

INTELLECTUAL PROPERTY QUARTERLY UPDATE



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OF DEVELOPING COUNTRIES



CENTER FOR INTERNATIONAL
ENVIRONMENTAL LAW

COUNTERFEIT MEDICAL PRODUCTS: NEED FOR CAUTION AGAINST CO-OPTING PUBLIC HEALTH CONCERNS FOR IP PROTECTION AND ENFORCEMENT

I. Introduction

In January 2009, the 124th session of the World Health Organization (WHO) Executive Board (EB) discussed the WHO Secretariat's report on counterfeit medical products (EB124/14). The report invited the EB to consider recommending a proposed resolution on counterfeit medical products to the 62nd World Health Assembly (WHA) to be held in Geneva from 18-27 May, 2009.

The draft resolution and report sought both a strong mandate on "counterfeit medical products" and to endorse the *Principles and*

Elements of National Legislation against Counterfeit Medical Products prepared by a multi-stakeholder initiative called the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

The report and the draft resolution presented counterfeit medical products as *the* central health problem pertaining to quality, safety and efficacy of medicines. This gave overwhelming weight to the problem of counterfeit medicines over equally significant and related public health problems of falsely labelled, spurious and substandard drugs.

The 62nd World Health Assembly of the World Health Organization will discuss a revised report of the WHO Secretariat on the public health implications of counterfeit medical products. The contents of this report will be of critical importance for access to medicines in developing countries

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in the context of attempts in the recent past to introduce an intellectual property (IP) enforcement agenda into the discussions on counterfeit, spurious and substandard drugs in the WHO as well as recent incidences of seizure of generic medicines in transit in the Netherlands.

II. Establishment of IMPACT

IMPACT was established in 2006 as an outcome of an *International Conference on Combating Counterfeit Medicines* organised jointly by the WHO, the Italian Medicines Agency (AIFA), and the International Federation of Pharmaceutical Manufacturers Association (IFPMA) in Rome.¹

The WHO provided secretarial support to IMPACT. However, the IMPACT taskforce was not established by the WHO Member States and did not receive any endorsement from the World Health Assembly. Thus, it was not a Member State driven initiative, but an initiative supported by the WHO Secretariat.

III. IMPACT Model Law

In less than a year from its establishment, the IMPACT Working Group on Legislative and Regulatory Infrastructure had developed the *Principles and Elements of National Legislation against Counterfeit Medical Products* (Principles) which was endorsed at the 2007 General Meeting of IMPACT.

These Principles were meant to serve as reference, or “model law,” for developing ad hoc national legislation aimed at effectively combating counterfeit medical products, and recognised that specific national and/or regional bodies of criminal, pharmaceutical, administrative, *intellectual property* and civil

legislation may have to be established or enhanced on the basis of the Principles.²

The IMPACT Principles did not reference the *WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs, 1999* as a basis for its work. While the WHO Guidelines regard high prices of legal drugs as a contributing factor to the proliferation of counterfeit drugs, IMPACT did not take into account drug prices as a factor behind counterfeiting. Rather, it held that inadequate regulation and enforcement contributes to counterfeiting. Hence, there is a need for developing a set of principles for establishing appropriate legislation and penal sanctions including a clear definition of counterfeit medicines.

Moreover, counterfeit medicines should be addressed through IP protection and enforcement along with pharmaceutical and medical devices regulation and criminal law. Thus, IMPACT adopted a one-size-fits-all model legislation in stark contrast to the WHO's traditional emphasis on the need for a national assessment of the current situation as the basis for a national strategy with regard to counterfeit medicines.³ In adherence to this approach, the IMPACT Principles advanced a broad definition of counterfeit medical products that conflated spurious and substandard drugs with counterfeit drugs, and proposed strong penal measures against the same through different mechanisms, including IP enforcement.

III.1 Definition of Counterfeit Medical Products

It is critical to understand the meaning of the word “counterfeit” in relation to the IMPACT Principles. The word is generally used in trade parlance with reference to trademark violation, and it is in this sense (copying of registered trademarks) that the word “counterfeit” has been defined in the TRIPS Agreement as well as EC regulations and various national laws. The US Food Drug and Cosmetic Act also defines the word

¹ IMPACT is composed of representatives of the WHO, Interpol, OECD, WCO, World Intellectual Property Organization (WIPO), World Trade Organization (WTO), IFPMA, International Generic Pharmaceuticals Alliance (IGPA), World Self Medication Industry, *Asociacion Latinoamericana de Industrias Farmaceuticas* (ALIFAR), World Bank, European Commission, Council of Europe, Commonwealth Secretariat, ASEAN Secretariat, International Federation of Pharmaceutical Wholesalers, European Association of Pharmaceutical Full-line Wholesalers, International Pharmaceutical Federation, International Council of Nurses, World Medical Association and *Pharmaciens Sans Frontiers*

² Third World Network, “WHO: Counterfeit taskforce may block legitimate access to generics”, *SUNS #6623*, 22 January 2009.

³ See South Centre, “The International Medical Products Anti-Counterfeiting Taskforce (IMPACT): Is the WHO on the Right Track?” *Intellectual Property Quarterly Update*, Third Quarter, 2008, pp. 6-7.

in the sense of a trademark violation. Therefore, the word “counterfeit” is, in common usage, in reference to a particular form of IPR violation i.e. trademark violation. The IMPACT Principles have advanced a definition that conflates counterfeiting as a particular form of IPR infringement with the problems of falsely labelled, spurious and substandard drugs. This definition builds upon a working definition adopted at a workshop held by the WHO and IFPMA in 1992, which states:

A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging.

The IMPACT definition modifies and broadens the scope the IFPMA-WHO 1992 definition. It states:

A medical product is counterfeit when there is a false representation in relation to its identity, history or source. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

The IMPACT definition broadened the scope of the IFPMA-WHO definition in the following ways: the scope of the definition was broadened from counterfeit medicines to counterfeit medical products; the requirement of deliberate and fraudulent intent in the former definition was removed, such that a mere false representation, regardless of intent, was made sufficient to establish counterfeiting. Thus, under the IMPACT definition, a drug with correct quality and active ingredients, but incorrectly labelled, is liable to be deemed as counterfeit.⁴

Moreover, the IMPACT definition expanded the scope of the IFPMA-WHO definition to deem a medical product counterfeit if there is a false representation not only about the product's identity or source, but also about the history of the product. The IMPACT definition did not explain the meaning of the word “history.” There is a possibility that “history” could require companies to disclose the history of the manufacturer as well as the product, including any previous seizures in relation to the product. Such disclosure may lead to the creation of new trade barriers for the generic industry.⁵

Further changes were made to the IMPACT definition at the third general meeting of IMPACT in Hammamet, Tunisia, in December of 2008. This revised IMPACT definition, which was presented in the report of the WHO Secretariat at the 124th Session of the EB, stated that:

The term counterfeit medical product describes a product with a false representation of its identity and/or source. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

*Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches of, or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.*⁶

This revised definition still applies to all medical products, which covers a broad

⁵ See Third World Network, “WHO : Concerns voiced over IMPACT, Secretariat's role on “counterfeits””, SUNS #6627, 28 January 2009.

⁶ See WHO, *Counterfeit Medical Products : Report by the Secretariat*, EB124/14, 18 December 2008, paragraph 10.

⁴ *ibid*, p.8.

range of items ranging from drugs to vaccines, to diagnostic kits, as well as to raw materials used in production. In its explanatory footnote 1, the definition states that counterfeiting is done deliberately and fraudulently and that criminal intent and/or careless behaviour shall be considered during legal proceedings for the purpose of imposing sanctions.

While this seems to reintroduce the element of intent as in the IFPMA-WHO definition, when read with the main part of the definition itself, this explanation implies that any act of counterfeiting as defined in the definition (which still states that mere false representation as to identity or source is counterfeiting) is necessarily done with deliberate and fraudulent intent. Hence, it presumes the existence of intent, which has to be rebutted by the defendant. This is contrary to normal criminal procedures where the burden of proving intent lies on the prosecution. Thus, the definition lowers the standard of proof.

It is interesting to note that the element of intent has been explained in a footnote in ambivalent language instead of being introduced in clear terms within the main definition itself. Further, fraudulent intent is made relevant only for determining sanctions and not for establishing culpability. This means that intent can be considered only at the trial stage and not while determining whether a medical product consignment can be seized on the suspicion of their being counterfeit.

Explanatory footnote 2 states that "false representation as to *identity*" in the definition includes misleading statement with respect to name, composition, strength or other elements. With regard to misrepresentation as to name, this explanation implies that even a trademark violation per se, i.e. using a name similar to a brand name will amount to counterfeiting. From a public health perspective, the identity of a medicine is established by its generic name (designated as International Non-Proprietary Names by the WHO).

Since generic names are not protected by trademarks, where the label of a medicine contains a generic name that is similar to a registered trademark (brand name), it can be deemed to be a counterfeit under this definition. For instance, a medicine which

bears the generic name *paracetamol* in its label may be held as counterfeit under this definition if there is a registered brand name called *Paramol*.⁷

Moreover, the explanation states that even misrepresentation as to composition, strength or other elements can mean false representation as to identity, and thus, a medical product making such misrepresentation will be counterfeit. This should be read with the second sentence of the revised definition which states that false representation as to the identity or source of a medical product applies not only to the product itself, but also to its container, or other packaging or labelling information.

This is in consonance with the expanded scope of trademark protection in developed countries, which covers non-traditional trademarks like colour marks, olfactory (scent) marks, taste marks, etc.⁸ Thus, the revised IMPACT definition promotes an expanded understanding of IPRs which is not followed by most developing countries.

Under such an expanded understanding, any off-patent generic medicine can be treated as counterfeit if it bears similarity as to colour scheme, shape, smell or taste of another medicine, even if the generic medicine is of good quality, safe and efficacious.

Explanatory statement in footnote 3 states that "false representation as to *source*" in the definition means any misleading statement with respect to the manufacturer, country of manufacturing, country of origin, marketing authorization holder, or steps of distribution. This can create particular problems for generic manufacturers in developing countries. This is because in many developing countries and LDCs, active pharmaceutical ingredients (API) are imported in bulk from other developing countries like India or China and are formulated and repackaged thereafter.

If the information on the end-product's packaging does not disclose the country of

⁷ See Kappoori M. Gopakumar and Nirmalya Syam, "International Nonproprietary Names and Trademarks: A Public Health Perspective", *Journal of World Intellectual Property*, vol.11, no.2, 2008, pp.63-104.

⁸ See WIPO, *Representation and Description of Non-Traditional Marks: Possible Areas of Convergence*, SCT/19/2, April 28, 2008.

origin of the API (which need not be disclosed because the package should only give information about quality, safety and efficacy), then, under this definition, it can be regarded as counterfeit. This is further clarified by the explanation in footnote 4 which states that the term “ingredients” or “components” in the definition applies to all components of a medical product, which includes the API for a formulation drug.

Thus, even if a generic formulation contains correct ingredients and is therefore of good quality, safe and efficacious, it will be counterfeit under this definition if it contains any misleading statement about the country of origin of the product or its ingredients. Moreover, the definition even includes misleading statements as to the manufacturer as grounds for deeming a medical product counterfeit.

This reflects the view of European pharmaceutical manufacturers that parallel importation of medicines constitutes an entry point for counterfeit medicines. They call for a ban on re-packaging and re-labelling of drugs along with a system for tracking and tracing medicines back to their production site.⁹ Thus, the IMPACT Principles have serious implications for parallel importation.

The definition might also extend the ambit of counterfeits beyond trademark violations as contained in the TRIPS agreement and other national and regional IP laws, to include patent violations. The definition does not explicitly exclude patent violations from the ambit of counterfeiting and merely states that patent violations or disputes should not be confused with counterfeiting of medical products.

III.2 Responsibilities of Governments

Having broadly defined counterfeit medical products, the IMPACT Principles lists a large number of responsibilities for governments, manufacturers, retailers and other operators in the supply and distribution chain of medicines for inclusion in national legislations on counterfeit medical products.

They require governments to establish an adequate legal regime comprised of criminal, administrative, and civil frameworks that can be applied to counterfeit medical products, in transit/trans-shipments, bonded warehouses, free-zones and all situations of international trade.¹⁰ Thus, the criminal, administrative, or civil measures that are taken to regulate the proliferation of counterfeit medical products should be applied to all situations of international trade in medical products, including transit or trans-shipment.

In addition, the IMPACT Principles require governments to regulate the manufacture, import, export, distribution, supply, donation and sale of medical products, and to establish regulations for a distribution system that includes measures for tracing medical products throughout distribution channels.

They also require governments to establish legal mechanisms for coordination and information exchange among health, regulatory, police, customs and other enforcement authorities at the national, regional and international levels. Such information exchanged is to be used in legal, regulatory or investigative actions against those involved in counterfeit medical products; authorizing undercover operations during investigations in order to obtain samples anonymously; ensuring penal prosecutions and severe sanctions against violators of anti-counterfeiting laws and regulations, including the confiscation, forfeiture and destruction of counterfeit medical products; and fostering bilateral and multilateral cooperation with other governments and regional and international organizations like WHO, Interpol, WCO, EC, among others.¹¹

Thus, a government's responsibilities include international cooperation in all aspects of deterring counterfeit medical products, including collaboration with international

⁹ South Centre, *supra* note 2, p.12.

¹⁰ See WHO-IMPACT, *Draft Principles and Elements of National Legislation against Counterfeit Medical Products*, Background Document for a Meeting of Experts, Lisbon, 10-11 December 2007, p.5.

¹¹ *ibid*, p.6.

organizations and the enforcement of severe penal measures against counterfeiting.

The call for international cooperation in the IMPACT Principles should be seen in the context of international cooperation taking place at the behest of developed countries on IP enforcement in other fora which advances a TRIPS plus agenda of IP enforcement. Indeed, IMPACT is a part of this concerted agenda. The IMPACT Principles clearly state that, while the Principles do not specifically address IPR issues (*sic*), the Principles may have to be expanded and periodically updated in order to take into account other international instruments and reflect current and emerging situations.¹²

Thus, the IMPACT Principles require international cooperation on the issue of counterfeits in different multilateral, plurilateral, regional and bilateral fora like the Anti-Counterfeiting Trade Agreement (ACTA) and the IP enforcement initiatives in forums like the World Customs Organization (WCO), WIPO and WTO, among others.

Any IP enforcement standard that is agreed to in these countries, or which is regionally implemented through Economic Partnership Agreements (EPAs) or regional or bilateral free trade agreements (FTAs) or through national anti-counterfeit legislations in various countries, can then be used to update the IMPACT Principles with regard to the application of such TRIPS plus IP enforcement standards for counterfeit medicines.

Indeed, the haste to develop and adopt the IMPACT Principles can be seen in the context of the aforementioned global developments on IP enforcement. The European Commission (EC) is a leading supporter of IMPACT and has provided funding for the development of the IMPACT Principles.

The EC has established that its anti-counterfeiting strategy will build on the results of IMPACT.¹³ Article 51 of the TRIPS agreement requires States to only establish procedures that enable IPR holders to request that customs authorities seize goods being imported at the border, where they are suspected of constituting a trademark

counterfeit good or a pirated copyright good.

The European Council Regulation No. 1383/2003 goes beyond the requirements of TRIPS and empowers customs authorities to take *suo moto* action to seize goods meant for import, export, or in transit. The EC regulation also authorizes seizure of goods that are suspected of infringing patents, which means that drugs that are suspected of infringing patents can be seized by customs authorities in the European Union. Such seizures of drugs suspected to be patent infringing are included in the EU customs statistics for seizures and the broad heading of counterfeit and pirated goods. This inflates the statistics on counterfeit goods, thereby magnifying the extent of the problem of counterfeiting.¹⁴

There are concerted attempts to devise similar standards empowering customs authorities to seize any IP infringing good including medical products meant for import, export or during transit, in the WCO, in the ACTA negotiations, in anti-counterfeiting statutes that are being legislated in some African countries (e.g. Kenya), and in some EPAs and FTAs.

The extent to which such laws and regulations which largely reflect the IMPACT Principles can impede access to medicines in developing countries is evident from the recent incidents of seizures of shipments of Indian generic drugs to Brazil, Colombia and Peru while in transit through Dutch ports, under EC Regulation No. 1383/2003.

A shipment of the drug *Losartan* by an Indian generic company to Brazil was seized in transit in Rotterdam on an application from a third company (Merck/DuPont) which claimed to hold IPRs over the drug in the Netherlands. Thus, the shipment was seized in spite of the fact that the drug was never brought onto Dutch territory and was not patented either in India or Brazil. In a remarkable similarity to the IMPACT Principles, the EC Regulation placed the burden of proving the legality of the shipment on the supplier.¹⁵

¹⁴ *ibid*, p.11.

¹⁵ See Maria Nazareth Farani Azevedo, "The Primacy of Health over Trade and Intellectual Property Enforcement", *South Bulletin: Reflections and Foresights*, Issue 31, 1 February 2009, South Centre, p.6.

¹² South Centre, *supra* note 2, p.7.

¹³ *ibid*, p.10.

In the face of an unfavourable prosecution under the EC Regulation, the Indian generic company entered into an agreement with the patent holder (Merck/DuPont) wherein it was agreed that the seized consignment will be released and taken back to India. Thus, the generic medicines could not reach the patients they were meant for, in spite of the fact that the consignment did not breach any standard of quality, safety or efficacy.

IV. The WHO Secretariat Report

At the 61st WHA in May 2008, the WHO Secretariat presented a Report on Counterfeit Medical Products (A61/16) which cited a 10 fold increase in counterfeiting from 2000 to 2007 and concluded that counterfeiting is a major public health challenge in many countries.

The report went on to state that the WHO launched IMPACT in 2006 in order to coordinate global action to halt the production, movement and commerce of counterfeit medical products. Thus, the report gave the impression that IMPACT is an initiative of the WHO in support of common strategies against counterfeit medical products and presented an account of IMPACT's work.

A draft resolution was also proposed urging Member States to establish and enforce national legislations based on the IMPACT Principles. It was decided that further discussion on the draft resolution and the Secretariat report will continue in the 124th Session of the WHO Executive Board.

At the 124th EB meeting, developing countries questioned the use of the term "counterfeit" by the WHO Secretariat to describe problems relating to the quality, safety and efficacy of medical products, thereby propagating the views of IMPACT.¹⁶ In the context of the definition of counterfeit medical products advanced by IMPACT which featured in the proposed resolution, the developing countries had reasons to be concerned that the use of the term "counterfeit" would result in the WHO addressing health concerns through IP enforcement measures.

While the developing countries unequivocally recognised the WHO as the appropriate forum for the debate on "... methodologies focused on the quality, safety and efficacy of medicines and other medical products ...", they stressed upon the need to ensure that norm-setting or definitional issues regarding quality, safety and efficacy of medical products are not used to undermine access to legitimate generic medicines, which are an integral part of national public health policies in many developing countries.¹⁷

Thus, developing countries have agreed that there is a necessity to adequately regulate medicines to ensure their safety, quality, affordability and efficacy given the fact that poor quality, harmful and substandard medicines pose a major threat to public health. Hence, there is a need for the WHO to provide normative support and technical assistance to developing countries to increase drug quality and safety by strengthening national drug regulatory capacities. The Department of Essential Medicines and Pharmaceutical Policies in the WHO has been providing this kind of support, and the WHO Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property also recognises that mechanisms to regulate the safety, quality and efficacy of medicines and other health products are critical components of a well-functioning health system.

The GSPOA stresses the need to establish and strengthen mechanisms that will improve ethical review and regulate the quality, safety and efficacy of health products and medical devices. The emphasis in the GSPOA and in the existing programmes of the WHO relating to quality, safety and efficacy issues has been on building up national drug regulatory capacities, encouraging compliance with good manufacturing practices (GMP) standards and strengthening the WHO pre-qualification programme.

It is noteworthy that the focus under this approach has not been on promoting greater involvement of law enforcement agencies (e.g. customs authorities), or the use of

¹⁶ Third World Network, *supra* note 4.

¹⁷ Azevedo, *supra* note 14.

trademark or other IP tools to guard against suspected or infringing uses of pharmaceutical brands.¹⁸ The Secretariat's report that was presented at the EB meeting, based on the IMPACT proposals, marked a fundamental shift from the traditional approach of the WHO in focusing on quality, safety and efficacy issues.

At the EB meeting, most developing countries agreed that the WHO should maintain its focus on the traditional approach and make more efforts to strengthen the drug regulatory authorities in the developing countries to address issues of quality, safety and efficacy, as stated in the GSPOA.¹⁹

Many developing countries also raised questions about the legitimacy of IMPACT and its relationship with the WHO. The lack of transparency with regard to its activities, funding sources, relationship with the private sector, and participants, raises serious questions about the legitimacy of IMPACT.²⁰ It was pointed out that IMPACT was not endorsed by the Member States of the WHO and did not have the mandate of the World Health Assembly. Questions were also raised regarding the lack of representation of developing countries in IMPACT, as well as the quality and objectivity of the data used by IMPACT.

In this context, the EB Members agreed that counterfeit medical products constituted a serious public health problem and decided that WHO Secretariat should prepare a revised report for the 62nd WHA in May 2009, taking into consideration the comments of Members. The report is to focus specifically on the public health impact of counterfeiting and contain new information. The Secretariat was also asked to prepare a separate report on the role, function and membership of IMPACT.

Thus, the EB did not recommend any resolution on counterfeit medical products to the 62nd WHA.

V. Conclusion

The issue of counterfeit medical products will be discussed in the 62nd WHA on the basis of the two reports that are to be submitted by the WHO Secretariat to the WHA.

During the discussions, it is imperative that the developing countries ensure that the activities of the WHO are focussed on the issue of quality, safety and efficacy of medicines and are not co-opted through a discussion on counterfeiting, thereby using the WHO as forum to promote the IP enforcement agenda of the developed countries and multinational pharmaceutical companies.

The discussions in the WHA should also consider the negative implications of anti-counterfeiting actions, such as the seizure of suspected IP infringing medicines in transit, on: access to medicines and the right to health, in the context of recent incidents; the emerging trend of TRIPS plus anti-counterfeiting legislations in various countries; and the discussions of similar standards in plurilateral agreements like ACTA, bilateral and regional trade agreements and in other multilateral forums.²¹

¹⁸ South Centre, *supra* note 2, p.2.

¹⁹ Third World Network, *supra* note 1.

²⁰ South Centre, *supra* note 2, pp.4-7.

²¹ An update on the 62nd World Health Assembly will be published in the next issue of the IP Quarterly Update.

AN OVERVIEW OF RELEVANT IP DEVELOPMENTS IN VARIOUS FORA

Below is an overview of updates involving intellectual property issues in various fora for the first quarter of 2009.

United Nations Environment Programme (UNEP)

25th Session of the Governing Council / Global Ministerial Environment Forum (GC/GMEF)

The 25th Session of the GC/GMEF took place from 16th-20th of February in Nairobi, Kenya (Official Website, President's Summary, Decisions Adopted, and Working Documents)

In addition to the breakthrough agreement on chemicals management, including an agreement to commence negotiations on a treaty to tackle the global mercury pollution crisis (summary), the importance of technology in addressing the dangers of climate change was noted, recognized and reaffirmed in both the President's Summary and Decisions Adopted.

Continuing with the technology theme, the GC/GMEF featured a "Technology Tent" displaying innovative technologies to assist countries around the world in addressing environmental concerns (more information).

During a briefing on the GC/GMEF outcome on March 11th, 2009, in Geneva, Hussein Abaza (UNEP) re-iterated the necessity to increase the transfer of technology. Mr. Abaza also suggested development of organic and low-water technologies as part of the "green-new deal," to help displace the prevalence of unsustainable, patented agricultural products and methods.

Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol

The 57th Meeting of the Executive Committee took place from 30 March – 3 April 2009, in Montreal, Canada http://www.multilateralfund.org/57th_meeting.htm.

The Executive Committee approved investment projects and activities worth over US \$27.5 million for 84 developing countries to phase out ozone depleting substances including, in some cases, hydrochlorofluorocarbons (HCFCs). Continuing its efforts to address the remaining CFCs ahead of the 2010 Montreal Protocol phase-out deadline, the Committee earmarked funds for Botswana, Equatorial Guinea, and Sierra Leone aimed at phasing out their entire CFC consumption. A total of 38 countries submitted project proposals.

The Committee addressed the funding of HCFC phase-out projects, including the choice of HCFC phase-out technologies in relation to their costs and impacts on climate. New approaches were discussed, one of which entailed shifting incremental operating costs from direct payment to enterprises, as had been the practice, to payment to countries based on a percentage of the capital cost associated with the conversion from HCFCs to the most cost-effective non-HCFC technology available. Those resources could be used at governments' discretion to establish, for example, a framework to address, climate-related impacts. The other new approach involved a strategy for second-stage conversions beyond 2015, taking into account compliance needs and cost-effectiveness. These approaches are still under discussion.

The Committee reviewed a status report on the analysis of the prioritization of HCFC phase-out technologies to minimize environmental impacts (UNEP/OzL.Pro/ExCom/57/59). Additionally, the Committee reviewed a report on relevant elements of the operation of the Clean Development Mechanism of the Kyoto Protocol (CDM) and the amounts of HCFC-22 production available for credits (UNEP/OzL.Pro/ExCom/ 57/62). A detailed review of these documents might provide insight into current financing trends in the transfer of certain technologies.

UN Framework Convention on Climate Change (UNFCCC)

Expert Group on Technology Transfer

A special meeting of the Expert Group on Technology Transfer (EGTT) was held in

Bonn from 24 - 26 February. Meeting documents are available here. The EGTT discussed and finalized three advance reports on: (1) performance indicators for technology development and transfer²²; (2) recommendations on financial options for the development and transfer of technologies²³; and (3) a long-term strategy to support the development and transfer of technologies²⁴.

These advance reports follow from the interim reports that were presented at the 14th Conference of the Parties (COP 14) in Poznan, Poland. The advanced reports will be made available as input to the negotiations on technology and financing under the Ad Hoc Working Group on Long-term Cooperative Action under the Convention (AWG-LCA). The next round of the AWG-LCA will take place in Bonn at the end of March 2009.

Conferences

Climate Change: Global Risks, Challenges & Decisions

The University of Copenhagen hosted an International Scientific Congress on climate change on 10-12 March 2009 in Copenhagen, Denmark (Programme). The congress was organized in cooperation with nine other universities in the International Alliance of Research Universities (IARU).

The main aim of the congress was to provide a synthesis of existing and emerging scientific knowledge that is necessary in order to make intelligent societal decisions concerning application of mitigation and adaptation strategies in response to climate change.²⁵

Broad surveys of technological perspectives, ranging from biofuels, to carbon capture and storage (CCS), and enhanced utilization of natural ecosystems, were discussed.

All the findings of these surveys will be compiled in a book on climate change, and a synthesis report with the main findings will be handed over to policy makers in June. The preliminary messages from the congress were handed over to the Prime Minister of Denmark and COP15 Chairman on 12 March 2009.²⁶

World Customs Organization (WCO)

Enforcement Committee, 28th Session

The 28th session of Enforcement Committee met from the 23rd-27th February, in Brussels. The Enforcement Committee seeks to develop model laws to help countries in drafting or revising their national customs legislations pertaining to border measures for IP enforcement that go beyond the requirements of the TRIPS Agreement. This was the first meeting of the Enforcement Committee since the dissolution of the WCO's controversial SECURE Working Group (please see the Fourth Quarter 2008 *IP Quarterly Update*, pg 20).

Preceding the 28th session of the Enforcement Committee, the Secretary-General of the WCO met with customs attaches in Brussels on the 13th of February 2009. A summary published by the Canadian Society of Customs Brokers (<http://www.cscb.ca/listinfo/wcocustomsattachesfeb09.pdf>), reports that "Mr. Uri Bruck...the former Chairperson of the SECURE Working Group, had suggested to Working Group delegates that a 'brainstorming' session be held for Members to discuss the future of work relating to IP rights within the WCO and to find constructive solutions in co-operation with all Members wishing to participate."

On 9 March, the first brainstorming meeting was held to discuss the possible establishment of a new body to replace SECURE (Standards Employed by Customs for Uniform Rights Enforcement), which had been suspended in December 2008.

²²

<http://unfccc.int/resource/docs/2009/sb/eng/inf01.pdf>

²³

<http://unfccc.int/resource/docs/2009/sb/eng/inf02.pdf>

²⁴

<http://unfccc.int/resource/docs/2009/sb/eng/inf03.pdf>

²⁵ Presentations from 58 different sessions focusing on different technologies are available at <http://www.iop.org/EJ/volume/1755-1315/6>

²⁶

http://climatecongress.ku.dk/newsroom/congress_key_messages/

The World Health Organization (WHO)

WHO Executive Board

The 124th Session of the WHO Executive Board was held from 19 - 26 January 2009 in Geneva, Switzerland.

IP issues were raised in respect of the following technical and health matter on the agenda: pandemic influenza preparedness (sharing of influenza viruses and access to vaccines and other benefits); the role and responsibility of the WHO in health research; counterfeit medical products; and a Global Strategy and Plan of Action for the Intergovernmental Working Group on Public Health, Innovation and IP.

Pandemic Influenza Virus Access and Sharing

The Board reviewed the report of the resumed Intergovernmental Meeting (IGM) on Pandemic Influenza Preparedness, held in Geneva from the 8th to 13th of December, 2008 (EB124/4 and EB124/4 Add.1). The IGM made progress on the text of a *Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits*. In preambular paragraph thirteen (PP13) of the *Framework*, the IGM members acknowledge their mutual obligations under both the Doha Declaration on the TRIPS Agreement and Public Health, as well under the Global Strategy on Public Health, Innovation and IP, as adopted in resolution WHA61.21.

In Section 6 of the *Framework*, two draft versions of a benefit sharing provision were included. The first provides for a discretionary grant of a non-exclusive, royalty-free license to influenza vaccine manufacturers from any Member State, where the vaccine was developed from a clinical specimen collected from within that Member State. The alternative clause provides for the possibility of discretionary grants of non-exclusive, royalty-free licenses to vaccine manufacturers in developing countries.

Next Session of the Resumed Intergovernmental Meeting on Pandemic Influenza Preparedness is from 15 to 16 May 2009. The topic is about sharing of

influenza virus and access to vaccines and other benefits.

WHO Health Research

Regarding the WHO's role and responsibilities in Health Research, the Board reviewed a draft of the *WHO Strategy on Research for Health* and recommended that the 62nd World Health Assembly (18-22 May, 2009) adopt a resolution endorsing the *WHO Strategy* (EB124/12). The draft *WHO Strategy* identified IP as a barrier towards reaching the goal of strengthening links between research, policy and practice. The lack of standards for information system interoperability in the area of health care informatics was specifically identified.

In addition, the WHO launched an online public hearing from 7 March until 15 April 2009 that will contribute to an intergovernmental mandate to come up with ways to address the shortage of research on diseases which predominantly affect developing countries (<http://www.who.int/phi/en/>).

Counterfeit Medical Products

The Secretariat's report on Counterfeit Medical Products (EB124/14) invited the EB to consider recommending a draft resolution on counterfeit medical products to the 62nd World Health Assembly (See Focus Piece for a detailed discussion). Developing countries questioned the use of the term "counterfeit" by the WHO Secretariat to describe problems relating to the quality, safety and efficacy of medical products. In the context of the definition of counterfeit medical products advanced by IMPACT which featured in the proposed resolution, the developing countries had reasons to be concerned that the use of the term "counterfeit" would result in the WHO addressing health concerns through IP enforcement measures.

Brazil specifically pointed to the negative implications of this for access to generic medicines of standard quality in light of recent detentions/seizures of medicines in transit by Dutch authorities (*See discussion WTO coverage, below*). While developing countries unequivocally recognised the WHO as the appropriate forum for the debate on "... methodologies focused on the

quality, safety and efficacy of medicines and other medical products ...", they stressed upon the need to ensure that norm-setting or definitions on issues of quality, safety and efficacy of medical products are not used to undermine access to legitimate generic medicines, which are an integral part of national public health policies in many developing countries.

Many developing countries also raised questions about the legitimacy of IMPACT and its relationship with the WHO. It was pointed out that IMPACT was not endorsed by the Member States of the WHO and did not have the mandate of the World Health Assembly. Questions were also raised regarding the lack of representation of developing countries in IMPACT, the quality and objectivity of the data used by IMPACT. In this context, the Executive Board Members agreed that counterfeit medical products constituted a serious public health problem and decided that WHO Secretariat should prepare a revised report for the 62nd World Health Assembly in May 2009 taking into consideration the comments of Members. The report should specifically focus on the public health impact of counterfeiting and contain new information. The Secretariat was also asked to prepare a separate report on the role, function and membership of IMPACT. Thus, the Executive Board did not recommend any resolution on counterfeit medical products to the 62nd World Health Assembly.

Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property Finally, with respect to the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, the Secretariat presented a report entitled *"Public health, innovation and intellectual property: global strategy and plan of action"* (EB124/16). A previously adopted resolution (WHA61.21) had requested the Director-General to undertake a number of immediate and medium-term actions, including: (1) finalization of the outstanding components of the Plan of Action; (2) preparation of a Quick Start Programme; and (3) establishment of a results-oriented and time-limited expert working group. The Secretariat's report provided an update on these activities.

Outstanding components of the Plan of Action, including time frames, progress

indicators for key elements and estimated funding needs, were finalized and proposed for consideration by the 62nd Health Assembly later this year (EB124/16 Add.1 and EB124/16 Add.2).

The following progress indicators were proposed for "Technology Transfer": (1) the number of health-related technology transfers relevant to the scope of the strategy; and (2) the number of national, regional and global coordination and collaboration initiatives aimed at increasing and facilitating transfer of health-related technology, including between public and private entities.

In addition, indicators proposed for "Application and Management of Intellectual Property to Contribute to Innovation and Promote Public Health" included: (1) the number of countries engaged in initiatives to strengthen capacities to manage and apply intellectual property rights to contribute to innovation and promote public health, including capacities relevant to the development and application of international agreements; (2) the number of countries integrating flexibilities for protection of public health of the WTO TRIPS Agreement into national legislation; and (3) the number and type of initiatives between secretariats and governing bodies of relevant regional and international organizations aimed at coordinating work relating to IP and public health.

The preparation of the Quick Start Programme to implement a number of specific actions of the Global Strategy and Plan of Action, as well the establishment of an expert working group has begun. The expert working group is composed of both policy makers and technical experts in the fields of public health, biomedical science, finance, and economics.

The Secretariat's report noted a clear link between the proposed WHO strategy for Health Research (EB124/12) and Technology Transfer as a key element of the Intergovernmental Working Group on Public Health, Innovation and IP, but no mention was made to the link between Technology Transfer and the programme on Climate Change and Health (EB124/11).

The World Intellectual Property Organization (WIPO)

Information Meeting on IP Financing

WIPO held an information meeting on IP Financing on March 10th, 2009 in Geneva, Switzerland.

Committee of Experts of the IPC Union

The 41st Session of the Committee of Experts of the International Patent Classification (IPC) Union met from March 16th – 20th, in Geneva, Switzerland. The Committee met to particularly discussed the report of the special Task Force on projects CE 404 (Procedures of revision and publication of the IPC) and CE 405 (IPC revision policy and consistency of application), and continue its ordinary work, i.e. the adoption of results of the IPC Revision Working Group and the IPC Advanced Level Subcommittee.

Several tasks outlined by the IPC Revision Working Group in a status report were: (1) Removal of Non-Limiting References from the Scheme; (2) Renumbering of Pre-Reform Residual Main Groups; (3) Introduction of Residual Main Groups in IPC Subclasses; (4) IPC Definitions Program.

In addition, a report on the advanced and core-level reclassification of patent files was presented to the Committee (IPC/CE/41/3).

The Committee was also invited to take note of a status report submitted by the European Patent Office on the Master Classification Database (IPC/CE/41/4 Annex).

Finally, the Committee was presented with a paper, commissioned by WIPO, which explains the current concordance table for 35 different fields of technology, in comparison to the previous concordance. (IPC/CE/41/5 Annex).

The report also provides an explanation of the general approach. The new concordance was used in WIPO's 2008 World Patent Report and can be found at: <http://www.wipo.int/ipstats/en/statistics/patents>.

Working Group on the Development of the Lisbon System (Appellation of Origin)

The first session of the Working Group on the Development of the Lisbon System met in Geneva, from March 17th – 20th, 2009.²⁷

Among items discussed were potential improvements to the procedures under the Lisbon Agreement. The prepared document (LI/WG/DEV/1/2 Rev.) proposes new provisions in the Lisbon Regulations, including: (1) specific procedures for the notification and recording of an acknowledgement or acceptance of a registered appellation of origin; and (2) specific procedures for the submission of notifications by electronic means.

Audit Committee

The 12th Meeting of the WIPO Audit Committee met from March 23rd – 26th, in Geneva.

Standing Committee on the Law of Patents

The thirteenth session of the WIPO Standing Committee on the Law of Patents (SCP) met from the 23rd to the 27th of March, in Geneva, Switzerland. Delegations from 103 countries, 10 international organizations and 28 non-governmental organizations participated in the Committee which was chaired by Maximiliano Santa Cruz from Chile.²⁸

The Committee decided that the Report on the International Patent System (SCP/12/3 Rev.2 and SCP/12/3 Rev.2 Add), which was presented in the previous (12th) session of the SCP and was revised on the basis of additional comments from States and other stakeholders, will remain open for further comments.

At the twelfth session of the SCP, the members had agreed on a non-exhaustive list of issues for possible examination by the SCP (see SCP/12/5 Prov. at ¶ 85). From this list, two topics were chosen for the Secretariat to prepare preliminary reports for an upcoming meeting. These are: "transfer of technology" and "opposition systems."

²⁷The official summary of the Working Group is available at

http://www.wipo.int/edocs/mdocs/mdocs/en/li_wg_dev_1/li_wg_dev_1_3.pdf

²⁸ The agenda (SCP/13/1) can be found at

http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=119212

In addition, two new topics were added to the non-exhaustive list: "patents and the environment, with a particular attention to climate change and alternative sources of energy" and "patent quality management systems."

The Secretariat presented preliminary studies on four previously chosen topics from the above list: "Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights" (SCP/13/3); "Dissemination of Patent Information" (SCP/13/5); "Standards and Patents" (SCP/13/2); "Client-Attorney Privilege" (SCP/13/4). It was agreed that all of the studies will remain open for further comment.

Additional research on exclusions, limitations and exceptions will be commissioned to a panel of external experts (see SCP/13/7 at ¶ 9). The Asian group had been the first to request that SCP/13/3 be submitted to a panel of outside experts, to help position the report in a socio-economic and public policy context. Developing countries were specifically calling for greater information on compulsory licensing, public health, education, public morality, as well as examination of patents on software, business methods, genetic material and life forms. Bolivia, in its first intervention, also asked for a study on the exclusion of both climate change technologies and life-forms from patentable subject matter. Group B was clearly opposed to further studies on SCP/13/3, especially the use of an external panel of experts, citing cost-benefit concerns.

Further studies will be conducted by WIPO on the topics of dissemination and client-attorney privilege. The Secretariat will prepare a concept paper on technical solutions to improve greater access to, and dissemination of, patent information. In addition, the Secretariat will expand on SCP/13/4, using external experts in the area of client-attorney privilege, if necessary.

Notably, no further studies will be conducted on Standards and Patents (SCP/13/2).

Both developing and industrialized nations were concerned with the organization of a

conference on Global Challenges, to be held on July 13th and 14th, 2009, in Geneva.²⁹ Developing countries raised concerns over the lack of their inclusion in the planning process, especially the selection of topics to be addressed by the conference. Members of Group B expressed a strong desire to have the agenda finalized so that a high-level of attendance is possible.

The fourteenth session of the SCP is tentatively scheduled to be held from November 9th to 13th, 2009, in Geneva.

Committee on Development and IP

The Third Session of WIPO's Committee on Development and IP (CDIP) was held from April 27 to May 1, 2009. 111 Member States and 49 Observers participated in the meeting.

The Committee reviewed the progress made on some of the nineteen recommendations slated for immediate implementation. Detailed discussions were held on recommendations 1, 3, 4, 6 and 7. Numerous developing and least developed countries called for the publication of materials to help review the efficacy of certain programs and policies referenced by the secretariat in document CDIP/3/5.

The Committee also discussed Annexes I, II and III of document CDIP/3/INF/2 containing project documents on recommendations 2, 5 and 8, for which activities had been approved by the second session.

In developing the work program to implement adopted recommendations, the Committee agreed to proceed on the basis of the following guidelines: (i) each recommendation would be discussed first in order to agree on the activities for implementation; (ii) recommendations that dealt with similar or identical activities would be brought under one theme, where possible; and (iii) implementation would be structured in the form of projects and other activities, as appropriate, with the understanding that additional activities may be proposed. The Committee agreed on

²⁹ The general information is available at http://www.wipo.int/export/sites/www/meetings/en/2009/ip_gc_ge/pdf/ip_gc_ge_09_inf_1.pdf

the activities for implementing the following thematic projects: (i) Intellectual Property and the Public Domain, grouping recommendations 16 and 20; (ii) Intellectual Property and Competition Policy, grouping recommendations 7, 23 and 32; and (iii) Intellectual Property, Information and Communication Technologies, the Digital Divide and Access to Knowledge, grouping recommendations 19, 24 and 27. See CDIP/3/4 and CDIP/3/4 ADD.

The Committee discussed coordination mechanisms and modalities for monitoring, assessing and reporting on the implementation of recommendations. Pakistan put forward a detailed proposal which recommended, *inter alia*, that the General Assembly further mainstream the Development Agenda into its discussions as well as the work of all WIPO Committees, and that the Director General report on this mainstreaming before each Committee meeting. Senegal, on behalf of the African Group, put forward its own proposal, which called for the creation of a Working Group to analyze Member State submissions on these topics. South Africa, among other developing countries, expressed concern over the Pakistani proposal's emphasis on coordination, which they felt neglected monitoring and assessing. However, Thailand expressed concern that the African Group proposal would delay consideration of this issue by the General Assembly beyond 2009.

Germany, on behalf of Group B of Industrialized Countries, expressed preference for maintaining existing organizational structures within WIPO. They discouraged the creation of any new, bureaucratic procedures or the duplication of activities. Both Group B and the European Communities supported maintaining all WIPO Committees on equal footing, without the supremacy of any Committee.

Despite the Chair's explicit preference for working with the proposal made by Pakistan, the Committee decided to have Member States submit their proposals to the Secretariat by June 30, 2009, in a compromise from the African Group's original proposal. These submissions, in addition to the ideas offered in the discussions during the Third Session of

CDIP, shall be presented to the fourth session of the CDIP by the Secretariat for further discussion and possible decision by the WIPO General Assembly. Thus, because the fourth session of the CDIP comes after the 2009 WIPO General Assembly, these mechanisms and modalities are unlikely to be considered by the WIPO General Assembly before 2010. I

Unlike most WIPO Standing Committees, which allow NGO interventions regularly, it was only after considerable lobbying from CIEL that a limited number of NGO interventions were allowed by the Chairman, Ambassador C. Trevor Clarke of Barbados.

The World Trade Organization (WTO)

TRIPS Council Meeting

A meeting of the TRIPS Council was held from 3 - 4 March 2009 in Geneva, Switzerland. Issues that were discussed included: the recent seizure/detention of drugs destined for South American nations; the extension of higher level Geographical Indication (GI) protection to products other than wines and spirits; and an amendment of the TRIPS agreement to include a requirement for the disclosure of origin of genetic resources in patent applications. In addition, a special session was held to discuss establishing a GI register.

The seizure/detention of drugs destined for Brazil, Peru and Columbia was paramount at the TRIPS Council Meeting. Brazil issued a statement arguing, *inter alia*, that the seizure of US\$55,000 worth generic anti-hypertension drugs was a violation of both GATT and WTO principles and that EC regulation 1383/2003, under which Dutch customs officials seized the goods in transit, is inconsistent with WTO rules. The Brazilian minister further elaborated that the goods were in transit and TRIPS does not confer extraterritorial powers on the Dutch authorities to seize the same.

India also delivered a statement at the WTO TRIPS Council Meeting, addressing the issue in light of the public health dimension of the TRIPS Agreement. The statement emphasized the legality of the generic drugs confiscated under both relevant domestic and international laws, and the

circumvention of public policy based flexibilities afforded under TRIPS. India argued that the confiscation “runs counter to the spirit of the TRIPS Agreement and resolution 2002/31 of the Commission on Human Rights on the right to enjoy the highest standards of physical and mental health.” India further stated that the confiscation violated the letter of the TRIPS Agreement, for the action was inconsistent with Articles 41.1 and 41.2, governing the enforcement of IPRs. India also referred to a letter by Medecins Sans Frontiers expressing concern over their practice of temporarily storing generic medicines destined for developing nations in Europe and asking for clarification on the relevant EC regulations.³⁰

In its response the EU stated that its actions were taken in an effort to stem the trade in counterfeit medicines, and does not reflect a maximalist IP enforcement policy. The EU argued that it remained committed to providing access to medicines as shown through: the TRIPS Agreement’s flexibilities; the Doha Declaration; the adoption of EU Regulation 953/2003 on tiered pricing; and the funding of projects and programs in developing countries. The EU further argued that the EU customs regulation at issue is fully in line with the WTO requirements, for “Article 51 and footnote 13 of TRIPS clearly allow WTO Members to apply border measures to goods under other customs situations, including in transit, which are suspected to infringe other intellectual property rights, including patents.”

During the TRIPS council meeting, *The Financial Times* reported that additional quantities of HIV/AIDS medicines destined for Nigeria were seized/confiscated.³¹

On 18 February, 2009, Oxfam International, Health Action International, Knowledge Ecology International, and thirteen other non-governmental organizations issued a strongly-worded

statement calling on the EU to review and modify its counterfeiting regulations which led to the seizures.³² The letter also suggested that under Article 5 of the Dispute Resolution Agreement, the Director-General may assist Members in settling a dispute.

On 04 March 2009, Pascal Lamy, Director General of the WTO, sent a response to the 18 February Letter by NGOs, answering that he did not believe that Article 5 of the DSU was of relevance in this case.³³ He also states that the Members concerned are seeking bilateral resolution.

On 13 March 2009, the WHO released its own statement, expressing “major concern” over the recent events.³⁴ The letter reminded WHO Member States of “their commitment to improving the delivery of and access to all health products and medical devices by effectively overcoming barriers to access,” with the adoption of a resolution on the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (WHA61.21), in May 2008.

TRIPS Council Meeting, Special Session

A special session of the TRIPS Council was held on 5 March, 2009 in Geneva, Switzerland. On the agenda was the continuation of discussion on developing a multilateral register for highly-protected Geographic Indications (GI) for wines and spirits. In the fifteenth year of discussions, the European Community has garnered support for the register by tying the register issue to two other popular issues: extension of high-level GI protection to products other than wines and spirits; and an amendment to the TRIPS agreement for the disclosure of the origin of genetic material or traditional knowledge to help combat biopiracy and misappropriation (see TN/C/W/52 and discussion below).

³⁰http://www.msfaccess.org/fileadmin/user_upload/m edinno_v_accesspatents/EC%20letters.pdf

³¹ http://www.ft.com/cms/s/0a0a0a9e-0928-11de-b8b0-0000779fd2ac,Authorised=false.html?_i_location=http%3A%2F%2Fwww.ft.com%2Fcms%2Fs%2F0%2F0a0a0a9e-0928-11de-b8b0-0000779fd2ac.html%3Fnclick_check%3D1&_i_referer=&nclick_check=1

³² http://www.ft.com/cms/s/0a0a0a9e-0928-11de-b8b0-0000779fd2ac,Authorised=false.html?_i_location=http%3A%2F%2Fwww.ft.com%2Fcms%2Fs%2F0%2F0a0a0a9e-0928-11de-b8b0-0000779fd2ac.html%3Fnclick_check%3D1&_i_referer=&nclick_check=1

³³ <http://www.keionline.org/misc-docs/seizures/dglamyresponse.pdf>

³⁴ <http://www.who.int/mediacentre/news/statements/2009/access-medicines-20090313/en/index.html>

The European Communities presented written responses to answers previously posed by Members in the December 2008 session.³⁵ Four key, interwoven issues are addressed in these responses: (1) what are the consequences or legal effects of registration; (2) member participation and coverage; 3) what information will have to be noted in the register; and 4) how the information will be registered after being notified.

On 11 March 2009, Director-General Pascal Lamy held an informal consultation with Ambassadors of interested nations. The two issues sought to be tied to the GI register - the extension of high-level GI protection to products other than wines and spirits, and the amendment to the TRIPS Agreement - were discussed

This consultation followed the July 2008 letter (TN/C/W/52), signed by 110 member states, which presented modalities to link the three afore mentioned issues. Despite agreement in principle on the creation of a GI register as the *quid pro quo* for both the extension of high-level GI protection and the disclosure of origin requirement, considerable disagreement remains. Both substantive and procedural issues, such as the appropriate forum for negotiating the agreement, and the inclusion of benefit-sharing provisions in the disclosure of origin requirement, are being contested. The next informal consultation will be held on 9 April 2009.

Working Group on Trade and Technology Transfer

The 27th session of the Working Group on Trade and Technology Transfer met on 10 March 2009. Since the previous meeting, the Working Group prepared its annual report to the GC (WT/WGTTT/10). The annual report summarized efforts from 2008 on the relationship between trade and transfer of technology. The report was largely based on a presentation by the Philippines and the World Bank's *Global Economic Prospects 2008: Technology Diffusion in the Developing World*. The Working Group expects to continue its work towards generating modalities to help increase the flow of technology to

developing countries. The official Meeting Notes for the 26th and 27th session of the Working Group are not yet available online.

Trade Policy Review Board

A recent review of Brazil's implementation and enforcement of IP rights gave the nation high-marks for its IP policies from the year 2004 through 2007. In the time period under review, Brazil adopted a new IP legislation, creating a "comprehensive and modern IP protection law" that now includes protection for integrated circuit designs, as well as improved enforcement of obligations under the TRIPS agreement. In addition, Brazil also developed guidelines and regulations for genetically modified organisms.

The following were also noted during the time period that was reviewed: (1) a decline in the number of Brazilian patents issued and industrial designs registered; (2) an average patent prosecution timeline of seven years; (3) the issuance of one compulsory license for HIV/AIDS medication in 2007; and (4) IP imports totalling US\$ 2.25 billion in license & royalty fees, versus US\$ 350 million in fees from IP exports.

The United States and European Union asked for Brazil to make further efforts on IP enforcement, accede to the WIPO internet treaty, and participate in the WTO Government Procurement Act. In 2006, Brazil began giving small and medium-sized enterprises a ten percent preference margin for competing in government procurement contracts.

The European Communities is scheduled to have its Trade Policy Review on the 6th and 8th of April, 2009.

USTR Section 301/306 Submissions

The 2009 version of the Pharmaceutical Research and Manufacturers of America (PhRMA) Special 301 was published in February.³⁶ PhRMA recommended that the Philippines and Thailand be designated Priority Foreign Countries under "Special 301" for 2009 and the Peoples Republic of China (PRC) continue to be designated under Section 306 Monitoring, in

³⁵ <http://www.ip-watch.org/weblog/wp-content/uploads/2009/03/20090223-elements-main.pdf>

³⁶ <http://www.phrma.org/files/PhRMA%20Special%20301%20Submission%202009%5B2%5D.pdf>

accordance with relevant provisions of the Trade Act of 1974, as amended.

Thai Prime Minister, Abhisit Vejjajiva, called on the United States not to intimidate Thailand over the compulsory licensing (CL) of essential drugs that save millions of lives, adding that the Kingdom would comply with the WTO's regulations on CL, stating: "If the US decides that the situation has worsened, I think it will produce a negative impact. There will be pressure from our society to expand CL if they treat us that way" (Bangkok Post article).

The International Intellectual Property Alliance (IIPA) 2009 *Special 301 Submission* was also released.³⁷ The submission states that the "IIPA has analyzed the copyright law and enforcement problems in 48 countries/territories, and has recommended 39 of them for placement on the Priority Watch List or Watch List, or for monitoring under Section 306 of the Trade Act. We also mention specific issues in nine additional countries/territories that deserve increased U.S. government attention."

In April of last year, the American University's Program on Information Justice and Intellectual Property (PIJIP) released a comparison showing that 86% and 75% of the countries requested by IIPA and PhRMA are placed on the USTR Special 301 report, respectively.

Developments in Bilateral and Other Fora

Anti-Counterfeiting Trade Agreement (ACTA)

After denying a recent request for ACTA related documents, the US Trade Representative (USTR) released a summary highlighting some elements of the ACTA negotiations.³⁸

According to the USTR summary, the ACTA aims to fight counterfeiting and piracy by "building on" existing international IP laws. Key chapters of the ACTA identified in the

summary were: the legal framework for IPR enforcement, enforcement practices; and institutional arrangements. The legal framework chapters contain terms on civil and criminal enforcement, border measures, and special measures pertaining to the digital environment.

Knowledge Ecology International's previous request for documents to be released under the US Freedom of Information Act was denied by USTR officials, who believed the secrecy of the documents to be "in the interest of national security."

The USTR letter came less than three-weeks after US President Obama's memo clearly stating that, "all agencies should adopt a presumption in favour of disclosure;...usher in a new era of open Government;...should not wait for specific requests from the public;...and [a]ll agencies should use modern technology to inform citizens about what is known and done by their Government. Disclosure should be timely."

Australia-ASEAN-New Zealand Free Trade Free-Trade Agreement

The Australia- New Zealand-ASEAN- Free Trade Agreement (AANZFTA) was signed on 27 February 2009. It will come into force 60 days after Australia and New Zealand, and at least four ASEAN Member States, ratify the Free Trade Agreement (FTA). The target date for AANZFTA to come into force is the second-half of 2009, and no later than 1 January 2010.

Chapter 13 of the AANZFTA addresses IP issues, with the Parties agreeing to establish a Committee on IP to monitor specific obligations on protection of IP rights, government use of software, and transparency.

European Union – India FTA

The sixth round of negotiations on a European Union – India FTA took place in New Delhi, India from 17 – 19 March 2009. The negotiations were conducted amid peaceful protests in New Delhi denouncing the secretive, unilateral decision making by the EC and India on issues such as IPRs, investment, services, agriculture, fisheries, and labour (video).

³⁷ See <http://www.iipa.com/rbc/2009/2009SPEC301COVERLETTER.pdf>

³⁸ http://www.eurekalert.org/pub_releases/2008-11/bc-tku110708.php

In response to the protests, the EU Ambassador Daniele Smadja met with three representatives of Forum of FTA, organizers of a protest. "We were disappointed but not surprised by the Ambassadors statement that all negotiating texts are secret and will not be made available even to EU Parliamentarians," according to one representative at the meeting (Media Release).

The European Parliament issued a statement on the 26th of March, announcing the adoption of a report pushing for a signed EU-India FTA by the end of 2010.³⁹ The report was adopted by approximately a 3-2 vote margin. In addition, the report also welcomed the approval of a Joint Action Plan (JAP) which came out of the 9th EU-India joint summit in September of 2008. The JAP strives to promote sustainable development through, in part, a Work Programme on energy, clean development and climate change, as well as the strengthening of IPR enforcement.

The 26th of March statement also contained a reference to the current dispute over generic medicines seized/detained by Dutch Authorities (see *WTO TRIPS Council Meeting*, above).

MEPs called on the EU and India "to ensure that commitments under the FTA do not preclude access to essential medicines whilst India is developing its capacity from a generic to a research based industry."

The MEPs "welcomed India's commitment to a strong IPR regime and to the use of TRIPS flexibilities to meet its public health obligations, particularly in relation to access to medicines."

The report also mentioned that "India is one of the major sources of counterfeit medicines seized by the customs services of [EU] Member States (accounting for 30% of the total)." However, the report neither mentions that India is the world's largest producer of generic medicines, nor clarified whether the percentage quoted includes medicines such as those recently confiscated/seized by Dutch authorities.

On a related note, The Guardian reports that India has entered 200,000 medicines into the public domain.⁴⁰ The medicines are listed in a database, the Traditional Knowledge Digital Library. The European Patent Office will now use the database to check that patent applications from companies are valid.

EU – ASEAN FTA

Negotiations over the EU – ASEAN FTA is raising concerns regarding IP protection measures that may go beyond provisions found in the current TRIPS agreement. The issues raised include concerns on agriculture, biodiversity and access to medicines.

The Bangkok Post reports that the EU Proposal would prevent the marketing of generic versions of medicines that are not even protected by patents, as well as those produced or imported under compulsory licenses. Thailand is one of the most frequent users of TRIPS flexibilities allowing for compulsory licensing. One expert quoted believes that the proposal would increase standards of IPR protection; increase the duration of both exclusive rights and regulations on marketing that favour monopolies; and limit public access to medicines.

EU - African, Caribbean and Pacific (ACP) Nations Economic Partnership Agreement (EPA)

In January, the European Centre for Development Policy Management (ECDPM) released a detailed briefing note regarding the status of the EU-ACP negotiations, which have extended well beyond the 2007 target for completion. Many organizations have issued statements urging African Member States not to sign EPA proposals as scheduled for mid-2009.

South Centre issued a press release on 16 February 2009, cautioning African nations that the EPA "is likely to bring more losses than gains for Africa."

On 26 February, 2009, Guyana's President Bharrat Jagdeo called for a delay in implementing the EU EPA because of the

³⁹http://www.europarl.europa.eu/news/expert/infopress_page/026-52629-082-03-13-903-20090325IPR52628-23-03-2009-2009-false/default_sv.htm

⁴⁰

<http://www.guardian.co.uk/world/2009/feb/22/india-protect-traditional-medicines>

global financial crisis. Several trade groups have called on their respective governments in either the Economic Commission of West African States (ECOWAS) or the East Africa Community, to request extensions beyond the July 2009 deadline.

If the Parties were to agree to a delay, the additional time could help clarify IPR provisions in the EPA, especially regarding the developmental impact of IPR provisions on technological advancements and innovation. (see D. Shabalala, *The Problem of IP in EPAs with the ACP Countries*, CIEL, 2007; Dorica Suvye Phiri, EPAs and IPR protection, South African Institute of International Affairs (SAIIA), 2008).

Japan – India EPA

The Economic Times reports Indian Pharmaceuticals Secretary Ashok Kumar said that India would ask the Japanese authorities to appoint a separate agency to help Indian companies export their medicines to Japan.⁴¹ The article states that the Japanese Government is making regulatory changes to reduce health care costs and expects overall market penetration by generic drugs to reach 30% in volume by 2013, from the current level of 5%. India is currently the world's largest producer of generic medicines.

US – Peru FTA

The US – Peru FTA entered into force on 1 February, 2009. Concerns have been raised over “rushed” revisions to Peru's IP laws in the days before US President George W. Bush left office.⁴² The revisions, enacted without debate in Peru's Congress, are thought to create ambiguities that could facilitate biopiracy and hamper Peru's position as a protector of knowledge.

Peru is a member of the Andean Community of Nations (CAN). Modifying a CAN regulation, the Peruvian amendment states that biological material, “in whole or in part,” cannot be patented. However, the amendment omits explicit exclusion of

“genome or germplasm” from patentable subject matter, which is found in the CAN regulation, raising the possibility of patents on genetically modified organisms (GMOs).

Moreover, rules protecting indigenous knowledge related to biological resources have also been changed. CAN requires the presentation of a 'certificate of origin' before patenting, which proves access has been officially authorized. The Peruvian amendment merely requires the filing of a license before patenting, which can be issued by lesser authorities. Additionally, the failure to use the license will incur only a penalty, rather than cancellation of the patent as the CAN mandate stipulates.

⁴¹http://economictimes.indiatimes.com/News/News_By_Industry/Healthcare__Biotech/Pharmaceuticals/India_seeks_easy_entry_for_drug_cos_in_Japan/articleshow/4061234.cms

⁴² <http://www.scidev.net/en/news/revised-laws-could-promote-biopiracy-in-peru.html>

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 organizations, such as 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 organizations. 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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