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RWANDA AND CANADA: LEADING THE IMPLEMENTATION OF THE AUGUST 2003 DECISION FOR IMPORT/EXPORT OF PHARMACEUTICALS PRODUCED UNDER COMPULSORY LICENSE

The Fourth Ministerial Conference of the World Trade Organization (WTO) in 2001 issued the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration). The Declaration is significant for establishing legal certainty on the freedom of countries to determine the grounds for granting a compulsory license, what may constitute a national emergency or other circumstances of extreme urgency, and the applicable regime for exhaustion of intellectual property (IP) rights.[1] The Declaration determined that a public health crisis is a circumstance amounting to a national emergency. It also shifted the burden of proving otherwise to the country disputing the various determinations made by another state. In the Declaration, Members of the WTO agreed that:

> … the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.[2]

The Declaration paved the way for the amendment of Article 31 of the TRIPS

[1] WTO (2001), WT/MIN(01)/DEC/2, para. 5(b)(c).

[2] Id., para. 4.

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Agreement in order to enable the export of pharmaceuticals produced under compulsory license to countries with limited or no pharmaceutical manufacturing capacity.

The adoption of the Protocol Amending the TRIPS Agreement in 2005 follows a provisional arrangement under the Decision of the General Council on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the August 2003 Decision).[3] Under Article 31 of the TRIPS Agreement countries can grant compulsory licenses for the use of inventions protected by patent. However, such license should be predominantly for the supply of the domestic market. A restriction on the exportation of products produced under compulsory license creates a situation where countries with limited or no domestic manufacturing capacity will not be able to import the cheaper products from countries that have manufacturing capacity. The August 2003 Decision and the Protocol amending the TRIPS Agreement established a system whereby countries with manufacturing capacity in the pharmaceutical sector will be able to produce, under compulsory license, pharmaceuticals for export to countries with limited or no manufacturing capacity.

Although the August 2003 Decision has expanded the scope of flexibilities, its numerous conditions, including notification, preshipment and labelling requirements and regulations to prevent re-exportation continue to raise questions regarding its utility and feasibility. The scepticism arising from the cumbersome procedures required to use the August 2003 Decision was further heightened with the adoption by several developed countries of implementing legislation that incorporate additional legal requirements.

The scepticism regarding the utility and functionality of the August 2003 Decision and the implementation of the Decision were put to test when Rwanda officially notified the TRIPS Council that it will import drugs from Canada under the system (IP/N/9/RWA/1). There are no notifications yet under paragraph 1(b) of the August 2003 Decision, which requires that countries notify their *intention* to use the system as importing countries. However, Rwanda has directly notified that it expects to import a specific pharmaceutical product from a generic manufacturer in Canada under paragraph 2(a) of the August 2003 Decision. This is because the requirement under paragraph 1(b) does not apply to Least-Developed Countries (LDCs). Canada has also notified the TRIPS Council that it has authorized the manufacture and export of the pharmaceutical product concerned to meet Rwanda's needs (IP/N/10/CAN/1).

This article provides a detailed analysis of the Rwanda-Canada use of the system created under the August 2003 Decision for the import/export of pharmaceutical products manufactured under compulsory license. It will describe the various procedures that the importing country, the generic pharmaceutical company and the exporting country have to go through, identifying lessons from the experience. The precedent that may be established by this case is critical to the continued utility and functionality of the system under the August 2003 Decision.

I. Canada: Implementation of the August 2003 Decision

Canada has not ratified the protocol amending the TRIPS Agreement that incorporated the system created by the August 2003 Decision. However, Canada was the first country to introduce domestic legislation for the implementation of the August 2003 Decision to enable the production and export of generic pharmaceutical products from Canada to countries with limited or no pharmaceutical manufacturing capacity. The legislation sets out the procedures required to obtain authorisation to make, construct and use patented inventions solely for purposes directly related to the manufacture of pharmaceutical products and to sell it for export to a country listed in the schedules attached to the legislation.[4] The legislation is supported by Regulations for Use of Patented Product for International Humanitarian Purpose as well as by the amendments to the legislation on food and drug. The elements of the legislation outlined below are selected to help in the understanding of the use of

[3] See WTO (2003), WT/L/540 for the Decision and WTO (2006), WT/L/641 for the Protocol.

[4] Canada Patent Act, as on September 17, 2007, available at. http://laws.justice.gc.ca/en/P-4/index.html?noCookie.

the August 2003 Decision by Rwanda and Canada.

According to Article 31(b) of the TRIPS Agreement, before issuing the grant of compulsory license, the person seeking the compulsory license must first make efforts to obtain the license voluntarily from the patent holder on reasonable commercial terms and conditions. It is when such efforts are unsuccessful 'within a reasonable period of time' that a compulsory license can be issued. The Canadian legislation defines the time-period considered reasonable for generic manufacturers to request a compulsory license in lieu of the effort to secure a license from right holders. It determines that such requirement is met when a 30-day period for achieving an agreement for a voluntary license lapses.[5]

The requirement under the TRIPS Agreement to seek a voluntary license at reasonable commercial terms and conditions can be waived in the case of national emergency or other circumstances of extreme urgency or in the case of public non-commercial use. In such cases the patent right holder must be informed as soon as reasonably practical. However, the Canadian legislation on the use of patents for humanitarian purposes does not provide the same waiver for national emergency or other circumstances of extreme urgency or public non-commercial use of the patented invention from the obligation to seek voluntary license within 30 days. Under the Canadian legislation seeking a voluntary license is always the prerequisite to apply for a compulsory license for the use of patents for humanitarian purposes.

The annex to the Canadian legislation contains an initial list of products largely based on the World Health Organization (WHO) Model List of Essential Medicines. In effect, Canada implements the August 2003 Decision only with respect to a selected number of known drugs. The August 2003 decision does not limit the drugs or diseases to which it would apply. This is supported by the fact that during the negotiation for the August 2003 Decision, developed countries abandoned their demand to include a limited list of products that could be subject to the August 2003 system because of objections from developing countries. Developing countries considered that such a list would pose serious difficulties for addressing public health concerns in cases of emergency.[6]

Another important aspect of the Canadian legislation relates to the requirement for the regulatory approval process of drugs manufactured under compulsory license for export under the Canadian access to medicine regime. The national approval procedure for export of drugs functions in addition to the pre-qualification approval procedure by WHO. Many developing countries require the pre-qualification approval by WHO in order to permit the importation of pharmaceuticals. Canada pledges to use fast track procedures for the regulatory approval of pharmaceuticals produced under compulsory license for export to eligible importing countries.[7]

Furthermore, Section 21.04(1) of the Canadian Patent Act requires that importers other than a government agency must acquire permission from the government of the importing country to import the generic product produced under compulsory license. The Patent Act also defines the duration of the compulsory license to be only two years, whereas the August 2003 decision imposes no such time limitation.[8]

With respect to payment of compensation to the right-holder in case of a compulsory license, Canada adopted a sliding scale formula linking the royalty rate to the ranking of the importing country on the UN Development Program's Human Development Index (HDI). The royalty cannot exceed 4% of the value of the contract for the supply of the product in the case of the country with the highest HDI ranking.[9]

[5] See Canada Patent Act, as on September 17, 2007, Article 21.04(3)(c).

[6] See Richard Elliot, *Int. J. Intellectual Property Management, Vol. 1, Nos. 1/2, 2006* for further discussion.

[7] The AIDS in Africa Working Group and the Access to Drugs Initiative: University of Toronto, Faculty of Law, International Human rights Programme (January 2007), Making Canada's Access to Medicines Regime Work for Countries in Need: A Case Study on Ghana, available at http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_ut.stu_05_e.pdf, p. 12.

[8] See Canada Patent Act, as on September 17, 2007, Article 21.09.

[9] See Canada Patent (International Humanitarian Purpose), Regulations, 8.

II. Rwanda: Least-Developed Country and Utilization of the August 2003 Decision

Upon the adoption of the laws and implementing legislation in Canada, Rwanda became the first country to notify the WTO on 17 July 2007 of its intention to import 260,000 packs of a fixed-dose combination of Zidovudine, Lamivudine and Nevirapine – antiretroviral used for the treatment of HIV/AIDS- for two years.

Rwanda and all other LDCs are not required to implement the TRIPS Agreement other than the obligation to provide national treatment and most-favoured-nation treatment under Articles 3 and 4 of the TRIPS Agreement taking into account the applicable exceptions. In addition LDCs benefit from the following decisions:

a) Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, *Decision of the Council for TRIPS of 27 June 2002,* IP/C/25. According to this decision LDCs will not be obliged, with respect to pharmaceutical products, to implement or apply the sections on patent and protection of undisclosed information of the TRIPS Agreement or to enforce rights provided for under these sections until 1 January 2016.

b) Least-Developed Country Members — Obligations under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, *Decision of 8 July 2002,* WT/L/478. This decision waived the obligation of LDCs to make available exclusive marketing rights for products that are not protected by patent pending the introduction of product patents in the LDC concerned, until 1 January 2016.

As an LDC benefiting from the transition period for implementation of the TRIPS Agreement, including Article 31 of the agreement, it is not necessary for Rwanda to ratify the Protocol amending the TRIPS Agreement that incorporated the system created under August 2003 Decision. However, the system created under the August 2003 Decision precisely targets countries such as Rwanda that have limited or no manufacturing capacity in the pharmaceutical sector. The system ensures that LDCs have access to products produced in the territories of WTO members with adequate manufacturing capacity that are parties to the TRIPS Agreement.

The notification by Rwanda of its expectation to import the specific pharmaceutical product is made under paragraph 2(a) of the August 2003 Decision. Under the paragraph, the notification is expected to include:

i. the names and expected quantities of the product(s) needed;

ii. confirmation to the effect that the importing country, other than an LDC, has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question; and

iii. confirmation that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision;

Rwanda has provided information on the name and the quantity of the product it expects to import. The notification includes a proviso to the effect that

> … because it is not possible to predict with certainty the extent of the country's public health needs, [Rwanda] reserves the right to modify the foregoing estimate as necessary or appropriate.[10]

As an LDC, Rwanda is not required to establish that it has no/limited manufacturing capacities in the pharmaceutical sector for the product in question in order to benefit from the system. As a result, the notification from Rwanda does not contain information with respect to the manufacturing capacity of the country. Moreover, Rwanda made use of the extended transition period for LDCs under the *Decision of the Council for TRIPS of 27 June 2002* (IP/C/25) to fulfil the requirement with respect to confirming the availability of patent and issuance or intention to grant compulsory license. The notification states that:

> Pursuant to Paragraph 7 of the Doha Declaration and implementation thereof by the TRIPS Council (*Decision of the*

[10] WTO (2007), IP/N/9/RWA/1.

> *Council for TRIPS of 27 June 2002*), we have decided that we will not enforce rights provided under Part II Section 5 of the TRIPS Agreement that may have been granted within Rwanda's territory with respect to the Product.[11]

In short, Rwanda will not enforce patents that may have been granted in its territory with respect to the product it expects to import. This is precisely what the *Decision of the Council for TRIPS of 27 June 2002* (IP/C/25) authorises LDCs to do. The approach taken by Rwanda resolves the dilemma countries face in using the system where patents are not enforced in the country either as a result of the implementation of flexibilities under the TRIPS Agreement, or no application being made to acquire a patent domestically. Where a patent is not registered in a developing country that is not benefiting from the transition period for pharmaceutical products, the country can simply declare that there are no patents in force and notify its decision to import a product patented in another country under the system.

III. Securing the License: Generic Manufacturers, Multinational Companies and the Canadian Patent Act

The Canadian pharmaceutical company Apotex Inc., offers on a non-for-profit basis its Apo-Triavir - a fixed dose combination of three drugs indicated for the treatment of HIV infection. The company website indicates that *each individual component* of the product was evaluated in bioequivalence studies and shown to be bioequivalent to the original products.[12] The triple combination dose is evaluated and approved in Canada and fully conforms to all the regulations and health requirements for marketing a drug in Canada's healthcare system.[13]

The product was the first test case for the Canadian access to medicine regime. Originally, while the three individual drugs were on the controversial list of eligible drugs under the access to medicine regime, the triple combination - Apo-Triavir was not. As a result, the schedule for the list of eligible products had to be amended later to add Apo-Triavir. The regulatory approval was secured in June 2006, and followed by WHO pre-qualification status in August 2006.[14] The whole initiative and research and development for the product was undertaken on humanitarian grounds and planned for supply at no-cost.[15]

Apotex Inc. began arrangements for the utilisation of the drug with Médecins Sans Frontières (MSF). Although Apotex Inc. secured the regulatory approval, it was not able to produce and export the drug without a compulsory license, since the patents on the individual drugs that constitute the fixed dose combination belong to Glaxo Group Limited, Welcome Foundation Limited, Shire Biochem Inc., and Boehringer Ingelheim Pharmaceuticals Inc (BI). MSF, on the other hand, faced the challenge of convincing the countries, especially Rwanda, that it was worthwhile to take the risk in pursuing the importation of cheaper generic versions of the drug to be produced under compulsory license. Other developing countries that issued compulsory license were facing criticism and challenge from corporations and developed country governments.[16]

Apotex Inc. requested royalty free licenses for the manufacture of Apo-Triavir through a letter written on 13 July 2007 and addressed to the companies that own the patents on the drug. The letter states that the company will manufacture Apo-Trivavir exclusively for export to the government agency called the "Treatment and Research Aids Center" of Rwanda. The company confirmed that it will produce the product at its own cost, and the license on the patents will be for two years in order to facilitate the sale. Furthermore, with respect to the sale of the product, it proposed the following terms:

A fixed does combination tablet of lamivudine (150 mg) + nevirapine (200 mg) +

[11] Id.
[12] http://www.apotex.com/apotriavir/default.asp
[13] Ibid.

[14] Letter from Apotex Inc., to Director, Patent Policy Directorate, Industry Canada and Director, Therapeutic Product Directorate, Health Canada, *Re: CAMR Consultation Paper,* January 23, 2007, available at http://camr-rcam.hc-sc.gc.ca/review-reviser/camr_rcam_apotex_18_e.pdf.
[15] House of Commons, Canada, Standing Committee on Industry, Science and Technology, 39th Parliament, no. 055, 1st Session, Monday, April 23, 2007.
[16] ICTSD, "Rwanda Becomes First Country to try to use WTO Procedure to Import Patented HIV/Aids Drugs", 27 *Bridges 11, 22 July 2007.*

zidovudine (300 mg), will be manufactured and sold;

- 15,600,000 tablets will be manufactured and sold at a price of USD $0.405 per tablet;
- The drugs will be exported to Rwanda; and
- Treatment and Research AIDS Center, an agency of the Rwanda Ministry of Health, will purchase and receive the drug for sale in Rwanda.[17]

Apotex Inc. requested a reply within 30 days of the receipt of the letter and informed that if it does not receive a reasonable response, it would file a request for a compulsory license. The notification by Rwanda for the importation of the product was received by the WTO on 17 July 2007, which assisted Apotex Inc., in the process of seeking the voluntary license.[18]

Glaxo and Welcome Foundation replied on 8 August 2007to the request of Apotex Inc., stating that they recognized Apotex Inc.'s proposal as *a humanitarian initiative*. The companies consented to the granting of an authorization to manufacture and export to the Treatment and Research Aids Center of Rwanda the requested amount of tablets of a fixed dose combination at the proposed price. Glaxo also stated that in agreeing to a royalty rate of 0%, it is relying on the representation that Apotex Inc. would derive no profit from its sale of the product at the proposed price.[19]

The reply from the Glaxo and Welcome Foundation as right-holders conveys that they consent to the Canadian government's issuance of a compulsory license under the domestic legislation for access to medicine. Shire also responded through a letter dated 13 August 2007 stating that it does not object to the issuance of a compulsory license for the purpose of manufacturing the combination in Canada for export to Rwanda. The patentees in this regard can be considered voluntarily agreeing to the terms of compulsory license as proposed by Apotex that include royalty-free license. All of the right-holders showed interest for the exploitation of their patents under the humanitarian initiative. BI Inc., on the other hand, made a counter-offer that it considered to be more favourable than what Apotex Inc. had proposed and the Canadian legislation supports by offering terms and conditions of license that include:

- The licence is totally royalty free thereby Apotex Inc., is not required to pay anything to BI for the licence;
- Apotex Inc., is permitted to extend the licence to other WHO defined developing countries in addition to Rwanda by way of a simple letter of intent to BI;
- The licence permits Apotex Inc., to use Nevirapine for the entire patent life of the product as opposed to the minimum two year term provided by Canadian law;
- Apotex Inc., agrees to clearly mark its product that it is solely for use in the importing country and to differentiate its product as required under Canadian legislation;
- Apotex Inc., agrees to also provide details to BI of the quantity manufactured and exported for tracking purposes in the case of diversion of the product to a non approved importer as required under Canadian law;
- The Apotex Inc., product containing Nevirapine must also meet any requirements of Health Canada for such an exported product as required under Canadian law.[20]

Where the right-holders consent to the use of their patents, there is no need for compulsory license. In this case, Apotex Inc. filed for compulsory license on 28 August 2007. In the application for compulsory license Apotex Inc. declared that it sought from the patentees a license to manufacture

[17] Canada, Intellectual Property Office, Application Pursuant to Section 21.04 of the *Patent Act* and Canadian Letters Patent Nos. 2,311,988, 2,070, 230, 2,068,790, 2,059,263, 2, 009, 631, 2,216, 634, 2,105,287, 2,030,056, September 4, 2007 (hereinafter application for compulsory license). The application is available at http://strategis.gc.ca/sc_mrksv/cipo/jcpa/p4-e.html, p.18.

[18] The notification was published on 19 July 2007. See WTO (2007), IP/N/9/RWA/1.

[19] Application for compulsory license, cited above fn 15, p.7.

[20] Boehringer Ingelheim Pharmaceuticals Inc , "Boehringer Ingelheim Offers a Licence to Apotex to Export BI's patented product nevirapine to Developing Countries with terms better than that required by Canadian Legislation," *News Release*, 22 August 2007, Boehringer Ingelheim (Canada) Ltd./Ltée, , available at http://www.pasteurella.ca/.

and sell the pharmaceutical product for export to Rwanda on reasonable terms and conditions and such efforts have not been successful.

Canada granted authorization to Apotex Inc. on 19 September 2007 to make, construct and use, the patented inventions identified in the application solely for the purposes directly related to the manufacture of the products identified in the application and to sell it for export to Rwanda.[21] This first authorization falls under Canada's *Access to Medicines Regime* (CAMR), and the regulation for the *Use of Patented Product for International Humanitarian Purposes* introduced to implement the August 2003 Decision.[22] The authorization does not specify if the authorities are satisfied that indeed the patent right-holders did not accommodate the demands of the applicant on reasonable commercial terms and conditions. The authorization shows that the grant of compulsory license is more or less straightforward once the necessary formal requirements are met.

The companies in their replies to Apotex Inc., have made several references to rules and regulations with respect to marking and packaging, prevention of diversion and safety and efficacy of the proposed combination. Glaxo insisted that in order to avoid confusion, Apotex Inc., use the identification of the product as approved by the WHO Prequalification Programme list for HIV/AIDS drugs as opposed to the proposed Apo-TriAvir. Glaxo expressly reserved its position on the trademark it owns to a combination dose called TRIZIVIR. Almost all the right-holders requested adherence on part of Apotex Inc. to the applicable procedures under the Canadian legislation. Shire, for example, stated that:

> We assume the product will be marked in accordance with all applicable regulations and that the product's appearance will be posted on a website.[23]

Apotex Inc. officials stated that the companies put forward numerous conditions for issuing a voluntary license. However, at least BI Pharmaceuticals contested the assertion that it has denied license on reasonable terms. [24]

Whether the references to the marking, packaging and information on anti-diversion measures could be considered as unreasonable commercial terms and conditions could be open for legal arguments in the domestic courts. However, this case shows that the right-holders can reply in whatever manner they prefer leaving the applicant in a difficult position to negotiate the license. The exact scope and content of the letters and communication between right-holders and applicants for compulsory license for export can give rise to disputes. The declaration by the applicant on the effort undertaken to secure voluntary license can, in any case, be challenged before a court of law in accordance with Article 21.14 of the Canadian Patent Act.

The multinational companies whose patent rights were subjected to compulsory license may opt not to challenge any procedure of the compulsory license considering the sensitivity and humanitarian nature of the case. However, this should not be an excuse for domestic laws in supplier countries to fail to implement the August 2003 Decision and the subsequent amendment effectively and least restrictively.

IV. Canada: Notification under Paragraph 2 (c) of the August 2003 Decision:

To complete the procedure that operates the system established by the August 2003 Decision, Canada notified the TRIPS council on 4 October 2007 of its authorization of a compulsory license to Apotex Inc., in accor-

[21] Canada's Commissioner of Patents authorization can also be found at: http://strategis.gc.ca/sc_mrksv/cipo/new/CAMR_Authorization.pdf.

[22] The WTO General Council Decision was implemented in Canada by an *Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa Act)*, of 2004. The text of Canada's Patent Act may be found at http://laws.justice.gc.ca/en/showdoc/cs/P-4/bo-ga:s_21_01//en#anchorbo-ga:s_21_01.

[23] Application for compulsory license, cited above fn 15, p 12-13.

[24] Boehringer Ingelheim , "Boehringer Ingelheim comments the nevirapine production for Rwanda by Apotex", News Release, 01 October 2007, available at http://www.boehringer-ingelheim.com/corporate/asp/news/ndetail.asp?ID=4934.

dance with paragraph 2(c) of the August 2003 Decision. Paragraph 2(c) requires that:

> … the exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

Canada simply attached the authorization it issued to Apotex Inc. to satisfy the requirements under the paragraph. It also provided the website of Apotex Inc. to satisfy the requirement under paragraph 2(b) (iii) of the 30 August 2003 Decision where the company will post the information on the shipment (quantities and distinguishing features).

Once the notification procedures are completed, Apotex Inc. can start exploiting the patent for the production of the pharmaceuticals in Canada for exportation to Rwanda. It should provide the relevant information on the export of the product in its website. It has already provided a webpage on the product.[25] Rwanda would be the first country to import cheaper drugs indicated for the treatment of HIV/AIDS produced under compulsory license. The remaining challenge is whether Apotex Inc. can start delivering the products soon. Also it remains to be seen if the threat of diversion of exports is a real challenge.

V. What Next?: Synthesis and Lessons Learned from the Rwanda-Canada use of the August 2003 Decision

The use of flexibilities that depends on the cooperation of other member states of the WTO is one of the most challenging legal dilemmas for developing countries. The Rwanda-Canada case so far is a success because of various factors that worked together, namely (1) an offer from a generic manufacturer to produce a new fixed dose combination drugs at no cost, (2) consent for royalty free use of their patents and non-opposition by right holders against the compulsory license, (3) the Rwandan government's willingness to take the risk of navigating the untested system under the August 2003 Decision in order to address a public health problem, (4) the Canadian government that put in place a law that, at least in the present case, appears to be working, and (5) legal and public support from MSF that assisted the various actors navigating the procedural requirements.

The picture could be different in a situation where one of the above factors do not exist. Generic manufacturers may not always be interested in producing pharmaceuticals under the August 2003 system at a no-cost basis, as Apotex Inc. did. The response from right-holders could be different from the current case, where the generic producer proposes a price of the product that will include a certain percentage of profit margins. In addition, the sensitivity and urgency of addressing the problem of HIV/AIDS might also have caused the concerned actors to facilitate the functioning of the system. As a result, the Rwanda-Canada case provides only a limited but important aspect of how the August 2003 Decision operates.

If there is anything that the Rwanda-Canada use of the August 2003 Decision can prove to developing countries and public interest groups is that the use of the system does not solely rest on the terms agreed in the WTO. The implementing legislation in exporting countries can introduce new concepts, such as a list of eligible products and procedures. Rwanda has declared in its notification that it expects to import the estimated amount of the product concerned in the next two years, from Apotex Inc. For Apotex Inc., the license will expire either at the end of the second year since the first exportation or when the last of the pharmaceutical product it is authorized to export leaves Canada's territorial waters, which ever is the earliest.[26] The license can be renewed only in cases where the quantities of the pharmaceutical product authorized to be produced and exported were not exported

[25] See http://www.apotex.com/apotriavir/default.asp

[26] Canada Patent Act, as on September 17, 2007, Article 21.13.

during the validity of the license.[27] It is perfectly possible under the August 2003 Decision for Rwanda to notify its expectation to import the product for over two years from the same company for its public health need. However, its notification has to be limited to two years expectation because of the Canadian law. After the expiry of the license, Apotex Inc., has to go through the process to obtain the license all over again because of the Canadian legislation. If Apotex Inc., is going to submit new request, it has also to include notification from Rwanda to the WTO. Rwanda will be required to submit a new notification because of the Canadian law for importation beyond two years. As a result, the first important lesson from this case relates to the need to closely examine the implementation legislations of developed countries.

The difference in implementation legislation among exporting countries can also be challenging for importing countries. The European Parliament and the EC regulation No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems was issued in May 2006. Like the Canadian legislation, it provides for 30 days limit as a 'reasonable period' for negotiation of voluntary license. However, the Regulation is different from Canada's legislation, since it makes a clear waiver for seeking voluntary license in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. This exemption would allow European countries to initiate the process by themselves to respond to emergency situations, or government use of inventions in assisting countries with no, or limited manufacturing capacity. Subsequent legislation by other countries may develop their own unique aspects and mechanisms. Such a trend may further complicate the use of the system.

For developing countries, the Rwanda-Canada case demonstrates that the August 2003 Decision is a viable option for increasing access to medicines. The legislation crafted in Canada and the European Union to implement the Decision, however, should be examined in order to develop a better domestic legislation in those developing countries with manufacturing capacity in the pharmaceutical sector. Since there are developing countries with adequate pharmaceutical manufacturing capacity, developing countries should cooperate among themselves to facilitate the use of the August 2003 Decision.

Furthermore, those developing countries with limited or no pharmaceutical manufacturing capacity, should notify their intention to use the system in accordance with paragraph 1 (b) of the August 2003 Decision. Notification of intention to use of the system does not depend on ratification of the Protocol amending the TRIPS Agreement.

[27] Id., Article 21.12.

AN OVERVIEW OF RELEVANT DEVELOPMENTS IN THE VARIOUS IP FORA

The following is an overview of the developments in the various fora dealing with intellectual property issues in the third quarter of 2007.

The World Trade Organization

The third quarter of 2007 was defined by the active resumption of Doha Round negotiations. Several rounds of discussions took place in small groups such as the G4, but did not result in measurable forward movement. The majority of discussions continued to be focused on Agricultural Subsidies and Non-Agricultural Market Access (NAMA). There has been limited progress on issues in the TRIPS Council.

Council for TRIPS

The TRIPS Council did not meet formally during the third quarter of 2007. However several special sessions and informal meetings took place during this period.

Special session of the TRIPS Council

Geographical Indications

A special session of the TRIPS Council met 23 July 2007 (Report TN/IP/17) focused on discussion of a multilateral register for geographical indications. There was no change in the positions of the Member States on the issue. The proposals previously made remain on the table: proposal by Hong Kong, China in TN/IP/W/8; "Joint Proposal" by Argentina, Australia, Canada, Chile, Costa Rica, the Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Japan, Mexico, New Zealand, Nicaragua, Paraguay, Chinese Taipei and the United States in TN/IP/W/10, Add.1, 2 and 3; and proposal by the European Communities in TN/IP/W/11. The European Community continues to insist on a legally binding multilateral register, which is opposed by the major New World economies i.e. the United States, Australia and New Zealand, and significant players in Latin America and Asia. The African group has yet to take a unified position on the issue, although South Africa remains significantly concerned by any move towards a legal register.

A formal meeting of the Council for TRIPS was held from 23-24 October 2007 and will be covered in the Fourth Quarter IP Quarterly of 2007

Biodiversity, Genetic resources and the Convention on Biological Diversity

On 19 September 2007, Peru submitted a communication, dated 13 August 2007, (IP/C/W/493) on "Combating Biopiracy: the Peruvian Experience." The communication focused on Peru's mega diversity and the risks that it faced from biopiracy. The report describes cases of biopiracy that Peru has experienced and actions that Peru has taken to identify, remedy or prevent misappropriation of Peru's genetic resources.

Several countries requested that they be added to the list of co-sponsors of the proposal to amend the TRIPS Agreement by adding an article 29bis (WT/GC/W/564/Rev.2 issued with the joint symbols TN/C/W/41/Rev.2 and IP/C/W/474). Paraguay requested to be added to the list of co-sponsors in a communication dated 20 June 2007 (TN/C/W/41/Rev.2/Add.5). In a communication dated 5 June 2007, the African group also requested that they be added to the list of co-sponsors (TN/C/W/41/Rev.2/Add.4). Least-developed countries also expressed their strong support for the proposal.

Implementation of Article 66.2 on technology transfer

At the end of the 3rd Quarter of 2007, several developed countries reported on their implementation of the transfer of technology requirements under article 66.2. The article states that "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base." The reports are the result of a 2003 decision of the TRIPS Council (IP/C/28) requiring developing countries to report on their implementation of their obligations under the article.
Switzerland reported in a communication dated 25 September 2007. Regarding the methods of technology transfer, the communication notes that the majority of Switzerland's work is carried out through devel-

opment aid but also focuses on its encouragement of investment in LDCs, arguing that investment will enable technology transfer to LDC private sector actors.
Japan reported in a communication dated 1 October 2007 (IP/C/W/497/Add.1). It noted that it focused its activities on accepting trainees on intellectual property issues and the running of intellectual property training courses.

UNCTAD also submitted the report on its technical assistance activities on 27 September 2007 (IP/C/W/495**).** According to the report, in the areas of technology transfer and intellectual property rights, UNCTAD undertook research and policy analysis that includes:

a) *Compendium of International Arrangements on Transfer of Technology: Selected Instruments*;
b) UNCTAD's series *Transfer of Technology for the Successful Integration in the Global Economy;*
c) *Home-country measures in promoting transfer of technology;*
d) The UNCTAD-ICTSD project on Intellectual Property Rights and Sustainable Development that produced A *Resource Book on TRIPS and Development, A Study Series* on various topical intellectual property issues and *Regional Research Agenda* made up of a series of policy-oriented research papers on specific IP issues, written by field-based experts representing each region.

In the field of technical assistance UNCTAD reported its activities on IPRs and local pharmaceutical production and supply capacity of essential medicines that would involve:

- The preparation of a *Stakeholders' Reference Guide to IP and Related Policies*;
- The organization of training courses for stakeholders from developing countries; and
- The preparation of country reports on the national intellectual property and investment regimes of selected developing countries.

The WTO Secretariat also submitted its report on technical cooperation in the TRIPS area (IP/C/W/404). The report indicated that:

> "The Secretariat's technical cooperation activities in relation to TRIPS have continued to be directed towards assisting Members to understand the rights and obligations, including the available options, which flow from the TRIPS Agreement and relevant decisions of WTO bodies. In particular, Members have received assistance to use the mechanisms under the TRIPS Agreement, such as the Paragraph 6 Mechanism on TRIPS and public health and in regard to notifications and reviews of national legislation."

Accordingly, a significant part of the work of the Secretariat has been concerned with providing information on notification and review procedures, the meaning of particular provisions of the TRIPS Agreement, the options available under these provisions and matters under discussion or negotiation in the TRIPS Council. The Secretariat also has organised numerous meeting in and outside Geneva.

Priority Needs Assessment for Least Developed Countries

In line with paragraph 2 of the November 2005 Decision on the Extension of the Transition Period under Article 66.1 for Least-Developed Country Members, several LDCs submitted "priority needs for technical and financial cooperation in order to assist them taking steps necessary to implement the TRIPS Agreement". Sierra Leone's report was communicated on 28 September 2007. It noted specifically that it retained maximum flexibility under the TRIPS Agreement and that developed countries remained obligated under article 66.2 to ensure technology transfer to LDC. The report focused on the goal of creating a sound and viable technological base and also noted that a priority area was assistance in attendance at multilateral IP negotiations.
Uganda's report was communicated 3 October 2007. It noted the cross-cutting nature of policy and the need for coherence with other national policy objectives in carrying out legislative and policy reform.

Enforcement

In a communication in preparation for the October year end meeting of the TRIPS

Council Japan took up the issue of enforcement (IP/C/W/501) previously presented by the United States and the European Communities at previous meetings of the TRIPS Council. The communication states that it aims to share Japan's recent experiences with enforcement. The issue of enforcement remains a priority for developed countries at the WTO with continuing attempts to make it a permanent agenda item on the TRIPS Council and further moves to bring the issue to dispute settlement (see section below on Disputes.)

2003 Paragraph 6 Doha Waiver and 2005 Public Health Amendment

In July 2007, Rwanda notified to the WTO that it intended to make use of the 2003 Waiver that allows it to import pharmaceuticals from a third country under a compulsory license (IP/N/9/RWA/1). The notification is for the import of a fixed dose combination HIV/AIDS drug, TriAvir from a Canadian pharmaceutical manufacturer, Apotex. The Rwanda notification also states that, pursuant to paragraph 7 of the Decision, it will not enforce any patent rights granted to TriAvir in Rwanda. Paragraph 7 of the decision states that:

> "Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS."

Rwanda, as an LDC, is not required to apply provisions of the TRIPS Agreement on pharmaceuticals until 2016. This is the first notification from an importing member that the WTO has received.

In response to the stated intention of Rwanda and at the request of Apotex, on 8 October 2007, Canada also issued a notification (IP/N/10/CAN/1) that it will act as an exporting member under the decision, based on its own domestic law implementing the 2003 Decision.

With respect to the 2005 Amendment, 11 Member States have ratified it so far. From developing or least developing states, only El Salvador, India and the Philippines have notified their ratification of the amendment. The most recent ratification is from Singapore on 28 September 2007. The European Union is in the process of ratifying the amendment but the issue is being held up by disagreement between the European Commission and the European Parliament on the European Commission's continuing push for more patent rights and stricter enforcement which would be detrimental to public health flexibilities in developing countries with which the EU is negotiating bilateral and regional trade agreements.

The Secretariat released a report on the status of the ratification of the Protocol Amending the TRIPS Agreement (IP/C/W/490/Rev.1). By the third quarter of 2007 there were 11 member countries that accepted the Protocol out of which four are from Asia and one from Latin American. There are no African countries that have ratified the Protocol.

The Secretariat also released a report on the annual review of the August 2003 Decision of the General Council on the Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health. According to the report, there are no developing countries that have notified the TRIPS council of their intention to use the August 2003 Decision in accordance with paragraph 1(a) of the Decision. Rwanda and Canada have become the first countries to utilise the system by submitting their notification under Paragraph 2.

Disputes

On 13 August 2007, the US requested the institution of a panel against China in the complaint it had brought on China's enforcement of copyright as well as what it argues is the lack of copyright enforcement during China's required window for content review. The cases are "China – Measures

Affecting the Protection and Enforcement of Intellectual Property Rights" (WT/DS362/1) and "China – Measures Affecting Trade Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products" (WT/DS363/1).
On 25 September 2007, a panel was established, after a second request by the US.

A formal meeting of the Council for TRIPS was held from 23-24 October 2007 and will be covered in the Fourth Quarter IP Quarterly of 2007

World Intellectual Property Organization (WIPO)

The Assemblies of the Member States of WIPO took place from 24 September – 3 October 2007, in the final part of the third quarter. The Ambassador of Nigeria, Mr. Martin Ihoeghian Uhomoibhi was elected Chair of the General Assembly. The Assemblies included the final outcomes of meetings that were held during the third quarter whose deliberations will be covered in this section on the Assemblies. Several significant developments took place at the Assemblies but the entire meeting was overshadowed by discussions regarding the internal audit report (containing accusations of misconduct against the Director-General), PCT fees, and the desk-to-desk assessment reports. The ongoing controversy also limited discussion of several items on the agenda and precluded the WIPO General Assembly from adopting the Program and Budget of the organization for the biennium. The United States, supported by several Group B countries insisted on a discussion of the accusations against the Director General in the plenary of the meeting but this was opposed by the African Group who argued for further investigation, discussion in a more appropriate forum, i.e. the audit committee, and a return to the discussion at the next General Assembly. The two sides could not reach agreement and the Assemblies concluded with no resolution of the matter nor any indication of the way forward.

Provisional Committee on Proposals Related to the WIPO Development Agenda (PCDA)

The resumed session of the PCDA was held 4 September 2007. The meeting was to identify a set of proposals from the 45 already agreed that might be more immediately or easily implemented or that were already being implemented by the organization and had few or no budgetary implications. There was consensus that the exercise was in no way intended to create a priority list or to prejudge the sequence of implementation of the development Agenda proposals. The final list of 19 proposals was submitted by the Chair at the WIPO General Assembly. The list is available in Annex B to Agenda item 18 in the Draft report of the Meeting (A/43/16 PROV.)

At the WIPO Assemblies, all Member States formally adopted the recommendations of the PCDA, including the immediate implementation of the list of recommendations identified by the resumed session and submitted by the Chair.

All delegations spoke in favour of the Development Agenda proposals but concerns about budgetary implications were raised by some members. Developing country members emphasized the need to ensure that sufficient budgetary resources were allocated to the new Intellectual Property and Development Committee and to the implementation of proposals. Brazil noted the necessity of ensuring proper allocation of human resources and the addition on new expertise necessary for achieving the Development Agenda goals. Industrialized country members suggested caution in committing resources.
Developing country Member States also noted that the setting up of the new committee did not preclude the raising of development-related issues in other committees at WIPO. Brazil proposed that the Development and IP Committee meet twice a year and that financing be provided for developing country delegates to attend. The proposal was approved and adopted along with the PCDA recommendations. However, the US reserved its position on any budgetary implications that went beyond those agreed to at the present Assemblies. It noted, in particular the potential effect its own proposal to reduce Patent Cooperation Treaty fees by 15%, as well as any decision on the Program and Budget for the 2008-2009 biennium. The United Kingdom also noted reservations regarding further budgetary implications of proposals decisions on which it argued should be left to the Committee on Development and IP.

The adopted decision was:

- To adopt the recommendations for action in the 45 agreed proposals, contained in Annex A.
- To immediately implement the recommendations, contained in the list of 19 proposals (Annex B). Member States stressed that it did not, in any way, imply that these proposals had been accorded a higher priority than the others or that their implementation, or aspects of it, would not be discussed in the Committee on Development and Intellectual Property, in coordination with relevant WIPO bodies.

They also called upon all the Member States, the Secretariat and other relevant WIPO bodies to ensure the immediate and effective implementation of these proposals.

- To establish a Committee on Development and Intellectual Property to:

(a) develop a work-program for implementation of the adopted recommendations;

(b) monitor, assess, discuss and report on the implementation of all recommendations adopted, and for that purpose it shall coordinate with relevant WIPO bodies; and

(c) discuss intellectual property and development related issues as agreed by the Committee, as well as those decided by the General Assembly.

- The Committee will be composed of the Member States of WIPO and open to the participation of all accredited intergovernmental and non-governmental organizations (NGOs). It will consider and adopt rules of procedure based on the WIPO General Rules of Procedure at its first meeting. The Committee will have two five-day sessions annually, with the first one convened in the first half of 2008. As done during the sessions of the PCDA in 2006 and 2007, WIPO will provide financing for the participation of representatives from developing countries, including LDCs, as well as from countries with economies in transition, to attend the meetings of the Committee.
- For the first meeting of the Committee, the present Chair of the PCDA will prepare initial working documents, including a draft work program, in consultation with Member States and the Secretariat. The draft work program should address*, inter alia*, the financial and human resources requirements for inclusion in WIPO's budgetary planning process.
- The Committee will report and may make recommendations annually to the General Assembly.
- The PCIPD ceases to exist and the mandate of the PCDA is not renewed.

Standing Committee on the Law of Patents (SCP)

The impasse that had been reached at the 2006 General Assembly over the agenda of the SCP began to be resolved. During interim consultations with Member States, the Chair of the General Assembly, Ambassador Manalo, produced an outline (available in the appendix to WO/GA/34/5) of a report that he recommended be carried out by the secretariat and distributed by March 2008. The report on the international patent system would cover the "different needs and interests of all Member States, which would constitute the working document for a session of the SCP to be held in the first half of 2008. The report will contextualize the existing situation of the international patent system, including references to the WIPO Development Agenda process, and will contain no conclusions." The recommendation was adopted by the General Assembly.

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)

The 11th session of the IGC met from 3 July – 12 July, 2007. Under a decision from the 10th session, to facilitate substantive discussion, several issues and questions were put forward to be addressed in two documents including comments from Member States and observers collated during an intersessional process, one on Traditional Cultural Expressions (WIPO/GRTKF/IC/11/4(a)) and one on Traditional Knowledge (WIPO/GRTKF/IC/11/5(a)).

While the issue of genetic resources was on the agenda, it was not discussed. The committee also had to determine what to recommend to the 2007 WIPO General Assembly as to the renewal of the IGC Mandate.

Developed countries, particularly the US and Japan, continued to insist that it was too soon to address substantive issues, calling for further studies and further work. The US

emphasized that national experiences should be examined and that a first step would be to examine the role that existing intellectual property mechanism can play. Japan simply stated that it saw no necessity for providing intellectual property protection to traditional knowledge and that it was not yet time to have a substantive discussion. Variations on these themes were restated by the European Union and other Group B industrialized countries.

However, developing countries were unanimous in their desire for further, deeper discussion and actively engaged in stating their positions and opinions on the issues. What emerged was a strong agreement on the nature, scope and application of the protection of traditional cultural expressions and traditional knowledge. This stance was mirrored in many ways by the comments of indigenous people's groups, although there remain some significant differences between these groups and developing countries including:

- full recognition of customary law
- indigenous people's sovereignty over Folklore and TK.

While the discussion was useful in identifying an almost unanimous approach on the part of developing countries, and strong agreement with indigenous people's groups, it remained difficult to determine the direction in which the discussion was heading. A question that was not been answered is "to what end' the committee's discussions were aimed. Again, developing countries and indigenous groups were unanimous in arguing that a binding legal instrument was required. The substantive discussion concluded without any decision and was followed by two days of informal meetings to negotiate the recommendation regarding the renewal of the mandate of the IGC.

The decision of the committee essentially recommends that the mandate be renewed for an additional two years under the same conditions directed by the 2005 WIPO General Assembly (WO/GA/34/9). Attempts by developing countries to include language directing the committee to converge on agreement about the outcome of the IGC failed, leaving vague and innocuous language on:

> "With respect to the content of paragraph (iii) [the mandate], the Committee agreed to work towards further convergence of views on the questions included in its previous mandates, in particular, within the areas of TCEs and TK, on the Lists of Issues agreed at its Tenth Session, with a view to making appropriate recommendations to the General Assembly."

In addition, while the discussion reflected real agreement on the part of the majority of WIPO Member States, the secretariat has been directed to make only a factual extract of the discussion, meaning that it is not to make any evaluation of the tone or nature of the discussion that suggests any convergence around any points.

At the 2007 General Assembly the Member States (WO/GA/34/16)

"(a) noted the agreement of the IGC that progress had been made on its substantive work to date, and that the IGC had agreed to work towards further convergence;
(b) welcomed the successful launch of the WIPO Voluntary Fund, called for further contributions to the Fund and encouraged further initiatives to ensure the effective participation of representatives of local and indigenous communities in the work of the IGC;
(c) approved the renewal of the IGC's mandate in the terms recommended by the IGC and set out in paragraph 9 of WO/GA/34/9, in particular:
- the Intergovernmental Committee will continue its work for the next budgetary biennium on questions included in its previous mandate;
- its new work will focus, in particular, on a consideration of the international dimension of those questions, without prejudice to the work pursued in other fora; and
- no outcome of its work is excluded, including the possible development of an international instrument or instruments;
(d) urged the IGC to accelerate its work and to present a progress report to the session of the General Assembly in September 2008; and
(e) requested the International Bureau to continue to assist the IGC by providing Member States with necessary expertise and documentation."

Programme and Budget Committee

The program and Budget Committee (PBC) met for its 12th Session from 11-13 September 2007. Two significant proposals were made. The first was from the United States (WO/PBC/12/5) regarding a 15% reduction in Patent Cooperation Treaty (PCT) fees, a major source of support for WIPO. The second was a proposal from Brazil (WO/PBC/12/8) for broadening the participation base in the PCT by lowering fees for users from developing countries. The US proposal had also been formally submitted by the US and Japan to the PCT Assembly. Both documents were noted by the committee and were to be considered by the PCT Assembly.

The 2006-2007 budget was approved as well as the 2008-2009 Biennium. However, approval of the 2008-2009 Program and budget was done without prejudice to the proposals on the PCT fees, or decisions on the development agenda at the General Assemblies.

At the Assemblies, discussion on the PCT fees proposals took place in the PCT Union Assembly. The US, supported by Japan, argued that the 15% across the board reduction would keep the secretariat from expanding too much while enabling better access to the patent system for small and medium enterprises. Brazil emphasized that its proposal was an alternative to the US proposal and that it would better serve the interests of small and medium businesses as well as serve to broaden the PCT base. The African Group expressed concerns about the impact of the US proposal on WIPO finances and its ability to carry out its work, particularly on the Development Agenda. The group expressed support for Brazil's proposal. Switzerland did not support any reduction of fees at this time as it believed that the future programmatic and financial situation of the organization was unclear. During the discussions the US clearly linked its approval for the program and budget and for further work on the Development Agenda on the reduction of fees across the board, not just for developing countries. There was no agreement on the fee reduction issue following several rounds of informal consultations. In any event, further progress was blocked by the refusal of the US and supporters from Group B industrialized countries to continue discussions on the issue until the issue of how to address the accusation against the Director General had been resolved. After some procedural manoeuvring, the African Group moved to vote to close the debate in the PCT, which failed. The PCT Union Assembly ended in confusion and did not resume discussions for the remainder of the Assemblies.

The Program and Budget suffered the same fate as the PCT fees discussion as the US and Group B countries had serious concerns about making a decision before resolving the issue of the PCT fees. During the discussion the African Group again took the lead in expressing support for the recommendation of the Program and Budget Committee for the revised 2006-2007 biennium and the 2008-2009 biennium. After the US had stated its intention to block consensus, the African group called for a vote that failed to reach the required 2/3 majority. The discussion ended without any decision on the budget for the upcoming year or the following 2008-2009 biennium.

WIPO Life Sciences Symposia

On 4 September 2007, WIPO held a Life Science symposium on Intellectual Property and Bioethics. Presenters included: Mr. Anthony Taubman, Global IP Issues Division, WIPO; Ms. Maria Fotaki, Director, Biotechnology Directorate, EPO; Mr. Felix Addor, Deputy Director General, Swiss Federal Institute of Intellectual Property; Mr. Peter R. Thomson, Manager Global IP Litigation & Transaction, Corporate Intellectual Property, Novartis; Ms. Karin Blumer, Senior Policy Advisor, Global Public Affairs, Novartis; Ms. Julie Morgan, Asia Pacific Program Coordinator, Franciscans International. Presentations are available at http://www.wipo.int/meetings/en/2007/lifesciences/sym_bioethics/.

On 19 September 2007 WIPO held a Life Sciences Symposium on Intellectual Property and Public Health. Panellists included: Mr. Gilles Barrier, First Secretary, Permanent Mission of France to the United Nations Office in Geneva; Ms. Prangtip Kanchanahattakij, First Secretary, Permanent Mission of Thailand to the United Nations and other International Organizations in Geneva; Mr. Maximiliano Santa Cruz, First Secretary, Permanent Mission of Chile to the World Trade Organization; Howard Zucker, Assistant Director General, Health Technology

and Pharmaceuticals, WHO; Mr. Adrian Otten, Director, Intellectual Property Division, WTO; Mr. Guilherme Cintra, Researcher, International Federation of Pharmaceutical Manufacturers & Associations; Ms. Pascale Boulet, Legal Advisor, Campaign for Access to Essential Medicines, Médecins Sans Frontières. Presentations are available at http://www.wipo.int/meetings/en/2007/lifesciences/sym_health/.

Upcoming WIPO meetings in the Fourth Quarter

- WIPO International Conference on Intellectual Property and the Creative Industries, 29 -30 October, 2007.
- Advisory Committee on Enforcement: Fourth Session, 1 – 2 November 2007.
- Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications: Eighteenth Session, 12 – 16 November 2007.
- Life Sciences Symposium on Intellectual Property and Life Sciences Regulation, 16 November 2007.

Other Multilateral Fora

World Health Organization

The 3rd Quarter was dominated by preparations for the second meeting of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) to b held 5 – 10 November 2007. The new draft Global Strategy and Plan of Action (A/PHI/IGWG/2/2) was released by the IGWG Secretariat on 31 July 2007, and was cautiously received by Member States with many calling it inadequate. The document, available at http://www.who.int/gb/phi/pdf/igwg2/PHI_IGWG2_2-en.pdf, is divided into the global strategy and the plan of action and includes all positive items suggested by Member States. The global strategy focuses on "diseases or conditions of significant public health importance in developing countries for which an adequate treatment for use in resource-poor settings is not available – either because no treatment exists or because, where treatments exist, they are inappropriate for use in countries with poor delivery systems, or unaffordable." This nevertheless turns out to be a list of 14 diseases identified as priorities by the document, although the methodology for the selection seems unclear.

The strategy is framed by 8 elements which also form the basis for the plan of action, which include:
Element 1. Prioritizing research and development needs
Element 2. Promoting research and development
Element 3. Building and improving innovative capacity
Element 4. Transfer of technology
Element 5. Management of intellectual property
Element 6. Improving delivery and access
Element 7. Ensuring sustainable financing mechanisms
Element 8. Establishing monitoring and reporting systems

Within these elements are encompassed a broad range of activities and actions reflecting the wide divergences from Member State submissions. An online consultation process was established to solicit comments from civil society and the general public. The document was also made available for discussion in regional consultations. The results of the online public consultations as well the reports of the regional consultations are available at http://www.who.int/phi/public_hearings/second/contributions/en/index.html. Regional consultations in preparation for the IGWG have been held.
The African Region's comments noted, *inter alia*, the need to:

- Address and clarify funding mechanisms in the strategy and plan of action
- Assist countries with regulatory reform to manage expanded R&D demands
- Ensure that governments took the lead
- Clearer linkage to recommendations of the Commission on Intellectual Property Innovation and Public Health.

The Eastern Mediterranean Region noted, inter alia, the need for:

- Consistency with the CIPIH report
- Binding language rather than 'best endeavour' clauses
- A stronger focus on implementation

- Ensuring that there is no limitation on the kinds of diseases to be addressed.

The European Region, noted *inter alia*:

- That the document was well balanced and comprehensive
- The need for fewer and more well defined priorities
- The need for a stronger link to the Millennium Development Goals
- Expanding the scope to include Type I diseases for prioritization.

The Western Pacific Region noted inter alia:

- Other possible mechanisms for incentives such as the R&D Treaty or Advanced Purchase Commitments may be needed
- The need for further fine-tuning of indicators and stronger link to monitoring mechanisms.

Member States have also provided individual submissions. Portugal on behalf of the EU noted, inter alia,

- That the number of actions and related indicators should be reduced
- That responsibilities and division of labour should be more clearly indicated
- That the quality, safety and rational use of medicines, and supporting regulatory capacities to combat substandard drugs and counterfeiting need a higher profile in the strategy.

A sub-regional meeting in Brazil which included Argentina, Brazil, Bolivia, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Honduras, Mexico, Peru, Suriname, Uruguay and Venezuela, produced a consensus document that more closely reflected the elements of the CIPIH report and provided alternative language to that contained in the secretariat document. It particularly emphasized high prices and noted that efforts to develop new products will be of no value if they cannot be made available and accessible to those who need them.

The Global Strategy and Plan of Action has generated significant discussion but Member States will go into the 2nd and final IGWG meeting with almost all issues unresolved and with a broad document as the basis of negotiations. The process will involve difficult technical discussions as well as deeply challenging political exchanges. As part of the process of involving other stakeholders, the secretariat has released a list of experts who will assist Member States and the secretariat (http://www.who.int/gb/phi/pdf/igwg2/listofexpert-en.pdf). However, the role of the group remains largely undefined and it is unclear the extent to which the secretariat will be able to draw on this expertise having already generated the primary document to be discussed without consulting such experts. Of the 15 individuals, 8 are from developing countries. The criteria for selection also remain unclear although a process of consultation with member countries was followed.

United Nations Conference on Trade and Development (UNCTAD)

Intergovernmental Group of Experts on Competition Law and Policy, 17–19 July 2007

The discussion at the meeting (report available at http://www.unctad.org/en/docs/c2clpd63_en.pdf) included a voluntary round table on competition policy and the exercise of intellectual property rights. The Chairman's summary notes that the group considered IP and Competition to be complementary in achieving similar welfare and policy goals. Participants suggested focusing on the exercise of IP rights rather than on IP as a competition danger in and of itself. In particular, it was suggested that economic effect of the exercise of rights should be the test rather than particular methods of exercising IP rights. Some questions were raised regarding the applicability of such presumptions for developing countries with much smaller and less diverse markets.

Other UNCTAD meetings in the fourth Quarter*:* UNCTAD-ICTSD Roundtable - Is product patent protection necessary in developing countries for innovation? R&D by Indian pharmaceutical companies after TRIPS, 11 October 2007, Geneva

Science, Technology, Innovation and ICTs for Development: UNCTAD XII preevent, 6 December 2007

The South Centre

On 9 July 2007 the South Centre held an event on "Towards an international sui generis regime for the protection of traditional knowledge" parallel to the 11th Session of WIPO's IGC. Speakers at the meeting included Dr. Xuan Li, Lead Economist and Acting Coordinator, Innovation and Access to Knowledge Programme, South Centre; Prof. Thomas Cottier, Managing Director of the World Trade Institute, Professor of European and International Economics Law, and Dean of the Faculty of Law, University of Bern; Mr. David Vivas-Eugui, Project Manager, Intellectual Property, Technology and Services, International Centre for Trade and Sustainable Development (ICTSD); Ms. Begoña Venero Aguirre, Chair, Intellectual Property Board of Appeals, Peruvian National Institute for the Defense of Competition and Protection of Intellectual Property (Indecopi), Lima, Peru. The Agenda and Presentations are available at http://www.southcentre.org/Events/2007Jul_Side_Event_3.htm.

The UN Internet Governance Forum (IGF)

The third round of IGF consultations took place in Geneva at the International Telecommunication Union on 3 September 2007. The consultations focused on the substantive preparation for the annual meeting of the IGF, to be held in November 2007 in Rio de Janeiro, Brazil. Discussions continue on sub-topics and the organisation of workshops, open forums, plenary sessions and dynamic coalitions on the broader theme.

The Advisory group met on 4 and 5 September 2007. It continued preparation on the framing of the agenda for the Rio de Janeiro meeting. The group also made available a draft programme paper for the meeting. The final version of a synthesis paper that summarises the content of contributions received as well as the discussions of the open consultations was made available 26 September 2007 (available at http://www.intgovforum.org/Rio_Meeting/IGF.SynthesisPaper.24.09.2007.rtf).

The second annual meeting of the IGF will be held in Rio de Janeiro, Brazil from 12-15 November 2007.

Regional and Bilateral Trade Agreements with Intellectual Property Provisions

The following section highlights the latest developments in U.S. and European bilateral and regional trade negotiations with developing countries with specific focus on IP issues.

Free Trade Agreements involving the United States

The Third quarter was marked by little activity. There were no further moves to renew Trade Promotion Authority (TPA) which expired on 30 June 2007. This continues to impair ongoing negotiations, notably with the United Arab Emirates and Taiwan.

The Democrat-dominated US House of Representatives has reached a deal to approve the ratification of the FTA with Peru and has also suggested that the agreement with Panama will be approved, but the FTA with Colombia remains delayed over issues relating to the government links to rightwing paramilitaries. The Peru agreement was only approved after IP, labour and environmental standards that Congress had insisted be included in the Agreements had be renegotiated. In order to provide a transition, the Andean Trade Promotion and Drug Eradication Act was extended for 8 months until February 2008 to ensure that the preference regime for Colombia and other States awaiting ratification still remained in force.

During the third quarter of 2007, Costa Rica ratified the agreement in a referendum on 7 October 2007, although some civil society groups dispute the outcome.

Free Trade Agreements involving the European Union

EU-ASEAN

Negotiations continue to be actively pursued by the EU, although commentators note that conclusion of the agreement may be years away.[28]

[28] http://www.bilaterals.org/article.php3?id_article=9851

African, Caribbean and Pacific Countries (ACP)

Although Economic Partnership Agreement (EPA) negotiations between the European Union (EU) and ACP countries are expected to be concluded by the end of the year, many ACP countries have been sceptical as to the possibility of having the trade agreements signed by 31 December 2007. The EU, however, remains committed to the deadline.

The EU is close to finalization of an agreement with the CARIFORUM group, including on intellectual property. However, discussions on October 7th did not lead to conclusions and one of the sticking points was on intellectual property. The next planned meeting is of CARIFORUM heads of state in early December to approve the negotiate text.[29]

The SADC group still maintains that it is not in a position to negotiate new generation issues such as intellectual property.

The ECOWAS group is still elucidating a response to the EU proposal although it has been offered an interim 'goods-only' agreement by the EU. ECOWAS EC Ministerial EPA negotiations are scheduled for 25 October 2007 in Brussels.

The CEMAC group remains far behind in evaluating and generating proposals on IP. Joint CEMAC-EC technical meetings are planned for 22-24 October 2007 and a joint ministerial meeting for 29 October 2007.

The Pacific group has indicated that it will in all likelihood exclude IP from its negotiations although it may commit to further negotiations after an interim agreement on goods is signed.[30] Negotiations on the interim agreement are expected to be completed in November 2007.

The ESA group has received a response to its proposal from the EU but there are no indications of further convergence between the two approaches on IP. The region continues to suffer from adjustments to the regional configuration as some countries plan to sign EPAs under the East African Community configuration.

Others:

The EU is also pursuing negotiation of FTAs with the following regions and countries:

- Central American Countries
- the Andean Community
- the Gulf Cooperation Council
- South Korea

[29] http://www.acp-eu-trade.org/index.php?loc=epa/

[30] http://www.ictsd.org/weekly/07-10-17/story2.htm

ABOUT THE IP QUARTERLY UPDATE

The IP Quarterly Update is published on a quarterly basis by the South Centre and the Center for International Environmental Law (CIEL). The aim of the Update is to facilitate a broader understanding and appreciation of international intellectual property negotiations by providing analysis and a summary of relevant developments in multilateral, plurilateral, and bilateral fora as well as important developments at the national level. In each IP Quarterly Update, there is a focus piece analysing a significant topic in the intellectual property and development discussions.

Today, in addition to the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), there are other multiple fronts of discussion and negotiation on intellectual property. These other fora range from international organisations, such the United Nations Educational and Scientific Organization (UNESCO), the Food and Agriculture Organization (FAO), the World Health Organization (WHO), the United Nations Conference on Trade and Development (UNCTAD), the World Customs Organization (WCO), INTERPOL, and the UN human rights bodies to regional and bilateral fora such as in the context of free trade agreement (FTAs) or economic partnership agreements (EPAs). In some cases, national processes or decisions, for example, invalidation of a key patent may have important international ramifications.

Consequently, all these processes constitute an important part of the international intellectual property system and require critical engagement by developing countries and other stakeholders such as civil society organisations. Multiple fronts of discussions and negotiations require a coordination of strategies and positions that is not always easy to achieve. The Quarterly Update is meant to facilitate such coordination and strategy development, and is therefore a vehicle for awareness raising as well as capacity development.

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