Report

The two-day seminar was opened by Mr. Khalil Hamdani, Director of UNCTAD's Division on Investment, Technology and Enterprise Development (DITE). Mr. Hamdani, after welcoming the audience, placed the seminar and UNCTAD's related work within the broader framework of the UN Millennium Development Goals (MDGs). According to Mr. Hamdani, large parts of developing country populations still have no regular access to essential medicines, especially in Africa. Acknowledging that effective promotion of affordable access to medicines (ATM) in developing countries depends on a multitude of different factors, Mr. Hamdani stressed that international agreements in the area of intellectual property rights (IPRs) have a strong impact on the design and implementation of public policies and development strategies of many governments in such key areas as public health, agriculture, culture, environment, research and development, and technology transfer. Developing country policy makers therefore face the challenge of how to adapt existing mechanisms for the protection of IPRs such as the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) so as to better address development needs.

After this general introduction, Mr. Hamdani briefly explained UNCTAD's work in the area of IPRs and developing country productive capabilities. Responding to mandates received from Member States at the Ministerial Conference in São Paulo in 2004 and from the Bangkok Plan of Action in 2000, as well as the UNCTAD Commission on Investment, Technology and related Financial Issues in 2005, DITE's International Arrangements Section is implementing a programme on the transfer of technology and intellectual property rights (TOT-IP). Under this programme, and with the support of the Governments of Germany and the United Kingdom, UNCTAD is assessing ways in which developing countries can develop their domestic capability in the production and supply of essential drugs, in cooperation with pharmaceutical companies.

It is in this context that this seminar was convened. The overall aim of this seminar was therefore two-fold:

- First, to seek to clarify the interfaces between intellectual property and other policies for the promotion of local pharmaceutical production and supply, and to identify strategies to improve access to medicines in developing countries, and in particular the Least Developed Countries, in pursuit of the UN Millennium Development Goals.

- Second, to generate ideas and creative thinking for UNCTAD's upcoming stakeholders' reference guide to intellectual property and related policies for the promotion of local pharmaceutical production and access to medicines in developing countries ("IP Guide"). This Guide is meant to provide concise and practical information on the ways international IPR rules may be used as tools for the promotion of local pharmaceutical production and access to essential medicaments.
The IP Guide is mainly addressed at developing country government officials and policy makers, local manufacturers of both patented and generic pharmaceutical products and their legal counsels, as well as civil society stakeholders.

The following sections will summarize the main issues presented and discussed in the course of the seminar, under the various headings of the programme.

Session I: Intellectual Property and Related Policies for the Promotion of Productive Pharmaceutical Capabilities and Access to Medicines

1.) Overview: The Relevance of Public Health-Related TRIPS Flexibilities for Local Pharmaceutical Production and Access to Medicines

Professor Frederick Abbott in his presentation explained the relevance of intellectual property rights (IPRs) at the different stages of the pharmaceutical production process. The overarching message was that considerable political will on the parts of governments and the private sector will be required to promote local pharmaceutical production. In particular, IPRs are relevant to the following stages of the production process:

- The choice of location: the waiver for least-developed countries (LDCs) to comply with TRIPS provisions on pharmaceutical patents until 2016 provides an important window of opportunity for generic pharmaceutical manufacturers to locate production in LDCs.

- Sources of funding for production: IPR compliance might be a pre-requisite to gain access to external funds for local production (e.g. multilateral, national government or private sector resources).

- The acquisition of technology: This may be done through various means:
  - Local research and development (R&D) would benefit from TRIPS-compliant exceptions to patents, in particular the research exemption and early working ("Bolar") exemption.
  - Voluntary licensing of IP: this would enable the transfer of soft technology and would avoid the political sensitivities surrounding compulsory licensing; on the other hand, politicians and local generic producers need to be prepared for tough negotiations; licensing agreements may include many restrictive business practices and thus progress may be slow.
  - Compulsory licensing/government use of IP: this is a legal means to help provide fast access to affordable drugs. On the other hand, non-cooperation by the patent holder might result in limited access to soft technology and is politically sensitive.

Professor Abbott pointed out that free trade agreements (FTAs) may impose important constraints on establishing local production facilities. In his view, a lack of technological know-how may be overcome by hiring skilled manpower from developed countries and by purchasing production facilities "turnkey" from developed country-based industries. On the other hand, the cost for this may be high. Another phase where IPRs, namely trademark and copyright, become relevant is that of distribution. Finally, Professor Abbott stressed the importance of competition law remedies to help ensure that health objectives will be met through market-based production and distribution of pharmaceutical products (see also item 4 below).
2.) Intellectual Property Rights (IPRs) and the Appropriate Trade and Fiscal Framework for Pharmaceutical Products
Dr. Kathy-Ann Brown in her presentation expressed the overall view that for many countries, sustainable local pharmaceutical production might be difficult to put into practice, and that attention should therefore be given to the facilitation of trade in medicines. While acknowledging that the WTO regulatory framework offers important flexibilities favouring local production in any sector (flexibilities in IPRs, export subsidies, trade-related investment measures), Dr. Brown stressed several other factors that challenge local pharmaceutical production:

- WTO flexibilities are time-bound (i.e. 10 years) which is comparable to 10-year tax-breaks offered for foot-loose FDI.
- WTO flexibilities might be eroded through regional and bilateral free trade agreements (FTAs) as well as bilateral investment treaties.
- Access to quality drugs seems more urgent than industrial policy goals.
- Developing country customers' preference for drugs manufactured in developed countries, due to perceptions about quality differences.
- Poor regional integration mechanisms in many developing countries may result in important non-tariff trade barriers (NTBs) for drugs (marketing approval standards, port charges, pre-shipment inspection and VAT could constitute NTBs).

3.) Drugs Procurement: Are IPRs an Issue?
Ms. Pascale Boulet in her presentation focused on the IPR-related obstacles arising in the drugs procurement process. Acknowledging that IPRs are only one among many factors affecting drug access, she stressed that the effective procurement of affordable essential drugs is complicated through the monopoly character of IPRs. In particular:

- Procurement in developing countries may be difficult as the patent status of the needed drug/substance in developing countries is often not clear.
- As illustrated by WHO and MSF data, IPRs have a direct effect on prices.
- New and effective fixed dose combinations (FDCs) may only be procured with the consent of the patent holder if any of the FDCs' individual pharmaceutical components are patented.
- Patent holders may use their patents on an individual pharmaceutical component to block the development by competitors of new and more efficient FDCs containing that component.
- Procurement of affordable drugs is not only complicated by patents. Other forms of exclusivity (e.g. exclusive test data protection; other forms of administrative protection) also prevent the availability of low-cost generic drugs alternatives.
- FTAs may require national drug authorities to refuse the granting of marketing approval for generic medicines before the expiry of the respective patent. This amounts to creating a patent enforcement duty for government bodies lacking the expertise to assess the quality of the respective patent.
- As several examples illustrate, monopoly rights may result in the unavailability of the protected substances in some countries, if the patent holder sees no interest in marketing the drug.

4.) Using TRIPS competition rules to ensure fair licensing terms for developing country producers
In his first presentation, Mr. Jonathan Berger focused on competition policies and IP licensing. The basic suggestion was that the TRIPS Agreement provides means to promote the local production of pharmaceuticals and access to medicines through an appropriate design of competition rules. In particular:

- The broad scope of TRIPS Article 8 allows using competition policy as an industrial policy tool for the promotion of local producers, as IPR abuse is not required to subject IPRs to regulatory control (the simple exercise of exclusive rights may restrain trade or affect international technology transfer).
- The presence of anti-competitive practices speeds up and facilitates the grant of compulsory licenses.
- The control of anti-competitive practices in IP licensing agreements should be used to encourage licensing of pharmaceutical patents.
- As far as developed country law and practice on the IPR - competition interface is concerned, there are considerable differences in approach. Developing countries may adapt to local condition practices related to:
  - excessive pricing;
  - discriminatory & predatory pricing; and
  - refusals to license.

Overall, the regulation of voluntary IP licensing should be guided by the access to medicines objective. Addressing the important issue of whether competition law and policy may actually be used in developing countries, the presentation referred to the lack in many of these countries of experienced competition authorities. On the other hand, national competition rules may provide important entry points for private party legal actions as a check against abuse by IPR holders. But these rules will only be effective where the government is willing and able to use the powers conferred on it under the TRIPS Agreement.

5.) IP Licensing - Experiences from India and South Africa

In his second presentation, Mr. Jonathan Berger gave a detailed overview of the complexities involved in the negotiations of reasonable licensing terms between developing country-based local producers and a multinational pharmaceutical company; in this context he shared a number of important insights from cases in South Africa and India. The basic message was that voluntary licensing does not happen in a vacuum; several factors come into play such as economic incentives, the effective use by the government of policy tools (pre-grant opposition or the possibility of compulsory licensing); and civil society involvement. Thus, a lot of political will is needed on the part of a government to establish and implement a comprehensive competition policy framework conducive to the local production of pharmaceuticals. National legislation needs to reflect the interfaces of IPRs, competition and public health policy. Where amendments to existing legislation are politically sensitive, this could perhaps be done first through non-binding guidelines (such as, for instance, the 1995 US Antitrust Guidelines for the Licensing of Intellectual Property). In any case, national legislation or guidelines would need to provide exact guidance on what constitutes excessive pricing and which remedies should be available.

6.) IPRs, Health Policy and Marketing Approval of Drugs in Developing Countries

A different perspective was provided by Professor Dorothy Akunyili, who shared with the participants some of her experiences from her work in the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC). The overarching issue was the important impact that counterfeiting of drugs may have on a national public health policy. In essence,
counterfeit drugs may act as barriers to trade and investment in pharmaceutical products. In response, NAFDAC has included the submission of evidence of trademark ownership as a pre-condition for the registration of pharmaceuticals and other regulated products. In addition, generic producers will be refused marketing authorization with respect to pharmaceutical products which are still on-patent.

7.) Discussion: the interplay of various policies to promote productive pharmaceutical capabilities
Session I was wrapped up by comments and a discussion on the presentations. A number of commentators and participants stressed the importance of local pharmaceutical production, despite the existing obstacles. In particular, they emphasized that from a public health perspective, exclusive reliance on drug importation and donations in many cases does not present a sustainable solution from a national health security perspective. As broad access to medicines is of key importance to a society's well-being, pharmaceutical products cannot be considered as ordinary commodities. This being said, participants were aware that local production is not feasible in all LDCs. In any case, participants agreed on the importance of political commitment, on the part of developing country and LDC governments, to cooperate in terms of:

- reducing non-tariff trade barriers on drugs trade and drugs approvals;
- scientific cooperation and use of global scientific data; and
- exploring possibilities for enhanced use by LDCs of TRIPS flexibility on regional cooperation.

Critical views were expressed with regard to some countries' practice to entrust drugs regulatory authorities with the obligation to verify the patent status of a drug submitted for marketing approval. Concerns in this context focused on the lacking IPR-related expertise of these authorities. There was also some discussion regarding the differentiation between counterfeit and generic drugs.

Session II: Coordinated Policies on Access to Medicines: The Way Forward

1.) The local production of pharmaceutical products - an economically feasible option?
Mr. Frank Schmiedchen presented the German Government's bilateral and multilateral technical assistance activities for the promotion of local pharmaceutical production in a number of selected LDCs and developing countries. The Government of Germany is committed to the Millennium Development Goals (MDGs), in particular Goal 8, Target 17 (i.e. to promote affordable access to medicines in cooperation with the pharmaceutical industry) and is planning to put the issue of IPRs and access to medicines on the agenda during Germany's hosting of the G8 summit in the summer of 2007. Mr. Schmiedchen emphasized the industrial development aspect of his Government's technical assistance activities, stressing the importance of enhanced generic competition as well as foreign investment in developing country and LDC production facilities. In this context, he invited the developed country-based pharmaceutical industry to cooperate, emphasizing the openness of the local production project for collaboration not only with multinational companies but also, and in particular with, small and medium-size enterprises (SMEs). Mr Schmiedchen then provided evidence on existing production facilities in countries such as Ethiopia, Tanzania and the DR Congo. He presented the factors needed to ensure sustainability of production, such as:
2.) Regional approaches to intellectual property, drugs regulation, procurement and trade

Professor Jerome Reichman developed his idea of promoting access to medicines and local production through the establishment of Regional Pharmaceutical Supply Centers (RPSCs) in LDCs and developing countries. This idea is based on the 30 August 2003 Decision by the WTO General Council to allow exportation of drugs produced or imported under a compulsory license within certain regional trading groups. The regional approach through RPSCs should create market incentives (economies of scale) for LDC-based local producers and foreign investors. The RPSCs would have the following functions:

- draw a list of priority drugs needed in the region;
- procure and distribute these drugs;
- harmonize standards for marketing approvals;
- stimulate investment in local production facilities, preferably in cooperation with multinational pharmaceutical companies; several options exist:
  - Price controls;
  - Issue of cumulative compulsory licenses (use of the TRIPS flexibility/Paragraph 6 Decision waiver for regional trade agreements);
  - The RPSCs could offer in return a large market exclusively to large pharmaceutical firms from the industrialized countries or the advanced developing countries (e.g. Brazil, India) to supply the market.
  - The "buy out" option: this would be an alternative to compulsory licensing. Purchasers (governments, inter-governmental organizations) would buy patents from pharmaceutical companies for specific drugs for a particular geographical area. The purchaser would then offer an open, non-exclusive, no-royalty license to any legitimate generic producer in that market. The "buy-out" would reimburse pharmaceutical companies for their lost opportunities to use their patents in the respective countries to recoup their R&D investment. As R&D cost recovery in developing countries (and particularly LDCs) is very low, the buy-outs would be comparatively cheap. They should be used to support the RPSCs in their procurement efforts.

Professor Reichman finally addressed a number of potential obstacles and limitations to his approach, regarding, inter alia, issues surrounding quality controls, enabling legislation, possible discouraging of patent incentives, re-exports, local distribution complexities, lack of political will and governance and political instability.

3.) Discussion: Feasibility of Proposed Strategies

The comments made by designated discussants as well as the larger audience centred around the feasibility of local pharmaceutical production as such as well as the regional approach to this issue. Some participants expressed doubts as to the political feasibility, referring to difficult experiences in regional cooperation made in the contexts of the Pan American Health Organization (PAHO) and the Southern African Development Community (SADC). Botswana was pointed out as a country apparently favouring importation of drugs rather than...
their domestic production. The point was made that technical assistance providers and donor governments need to be aware of these limitations and coordinate their activities accordingly. Participants agreed that the definition of regions for cooperation should be based on those governments willing to cooperate, irrespective of their geographic location. Even where successful, regions collaborating on pharmaceutical production will in the view of most participants continue to depend to some extent on the importation of active pharmaceutical ingredients (APIs) from abroad. In this respect, the importance for potential provider countries like India and China to fully use the available TRIPS flexibilities was highlighted. On the other hand, doubts were raised regarding the willingness of producers in those countries to supply an LDC market. Local producers in LDCs should focus their efforts on the production, to the greatest extent possible, of new ("2. line") HIV drugs, which face patent protection in non-LDC WTO Members. In this context, it was observed that the production of APIs might be costly and involve increased administrative efforts, due to safety requirements regarding intermediate substances needed in the production process. In addition, doubts were raised about suggestions made earlier that pharmaceutical production facilities may be purchased "turnkey" from OECD countries. As opposed to other industries, the pharmaceutical sector presents a number of particularities, in particular drug safety, which complicate such purchases.

It was acknowledged that the window of opportunity for the legal use of patented materials is short (i.e. 1 January 2016). However, many essential drugs currently on-patent will be off-patent by the end of the transition period, so that production may continue.

Finally, it was noted that UNCTAD would seek to present its activities on local pharmaceutical production at the UNCTAD XII Conference in Ghana in April 2008, with the indicated support of the German Government.