Debating Pharmaceutical IPRs - A joint UNCTAD - Stockholm Network event  
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REPORT

The half-day meeting was opened by UNCTAD staff and the Director of the Stockholm Network, which is a market-oriented think tank based in London. Mr. Kiyoshi Adachi, team leader of UNCTAD's Work Programme on Technology Transfer & Intellectual Property (TOT-IP) of the International Arrangements Section referred to UNCTAD's mandate to work on issues related to the building of developing countries' capacities in the supply and production of essential medicines.

The following debate, which was co-chaired by Ms. Helen Disney, Director of the Stockholm Network, and Mr. Christoph Spennemann, Legal Expert in UNCTAD's TOT-IP Programme, focused on a set of questions related to the pros and cons of IPR protection for pharmaceutical products. Each question was answered from a development and an industry perspective. Development-oriented comments were given by Dr. Graham Dutfield, Herchel Smith Senior Research Fellow, Centre for Commercial Law Studies, Queen Mary, University of London; and Mr. James Love, Director, Knowledge Ecology International. The industry perspective was provided by Dr. Eric Noehrenberg, Director, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and Dr. Meir Pugatch, Lecturer, Haifa University. This debate was followed by a questions and answers (Q & A) session. Each panelist had 5 minutes to respond to the following questions:

1. Are pharmaceutical IPRs a barrier to access to medicines or are they essential to it?

Answers to this question focused on the effect generic production of medicines has on drug prices. While Mr. Love stressed the rationale of patents as exclusive rights that serve primarily to raise the income of rights holders, Dr. Noehrenberg argued that the best way to bring down prices would be the negotiation of licensing agreements or partnerships with the patent holders.

2. Do pharmaceutical patents prevent or enhance pharmaceutical research and development?

Dr. Pugatch stressed the importance of patents as incentives for companies to engage in costly drug research and development (R&D). Referring to examples from Israel, he stated that even generic firms would rely on patents to recoup their drug development expenses. Small biotech firms in need of seed money would need to rely on patents as an essential means of financing their activities. On the other hand, Dr. Dutfield drew the audience's attention to the "neglected disease" issue, stressing that patents encourage pharmaceutical R&D only where there is a market demand for a respective medicine, requiring alternative means of R&D incentives for diseases disproportionately affecting poor countries.
3. Is there any hope at all for multilateral IP negotiations, and for whom?
Dr. Noehrenberg expressed the view that as a prerequisite to further negotiations, all stakeholders should agree that the current IP system does have the potential to promote access to medicines for the poor. Rather than questioning the IP system altogether, efforts should be directed at its adjustment to conditions prevailing in poor countries, such as, for example, through advance purchase agreements for small markets. In particular, the IP system could prove beneficial for the promotion of small-scale innovations, as recently highlighted in the report of a panel of experts established by the Indian Government ("Mashelkar Report", named after its chairman). Dr. Dutfield, after pointing out the fact that the Mashelkar Report has been criticized for plagiarism of recommendations taken out of a study financed by industry, voiced concern about the blocking effect of patent thickets on follow-on innovation, in particular in developing countries. According to Dr. Dutfield, the history of patent law shows that countries have always used the patent system according to their respective levels of development. Thus, policy space for the implementation of international IP rules would be more appropriate for both developing and developed countries than the harmonization of national patent laws through further negotiations.

4. Are compulsory licenses a legitimate tool for price negotiations or are they a predatory mechanism aimed at circumventing the rights of developers?
After a brief overview by Mr. Spennemann of existing types of compulsory licenses (CLs), Mr. Love stressed the view that CLs should not just be regarded as a negotiating tool with patent holders, but should actually be used to stimulate the generic pharmaceutical market. In his view, countries such as Brazil, which are hesitant to actually issue CLs, lack generic competition in the pharmaceutical sector. Mr. Love referred to a number of CLs recently issued in Thailand and expressed the view that these would also help African countries in their efforts to promote access to affordable medicines. Mr. Love finally stated that it has been the US domestic policy to make extensive use of CLs in other sectors of industry, such as the car industry and the manufacture of medical devices. On the other hand, Dr. Pugatch stressed the nature of CLs as an exception to patent rights. Thus, CLs should not be used, as in the case of Thailand, as a regular tool to gain benefits for generic producers. In this context, Dr. Noehrenberg criticized the low royalty rate to be paid to the patent holder of one of the drugs for which a CL has been issued in Thailand (0.5 % of total domestic sales).

5. Are pharmaceutical IPRs a zero sum game or can they lead to win-win results?
All four speakers were asked for their views. In Dr. Dutfield's view, IP system itself should not be blamed for its alleged failure to promote access to medicines by the poor, but rather it is the way it is being used by the pharmaceutical industry. Dr. Dutfield referred to the Novartis case currently pending in India, as an attempt by the pharmaceutical industry to attack a developing country government on its use of existing TRIPS flexibilities. Dr. Noehrenberg countered that Novartis as a tax-paying corporate citizen should be accorded the right to defend its interests, and that the IP systems, where used appropriately, can actually provide win-win results for both rights holders and users. He referred to the disclosure of a patented invention in exchange for the granting of exclusive rights. Mr. Love stressed the importance of alternative means for incentives in R&D investment in the area of neglected diseases, as the current patent system merely encourages the production of high-priced drugs for affluent patients in both developing and developed countries. Dr. Pugatch expressed the view that there is a need to move beyond the current debate on TRIPS flexibilities and focus negotiations on new issues such as the treatment of clinical test data protection under the TRIPS Agreement.
After this round of questions, the Chairs opened the floor for further discussions. One of the main topics of discussion was the appropriateness of the IP system for the promotion of pharmaceutical innovation and access to medicines. The panelists disagreed on the need to come up with alternative means to promote pharmaceutical innovation. Mr. Love's ideas about a non-exclusive prize mechanism to reward product improvements was received with caution by Dr. Noehrenberg, who said this option should be discussed further, provided it remained optional. In this context, opinions diverged regarding the importance of IPRs play in the access to medicines issue. While some participants stressed the importance of non-IP factors such as insufficient distribution systems in developing countries, another participant referred to a comparative study carried out by the Berne-based World Trade Institute, according to which drug prices in China are higher than in India, while drugs availability and local production capacities in China are lower than in India. India introduced product patent protection much later than China. Dr. Noehrenberg questioned the study and referred to IFPMA surveys showing the contrary. Opinions also diverged on the importance and efficacy of CLs as a tool to promote access to affordable medicines. There seemed to be agreement on the need to reform the current IP system in the pharmaceutical context. Alternative models of innovation such as prize funds received considerable attention, but their relationship with the current IP systems remains unclear and has to be clarified further.

In conclusion, there seems to be considerable interest among all stakeholders to discuss further the proposed alternative models of pharmaceutical R&D innovation, and their relationship with the current IP system. Stockholm Network voiced interest to hold a follow-up debate with UNCTAD on this or related topics.