UNITED NATIONS
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THE USE OF INTELLECTUAL PROPERTY RIGHTS' FLEXIBILITIES TO PROMOTE PHARMACEUTICAL PRODUCTION IN ETHIOPIA

Report on a Workshop and a Briefing Session

UNCTAD organised a workshop on the use of intellectual property rights' flexibilities to promote local pharmaceutical production in Ethiopia, held from 3-4 May 2016, and a high level dinner briefing session, on 4 May 2016, in Addis Ababa, Ethiopia (for details, see Annex I to this report). The workshop and the high level briefing session were organised in collaboration with the World Health Organisation (WHO) and the Ministry of Industry and Ministry of Health of Ethiopia. The purpose of both events was for UNCTAD to receive multi-stakeholder approval of its recommendations made to the Government of Ethiopia in its advisory report on "Intellectual Property and Local Pharmaceutical Manufacturing in FDR Ethiopia" in response to an invitation from the Ministry of Industry. The report contains recommendations on the targeted use of WTO TRIPS flexibilities in Ethiopia's domestic intellectual property law to promote the development of the domestic pharmaceutical industry in the context of the National Strategy and Plan of Action for Pharmaceutical Manufacturing Development (2015-2025).

Participants from eight pharmaceutical manufacturers, two research centres and two universities (Addis Ababa University and Adama Science and Technology University), the Ethiopian Intellectual Property Office (EIPO), the Ministry of Science and Technology, the Ministry of Industry, the Food, Beverage and Pharmaceutical Industry Development Institute, and from regulatory authorities attended the workshop (see Annex II).

The high level briefing session was chaired by Dr. Mebrahtu Meles, State Minister of Industry, and attended by the chairpersons of the Legal and Administrative Affairs Standing Committee, the Trade and Industry Affairs Standing Committee and the Science, Communication Technology Standing Committee of the of the House of Peoples' Representative of Ethiopia, Director of EIPO, and one representative of the State Minister of Science and Technology. Two UNCTAD staff and three WHO staff facilitated the discussion during the workshop and the dinner briefing.

Financing for this workshop was provided under the initiative of the German Federal Ministry for Economic Cooperation and Development (BMZ) to support local production of pharmaceuticals in developing countries.

Introduction

The workshop was opened by representatives from the Ministries of Industry and Health as well as Mr. Christoph Spennemann, Officer in Charge of the Intellectual Property Unity of the Division on Investment and Enterprise of UNCTAD (see Annex I for the programme).

Workshop Discussion

During the workshop staff of World Trade Organisation, World Health Organisation, UNCTAD, and EIPO, made the following presentations:

- Mr. Antony Taubman, Director, and Mr. Roger Kampf, Counsellor, Intellectual Property Division, WTO, made a presentation outlining the relevant international actors and international policy instruments, such as the Sustainable Development Goals, the WTO Declaration on the TRIPS Agreement and Public Health, and the interface between the TRIPS Agreement and public health, including the provisions on patents, exhaustion of IP rights, pharmaceutical test data protection, and enforcement.
- Ms. Josefita Pardo de León, Legal Affairs Officer , Accessions Division of WTO, presented on the status of Ethiopia's WTO accession, provided an overview of the specific accession commitments of selected LDCs, including the average bound tariff rate for pharmaceutical products, and selected national action plans in acceding LDCs for implementation of the TRIPS Agreement;
- WHO provided some background to the National Strategy and Plan of Action for Pharmaceutical Manufacturing Development (2015-2025);
- Mr. Christoph Spennemann presented in detail the recommendations of UNCTAD's advisory report on IP and local pharmaceutical production to exclude pharmaceutical product patent from current law and enhance the use of IP tools that support incremental innovation. He focused on the transition period for LDCs for the implementation of the TRIPS Agreement in general that lasts until 2021 and for the implementation of obligations with respect to pharmaceutical products and undisclosed pharmaceutical test data that lasts until 2033. He outlined the experience of other countries on patent and pharmaceutical sector strategies, the relationship between patent and access to medicine, and patent, investment and innovation. He stressed that where an LDC does not exclude pharmaceutical product patent, it can nevertheless implement the various flexibilities available under the TRIPS Agreement, especially with respect to defining subject matter

eligibility, patent examination, exceptions to the rights granted by patent and enforcement procedures.

- The head of the Ethiopian patent office (EIPO) presented EIPO's work and expressed his support for UNCTAD's recommendation to amend the Ethiopian patent law to exclude pharmaceutical products from patent protection.
- Mr. Ermias Biadgleng, Legal Affairs Officer, IP Unit, UNCTAD, presented UNCTAD's recommendations for an IP policy concerning pharmaceutical trademark and prescription policy, unfair competition and anti-counterfeiting measures, infringement and remedies (criminal, civil and administrative procedures, injunctions, damages, disposal/destruction of goods, border measures and goods in transit). Special attention should be given to trademarks that are likely to mislead the nature or characteristics of a pharmaceutical product, especially, confusing the generic names of different categories of products. He also presented the recommendations of UNCTAD's advisory report on IP and local pharmaceutical production to improve coordination between EIPO and EFM-HACA, to revise the utility model protection, to avoid criminal procedures for enforcement of IP rights, and increase the support for regulatory authorities to prevent the import and distribution of substandard, spurious, falsely labelled, falsified and counterfeit.

Each session was followed by open discussion. Participants endorsed UNCTAD's recommendation on the exclusion of pharmaceutical product patent. Participant also highlighted the problem of conflicting trademarks in the local market. Some argued on the relevance of trademarks to promote access to medicine.

Workshop Evaluation

At the end of the workshop participants were requested to evaluate the workshop, its preparation, methodologies and discussions during the workshop. 63% of the participants and the remaining 37%, stated that their participation in the workshop will be definitely useful or mostly useful for their work, respectively. The quality of the workshop discussion and presentations was 'excellent' for 58% of participants, while one participant found them 'fairly good', and another one stated they 'can be improved", while the remaining participants rated the them as "good." The general expertise of the workshop facilitators was rated as 'excellent" by 63% of the participants and "good" by the remaining. The group discussions, however, were rated excellent only by 32% of participants, while 58% of the participants still find them 'very good". Two participants consider the group discussions as 'fairly good' or can be improved. UNCTAD’s overall organisation of the event was considered as excellent by 79% of respondents.

Although participants overwhelming provided high rating from workshop on various criteria, the provided areas for further improvement, including:

1. More time for discussion and the possibility of organising group discussions;
2. The video presentation could be improved.

3. There is a need for continuous training, also to cover other relevant topics; and support to address practical problems that local manufacturers would face in the implementation of the National Strategy and Plan of Action
4. It was an eye opening session- local manufacturers did not know the IP dimensions of pharmaceuticals.
5. Workshop materials should be available in soft copy.
6. The UNCTAD study and its recommendations need to be followed.

High level Briefing session

The high level dinner briefing session on IP policy and local pharmaceutical manufacturing was organized to present UNCTAD's advisory report on IP and local pharmaceutical production in Ethiopia and to build consensus on the way forward to implement 'Objective 8' of the National Strategy and Plan of Action for Pharmaceutical Manufacturing Development (2015-2025, National Strategy) adopted in October 2015 by the Ministry of Industry and Ministry of Health of Ethiopia. Objective 8 of the National Strategy prioritises the goal of "exploiting the LDC Status to locally produce patented products." UNCTAD presented its advisory report that includes recommendations for exclusion of pharmaceutical product patent, improvement of the utility model and trademark protection to support incremental innovation, among others. Participants endorsed the recommendations, although they had differences whether to review the entire Inventions, Minor Inventions and Industrial Designs No. 123/1995 Proclamation (Patent Proclamation) or amend only the relevant provisions concerning pharmaceutical product patent. It was agreed that UNCTAD in consultation with WHO would draft a provision to be inserted into the Patent Proclamation to reflect the LDC transition period for pharmaceutical products (2033).

Workshop Announcement I
3-4 May – Addis Ababa I Ethiopia

ANNEX I

THE USE OF INTELLECTUAL PROPERTY RIGHTS' FLEXIBILITIES TO PROMOTE LOCAL PHARMACEUTICAL PRODUCTION IN ETHIOPIA

The United Nations Conference on Trade and Development (UNCTAD), in collaboration with FDRE Ministry of Industry and Ministry of Health, is organizing a day-and-a-half workshop on the use of intellectual property rights' flexibilities to promote local pharmaceutical production in Ethiopia. The workshop will take place on 3-4 May 2014 in Addis Ababa, Ethiopia. The objective of the workshop is to enhance the understanding of participants of the interface of intellectual property and local pharmaceutical production. The workshop is organised in response to the invitation to contribute to the implementation of National Strategy and Plan of Action for Pharmaceutical Manufacturing Development (2015-2025) in collaboration with the World Health Organization. Financing for this workshop is provided under the initiative of the German Federal Ministry for Economic Cooperation and Development (BMZ) to support local production of pharmaceuticals in developing countries.

Who can attend:

- The workshop is free of charge but open only for participants designated by local generic pharmaceutical industries, university (school of pharmacy or engineering), and targeted government agencies.
- The full name and contact address, including email of the designated participant should be received before 25 March 2016, preferably by email or letter. Up to 30 participants will be accepted for the workshop.

Venue

- The workshop will be held at Radisson Blu, Addis Ababa.
- Lunch will be offered to all participants at the workshop location.

For more information and registration, please contact, Mr. Kedir Tahir Hagos, Ministry of Industry, kediro2@yahoo.com, Daniel Berman, WHO, dmberman@hotmail.com, or Ermias

Biadgleng, UNCTAD, ermias.biadgleng@unctad.org

The Use of Intellectual Property Rights' Flexibilities to Promote Local Pharmaceutical Production in Ethiopia

WORKSHOP PROGRAMME Tuesday , 3 May 2016		
TIME		FACILITATORS
14h00 – 14h15	Registration	MOI & UNCTAD
14h15 – 14h45	Welcoming address	MOI, MOH, Mr. Christoph Spennemann, Legal Officer and Officer-in-Charge, Intellectual Property Unit, UNCTAD
14: 45 – 15:15	The National Strategy and Plan of Action for Pharmaceutical Manufacturing Development (2015-2025)	WHO and MOI
15h15 – 16h00	Setting the scene - Ethiopia's accession to the WTO: what to expect in terms of intellectual property and tariffs and trade in industrial goods. - The TRIPS Agreement - Objectives/ Minimum Standards - Intellectual Property Rights, innovation & investment - LDC transition periods 2021 and 2033	Ms. Josefita Pardo de Leon, Legal Affairs Officer and Secretary of the Working Party on the Accession of Ethiopia, WTO Mr. Antony Taubman, Director, and Mr. Roger Kampf, Counsellor, Intellectual Property, Government Procurement and Competition Division, WTO UNCTAD
16h00 – 16h30	Tea Break	
16:30 – 17:00	Q&A	
17:00 – 17:45	Recent trend: Patents, Invention - Pharmaceutical product and process patent	Mr. Christoph Spennemann, UNCTAD

	- Trend: proliferation of patents - India: product patent and shifting marketing strategy - Current law and trends on pharmaceutical product patent in Ethiopia	EIPO
17h45 – 18h15	Q&A	
18h30 – 20h30	**Reception**	
Wednesday, 4 May 2016		
09h00 – 10h00	LDC Transition Period: An Opportunity for Local Pharmaceutical Production? • Patents and pharmaceutical sector strategy: lesson from the European and Indian experience • Patents, essential medicine and pricing • Pharmaceutical test data protection • Patents, investment and innovation • Research & innovation in LDCs	Mr. Christoph Spennemann UNCTAD;
10h00 – 10:30	Q&A and Exchange of views on utilisation of LDCs transition period	
10:30 – 10:45	Tea Break	
10h45 – 11h15	Q&A and Exchange of views on utilisation of LDCs transition period	
11:15- 12:00	TRIPS flexibilities and Ethiopian Patent law • Patentability; • Facilitating generic approval, research and parallel importation • Competition regulation and licensing practices • Use without authorisation	Mr. Christoph Spennemann, UNCTAD
12:00 – 12:30	Q&A	
12h30 – 14h00	**Lunch**	
14h00 – 16h00 (with 15 minutes coffee break)	Pharmaceutical Trademark, unfair competition and anti-counterfeiting measures • Trademark practices; • Trademarked registration and product registration; • Prescription policy; • Unfair competition and comparative advertisement - Counterfeiting, infringement and remedies (criminal, civil and administrative procedures, injunctions, damages, disposal/destruction of goods) • Border measures and goods in transit.	Mr. Ermias Biadgleng, UNCTAD
16h00 – 16h30	Feedback and Evaluation	
16h30 – 17h00	Closing remarks	MOI, MOH, Mr. Christoph Spennemann, UNCTAD.
End of Workshop		

Annex II

List of participants

	Getachew Mengistie	School of Pharmacy, AAU
1.	Abebe Hagos	Pharmacure Pharmaceuticals
2.	Bonsamo Gobena	FBPIDI
3.	Shiferaw Segedu	VDFACA
4.	Bekele Tefera	RBEC
5.	Ashenif Tadele	EPHI
6.	Dr. Esayas Gelaye	NVI (National Veterinary Institute
7.	Shegaw Aderaw	Sino-Ethiop Associate Africa
8.	Sufyan Abdulber	FMoH
9.	Tegegn Aklilu	Cadila Pharmaceuticals
10.	Yohannes Fisseha Weldearegay	Medsol
11.	Tadesse Mossu	Ministry of Trade
12.	Wondewossen Beyen	MoST
13.	Dr. Mandefero Eshete	EIPO
14.	Agema Bekele	EFMHACA
15.	Shiferaw Fayissa	ASTU
16.	Emshaw Bekele	EIPO
17.	Alem Denekew	Fews Pharmaceuticals
18.	Asemelash Gebre	Asmi Industries
19.	Aschenafi Assefa	Ministry of Industry
20.	Zemen Hunde	Zenith Gebs Eshet Ethiopia Ltd.
21.	Mr. Mohammedsiraj Osman YASSIN	Addis Pharmaceutical Factory (APF) Adigrat
22.	Ermias Biadgleng	UNCTAD
23.	Christoph Spennemann	UNCTAD
24.	Daniel Berman	WHO
25.	Abraham Gebregiorgis	WHO
26.	Kedir Hagos	WHO
Via video-conferencing		
27.	Taubman, Antony	Director, Intellectual Property Division, WTO Secretariat
28.	Roger Kampf,	Counsellors, Intellectual Property Division, WTO Secretariat
29.	Ms Josefita Pardo de Leon	Legal Affairs Officer , WTO Secretariat

Annex III: Results of Workshop Evalaution

WORKSHOP EVALUATION FORM

1. After the workshop, how well did you feel prepared concerning the topics/the content of the workshop?	
Very well prepared	✓✓✓ ? ✓✓✓
Sufficiently prepared	✓✓✓✓✓✓✓✓✓✓✓
Insufficiently prepared	
2. Do you think you have a clear idea about the topics of the workshop?	
Yes, very much so	✓✓✓✓✓✓✓
Yes, generally	✓✓✓✓✓✓✓✓✓✓
Not so much	
Not at all	
3. Did the workshop in general meet your expectations?	
Yes, very much so	✓✓✓✓✓
Yes, generally	✓✓✓✓✓✓✓✓✓✓✓✓✓
Not so much	
Not at all	
4. Do you think having participated in this workshop will be useful for your work?	
Yes	✓✓✓✓✓✓✓✓✓✓✓
Mostly yes	✓✓✓✓✓✓✓
Cannot say	
No	
5. How do you assess… a) … the workshop's methodology and efficiency?	
Excellent	✓✓✓✓✓✓✓✓✓
Good	✓✓✓✓✓✓
Fairly Good	✓
Could be improved-please explain.	The video presentation could be improved.
b) … the quality of workshop discussions and presentations?	
Excellent	✓✓✓✓✓✓✓✓✓✓
Good	✓✓✓✓✓✓
Fairly Good	✓
Could be improved-please explain.	✓
c) … the workshop's overall duration?	
Excellent	✓✓✓✓✓✓✓✓✓
Good	✓✓✓✓✓✓✓
Fairly Good	✓
Could be improved	✓
d) … the workshop facilitators' general expertise in their field?	

Excellent	✓✓✓✓✓✓✓✓✓✓✓
Good	✓✓✓✓✓✓✓
Fairly Good	
Could be improved	
e) … the cooperation and communication with the workshop facilitators?	
Excellent	✓✓✓✓✓✓✓✓✓✓✓✓✓✓
Good	✓✓✓✓
Fairly Good	
Could be improved-please explain.	
f) … the group's professional experience and skill levels?	
Excellent	✓✓✓✓✓✓✓✓
Good	✓✓✓✓✓✓✓✓✓✓✓
Fairly Good	
Could be improved	
g) … the exchange of information and experience at group level?	
Excellent	✓✓✓✓✓✓
Good	✓✓✓✓✓✓✓✓✓✓✓
Fairly Good	✓
Could be improved-please explain.	
h) … the working atmosphere within the group?	
Excellent	✓✓✓✓✓✓✓✓✓✓
Good	✓✓✓✓✓✓✓✓✓
Fairly Good	✓
Could be improved-please explain.	✓
i) UNCTAD's overall organisation of the event?	
Excellent	✓✓✓✓✓✓✓✓✓✓✓✓✓✓
Good	✓✓✓✓
Fairly Good	
Could be improved-please explain.	
6. What is your overall assessment of the workshop?	
Excellent	✓✓✓✓✓✓✓✓✓
Good	✓✓✓✓✓✓✓✓✓✓
Fairly Good	
Could be improved	
7. Do you have any remarks/ suggestions?	
• Good workshop. There is a need for continuous training, also to cover other relevant topics; • Workshop materials should be available in soft copy. • Better preparation on the presentations from Ethiopian institutions. Most examples were based on other countries, without sufficient analysis of the current situation in Ethiopia. EIPO should have provided an in-depth presentation; • The UNCTAD study and its recommendations need to be followed. • The participation need to be enhanced by involving the right government offices.	

- I have understood the TRIPS flexibilities and how they can promote local pharmaceutical production.
- It was an eye opening session- local manufacturers did not know the IP dimensions of pharmaceuticals.
- The workshop should have a group discussion to assist experience sharing and could be more interactive, than a one way communication. There should be more time for discussion. Extend the duration to 3 days.
- The outcome of the workshop should be recommended to the government.
- Improve the use of the workshop time.
- Support to address practical problems that local manufacturers would face in the implementation of the National Strategy and Plan of Action