INTELLECTUAL PROPERTY QUARTERLY UPDATE

AN INTERGOVERNMENTAL ORGANIZATION OF DEVELOPING COUNTRIES

CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

THE DANGERS OF INCLUDING PATENT INFRINGEMENTS IN ACTA: SOME IMPLICATIONS FOR ACCESS TO MEDICINES

I. Introduction

An international agreement to address counterfeiting is being drafted amongst the US, the EU, Canada, Japan, Korea, Mexico, Morocco, New Zealand, Singapore and Switzerland.[1] The Anti-Counterfeiting Trade Agreement (ACTA) is being negotiated behind closed doors, and in some cases industry groups have been given special access to the details of the negotiations while public interest groups are shut out of the process.[2]

In spite of the fact that closed negotiations have made it difficult for public health advocates to offer a technical analysis, public health groups have indicated concern that ACTA may negatively impact on access to medicines.[3]

[1] USTR, "Ambassador Schwab Announces U.S. Will Seek New Trade Agreement to Fight Fakes", Press Release, Office of the USTR, 23 October 2007, online: USTR http://www.ustr.gov/Document_Library/Press_Releases/2007/October/Ambassador_Schwab_Announces_US_Will_Seek_New_Trade_Agreement_to_Fight_Fakes.html (accessed 21 July 2008); Morocco and Singapore were included as parties in ACTA negotiations in an EC document, "Anti-Counterfeiting: EU, U.S. and Others Meet in Washington to Advance ACTA", Washington, 31 July 2008, online: EC http://trade.ec.europa.eu/doclib/docs/2008/august/tradoc_140017.pdf (accessed 11 August 2008).

[2] For example, in Canada the government has reportedly created an Intellectual Property and Trade Advisory Group, which has provided members with access to "in-depth exchanges on technical negotiating issues" on the condition that members sign a confidentiality agreement. See Michael Geist, "Public left out of anti-counterfeiting trade talks", 28 July 2008, *The Star*, online: the Star http://www.thestar.com/Business/article/468267 (accessed 11 August 2008).

[3] See Peter Maybarduk, Staff Attorney, Essential Action

INSIDE

If the scope of ACTA aims to address the issue of counterfeit medicines and at the same time encompasses intellectual property (IP) broadly and includes patents then the ACTA enforcement regime has the potential to restrict the use of IP-related safeguards for access to medicines such as compulsory licensing and parallel importing. Any approach that an enforcement regime takes to remove counterfeit medicines from markets should be tailored such that it does not negatively influence the use of safeguards by governments and third parties that aim to secure access to medicines.

II. ACTA and Counterfeit Medicines

ACTA is a plurilateral agreement that aims, according to the USTR, to:

> Establish… a common standard for IP enforcement to combat global infringements of IP particularly in the context of counterfeiting and piracy…[4]

An ACTA discussion paper indicates that the legal framework set up for IP enforcement will include criminal sanctions for IP infringements, including ex officio authority for enforcement officers to take action against infringers.[5]

It is increasingly evident that counterfeit medicines will be addressed as part of ACTA. Chief amongst the public rationales under which ACTA is being negotiated are issues of health and safety – including those of pharmaceuticals. For example, the EU press materials for ACTA persistently cite the "danger of health threats from counterfeit food and pharmaceuticals drugs" as one way that ACTA will contribute to fighting counterfeiting[6], and Peter Mandelson, the EU Trade Commissioner, has said that "when people reach for chemicals that are fake or medicines that are not real, they are at a very great risk of killing themselves".[7] Australia has expressly listed counterfeit medicines as one of the impacts of counterfeits on consumers[8], and an access to information request suggests that Canada has been sure to include the pharmaceutical industry in confidential ACTA consultations whereas other relevant industry groups were excluded.[9]

A considerable amount of input on ACTA from the pharmaceutical industry is being offered to governments involved in ACTA negotiations through other means. Industry groups for pharmaceutical research and biotechnology companies as well as for generics companies made submissions to the office of the U.S. Trade Representative (USTR) concerning ACTA.[10] In Canada, both

"Re: Comments of Essential Action on the Proposal for an Anti-Counterfeiting Trade Agreement", letter to Rachel S. Bae, Director for Intellectual Property and Innovation, Office of the United States Trade Representative, 21 March 2008, online: Essential Action http://www.essentialaction.org/access/index.php?/archives/131-Comments-on-Proposed-Anti-Counterfeiting-Treaty.html; and "Secret Treaty May Interfere with Access to Generic Drugs", *Essential Action's Global Access to Medicines Bulletin,* Issue #6, 7 August 2008, online: Essential Action http://www.essentialaction.org/access/.

[4] USTR, "Fact Sheet: Anti-Counterfeiting Trade Agreement", USTR, October 2007, online: USTR http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/asset_upload_file122_13414.pdf (accessed 11 August 2008).

[5] A discussion paper on ACTA was reportedly circulated to industry representatives and Wikileaks obtained a copy of the document. It is available online: "Discussion Paper on a Possible Anti-Counterfeiting Trade Agreement", at 2-3, Wikileaks, online: Wikileaks http://file.sunshinepress.org:54445/acta-proposal-2007.pdf (accessed 21 July 2008).

[6] See EU, "Anti-Counterfeiting: European Union, United States and Others Meet in Washington to Advance Anti-Counterfeiting Trade Agreement", European Union, Press Release No. 75/08, 31 July 2008, online: EU http://www.eurunion.org/eu/index.php?option=com_content&task=view&id=2418&Itemid=58 (accessed 11 August 2008); "Major New International Anti-Counterfeiting Pact in the Works", 23 October 2007, online: Government Technology http://www.govtech.com/gt/articles/158122 (accessed 11 August 2008).

[7] William New, "South Korea Urged to Strengthen IP in EU Trade Talks", Intellectual Property Watch, 21 November 2007, online: IP Watch http://www.ip-watch.org/weblog/index.php?p=833 (accessed 11 August 2008).

[8] Australian Government, "Department of Foreign Affairs and Trade Discussion Paper: An International Proposal for a Plurilateral Anti-Counterfeiting Trade Agreement (ACTA)", 13 November 2007, online: Department of Foreign Affairs and Trade: http://www.dfat.gov.au/trade/acta/discussion-paper.html (accessed 11 August 2008).

[9] Michael Geist, "Public left out of anti-counterfeiting trade talks", 28 July 2008, The Star, online: the Star http://www.thestar.com/Business/article/468267 (accessed 11 August 2008).

[10] PhRMA, "Pharmaceutical Research and Manufacturers of America (PhRMA) Anti-Counterfeiting Trade Agreements (ACTA) Comments", Response to Request for Written Comments 73 Fed. Reg. 8910 (Feb 15, 2008) for the Office of the USTR, 21 March 2008, online: USTR

of Canada's Research-Based Pharmaceutical Companies and the Canadian Generic Pharmaceutical Association are reported to be on an Intellectual Property and Trade Advisory Group to the Minister of Industry, which has no public interest representation.[11] In the EU, the European Generics Association has released a position paper on ACTA[12], the details of which suggests that the group has had considerably more access to the context of the agreement than what has been made public.

All of this points to the fact that the governments negotiating ACTA intend for it to address counterfeit medicines. What is key about this is that, in their statements, all these governments appear to equate "counterfeit" with "IP infringing" and aim to harness the power of public health safety concerns to the issue of IP enforcement. While this is a dangerous and inaccurate conflation, even more dangerous is the conflation of patent infringements with counterfeits, which may take place under ACTA. Furthermore, ACTA's goals focus broadly on intellectual property rights and do not, so far, distinguish between patents and other forms of IP such as copyrights and trademarks. This has consequences for two main areas: the expansion of border measures and precautionary measures from other IPRs to patents[13]; the application of IP criminalization to patent infringements. Both of these developments pose serious dangers for ensuring proper competition in pharmaceutical production and for ensuring access to medicines through safeguards. If counterfeit medicines are to be addressed effectively then the agreement will have to take an approach that effectively and carefully distinguishes counterfeits from alleged patent infringements.

III. Including Patents in the Scope of ACTA Would Have Negative Public Health Consequences

An ACTA agreement that blurs the distinctions between counterfeits and other legitimate medicines that are the subject of IP-related disputes – including parallel importing, compulsory licenses, and generics[14] – could do more harm than good for public health.

Counterfeits are not, and should not, be equated with patent infringements and concepts, definitions and measures designed to address counterfeits should not be extended to patents. The generics industry has raised concerns that ACTA does not adequately distinguish the business use of patents from how the concept of counterfeits may be defined and applied within an ACTA enforcement regime. A position paper release by the European Generics Association (EGA) on counterfeiting and patent infringement in the context of the ACTA identifies that "patent infringement during the normal legitimate business development of a product" should not become a crime, and should remain a private civil matter.[15] In addition, the EGA proposal recommends that any definition of counterfeits adopted within ACTA, clearly not be addressed at patents or patent infringement. They point positively to the

http://www.ustr.gov/assets/Document_Library/Federal_Register_Notices/2008/July/asset_upload_file319_14999.pdf (accessed 11 August 2008); and GPhA, "Comments of the Generic Pharmaceutical Association on the Anti-Counterfeiting Trade Agreement", 21 March 2008, online: USTR http://www.ustr.gov/assets/Document_Library/Federal_Register_Notices/2008/July/asset_upload_file525_14997.pdf (accessed 11 August 2008).

[11] Michael Geist, "Public left out of anti-counterfeiting trade talks", 28 July 2008, The Star, online: the Star http://www.thestar.com/Business/article/468267 (accessed 11 August 2008).

[12] European Generic's Association, "Position Paper: EGA Statement on Counterfeiting and Patent Infringement in the Context of the Anti-Counterfeiting Trade Agreement (ACTA)" June 2008, online: EGA http://www.egagenerics.com/doc/EGA_pos_ACTA_june2008.pdf (accessed 4 July 2008).

[13] The European Union, for example, has been seeking such an expansion in its Free Trade Agreements with other countries. A good example is the EU's proposals to African, Caribbean and Pacific group of countries available at

[14] Outterson & Smith discuss the tendency of the pharmaceutical industry to conflate counterfeit medicines with medicines that are generics, produced under compulsory licenses, or traded via parallel importing. Kevin Outterson & Ryan Smith, "Counterfeit Drugs: The Good, the Bad and the Ugly", 2006, *Albany J. of Science & Technology*. In this focus piece, counterfeit is used to denote medicines that are therapeutically harmful because they do not treat what they purport to treat. Thus a counterfeit medicine may not actually infringe any intellectual property right.

[15] European Generic's Association, "Position Paper: EGA Statement on Counterfeiting and Patent Infringement in the Context of the Anti-Counterfeiting Trade Agreement (ACTA)" June 2008, online: EGA http://www.egagenerics.com/doc/EGA_pos_ACTA_june2008.pdf (accessed 4 July 2008).

present WHO definition which clearly only applies to "mislabelling" of medicines and only to those situations in which the mislabelling is carried out "deliberately" and "fraudulently." Thus it excludes those situations where there are legitimate disputes about the trademark status of a label and the burden of proof lies with the accuser, both for precautionary measures and for determination of infringement, to show that the possessor of the goods, knows that the goods are mislabelled and that this was done with the intention to mislead and defraud. It remains unclear what definition of counterfeit medicines ACTA will apply, but ACTA may go further than the existing WHO definition, given attempts by the EU and others to adopt newer standards that lower the standard of proof for counterfeit medicines and expand the scope beyond mislabelling to include any false representation.[16] Whatever definition ACTA adopts, it poses a danger if the standards of proof and available measures it adopts for counterfeits are also applied without discrimination to patent infringements.

There are a number of situations in which patents themselves are contested in the pharmaceutical industry. Many patent (and trademark) disputes arise from legitimate, if conflicting, beliefs about the validity and scope of protection of trademarks and patents. Civil cases are the process by which such disputes are resolved and, in the absence of pre and post-grant patent opposition processes, the only means by which the validity and scope of a patent can truly be determined. The discussion below focuses on problems that arise when enforcement for (or rather, against) counterfeit medicines reaches beyond its mandate to include enforcement regarding patent infringement, and suggests that a better approach would specifically target regulatory safety in an effort to remove "bad medicines" – which may (but not always) be trademark infringing, but are not patent infringing – from the market.

Consider a situation where medicines which are the subject of a patent dispute are wrongly characterized as "counterfeits" subject to criminal sanctions and border and precautionary measures under an ACTA enforcement regime.[17] In such a case, product seizures could result in additional costs to litigation than already exist and in liability for producers who legitimately believe that their product was not patent infringing. Worse, the threat of litigious action could discourage using IP flexibilities to their fullest for securing access to medicines. For example, in 2007 the government of Thailand issued compulsory licenses for a number of medicines, including the HIV antiretroviral medicine Kaletra.[18] The patent holder, Abbott, retaliated by withdrawing its application to register seven new drugs in the country[19] and publicly stated that it "did not view [the move] as legal or in the best interests of patients".[20] This in turn was met with an international and Thai response defending the "legality" of the move. If the ACTA enforcement regime does not clearly distinguish such disputes from issues of "counterfeits", then a patent holder's view of the "legality" of medicines produced under a compulsory license could trigger the enforcement mechanisms (especially border and precautionary measures) of ACTA, particularly were any of the drugs to be exported to any countries that are party to ACTA. Seizures of medicines based on the allegation that they are "illegal" would delay or prevent the ability of governments to make use of such flexibilities. In such a case, patent disputes become conflated with

[16] For some attempts in this direction see the new definition proposed during the Second Session of the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, available at "Draft global strategy on public health, innovation, and intellectual property, White Paper", IGWG Outcome document at 14.00 hours, Saturday 3 May 2008, at p. 15, online: WHO http://www.who.int/phi/documents/IGWG_Outcome_document03Maypm.pdf (accessed 4 July 2008).

[17] We can see this conflation in the approach of the European Union. The EGA points to this in its proposal, discussing the approach of the EC Customs and Taxation Units "Community customs activities on counterfeit and piracy—results at the European border—2007". This report includes seizures related to patent infringement disputes in the EU, as counterfeits.

[18] "Drug Access: Thailand Will Maintain Compulsory Licenses for Kaletra, Efavirenz, Despite Companies' Drug Price Reductions, Health Minister Says" *Kaiser Daily HIV/AIDS Report,* 16 April 2007, online: Kaiser Network http://www.kaisernetwork.org/Daily_reports/rep_index.cfm?DR_ID=44254 (accessed 23 June 2008).

[19] Ogan Gurel, Abbott vs. Thailand has implications for innovation and access, WTN News, 1 May 2007, online: WTN News http://wistechnology.com/articles/3886/ (accessed 8 July 2008).

[20] Nicholas Zamiska, "Thai Move to Trim Drug Costs Highlights Growing Patent Rift", *Wall Street Journal*, 30 January 2007, online at: WSJ http://online.wsj.com/article/SB117008653444991209.html (accessed 8 July 2008).

issues of counterfeits, the latter of which will require a more specialized regime than one that targets medicines that are the subject of IP disputes if it is to function effectively.

Cross-border flows of medicines will also be impacted by ACTA as it focuses on border measures as a means of enforcement.[21] For example, Thailand also issued a compulsory license in 2006 for the HIV antiretroviral medicine Efavirenz and the medicine was sourced in India.[22] In this situation, it is evident that ACTA-style enforcement raises the prospect of border seizures of the drug, because ACTA negotiators are discussing granting enforcement officers "ex officio authority to take action against infringers (*i.e.,* authority to act without complaint by right holders)".[23] Again, the critical question here is: infringers of what? For counterfeit medicines, there is a significant difference to be noted between a counterfeit or "therapeutically harmful" medicine crossing a border, and a medicine manufactured under a compulsory license (which may be subject to allegations of patent infringement) crossing a border. Investing *ex officio* authority in enforcement officers for anything other than seizing counterfeit medicines will undermine the purpose of important flexibilities in the intellectual property regime. What's more, similar concerns are raised with the cross border flows of medicines vis-à-vis the use of parallel importing, which is also supposed to serve as a flexibility that governments retain in order to ensure access to medicines.

The ACTA negotiators risk overstepping the scope of what is necessary to reign in counterfeit (therapeutically harmful) medicines, a public health issue, by introducing a blanket IP enforcement regime that also encompasses medicines that are therapeutically beneficial but that may the subject of patent or trademark disputes. In doing so, they may be limiting the use of important safeguards which are intended to facilitate – rather than suffocate – access to medicines.

IV. The Need to Distinguish Patent Infringements from Counterfeit Medicines in ACTA

To help in illustrating the issues, Box 2 (see page 6) depicts different scenarios in which medicines may or may not pose a health concern and how they intersect with IP infringement. It point to a broad area of overlap where the ACTA failure to distinguish between patent infringements and principles of counterfeits applied to copyright and trademarks could be a major problem. The illustration focuses on patent-related IP concerns rather than trademark issues.[24] The differences between the situations are significant because enforcement efforts in one scenario may benefit public health, while in another scenario those same efforts would impact negatively on public health.

There is agreement about the use of enforcement at either end of the spectrum. In Scenario A, there is clearly no alleged infringement of IP and the medicines are good (i.e. therapeutically beneficial) medicines. This would of course, also cover production of medicines using information that was once patented but has entered the public domain. Therefore, under a general IP enforcement regime like ACTA, there should be no public health risk to the production and trade of such medicines; the patent holders have nothing to gain from restriction such production, nor do patients/consumers. There is, essentially no public health and safety concern, provided that the drugs are tested properly by a competent drug regulatory authority. There is also no IP enforcement concern, as it also covers the

[21] A discussion paper on ACTA was reportedly circulated to industry representatives and Wikileaks obtained a copy of the document. It is available online: "Discussion Paper on a Possible Anti-Counterfeiting Trade Agreement", Wikileaks, online: Wikileaks http://file.sunshinepress.org:54445/acta-proposal-2007.pdf (accessed 21 July 2008).

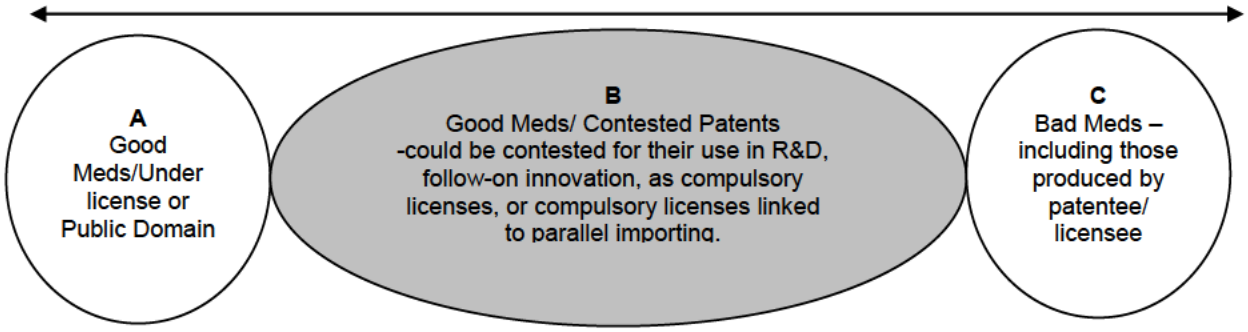
[22] "Drug Access: Thailand Will Maintain Compulsory Licenses for Kaletra, Efavirenz, Despite Companies' Drug Price Reductions, Health Minister Says" *Kaiser Daily HIV/AIDS Report,* 16 April 2007, online: Kaiser Network http://www.kaisernetwork.org/Daily_reports/rep_index.cfm?DR_ID=44254 (accessed 23 June 2008).

[23] "Discussion Paper on a Possible Anti-Counterfeiting Trade Agreement", Wikileaks, at 3, online: Wikileaks http://file.sunshinepress.org:54445/acta-proposal-2007.pdf (accessed 21 July 2008).

[24] The use of trademark litigation as a means of extending patent protection is another public health concern that is related to, but not the focus of, this discussion. The topic merits further research including an examination of trademark litigation as it related to patented products, with a focus on medicines that have entered the public domain.

situation where the medicines are produced under license.

Box 2: The crucial middle: Distinguishing between Counterfeits and Patent Infringements



In Scenario C, the medicines being produced are "bad" medicines with no therapeutic value – they are fakes, the core of the counterfeit definition. Everyone agrees that they need to be taken off the market, and a stronger enforcement regime may be one way of doing so. This scenario is a trademark issue rather than a patent issue. Unlike scenarios where therapeutically good medicines are involved, it is difficult to conceptualize the production of counterfeit medicines as a patent infringement if the medicines are bad. This is because in order for a medicine to demonstrate patent infringement, it must be using patented information and be sufficiently similar to violate the patent. One can presume that medicines that are patented or produced under license are not bad medicines provided effective approval and safety regulatory regimes are in place. Thus not respecting IP would mean, for example, a situation where the medicine itself is bad/therapeutically harmful but that it presents itself, through "its container, packaging, or other labelling information", as having been made by a particular company when it has not been. This is a trademark rather than a patent issue. In addition, one can have a situation were no trademark is affected such as when a product is without therapeutic value and presents itself as a legitimately approved product but with identity and name unrelated to any other product or brand, generic or otherwise.

Trademark concerns and public health concerns are aligned in this situation. In Scenario C two concerns arise for pharmaceutical companies related to trademark infringement: loss of revenue and loss of reputation.[25] In trademark language, Scenario C represents a risk that a company will lose "goodwill" that it has built up with a consumer market if a bad medicine is presented as being made by a company when it has not, in fact, been. Trademark infringement is also an issue for public health because patients suffer when medicines do not have the therapeutic value that they are presented to have and they are more likely to purchase medicines from what they perceive to be a reliable brand. Thus, there is an alignment of public health and private sector interests when it comes to enforcement of counterfeit medicines in Scenario C: both public health interests and trademark holders stand to gain, and the only people that stand to lose from stronger

[25] These issues are identified in by Claire Halfpenny in a note on Intellectual Property/Pharmaceuticals & Healthcare, "A criminal trade: the EU is set to fight counterfeiting by creating a series of new criminal offences", Addleshaw Goddard, May 2006, at 2, online: Addleshaw Goddard http://www.addleshawgoddard.com/asset_store/document/ip_publication_-_a_criminal_trade_the_eu_is_set_to_fi_ght_counterfeiting_by_111255.pdf (accessed 8 July 2008).

or criminal enforcement are the counterfeiters.

Scenario B represents situations where the medicines being produced are good (i.e. therapeutically safe) and there is an alleged patent infringement. This scenario overlaps significantly with a myriad of civil patent disputes that are an integral aspect of common business practice in the pharmaceutical industry. Disputes as to the scope and validity of patents occur as part of the normal exercise of rights and privileges of patents as other actors attempt to do follow-on research, conduct research and development, or adapt a product. In most countries patent infringement disputes are the primary way in which the scope and validity of a patent is actually determined. In the absence of a pre-grant opposition process it is impossible to determine, prior to the resolution of a case of alleged patent infringement, which cases will confirm patent infringement and which will not.

Under an ACTA regime that extends to patent infringements, scenario B situations which are normally resolved through civil litigation and/or administrative processes would become criminal activities and subject to pre-emptive actions at the border.[26] Criminalization of these disputes would mean tougher sanctions, which will subsequently impede activities that could be subject to patent disputes – activities which are critical to maintaining competition in the pharmaceutical industry. Criminal sanctions will significantly increase the risks taken by industry actors that rely on civil litigation over patents as part of their business model. A chilling effect would result, as companies will be less willing to engage in R&D and other practices that could subject them to litigation. This would have very real, very negative impacts on public health in the form of reduced access to medicines.

Extending border measures and precautionary measures to patent infringement cases under Scenario B will ensure that medicines will languish in storage while disputes drag on. If seizures were to occur during lengthy patent litigation medicines produced by generic competitors would be impounded and kept out of the market for the duration of the dispute and attempts at parallel trade would also be stifled.[27] A blunt IP-focused enforcement regime rather than a bad medicines-focused enforcement regime will inevitably result in the removal of medicines from the market for years at a time, and limit the negotiating tools that are intended to ensure that balance is maintained between IP and public health interests.

What the discussion above shows clearly is that there is no public health rationale for extending the scope of any IP enforcement regime to include patents and to treat patent infringements in any way as similar of patent infringements within an agreement that has any ambition to deal with counterfeit (therapeutically harmful) medicines. The stated concerns about public health and safety that are coming from some of the countries negotiating ACTA must be viewed with even greater scepticism and the focus of combating counterfeits must be returned to strengthening regulatory and safety authorities rather than to patent enforcement. The deliberate confusion surrounding counterfeits and their relationship to patents must be addressed, and the obfuscators challenged at every turn. As has been stated in an effort to separate our understanding of “the good, the bad, and the ugly” when it comes to counterfeit medicines:

> We also must speak more clearly about counterfeit drugs, with an improved lexicon. It is misleading to pretend that cross-border drugs from Canada and

[26] Broad enforcement of IP is one of the concerns that the generic industry has raised with governments in its feedback on ACTA. See: “Position Paper: EGA Statement on Counterfeiting and Patent Infringement in the Context of the Anti-Counterfeiting Trade Agreement (ACTA)” June 2008, at 3 and 5, online: EGA http://www.egagenerics.com/doc/EGA_pos_ACTA_june 2008.pdf (accessed 4 July 2008); and “Comments of the Generic Pharmaceutical Association on the Anti-Counterfeiting Trade Agreement”, July 2008 Federal Register Notices, 21 March 2008, online: USTR http://www.ustr.gov/assets/Document_Library/Federal _Register_Notices/2008/July/asset_upload_file525_149 97.pdf (accessed 22 July 2008).

[27] E.g., in 2002 the Federal Trade Commission identified that patent infringement disputes over pharmaceuticals averaged 25 months and 13 days in the first instance, and 37 months and 20 days at the appellate level in the United States, FTC, “Generic Drug Entry Prior to Patent Expiration: An FTC Study”, Federal Trade Commission, July 2002, at 47, online: FTC http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (accessed 23 July 2008).

> contaminated water passed off as erythropoietin (Epoetin alfa) by criminal gangs are similar issues. They have quite distinct causes, effects and indicated solutions.[28]

V. Points of Engagement

It is clear that there are many areas of concern where civil society as well as concerned developing and developed countries must act to ensure that a public health focus frames efforts to prevent the distribution of fake drugs. The moves in ACTA to extend coverage to pharmaceutical patents and apply principles and standard developed for copyright and trademark infringements to medicines are not isolated. The ACTA negotiations are part of a broader range of discussions and fora which include many of the same actors and are aimed at harnessing the power of public health and safety in the service of broader and harsher intellectual property enforcement for pharmaceuticals, including both patents and trademarks. The constellation of fora involved include: The Global Congress on Combating Counterfeiting (GCCC); the WHO Intergovernmental Working Group on Public Health Innovation and Intellectual Property (IGWG); WHO International Medical Products Anti Counterfeiting Taskforce (IMPACT); The World Health Assembly (WHA), and ACTA). Table 1 (see pages 9 - 10) outlines events that have been taking place. The timeline presented in Table 1 suggests a concerted and coordinated effort by a number of groups to put IP enforcement – including patent enforcement with respect to medicines – high on the international agenda. In particular, it illuminates how the broad issue of IP enforcement has become woven into the very specific issue of public health safety and therapeutically harmful medicines.

Even a cursory review reveals a commonality of actors across the different fora and discussions and the increasing linkage of public health and safety issues to IP enforcement. While the connections between the fora remain largely informal and it remains unclear which elements in one discussion (such as the new IMPACT definition of counterfeits) will be imported into other fora and discussions, there is an increasing sense of convergence and critical mass. For governments and civil society actors interested in ensuring that public health interests are defended, an awareness of these links and the various developments is a crucial first step. However, as this focus piece notes, the most immediate threat remains that of ACTA and the way in which it aims to extend concepts developed to deal with copyright and trademark infringements (such as counterfeits) to pharmaceutical patents without discrimination.

In addition, even if ACTA is limited to a select group of countries at first, it may become a de facto international standard to which other countries are, first, encouraged to comply and then finally, required to comply through the signing of regional and bilateral free trade agreements.

The deliberate secrecy and obfuscation with which ACTA is being negotiated makes it difficult to take action with a full understanding of what it entails. Appropriate action is also curtailed by the multi-pronged effort at increasing IP enforcement related to pharmaceuticals. It will require coordinated information sharing and strategizing among civil society groups in the ACTA negotiating countries, and linking concerns about ACTA explicitly to concerns raised by activities in other fora such as IMPACT, WIPO, WCO and the WHO where developing countries have significant alliances and capacity to act in concert. Thus:

- The issue of ACTA should be raised at the WHO and the question of how the WHO and Secretariat initiatives relate to the other enforcement efforts such as ACTA should be explicitly stated. Questions should also be raised about the WHO's relationship with IMPACT and with the IFPMA and how these may relate to ACTA.
- The issue of ACTA should be raised at WIPO, specifically in the Advisory Committee on Enforcement and in the Standing Committee on Patents.

[28] Kevin Outterson & Ryan Smith, "Counterfeit Drugs: The Good, the Bad and the Ugly", 2006, *Albany J. of Science & Technology*.

Finally, business groups in developing countries, especially those generic pharmaceutical manufacturers who have had access to texts and negotiators, must work harder to make available to public health organizations the content of the negotiations and the identities of negotiators so that civil society organizations and other governments can better monitor and contribute to the debate on ACTA.

Table 1: Timeline of Events

Date	The Fora - WHO, IMPACT, IGWG, GCCC, ACTA
14-15 Nov 2005	**The 2nd Global Congress on Combating Counterfeiting (organized by WIPO, WCO, and Interpol) produces the** Lyon Declaration **– which recommended consideration of Japan's suggestion to develop an international treaty on IP enforcement.**
2005	G8 Gleneagles**, releases** document on "Reducing IP piracy and counterfeiting through more effective enforcement**", committing to convene a group of experts in the fall of that year to develop a plan for next steps. -> KEI has reported this to be "first official step towards what would become the ACTA".**[29]
18 Feb 2006	**WHO International Conference on Combating Counterfeit Medicines releases the Rome Declaration; recommends the establishment of IMPACT.[30] Participants included WHO member States and select international and non-governmental organizations, though the conference is "organized by WHO and supported by the Italian Medicines Agency (AIFA), and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA)".[31]**
Feb 2006	**WHO launches International Medical Products Anti-Counterfeiting Taskforce (IMPACT).[32]**
30-31 Jan 2007	3rd GCCC Congress, in Geneva**, where the congress introduced a special session on health and safety from counterfeiting and piracy. Outcomes from the congress included** health and safety becoming 5th pillar of focus**, and** supporting the OECD report **and** the work

[29] Shaw, Aaron, "The Problem with the Anti-Counterfeiting Trade Agreement (and what to do about it)," KEStudies, Vol. 2 (2008). Online: KEStudies http://kestudies.org/ojs/index.php/kes/article/view/34/59 (accessed 3 July 2003).
[30] Art. 6, "Conclusions and Recommendations of the WHO International Conference on Combating Counterfeit Medicines: Declaration of Rome", 18 Feb 2006, online: WHO http://www.who.int/medicines/services/counterfeit/RomeDeclaration.pdf (accessed 4 July 2008).
[31] Invited organizations are listed online: WHO http://www.who.int/medicines/counterfeit_conference/en/index.html (accessed 4 July 2008).
[32] Information about impact, including the groups that participate in the taskforce, is available online: WHO http://www.who.int/impact/impact_q-a/en/index.html (accessed 4 July 2008).
[33] "Third Global Congress on Combating Counterfeiting and Piracy – Suggestions Extending from the third global congress", 30-31 January 2007, Geneva, online: GCCC http://www.ccapcongress.net/archives/Geneva/Files/Congress%20Recommendations_Geneva%20Jan%202007.pdf (accessed 4 July 2008).

	of IMPACT on counterfeit drugs.[33]
4 June 2007	OECD **releases a** report on the Economic Impact of Counterfeiting and Piracy. [34]
23 Oct 2007	**USTR** announces the negotiations of the Anti-Counterfeiting Trade Agreement (ACTA) **including Canada, EU, Japan, Korea, Mexico, New Zealand, and Switzerland.**[35]
13-16 Nov 2007, Jakarta	**The Summary Report from IMPACT's First ASEAN-China Conference on Combating Counterfeit Medical Products identifies that** "IMPACT is discussing the possible revision of the established WHO definition of counterfeit medicine", **but the meeting agreed to** remain with the WHO definition for "the purpose of collaboration and exchange of information among participating countries".[36]
Dec 2007 Portugal	**The Summary Report from the** IMPACT General Meeting **identifies that, after debate, there was** agreement that the "new definition" of counterfeit medical product was "more appropriate **since a) it encompassed all medical products and not just medicines and b) by avoiding the terms 'deliberately and fraudulently' relieved the investigators of the onus of proving the voluntary possession of counterfeit medical products by transferring the burden of proving their good intentions on those found in possession of counterfeits".. [37**
19 May 2008	**The IMPACT definition of counterfeit drugs is introduced into the "Draft global strategy on public health, innovation, and intellectual property" at the IGWG 2bis meeting. No agreement is arrived at but it appears in the outcome document for the meeting.**[38]
3-4 June 2008	ACTA negotiations formally begin **in Geneva.**
June 2008	European Generics Association (EGA**) releases a position paper on** counterfeiting and patent infringement in the context of the ACTA **which identifies the language from the present WHO definition of "deliberately and fraudulently mislabelled" as key to ensuring that "patent infringement during the normal legitimate business development of a product" does not become a crime, and remains a private civil matter.**[39]

[34] OECD, "The Economic Impact of Counterfeiting and Piracy: Executive Summary", Directorate for Science, Technology and Industry Committee on Industry, Innovation and Entrepreneurship, DSTI/IND(2007)9/PART4/REV1, online: OECD http://www.oecd.org/dataoecd/11/38/38704571.pdf (accessed 9 July 2008).

[35] "Ambassador Schwab Announces U.S. Will Seek New Trade Agreement to Fight Fakes", 23 Oct 2007, Office of the United States Trade Representative, online: USTR http://www.ustr.gov/Document_Library/Press_Releases/2007/October/Ambassador_Schwab_Announces_US_Will_Seek_New_Trade_Agreement_to_Fight_Fakes.html (accessed 4 July 2008).

[36] "IMPACT First ASEAN-China Conference on Combating Counterfeit Medical Products: Summary Report", Jakarta, 13-16 Nov 2007, at p.2, online: WHO http://www.who.int/impact/events/IMPACTJakarta07MeetingReport.pdf (accessed 4 July 2008).

[37] "IMPACT General Meeting: Summary Report", Lisbon, Portugal, 12-13 Dec 2007, at p. 2, online: WHO http://www.who.int/impact/events/IMPACTGeneralMeeting2007report.pdf (accessed 4 July 2008).

[38] "Draft global strategy on public health, innovation, and intellectual property, White Paper", IGWG Outcome document at 14.00 hours, Saturday 3 May 2008, at p. 15, online: WHO http://www.who.int/phi/documents/IGWG_Outcome_document03Maypm.pdf (accessed 4 July 2008).

[39] European Generic's Association, "Position Paper: EGA Statement on Counterfeiting and Patent Infringement in the Context of the Anti-Counterfeiting Trade Agreement (ACTA)" June 2008, online: EGA http://www.egagenerics.com/doc/EGA_pos_ACTA_june2008.pdf (accessed 4 July 2008).

VI. Conclusion

Enforcement efforts in pharmaceutical fraud need to focus on the suppliers of bad medicines rather than on patent holders' rights in pharmaceutical markets. The inclusion of patents in the proposed ACTA regime would significantly affect access to medicines and will have little or no effect on the public health and safety issues related to therapeutically harmful medicines. The best way to address the public health and safety issue posed by therapeutically harmful medicines is to strengthen regulatory regimes in a manner that allows them to carry out full and regular testing of all products prior to market entry, random testing of products in the market, and the ability to pull therapeutically harmful medicines from the market. None of that requires that authorities interfere with the normal market mechanisms for patent protection that create a proper balance between innovation and access, private rights and public interests.

AN OVERVIEW OF RELEVANT DEVELOPMENTS IN THE VARIOUS IP FORA

The following is an overview of developments in the various fora dealing with intellectual property issues in the second quarter of 2008:

I. The World Trade Organization

The second quarter of 2008 was marked by intense rounds of IP negotiations on outstanding implementation issues in the Doha Round. The WTO mini-ministerial convened in Geneva from 21-26 July, even with an extended deadline of 29 July to arrive at consensus on trade negotiations, was unsuccessful.

Progress in the Council for TRIPS during the second quarter of 2008

The Council on Trade Related Aspects on Intellectual Property Rights (TRIPS) met on the 17-18 June, 2008. During the Council meeting, Brazil submitted a communication that stressed the need for a balanced IP system, and that the debate on WTO-TRIPS compliance would benefit by drawing attention to the WIPO Development Agenda. The focus of this meeting of the TRIPS Council was primarily on issues concerning technical assistance to developing countries.

The outstanding implementation issues again figured during the TRIPS Council. However, nothing of substance was moved through. The issues relate to: a proposal to amend the TRIPS Agreement to include a requirement for disclosure of origin of biological resource so as to bring it in line with the UN Convention on Biological Diversity; the creation of a registry for geographical indications (GIs); and the possible extension of high-level GI protection (currently available under TRIPS), beyond wines and spirits.

Discussions on implementation on article 67 of the TRIPS Agreement, which requires developed country members to provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed countries, focused on the nature of technical assistance expected. Developing country members expressed the view that such technical assistance must be assessed to ensure that the TRIPS Agreement is contributing to its balanced implementation, including having regard to measures for prevention and mitigation of IP abuse and in consideration of the flexibilities inherent in the TRIPS Agreement. During the same week Uganda submitted to the WTO Council for TRIPS a detailed plan for addressing its priority needs for technical and financial cooperation (IP/C/W/510).

The next meeting of the WTO Council for TRIPS will be held on 28-29 October 2008.

Collapse of the Mini-Ministerial: Future of IP issues

On 9 June 2008, the Director-General of the WTO issued a report on his consultations on whether to extend enhanced protection for geographical indications beyond wines and spirits, and on patents and biodiversity (WT/GC/W/591). Another report on the "Multilateral System of Notification and Registration of Geographical Indications for Wines and Spirits" was issued by the chair of TRIPS special sessions Ambassador Manzoor Ahmad (TN/IP/18). All three issues that figure in the two reports are intellectual property subjects under the Doha Development Agenda. Both reports provide factual accounts of the latest state of the discussions without prejudice to how members would compromise during the final negotiations. The report outlines that members' opinions differ on whether these three subjects should be part of the "horizontal process" and whether they should be linked. Members continued to disagree on how best to deal with issue of extension of geographical indications, and the issues concerning the relationship between CBD and the TRIPS Agreement. The talks chaired by Ambassador Manzoor Ahmad on the multilateral GIs registry are part of the negotiations under the "single undertaking" of the Doha Development Agenda.

The collapse of the Mini-Ministerial convened in Geneva from 21-26 July continued with an extended deadline of 29 July, failed to arrive at consensus on IP negotiations. The Mini-Ministerial, convened

mainly as an attempt at achieving consensus on industrial goods and agriculture, for successful completion of the Doha round, went into an eventual deadlock. While all three IP issues loosely figured during the initial days of negotiations as a deal breaker or deal maker, nothing concrete came forth as countries held their positions strongly. In particular, the United States made it clear that it had no intention of discussing or negotiating these issues (especially concerning the "GI extension"). Thus at the end of the Mini-Ministerial, hope for an intense round of negotiations appeared lost, although with a possibility of extending the negotiating deadline by September/October. However, there have been no confirmed sources that point out to this new commitment by members. While there was broad consensus on accommodating the GI registry (part of the "single undertaking" of the Doha Development Agenda), the talks on considering all three IP issues together also drew support from a majority of WTO member countries. However, a group of 20 members firmly held the view that two IP issues (viz., GI extension and TRIPS-CBD) had no mandate for negotiation in the Doha round.

Disputes

There were no communications received from any WTO member states on complaints concerning TRIPS violations during the second quarter of 2008. No disputes involving the TRIPS Agreement was decided by the WTO Panels or the Appellate Body during this period.

Members accepting 2005 amendment of the TRIPS Agreement on patents and public Health

The 2005 amendment to the TRIPS Agreement, which made permanent a decision on patents and public health (adopted in 2003), will be formally built into the TRIPS Agreement when two thirds of the WTO members notify their ratification of the change. While the initial deadline was to expire on 1 December 2007, it was extended by the General Council to 31 December 2009. In this connection, three more members have implemented the decision taking the total to 17 members (the EU being considered as a single count). The new members who have conveyed their acceptance to the WTO are Mauritius (16 April 2008), Egypt (18 April 2008), Mexico (23 May 2008).

II. World Intellectual Property Organization (WIPO)

Activities at the WIPO prominently centred around three important committees viz., the WIPO Coordination Committee, the WIPO Standing Committee on the Law of Patents, and the WIPO Committee on Development and Intellectual Property.

The WIPO Coordination Committee

The WIPO Coordination Committee met in Geneva on May 13 and 14, 2008, for its Fifty Eighth (20th Extraordinary) Session. The WIPO Coordination Committee is an 83-member government executive body of the WIPO. The Committee gathered to elect the next Director General of the WIPO, who is expected to take office in October 2008 following the final approval by the WIPO General Assembly in September 2008. In all, 15 candidates filed their nominations. In a final close contest between Brazil's Mr. José Graça Aranha and Australian nominated Dr. Francis Gurry, the latter won by a thin margin of a single vote. Mr. Gurry is currently the Deputy Director General of WIPO.

The Assemblies of the Member States of WIPO will be held in Geneva from 22 September to 30 September, 2008. The Agenda of the General Assembly is available at:
http://www.wipo.int/edocs/mdocs/govbody/en/a_45/a_45_1_prov_1.pdf

Standing Committee on the Law of Patent (SCP)

The twelfth session WIPO Standing Committee on the Law of Patents met on June 23 to 27, 2008, in Geneva. The meeting was scheduled to discuss the process for arriving at a work programme for the SCP. It had been two years since the committee had formally met (the eleventh session being held in June 2005), after

discussions in the SCP went into a deadlock during an informal session held in April 2006. The 2007 General Assembly had charged the WIPO secretariat to prepare a report on the International Patent System, which it released in April 2007.

The 12th session of the SCP had gathered to discuss the report prepared by the secretariat (SCP/12/3). Although no concrete work programme for the SCP was defined, the discussions were based on document SCP/12/3. Mr. Maximiliano Santa Cruz of Chile was elected as the chair of the SCP. The committee, in discussing a future work programme, identified a non-exhaustive list of issues for further elaboration and discussion in the future session of the SCP (SCP/12/4 Rev.).[40] The committee further decided that the document SCP/12/3 would remain open for further discussion in the next session and for written comments to be submitted to the WIPO secretariat until the end of October 2008 by members, including accredited observers. The WIPO secretariat was asked to prepare four preliminary studies in the areas of: "dissemination of patent information (*inter alia* the issue of a database on search and examination reports); Exceptions from patentable subject matter and limitations to the rights, *inter alia* research exemption and compulsory licenses; Patents and standards; Client-attorney privilege". It was also decided that the WIPO secretariat would make provision for a conference on issues relating to the implications, including public policy implications, of patents on certain areas of public policy, such as health, the environment, climate change or food security. It was further decided that the members of the SCP, including accredited observers, could submit suggestions on the future work program of the SCP to the Secretariat.

The Thirteenth Session of the SCP is tentatively scheduled for the first quarter of 2009, in Geneva. No dates have been notified.

Committee on Development and Intellectual Property

The second meeting of the Committee on Development and Intellectual Property (CDIP), established by the General Assembly of the WIPO in October 2007, was held at the WIPO from July 7-11, 2008. The committee moved forward discussions on further developing a work program for implementing the 45 recommendations approved by the 2007 General Assembly.[41] The second meeting of the CDIP was chaired by Ambassador Trevor C. Clarke (elected chair during the first CDIP held in March 2008). The second meeting of the CDIP took forward its discussion from the first session concluded in March 2008 (PR/2008/540). The committee discussed the indicative figures for human and financial resource requirements associated with the implementation of adopted recommen-dations 2, 5, 8, 9 and 10 in the list of 26 recommendations. The committee also discussed implementation of adopted recommendations 20, 22 and 23 in Cluster B of the list of 26. It was also agreed that the proposed activities as agreed would be sent to the secretariat to review the human and financial resource requirements and that it would then be submitted to the third session of the CDIP.

Among the items for immediate implementation taken note of by the CDIP, was recommendation 1 in the list of 19 recommendations. Recommendation 1 requires that WIPO's technical assistance shall be, *inter alia*, development-oriented, demand-driven and transparent, taking into account the priorities and the special needs of developing countries, especially LDCs, as well as the different levels of development of Member States, among other things. This provision has been contentious since the First CDIP meeting held in March, where the Group of Friends of Development had proposed that the recommendation be taken into account in all technical assistance activities rendered by the WIPO, and that it should also be added to the manual of staff regulations and rules/ code of ethics. The debate continued in the second CDIP, with US successfully seeking the removal of any adjectives to the word "principles", since

[40] The list of issues can be accessed at: http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_4_rev.pdf

[41] The list of recommendations can be accessed at: http://www.wipo.int/ip-development/en/agenda/recommendations.html

there had been no discussion on differentiating "general" principles from "core" principles, as contained in the proposed column highlighting information on activities for implementation of adopted recommendations. Again, on US demand, the secretariat clarified that an office instruction within the UN system is one in which the Director General would send it so that it "completes the staff rules and regulations".

The committee also discussed implementation of adopted recommendations and agreed to the proposed associated activities concerning recommendation 3, 4, 6, 7 and 11. The Committee, most significantly, noted that there was a need to coordinate the activities of the CDIP with other relevant WIPO bodies for the purpose of implementation of the recommendations, although there were significant differences as to whether such coordination should be formal or informal, direct or mediated through the General Assembly. The CDIP also reviewed and commented on activities being implemented under adopted recommendation 12 in the list of 19 and a progress report to be filed by the secretariat was agreed, so as to keep track of the implementation of the 19 recommendations. It was also decided that the CDIP would begin discussions on a mechanism to monitor and assess such coordination at its next session. It was agreed that the draft report of the second session of the CDIP will be available for comments by member states and observer organizations and will be formally adopted in the third session of the CDIP in 2009. Further, to allow implementation of the agreed recommendations, a report featuring the discussions of both CDIP sessions will be presented to the WIPO General Assembly in September 2008 for recommending adjustments to the revised 2009 programme and budget. The WIPO General Assembly would be further called on to make resources available in a manner consistent with WIPO's program and budgetary processes.

The Third Session of the Committee on Development and Intellectual Property will be held in 2009. No dates have been notified.

III. Other Multilateral Fora

The United Nation Conference on Trade and Development (UNCTAD)

The member States of UNCTAD, gathered in Accra, Ghana, from 20 to 25 April 2008, for the twelfth session of the Conference. The conference agreed on a renewed mandate for UNCTAD in paragraph 153 of the Accra Accord (TD/l.414), which states, "taking into account the WIPO Development Agenda and without prejudice to the work undertaken in other forums, UNCTAD, within its mandate, should continue to undertake research and analysis on trade and development aspects of intellectual property, including in the areas of investment and technology". With this renewed mandate, it is expected that UNCTAD will continue its work in IP and development issues, along with other UN specialized agencies. The Accra Accord also called on the international community that it should continue its efforts to maintain the balance and effectiveness of the international intellectual property system, in line with the agreed recommendations of the WIPO Development Agenda.

World Health Organization (WHO)

Over the past 18 months, WHO Member States and other stakeholders have met in three meetings of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG), and also in regional consultations and other multilateral meetings linked to the IGWG process, to discuss ways to foster innovation, build capacity and improve access to health products to better respond to the global burden of disease. The resumed second session of the IGWG took place from 28 April to May 3, 2008 (IGWG 2bis). At the end of the resumed session, a draft plan of action was agreed as the chair's text. This was precursory to the final resolution to be adopted during the 61st session of the World Health Assembly (WHA) establishing a Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property. The sixty first session of the WHA met in Geneva from 19-24 May 2008. The Assembly discussed a number of public health issues and adopted several resolutions. Among the key resolutions adopted was the "*Global strategy on public*

health, innovation and intellectual property". The resolution, a main outcome on public health since the Doha Declaration on Public Health (2001), aims to promote and create new incentives to health innovation to tackle the global disease burden and to remove intellectual property barriers to essential research and development in the area of public health (WHA61.21). It is expected that the resolution will help speed up research and development in diseases disproportionately affecting the developing world and previously underserved areas, and furthering drug access and affordability.

The resolution does not in anyway change/affect the status of the TRIPS agreement in the context of the relationship between the TRIPS Agreement and public health. The Global strategy contains 8 major elements divided as follows: prioritizing research and development needs in the area of health; promoting research and development; building and improving innovative capacity; transfer of technology; application and management of intellectual property to contribute to innovation and promote public health; improving delivery and access; promoting sustainable financing mechanisms; establishing monitoring and reporting systems. The element on "application and management of intellectual property to contribute to innovation and promote public health", included the following issues:

- supporting information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries;
- providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade- Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products;
- exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases;

The global strategy was arrived at after heavy rounds of negotiations and compromises, as is specially reflected in element 5 concerning intellectual property issues and public health. The coming years will see active participation of the WHO on IP issues in relation to public health. The WHO secretariat will work out details of the plan of action that encompasses progress indicators and costing of the plan, and report back to the Executive Board and 62nd Health Assembly in May 2009.

World Customs Organization (WCO)

The World Customs Organization (WCO) held the third meeting of the Working Group on the Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE) in Brussels from 24 to 25 April 2008. The proposed SECURE is composed of 12 standards on customs and border measures. This Working Group meeting was considered as the last technical discussion on SECURE prior to its submission to the WCO Council for approval in June 2008. It was feared that if adopted in its current form, the standards of an extreme TRIPS-Plus nature would seriously undermine the WIPO development agenda, erode the legitimate flexibilities enshrined in the WTO TRIPS Agreement, and gravely erode the policy space of developing countries. The twelve standards included in the provisional SECURE represent a significant departure from the provisions of the TRIPS agreement. Although the draft text is termed "voluntary", it is likely to be evolved into compulsory regulations eventually, as previously experienced by developing countries in various bilateral and multilateral IP negotiations.

After effective coordination from developing countries, the WCO policy commission which met on June 23- 25, 2008 recommended that the WCO council, which

was to meet on June 26-28, 2008, should send SECURE back to the working group for further consideration. As per the recommendation, the WCO Council has decided to send back SECURE draft to the working group for continued discussion. On this basis, the SECURE Working Group will continue its examination of the Provisional SECURE Standards document, reporting to the Policy Commission in December 2008.

The third meeting of the WCO SECURE Working Group is scheduled for the 20 – 31 October 2008.

Universal Postal Union (UPU)

Current IP enforcement initiatives have also found mention at the Universal Postal Union (UPU). The 24th Universal Postal Congress (UPC) is meeting in Geneva from 23 July to 12 August 2008. The UPU is a specialized agency of the United Nations with 191 member states. A Memorandum of Understanding was signed between the WCO and UPU on 5 July 2007 which includes reference to the issue of counterfeit goods sent by post. A study was carried out by Postal Operations Council (POC) Committee 3 Support Project Group on UPU customs and security-related issues concerning intellectual property matters.

Among the proposals of a general nature proposed by the POC to the 24th UPC, Resolution 40, titled "Counterfeit and Pirated Items Sent through the Post", represents another departure on IP enforcement from TRIPS standards. One of the intentions of the resolution is to re-delineate the roles of stakeholders between the judiciary and customs as it states that "Customs and experts on intellectual property rights are primarily responsible for determining whether an item is counterfeit". On this basis, the resolution urges the UPU member countries to encourage their postal administrations to:

- take all reasonable and practical measures to support customs in their role of identifying counterfeit and pirated items in postal network;
- cooperate with the relevant national and international authorities to the maximum possible extent in awareness-raising initiatives aimed at preventing the illegal circulation of counterfeit goods, particularly through postal services.

The resolution was to be adopted with one amendment on 31 July at Committee 4 of UPC. However, a group of ten developing countries, i.e., Egypt, India, Jordan, Libya, Malaysia, Pakistan, Saudi Arabia, South Africa, Syria and Turkey plan to submit an appeal to re-open the debate in plenary to introduce further amendments to the resolution.

ACTA and the Group of 8 (G8)

A proposal for a plurilateral trade agreement called "the Anti-Counterfeiting Trade Agreement (ACTA)" is being secretly negotiated among a group of developed countries (see focus piece for more details). The ACTA aims to impose stricter standards for enforcement of IPRs, without making any distinction between various kinds of IPRs. The countries involved include the United States of America, European Union, Japan, Switzerland, Australia, New-Zealand, South Korea, Canada, and Mexico. The treaty would create its own governing body separate from existing international institutions dealing in IPRs standard setting, viz., the WIPO and the WTO. It was expected that the 34th G8 summit which took place in Toyako, Japan, from 7 July to 9 July, 2008, would adopt a treaty, which did not, however take place.
However, further discussion on ACTA continued in Washington, D.C., from July 29-31. The European Commission has confirmed that "Participants, who included Australia, Canada, the European Union, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland, and the United States, welcomed the statement in the July 2008 G8 Toyako Summit Declaration that G8 Members support "the acceleration of negotiations to establish a new international legal framework, the Anti-Counterfeiting Trade Agreement (ACTA), and seek to complete the negotiation by the end of the year".

It should be noted that the Washington meeting was the latest in a series to develop aspects of the proposed agreement and discussions focused on IP enforcement aspects concerning civil remedies for infringements of intellectual property rights,

including the availability of preliminary measures, preservation of evidence, damages, and legal fees and costs. The European Commission has confirmed that "Participants made steady progress, continued previous discussions on border enforcement of intellectual property rights, and agreed to continue their work at another substantive meeting to be held at a mutually convenient time in the near future."[42]

Convention on Biological Diversity

The Conference of Parties (COP) of the Convention on Biological Diversity (CBD) held its ninth meeting from 19-30 May 2008, in Bonn, Germany. The Conference of the Parties is the governing body of the Convention, and advances implementation of the Convention through the decisions it takes at its periodic meetings. In relation to substantive issues arising from decisions of the COP and Strategic issues for evaluating progress, the COP, *inter alia*, discussed issues concerning access and benefit sharing (ABS) and Article 8(j) and related provisions (UNEP/CBD/COP/9/29).

The 3rd plenary session of the meeting was on 30 May 2008, where the Conference of the Parties heard the report of the open-ended informal consultative group on access and benefit-sharing, established, as agreed at the first plenary session, for the purpose of recommending an agreed draft decision to the Conference of the Parties on the basis of its discussions. The draft decision UNEP/CBD/COP/9/L.27 as decision IX/12 was adopted. The 3rd session held on 30 May 2008, also adopted draft decisions UNEP/CBD/COP/9/L.25 A-I as decisions IX/25 A-I pertaining to issues concerning Article 8(j) and related provisions.[43]

IV. Free/ Preferential Trade Agreements and Intellectual Property Issues

ASEAN-JAPAN comprehensive Economic Partnership Agreements

On 13 April 2008, ten Governments of Brunei Darussalam, the Kingdom of Cambodia, the Republic of Indonesia, the Lao People's Democratic Republic, Malaysia, the Union of Myanmar, the Republic of the Philippines, the Republic of Singapore, the Kingdom of Thailand, and the Socialist Republic of Viet Nam, Member States of the Association of Southeast Asian Nations (hereinafter referred to as "ASEAN Member States"), and the Government of Japan have completed the signing of the Agreement on Comprehensive Economic Partnership among Member States of the Association of Southeast Asian Nations and Japan called "the AJCEP Agreement"." The AJCEP Agreement is comprehensive in scope, covering such fields as trade in goods, trade in services, investment, and economic cooperation. The AJCEP Agreement will enter into force on the first day of the second month following the date by which notifications have been made by Japan and at least one ASEAN Member State, for those signatory States that have made such notifications by that date. Article 53 of the Agreement contains a provision on "Fields of Economic Cooperation". It is agreed there under that "The Parties, on the basis of mutual benefit, shall explore and undertake economic cooperation activities" in various filed, intellectual property being one among them. However, the Agreement does not specify the contents in greater detail.[44]

Canada-Colombia Free Trade Negotiations

Canada concluded a free trade agreement with Colombia on June 7, 2008. The negotiation for an Agreement on Environment and a Labour Cooperation Agreement is still on. A legal review of the negotiated texts is being carried out after the conclusion of the Agreement. Following the legal review, the agreements will be

[42] The news release can be found at: http://ec.europa.eu/trade/issues/sectoral/intell_property/pr310708_en.htm

[43] The text of both the decision as adopted can be accessed at : http://www.cbd.int/doc/meetings/cop/cop-09/official/cop-09-29-en.doc#_Toc200551846

[44] The text of the agreement can be accessed at: http://www.mofa.go.jp/policy/economy/fta/asean/agreement.pdf

signed by the parties, released to the public, and proceed to each country's respective legislative bodies for ratification.

Canada-Peru Free Trade Agreement

On May 29, 2008, Canada and Republic of Peru signed a Free Trade Agreement (FTA). This was the second FTA signed by Canada in 2008 and Canada's fourth FTA with countries of the Americas.

Section E, which deals with the a chapter on "Geographical Indications for Wines and Spirits", in its Article 212 states that: "Pursuant to Part II, Section 3 of the TRIPS Agreement and as set out in Annex 212, each Party shall provide the legal means to protect geographical indications for wines and spirits". Accordingly, the Agreement would provide protection in accordance with Article 22.1 of the TRIPS Agreement and also in case of certain specific Canadian and Peruvian spirit names. Among other technical details, it further provides that in accordance with the application process under Peruvian law, and subject to the exceptions set out in Article 24 of the TRIPS Agreement, Peru shall take the necessary steps to provide the protection set out in Article 23 of that Agreement to the indications in paragraph 4 after an application has been made in good and due form. Similarly, Canada shall in accordance with the application process under Canadian law, and subject to the exceptions set out in Article 24 of the TRIPS Agreement, take the necessary steps to provide the protection set out in Article 23 of that Agreement to the indication in paragraph 6 after an application has been made in good and due form.[45]

EU-ACP: Economic Partnership Agreement

There was little progress in negotiations in terms any formal agreement in between the European Union and among the African, Caribbean and Pacific Group of States (excluding CARIFORUM which remains the only region to have initialled a full EPA with the EU so far). Negotiations were still on during the second quarter, and IP issues were still seen to be contentious. It should be noted that the EPAs contain an entire chapter devoted to Innovation and Intellectual Property, which recognize that "fostering innovation and creativity improves competitiveness and is a crucial element in their economic partnership, in achieving sustainable development, promoting trade between them and ensuring the gradual integration" of such economies in to global markets (Article 131). They also recognise that the protection and enforcement of intellectual property plays a key role in fostering creativity, innovation and competitiveness, and are determined to ensure increasing levels of protection appropriate to their levels of development (Article 131). Articles 134 to 138 of the EPA focus on innovation, while Articles 139 to 164 concern intellectual property.[46]

With the collapse of the Doha round, it is being predicted that there can be been renewed attention to conclude the EPAs at the earliest.

EU-ACN

After three rounds on negotiations for an trade agreement between the EU the Andean Community of Nations (ACN), composed of Peru, Colombia, Bolivia and Ecuador, a forth round has been postponed for third quarter of 2008. IP, biodiversity and traditional knowledge has been one of the issues on which agreement has not been reached. The CAN counts with a common regulation "Decision 486'" with respect to patents and biodiversity. Internal conflict has arisen within the CAN on whether the agreement should include provisions on patents and biodiversity. Bolivia has expressed concern that including this issue in the EU-ACN agreement may allow for broader patent claims with respect to biodiversity and override the dispositions of the common regulation on the matter.

US-FTAs

The US Congress has not moved ahead with any FTA during the second quarter of 2008.

[45] The Canada-Peru Free Trade Agreement can be accessed at : http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/peru-perou/peru-perou-table.aspx

[46] The EPAs text can be accessed at : http://trade.ec.europa.eu/doclib/docs/2008/february/tradoc_137971.pdf

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 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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