17.4 years
Population Growth Rate	2.3%
Birth Rate	45.76 births/1,000 population
Death Rate	23.03 deaths/1,000 population
Net Migration Rate	.23 migrants/1,000 population
Life Expectancy	40.22 years
HIV/AIDS Prevalence Rate	9%
Literacy Rate	29.6%
GDP Purchasing Power	$4,939,000,000
GDP Per Capita (real)	$160
Population Below Poverty Line	68%

Arunga Economic Community	
Population	76,782,667
Median Age	17.8 years
Population Growth Rate	2.43%
Birth Rate	42.74 births/1,000 population
Death Rate	18.53 deaths/1,000 population
Net Migration Rate	.17 migrants/1,000 population
Life Expectancy	43.58 years
HIV/AIDS Prevalence Rate	8.4%
Literacy Rate	57.35%
GDP Purchasing Power	$107,072,500,000
Ave GDP Per Capita (real)	$345
Population Below Poverty Line	59%

A Multi-Stakeholder Simulation for
"Developing Local Productive and Supply Capacity in the Pharmaceutical Sector – The Role of Intellectual Property Rights & TRIPS"

Can We Make A Licensing Deal?

Time	Activities	Material Distributed	Pedagogical Remarks
21st March 2007			
Session 1: Initial Briefing			
16.30 – 17.30	Introduction to the Simulation Exercise	▪ General Background of the simulation ▪ Socio-Economic issues to be negotiated ▪ Learning objectives ▪ Self-Assessment Questionnaire	Tie-in with the Guide – "Local Production & IP Guide"
22nd March 2007			
Session 2: Role Assignment and Preparation			
09.00 – 09.30	Role Assignments and Ground Rules	▪ Role specific Confidential Information	
09.30 – 09.45	Q&A		
09.45 – 10.30	Team Meeting (1) and Planning	▪ Negotiation Planning Sheet	
Session 3: Negotiation Round I & II: Exploring Positions and Solutions			
10.30 – 11.30	Round I: Initial Contacts & Exploring Cooperation Opportunities – Meeting limited to 15 minutes each		
11.30 – 12.30	Team Meeting (2)		
12.30 – 14.30	Round II (including working lunch): Clarifying Positions & Exploring Solutions		
14.30-- 15.30	Team Meeting (3)		
Session 4: Negotiation Round III & IV: Working Through and Reaching Agreements			
15.30 – 17.00	Round III: Negotiating Solutions		

17.00 – 17.45	Team Meeting (4)		
17.45 -- Open	Final Round IV: Concluding Negotiations		Get the results from each team/track
End of the Simulation			
23rd March 2007			
Session 5: Debriefing and Reflections			
9.00 – 11.00	Debriefing ▪ Presentation of group results ▪ Comments by the Resource Group ▪ Group Discussion		