Sectoral and Thematic Cases

The Bio-IPR Impacts of the EU-ASEAN FTA

(A preliminary study to be presented to the ASEAN Peoples' Forum)

EU's Bio-IPR demands on other countries

GRAIN[1] has compiled the European Union's trade agreements made with countries and found that all of these agreements obligating party states to adopt strict IPR system. For instance, party members must join UPOV (1991 Act) and accede to the Budapest Treaty. In certain cases, the parties must recognize the patent-on-life regime as well, such as in the EU-South Africa FTA that came into force in 1999, whereby South Africa is required to provide effective protection of highest international standards for patents on biotechnological inventions.

Examples of the patent-on-life-related agreements between the EU and other countries are as follows:

- EU-Jordan FTA, in force in 1997: Jordan must join UPOV and accede to the Budapest Treaty by 2007;
- EU-Tunisia FTA, in force in 1998: Tunisia must join UPOV (1991 Act) and accede to the Budapest Treaty by 2002;
- EU-South Africa FTA, in force in 1999: South Africa must provide effective protection of highest international standards for patents on biotechnological inventions, as well as acceding to the Budapest Treaty;
- EU-Morocco FTA, in force in 2000: Morocco must join UPOV (1991 Act) and accede to the Budapest Treaty by 2004;
- EU-Mexico FTA, in force in 2000: Mexico must accede to the Budapest Treaty within three years of the agreement's entry into force;
- EU-Bangladesh Cooperation Agreement, in force in 2001: Bangladesh must join UPOV (1991 Act) and accede to the Budapest Treaty by 2006;
- EU-Korea Trade and Cooperation Agreement, in force in 2001: Korea must make efforts to accede to the Budapest Treaty and join UPOV Convention (1991 Act) as soon as practicable;
- EU-Egypt FTA, signed in 2001: Egypt must join UPOV and accede to Budapest Treaty within five years of the agreement's entry into force;
- EU-Algeria FTA, signed in 2002: Algeria must join UPOV (1991 Act) within five years of entry into force (by 2006) and accede to Budapest Treaty;
- EU-Lebanon FTA, in force in 2002: Lebanon must join UPOV (1991 Act) and accede to the Budapest Treaty by 2008;
- EU-Syria FTA, signed in 2004: Syria must provide IPR protection of the "highest international standards" and shall also accede to the Budapest Treaty and the UPOV Convention (1991) within 5 years; and
- EU-West Africa EPA, under negotiation: The EU urges West African states to ratify UPOV Convention (1991) and accede to the Budapest Treaty.

Proposed Bio-IPR demands from the EU on ASEAN countries

The EU urges that the ASEAN states shall comply with

[1] Bilateral agreements imposing TRIPS-plus intellectual property rights on biodiversity in developing countries GRAIN ª% update of March 2008.

a) Article 1 through 52 of the Patent Co-operation Treaty (Washington, 1970, last modified in 2001);
b) Article 1 through 16 of the Patent Law Treaty (Geneva, 2000);
c) Article 2 through 9 of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure (1977, amended in 1980).

And it also asks for similar plant variety protection earlier demanded from its past parties, as follows:

The Parties shall co-operate to promote and reinforce the protection of plant varieties based on the International Convention for the Protection of New Varieties of Plants (UPOV) as revised on March 19, 1991, including the optional exception to the breeder's right as referred to in Article 15(2) of the said Convention.

The Impacts

Plant Varieties

Joining UPOV (1991 Act) will make plant variety protection (PVP) in ASEAN countries increasingly stricter, for example[2]:

- All plant varieties are required to be protected without prior public notification. In the case of Thailand, the designation of protected plant varieties is undertaken by the Plant Variety Protection Committee, which must take into account if such designation will affect (public/national?) food security, monopoly of plant breeding companies, or farmers' choice.
- Expansion of the PVP duration, from 15 to 20 years for general plant varieties and to 25 years for trees and vines;
- Expansion of the scope of protection to grant plant breeders vested rights that prohibit others from using the protected species for commercial and farming purposes, as well as forbidding exports, imports or seed saving of the protected species for commercial and farming purposes;
- Narrowing the "Farmers' Exemption" to save and exchange seed by giving UPOV members an optional right to withhold such farmers' exemption.

This protection granted to breeders or seed companies is similar to patent law's monopoly rights, whose potential long-term impacts are as follows[3]:

1) ***On public and overall research on plant breeding***: A study conducted in the US found that the legal plant protection system had clear negative impacts that reduced the flow of information and germplasm from private seed companies to public plant breeding institutions whereas the flow from the public sector to the hands of private sector increased.[4]

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[2] Wisut Baimai, Jakkrit Kuanpote, Witoon Lianchamroon, and Bantoon Sethasirote, "Signing up for destruction," 2006, Sustainable Agriculture Foundation.
[3] Most of this analysis is based on a report on Problems and Enforcement of the Plant Varieties Protection Act B.E. 2542 (1999) suffered by Thai farmers and agricultural sector written by the Biodiversity and Community Rights Action, Thailand (formerly known as BIOTHAI, which is now changed into BioThai Foundation).
[4] See van Wijk and Jaffé, op cit., p. 25.

In Thailand, such incidents had occurred before the legal plant protection system was put in place. Seed companies have paid high salaries to lure government plant breeders to work for them, a growing trend that could eventually weaken the public sector's plant breeding.

This study is consistent with a conclusion drawn by Charles E Hess, a renowned American agronomist of the University of California—Davis in 1993: "IPRs appear to slow the free flow of germplasm exchange, slow the diffusion of new knowledge, upset the balance between basic and applied research, and erode scientific integrity."[5]

2) ***On biodiversity***: Basic requirements of new plant protection are the seeds' uniformity and stability. These criteria promote plant breeding to meet with the needs of monoculture farming system on huge farmland.

The two basic requirements—uniformity and stability—stimulate breeders to work only with 'elite' germplasm; hence, a lack of diversity of genetic sources. According to a study by the world's biggest breeding association, two-thirds of the germplasm is tapped from genebanks while one-third is collected directly from farmers' fields. And very small amount of it (about 7%) is derived from 'exotic' genetic resource base. As for certain plant improvement, such as maize, the genetic material used is even restricted.[6]

Contrary to the argument that the IPR system will put more diversity in the seed supply, plant breeders will be pushed to focus merely on single genes making the difference between the new variety they are breeding and the existing other.

GRAIN points out that this is very dangerous. While farmers buy seeds of different labels and names, but they are being offered almost the same old seeds of very restricted genetic resource base.

3) ***Monopoly of the transnational seed companies***: Behind the intense pressure to promote breeders' rights protection is an effort to gain monopoly rights to plant varieties. The ultimate aim of seed companies is to force farmers to buy seeds every time they want to plant their crops. Legal measures are being used to undermine the farmers' rights alongside other mechanisms, such as making contractual agreements with individual farmers, using breeding technology that prevents the farmers from saving seed for further sowing.

Under the guise of a slogan of "creating incentives to plant breeding," the seed companies' actual desire is none but to gain a monopoly on plant varieties, maximize their profits and expand their realm of interests as widely as possible. In reality, the seed companies have already monopolized most of the world's seeds, as shown in the fact that 67% of the seed market is under the control of the world's top 10 seed companies. And the monopoly tends to increase (compared with the past decade, this seed industry monopoly has increased by 27%).

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[5] Quoted in L.J. (Bees) Butler, 'Plant breeders' rights in the US: Update of a 1983 study'

[6] See *ASSINSEL Position on Maintenance of and Access to Plant Genetic Resources for Food and Agriculture,* updated 23 April 1997, at http://www.worldseed.org/.

Company	2007 seed sales (US millions)	% of global propriety seed market
1. Monsanto (US)	$1.961	23%
2. Dupont (US)	$3.300	15%
3. Syngenta (Switzerland)	$2.018	9%
4. Groupe Limagrain (France)	$1.226	6%
5. Land O' Lakes	$917	4%
6. KWS AG	$702	3%
7. Bayer Crop Science (Germany)	$524	2%
8. Sakata (Japan)	$396	<2%
9. DLF-Trifolium (Denmark)	$391	<2%
10. Takii (Japan)	$347	<2%
Top 10 Total	**$14,785**	**67%**

All these seed giants have played an important role in Thailand's seed industry, both in terms of direct operation and joint investment with local agri-business giants. A study in 1996 found that apart from the public open-pollinated hybrid seed, nearly all of the country's seed market is in the hands of the transnational seed companies and the Charoen Pokephand conglomerate with its joint venture with foreign firms. Small local seed companies, on the contrary, have a meager market share.[7]

Thailand's Major Seed Industry

Company	Subsidiary/Joint venture in Thailand	Type of seed
Dupont	Pioneer Hi-bred	Sorghum, sunflower, animal feed crops, and baby corn
Monsanto Cargill	Charoen Pokephand Cargill Seed	Vegetable and the majority of corn
Syngenta	Pacific Seeds	Sorghum, sunflower, animal feed crops, and baby corn

The promotion of the IP plant protection in Thailand means that these corporate giants are provided with a business device to enable them to have increasing control over and monopoly on the market in the long run. Now, these corporations are in control of the corn and vegetable seed markets, whose (annual?) demands of 1,500-2,000 tons, respectively, can increase 10 times or more by the next decade, based on the current market structure.

In fact, the private sector's market expansion per se is not a bad thing. But its aim of dominating the public sector's seed production and replacing the farmers' saved seed should be carefully considered.

Seed Sale in Thailand

[7] Private Investment in Agricultural Research and International Technology Transfer in Asia, *Agricultural Economic Report* No 805, USDA, 1996.

Such domination will be more intense, particularly when the aforementioned companies are not local enterprises but the world's transnational seed and chemical corporations.

4) Abolition of the principles of benefit sharing of biological resources: Under the Convention on Biological Diversity, to which most ASEAN states are parties, prescribes that countries have rights over their biological resources. Access to and the use of genetic resources shall be subject to prior informed consent and equitable benefit sharing.

In Thailand, these principles have been put into practice in the form of a plant varieties protection act, stipulating that an application for registration of a new plant variety shall have details showing the origin of the new plant variety or the genetic material used in the breeding of the variety and the profit arising from the use of a plant variety shall be shared by the State or communities, as provided by law.

To sign the EU-ASEAN Free Trade Agreement is tantamount to acceding to the industrial IP regime. It will undermine or weaken international legal principles that farmers, communities and national sovereignty over biological resources are to be protected.

Budapest Treaty

The Budapest Treaty or the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure is an international treaty, signed for the first time in Hungary's Budapest on 28 April 1977 and entered into force on 9 July 1980. Amended on 26 September 1980, the Treaty is administered by the World Intellectual Property Organization (WIPO).

Seventy-two countries have signed this treaty and it came into force in 70 nations.[8] Contracting States to this Treaty also joined the Paris Convention for the Protection of Industrial Property (1883), African Regional Industrial Property Organization, Eurasian Patent Organization, and European Patent Organization, according to the Treaty's Article 9.1.a.[9]

Under this Treaty "deposits of microorganisms at an international depositary authority to be recognized for the purposes of patent procedure"[10] are allowed so as to meet with legal requirements for sufficiency of disclosure, as the application for a patent shall contain sufficient information to enable any person skilled in the art to which it pertains to make and use the invention and setting forth the best mode contemplated by the inventor to carry out his/her invention.

It is said that detailed description of a microorganism-related invention to enable other persons to carry out the invention is difficult or impossible. That is why the microorganism-related invention needs to have its biological material deposited with the depositary authority.

Moreover, the Budapest Treaty allows that it is not necessary for the patent applicant to deposit his/her biological material in all countries where the application is to be made. The deposit of a microorganism with any depositary authority recognized by all contracting States shall suffice.

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[8] http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=7

[9] WIPO website, Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Article 9 Intergovernmental Industrial Property Organizations.

[10] WIPO web site, Summary of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977), retrieved on 11 August 2006.

Costa Rica is one of the five Latin American countries signing a free trade agreement—CAFTA—with the United States and also required to accede to the Budapest Treaty. Office of the Ombudsperson of the Republic of Costa Rica, a constitutional independent organization investigated into the implications of joining the Budapest Treaty and came up with the following potential impacts:[11]

1) The Treaty does not require the depositor to indicate the source or the origin of the material in custody. This means that it does not demand proof of either the prior informed consent of the supplier of the material nor the certificate of origin.

2) The Treaty prohibits the IDA from providing information about the deposited materials. That means that interested third parties, indigenous people, rural communities and other suppliers of biological resources will see limits on the exercise of their right of opposition if their natural resources, or even their own genes, are deposited for patenting purposes.

3) The Treaty will consequently contribute to the lack of protection for biodiversity and will prevent the eventual sharing of benefits mandated by law to the providers of deposited biological materials. The Budapest Treaty neither facilitates a detailed description of the deposited material nor, as a consequence, contributes to the full disclosure of the invention. The incomplete information will be insufficient, under national legislation, to exercise the right of opposition to a patent application.

4) The arguments given in the affirmative verdict of the majority at the Legislative Assembly of Costa Rica on the bill for Accession to the Budapest Treaty to defend the notion that the Treaty promotes the description and disclosure of inventions, as shown by the analysis of the Office of the Ombudsperson (earlier mentioned), are not supported.

5) The Budapest Treaty does not define its subject matter, i.e. the word "microorganism", for the purpose of allowing the deposit of biological materials in general and expanding their protection through proprietary rights.

6) Some of the deposited biological materials do not qualify as microorganisms.

7) The WTO Council for TRIPS and several branches of WIPO continue discussing to what extent life forms are patentable or not. That means that, worldwide, the discussion is open. Therefore, the obligations regarding intellectual property rights at those multilateral fora are still uncertain. Meanwhile, bilateral and regional free trade agreements are compelling developing countries to approve more intellectual property treaties, such as Budapest, and more rigid clauses not yet completely accepted at the multilateral level.

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[11] Opinion of the Office of the Ombudsperson of the Republic of Costa Rica Regarding the "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure", submitted to the Legislative Assembly of Costa Rica in October 2007. (Reviewed, summarized and translated to English in July 20081) For more information:
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8) Costa Rica's national legislation does not allow the patenting of genetically modified microorganisms. Notwithstanding, because of the lack of definition of "microorganism" in the Budapest Treaty and the consequent lack of distinction between "not genetically modified" and "genetically modified" microorganisms, it can be understood that the Treaty includes all types of microorganisms.

9) In Costa Rica, private entities have never been involved in the registry procedure of industrial property. According to Rule 2.1 of the Regulations of the Budapest Treaty, private entities are allowed to have the custody of microorganisms; therefore, now that Costa Rica was compelled to adhere to the Treaty, its national law must be changed.

10) There has been a worldwide debate related to the economic, environmental and ethical impacts of the patenting of life forms. That debate seems to have been ignored with the imposition of the Budapest Treaty.

11) No member can unilaterally modify the Budapest Treaty. Every modification must be done through the Assembly and agreed to by all signatory countries of the Treaty. Therefore, any unilateral declaration made, for instance, by Costa Rica in order to clarify or redefine the scope of the Treaty does not have any validity. International treaties do not allow reservations or interpretive clauses.

12) What is worse, now that the US-DR-CAFTA has been approved, any modification of the subordinate treaties, i.e. Budapest and the UPOV Convention (1991 Act) will be much more complex.

13) The Budapest Treaty is not in line with the norms and ethical principles of Costa Rica. Therefore, it considers that civil society, the scientific community and the different congregations should have had a more broad discussion on this Treaty including its ethical, environmental, social, economic and legal implications. Unfortunately, this did not happen and the decision to vote the US-DR-CAFTA, with its obligation for Costa Rica to accede to the Budapest Treaty, at referendum was not taken with a generalized prior informed consent.

14) Accession to the Budapest Treaty has implications in the economic, legal and cultural fields and contravenes the human right to life, the human right to information and participation, and the human right to legal security.

Microorganisms are very important for the general use of the people. For instance, the information of the Land Development Department gathered in 2004 indicated that at least 1.5 million farming households were promoted by the authorities to use microorganisms to improve the soil quality and control plant pests, covering over 15 million rai (2.4 million hectares) of land. Such use of microorganisms helped reduce the farmers' use of agricultural chemicals and increase their household income by 9,400 million Baht in economic value. The Sustainable Agriculture Foundation (Thailand) estimated that there were several hundreds of thousands of farming families more which were encouraged by other non-governmental organizations to use liquid bio-fertilizer and not included in the abovementioned figures. Accession to the Budapest Treaty will adversely affect the farmers' long-term use and development of microorganisms, not to mention other economic impacts. Previously, BioThai estimated the economic capacity of Thailand's microorganism utility—calculated from the economic value of products derived from the global volume of microorganisms by comparing Thailand's biodiversity proportion with those of other areas of the world—to amount to 160,000-600,000 million Baht annually.

ASEAN is one of the world's regions richest in biodiversity, similar to Costa Rica and all countries in Latin America. To sign the Budapest Treaty and join UPOV will definitely affect the farmers, bio-resource base and sovereignty of those countries, as respectively described.

Impact of IP provisions from EC draft trade agreement with ASEAN on access to medicines

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In the past decades, major evolutions in the increase in IPR protection standards internationally and at the national level have been led by the U.S. However, the European Union (EU) has begun to develop a much more aggressive attitude on IP when negotiating trade agreements and drafts tabled during recent negotiations show a radical shift in policy. Thus, the U.S. and EU trade policy aims to strengthen IPR protection can now be seen as complementary: while the US requests to trading partners relate to higher substantive standards; the European Commission (EC), besides targeting the raising of the standards of some aspects of IPR protection (expanding the scope of IPR, extending the durations of protections, introducing new types of monopoly rights, or limiting the scope of TRIPs flexibilities), focuses largely on enforcement measures and means.

Recent changes in EU policy regarding trade and IP

In the past years, bilateral negotiations were not a priority for the EC, in part because of the fear that such proceedings could be interpreted as undermining the trade talks of the Doha Round within the WTO. However, the deadlock faced at the WTO prompted the EC to revise its strategy (Mayne, 2005, 10; CIEL, 2006). In 2006, as reported in the press, David O'Sullivan, Commission directorgeneral for trade, explained that "if Doha was not restarted within months, it might be a decade or more before a new multilateral agreement could be reached. Meanwhile bilateral deals [were] proliferating, not only between the U.S. and its trading partners but also among developing countries themselves" (Fleming, 2006; see also European Commission, 2006a). Therefore, in October 2006, the EC amended its priorities to include an increased emphasis on bilateral deals, announcing that "[it] will propose a new generation of bilateral free trade agreements with key partners to build on WTO rules by tackling issues which are not ready for multilateral discussion and by preparing the ground for the next level of multilateral liberalization" (EC, 2006b).

On another note, since the Summit of Lisbon in 2000, European leaders are calling for series of reforms regarding IPR, based on the following rational:

> The US economy, building on the emergence of the so-called 'new' knowledge economy and its leadership in information and communication technologies (ICTs), had begun to outperform all but the very best of the individual European economies. Europe, if it wished to protect its particular social model and continue to offer its citizens opportunity, jobs and quality of life, had to act with determination — particularly in the context of the mounting economic challenge from Asia and the slowdown of European population growth. The EU set itself 'a strategic goal for the next decade: to become the most dynamic and competitive knowledge-based economy in the world capable of sustainable economic growth with more and better jobs and greater social cohesion, and respect for the environment'. (European Communities, 2004)

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According to this framework of understanding, a new strategy on IPR and trade was developed, focusing on seeking substantial improvements in the international enforcement of intellectual property rights and increased protections of European IP owners' rights (See EC, 2009). The EC's competence to negotiate international agreements on intellectual property was established in 1994 by the Court of Justice of the European Communities when it decided that "the Community and its Member States [were] jointly competent to conclude TRIPs." In 2001, the Treaty of Nice, amending certain articles of the Treaty of Rome, outlined the Commission's competence to negotiate agreements with respect to the commercial aspects of intellectual property, and to negotiate agreements on the non-commercial aspects of IP as long as the proposal to do it, made by the Commission, and upon consultation with the Parliament, is unanimously agreed upon by the Council.

Since then, the EC is in the process of negotiating and has already concluded numerous bilateral or regional agreements. It is currently negotiating bilateral agreements with large trade powers, such as South Korea, India, and Russia, all of which include intellectual property protection provisions.

Among the agreements signed with regional blocs, the most recent ones are those between the EC and African Caribbean and Pacific countries (ACP). The EC is currently involved in a negotiation with the Andean Community of Nations (CAN), which began in September 2007. Three rounds have been undertaken, but the fourth one was cancelled at the end of 2008. Negotiations are also in process with MERCOSUR. In April 2007, the European Council adopted a mandate for the EC to start Free Trade Agreement negotiations with countries from the Association of South East Asian Nations (ASEAN) countries[4]. The European Commission took the decision to adopt a regional approach on the ASEAN negotiations (EC, 2008a). On 4 May 2007, the EU-ASEAN Economic Ministers meeting in Brunei agreed to enter into negotiations for a Free Trade Agreement. In addition to the FTA negotiations, the economic relations between EU and ASEAN are supported by the Trans-Regional EU-ASEAN Trade Initiative (TREATI), which is a framework for dialogue and regulatory co-operation developed to enhance the EU's trade relations with ASEAN. The initiative was officially launched as a key component of the Commission's Communication on "A New Partnership with South East Asia" in July 2003. An assessment of the progress made on the FTA negotiations should be undertaken by the EC in 2009. For now on, the regional negotiations with the ASEAN and the CAN both seem jammed due to the impossibility to find consensual acceptance of some of the EC requests. Since, the EC has stated the possibility of pursuing negotiations with individual countries, the blocks may be on the verge to split, which would leave countries that are ready to pursue negotiations bilaterally alone to face the European negotiators.

Until recently, the Community's approach regarding IPR when negotiating economic agreements was to include general commitments, such as "The Parties shall provide suitable and effective protection of intellectual, industrial and commercial property rights, in line with the highest international standards. This shall encompass effective means of enforcing such rights" (See, Article 39, EC-Morocco Agreement, 2000), however, recent new treaties now show very specific provisions including substantive and detailed legal language. These new requests originated in part from the "Strategy for the Enforcement of Intellectual Property Rights in Third Countries", which was adopted in 2004 (EC, 2004a).

These new generations of international treaties, whether they are economic partnerships (EPAs), association and cooperation, or free trade agreements, incorporate a wide scope of content. The majority of the agreements in force to date show demonstrate similar content and structure on intellectual property

[4] Burma - Myanmar, Brunei, Cambodia, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand, Vietnam.

(with the exception of treaties concluded with candidates for entrance to the European Community that contain specific language). Only the content and details of the agreement the EC has entered into with the ACP countries is publicly known. However, drafts of the IP chapter submitted by the EC for negotiations with CAN[5] as well as that for ASEAN were leaked. These drafts feature very similar demands and identical language for most of the provisions. It is also known that intellectual property protection is a key negotiating issue with MERCOSUR **(**See EC, 2008b).

Moreover, the EU, in a similar way to the US, developed its armory to pressure countries. Since 2004, under the pretext of identifying countries with which a "greater cooperation" is necessary, the EC is using the same type of means of pressure as the US do with its Trade Act Section 301. Thus the EU identifies and classifies different categories of countries, which according to it experts do not implement effective enough IPR protection:

"The action plan focuses on vigorous and effective implementation and enforcement of existing IPR laws. It proposes to identify priority countries where enforcement actions should be concentrated. Stress will be put on technical cooperation and assistance to help third countries fight counterfeiting but the Commission will not hesitate to trigger all bilateral and multilateral sanction mechanisms against any country involved in systematic violations." (EC, 2004b).

Meanwhile, the EC is increasing its human resources allocated to supervising enforcement ofintellectual property rights in third countries, affecting positions to specific places identified as key such as Bangkok, Beijing, and Moscow (Xavier Seube, 2009).

In the meantime, enforcement became a priority area for cooperation between the EU and nations sharing similar interests – mostly within the OECD. The United States and the EU have created the Working Group on Intellectual Property and, in 2006, approved the Action Strategy for the Enforcement of Intellectual Property Rights, which is not limited to bilateral cooperation but commits the Europeans and Americans to adopting actions that guarantee enforcement of intellectual property in third countries. (EU, 2006) The Japan – EC Joint Initiative for the Enforcement of Intellectual Property Rights in Asia was adopted in 2003 **(**EC, 2003). The EU, United States, Switzerland, Australia, Japan, Canada, South Korea, Mexico, and New Zealand also started the negotiations in October 2007 of an Anti-Counterfeiting Trade Agreement (ACTA), focusing on international cooperation, enforcement practices, and legal framework that contain proposed provisions on enforcement, which are very similar to EC demands in its bilateral and regional agreements. For example, the U.S. and Japan have proposed that willful trademark and copyright infringement on a commercial scale is subject to criminal sanctions, including infringement that has "no direct or indirect motivation of financial gain". In the area of Border measures, ACTA contains a proposal to delete all references to "in-transit" goods, which will lead to the seizure of material even in the absence of actual infringement. Another provision gives the State the duty to provide information about possible infringers, to allow the possibility of acting proactively and in anticipation for the defense of private rights.[6]

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[5] Documents from Subgroup 11 in charge of matters relating to intellectual property has used as the basis of the EC – CAN negotiations have leaked from its meetings, including the European proposal submitted on November 27th 2007 during the second negotiating round. See analysis provided by Xavier Seuba Hernandez for HAI on the potential impact on health of the EU-CAN agreement (HAI, 2009).

[6] "ACTA draft, Article 2.10: Disclosure of Information
With a view to establishing whether an intellectual property right has been infringed under national law and in accordance with national provisions on the protection of personal data, commercial and industrial secrecy and professional and administrative confidentiality, the competent authorities have detained infringing goods, shall inform the right holder of the

The content of the IP chapters of the agreements

At the beginning of February 2009, the EC draft on IP, tabled during talks with the ASEAN, was leaked and made public on the Internet.[7] Overall, this text not only increases IP holders' rights, and the legal means they can rest on or the actions from the part of states they can call upon, but it almost absolutely ignores any other type of interests at stake, such as consumers' needs, citizens' rights or development, economic or budgetary imperatives of governments. In doing so this draft represents a shift from the balanced approach sought by many countries when negotiating the TRIPs agreement.

Following this trend, Article 1 of the EC draft only mentions as a goal to facilitate the production and commercialization of innovative and creative products, to the exclusion of the issue of accessibility to them. This article also raises the issue of how and in the name of which criterions what constitute an "adequate and effective level of protection and enforcement of intellectual property rights".

Article 1 – Objectives

"The objectives of this Chapter are to:
(a) facilitate the production and commercialization of innovative and creative products between the Parties; and
(b) achieve an adequate and effective level of protection and enforcement of intellectual property rights"

When looking more in details, the draft features several types of problematic provisions as far as access to health products are concerned, either increasing IPR protection standards and reducing the flexibilities granted by the TRIPs agreement or provisioning IP holders with a vast and detailed range of tools and procedures dedicated to the enforcement of their IPR and the protection of their commercial rights – in such an univocal way that it eventually introduces potential barriers to legitimate trade.

1. Provisions increasing IP holders' rights

Under Article 2.1 of the EC draft, countries are required to implement any IP treaty to which they are parties, besides the TRIPs agreement. This implies the implementation of TRIPs plus or "extra TRIPs requirements" and puts additional pressure on countries to comply to these standards – this can for example apply to provisions included into free trade agreements that some of the countries of the ASEAN region have signed the United States. It could lead to the extension of IP rights granted to American IP holders to European IP holders, especially if one considers certain interpretations of the clauses regarding

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names and addresses of the consignor, importer, exporter, or consignee, and provide to the right holder a description of the goods, the quantity of the goods, and, if known, the country of origin and name and addresses of producers of the goods." In another section of the proposed text, a proposal on damages, again close to EC demands in the context of its bilateral or regional treaties, reads as follows:
"ACTA draft, Article 2.2: Damages
1. Each Party shall provide that in civil judicial proceedings, its judicial authorities on application of the injured party shall have the authority to order the infringer who knowingly or with reasonable grounds to know, engaged in infringing activity of intellectual property rights to pay the right holder damages adequate to compensate for the actual prejudice the right holder has suffered as a result of the infringement, taking into account all appropriate aspects, inter alia, the lost profits, the value of the infringed good or service, measured by the market price, the suggested retail price, unfair profits and elements other than economic factors or other legitimate measure of value submitted by the right holder."

[7] See, http://www.bilaterals.org/article.php3?id_article=14281

the most favored nation treatment and national treatment included in the TRIPS agreement that go in the same direction. The EC draft makes the provision for a "Most Favoured Nation" clause in its Article 2 bis, which should be included at a later stage of the negotiations. However, as in the CAN-EU draft, this provision has not been submitted by the EU yet. Harmonizing effects of the most favoured treatment and national treatment are to be feared, since by virtue of this provision any "advantage, favor, privilege, or immunity" granted to nationals of any country can be extended to all WTO member states.

In Article 2, again, what qualifies as an « adequate and effective » protection remains open to interpretation. – The experience with the US 301 report has shown that developed and developing countries understanding on that matters could vary greatly to the expense of the developing countries. Meanwhile, the Article 1 of the TRIPs agreement states that "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice", which was included in the CARIFORUM agreement, does not appear in the CAN-EU draft (Xavier Seube, 2009), which tend to limit the flexibilities upon which developing countries can rest.

According to the draft agreement on the IP chapter "shall complement and further specify the rights and obligations of the parties under the TRIPS Agreement and other international treaties dealing with intellectual property." While the TRIPs agreement was the product of multilateral negotiation seeking a balance between IP protection and consumers rights, the EC draft impose additional protection and interpretations of TRIPs that will alter the already shaky balance. In addition, by virtue of the obligation of a national treatment in the TRIPs agreement, the provisions contained in the ASEAN-EU agreement could benefit IP holders, within the ASEAN region, who are neither European nor from the ASEAN. As HAI mentioned « [U]nless there is the unlikely assumption that differentiated systems of enforcement exist, then they are imposing a certain interpretation of the TRIPs agreement onto national intellectual property right holders from TRIPs member states that had no part in its formulating. » (Xavier Seube, 2009)

One common feature of the agreements with the EC is to expand the scope of what is defined as falling under the realm of intellectual property rights. Thus, Article 2.2 adds categories of intellectual property rights were not mentioned by the TRIPs agreement and do not exist in the Thai IP law – "*sui generis* rights for non-original databases", "trade names". It also imposes exclusive property rights for "plant varieties" which is a controversial issue and the subject of an on-going review at the TRIPS Council and is currently not mandatory under the TRIPs agreement. Article 11, on Plant varieties moreover requests the enforcement of the UPOV 1991 convention which is not in favor of the interest of farmers in developing countries since UPOV requires higher protection than that required by TRIPS – which permits the protection of plant varieties through a *sui generis* system and not necessarily *via* patents.

Article 2 – Nature and Scope of Obligations

"1. The Parties shall ensure an adequate and effective implementation of the international treaties dealing with intellectual property to which they are parties including the WTO Agreement on Trade-related Aspects of Intellectual Property (hereinafter call TRIPS Agreement). The provisions of this chapter shall complement and further specify the rights and obligations between the Parties under the TRIPS Agreement and other international treaties in the field of intellectual property.
2. For the purpose of this Agreement, intellectual property rights embody copyright, including copyright in computer programs and in databases, *sui generis* rights for non original databases, and neighbouring rights, rights related to patents, trademarks, trade names insofar as these are protected as exclusive property rights in the domestic law concerned, designs, layout- designs (topographies)

of integrated circuits, geographical indications, including designations of origin, indications of source, plant varieties, protection of undisclosed information and the protection against unfair competition as referred to in Article 10*bis* of the Paris Convention for the Protection of Industrial Property (Stockholm Act 1967)."

Article 11 – Plant varieties

"The Parties shall co-operate to promote and reinforce the protection of plant varieties based on the International Convention for the Protection of New Varieties of Plants (UPOV) as revised on March 19, 1991, including the optional exception to the breeder's right as referred to in Article 15(2) of the said Convention."

Source: www.kobos.com/.../Kobos-Knows-Tea/The-Tea-Plant

Meanwhile, the proposal does not mention specific forms of protection for traditional knowledge or the provisions of the Convention on Biological Diversity, which is matter of interest for Thailand and other ASEAN countries. Thus, obligations such as to reveal the origin of genetic resources, prior informed consent, and share and fair distribution of benefits made from genetic materials (see the recent controversy over avian flu virus between member states of the WHO) are not included in the agreement.

Article 9 of the EC draft addresses the matter of patents. In its Article 9.1, the draft requires parties to comply with several international treaties: Patent Cooperation Treaty (Washington, 1970, last modified in 2001) ; Patent Law Treaty (Geneva, 2000) ; Budapest Treaty on the International Recognition of the Deposit of microorganisms for the Purposes of Patent Procedure (1977, amended in 1980). Those 3 treaties are also mentioned in the CAN-EU draft. By compelling parties to comply with the treaties, the provision expands parties' commitments and obligations in IP protection that are not required under the TRIPS agreement.

The Patent Law Treaty aims at harmonizing formal requirements for applying, obtaining, and maintaining patents. The provisions on the revocation conditions in article 10 and the addition of the priority claims in article 13 are extra TRIPs requirements , that will create lead to evergreening patents.

Article 9.1 – *International Agreement*

"The Parties shall comply with
(a). Article 1 through 52 of the Patent Co-operation Treaty (Washington, 1970, last modified in 2001);
(b) Article 1 through 16 of the Patent Law Treaty (Geneva, 2000);
(c) Article 2 through 9 of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure (1977, amended in 1980)."

While increasing obligations, by mentioning the Doha declaration under article 9.2.1 in the patent section, the EC draft may be interpreted as reducing the scope and impact of the declaration to patents, which is not limited to patent rights alone (and could for example be used by countries to remove barriers created by data exclusivity protection).

Article 9.2.2 Encourage parties to implement and respect the Decision of the WTO General Council of 30 August 2003 on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

But, countries must evaluate whether it is prudent to accept the European proposal's obligation to ratify an amendment to the TRIPs agreement that establishes a system that many people see as very non practical, burdensome and which is limiting room of maneuver for government and represent very limited incentives for pharmaceutical producers.

Article 9.2 – Patents and Public Health

"1. The Parties recognize the importance of the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the World Trade Organization. In interpreting and implementing the rights and obligations under this Article the Parties shall ensure consistency with this Declaration.
2. The Parties shall contribute to implementation and respect the Decision of the WTO General Council of 30 August 2003 on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, as well as the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005. Nothing in this Agreement shall be construed as to impair the capacity of the Parties to promote access to medecines."


Source: blog.foreignpolicy.com/ .../topic/borders?page=3

Similarly to what exists in the US FTAs, Article 9.3 is creating a linkage between the marketing authorization procedure and the patent protection and requiring an extension of exclusive rights for the patent holder. This extension of the protection is requested under the pretext of compensating delays in the marketing authorization procedure during which the patent owner could not make benefits on the market. The duration of the extension shall be calculated by taking the "period that elapses between the filing of the patent application and the first authorization to place the product on [the] market" and subtracting to it 5 years. This supplementary protection certificates will have the effect of increasing the effective period of patent protection, over and above the minimum patent term required by TRIPS, resulting in the absence of competition for a longer period and thus persistent high prices of medicines restraining access.

It is worth noting that the landmarks that are taken are on one hand the *filing* of the patent, and on the other one the *granting* of the marketing authorization. Thus the period referred to both includes the duration of the examination of the patent, during which the patent owner to not benefit yet from exclusivity rights and the duration of the process to grant the marketing approval. Contrary to US FTA that mentions "unreasonable" delays in either granting the patent or the marketing authorization the EC do not bother to argue about delays. Although at the time patent protection was set in the TRIPs agreement to be 20 years negotiators considered this duration long enough for the patent owner to secure a return on its investments in research, in EC FTAs, the time necessary to process the patent request and the marketing authorization become "objectively" seen as something the patent owner should be compensated for – which may tend to discourage in depth analysis of the patent request on the other hand.

Moreover because the date taken into account is the granting of marketing approval nothing is mentioned regarding the filing for it. This is particularly problematic since it allows the patent owner to request marketing authorization in a country long after the patent was granted – in many developing countries patent owners show no interest to market their products before years – which will then allow him to request for extensions of the patent duration.

See for example:
A patent owner requests a patent during year 1. The patent is granted during year 4 (in the US patent examination takes on average 3-5 years). The patent owner applies for marketing approval during year 15. The marketing authorization is granted during year 17. According to the EC draft, the patent owner will then be able to request a 12 years extension of the patent protection. If the patent owner has no interest to market a product in a country, he can wait until the last year of the patent protection to register his product and will then be able to prevent the entry of generic products and keep exclusive rights for another full 15 years (20 years minus 5, according to the draft).

Article 9.3 – Supplementary protection Certificates

"1. The Parties recognize that medicinal and plant protection products protected by a patent on their respective territory may be subject to an administrative authorization procedure before being put on their market. They recognize that the period that elapses between the filing of the application for a patent and the first authorization to place the product on their respective markets, as defined for that purpose by the relevant legislation, may shorten the period of effective protection under the patent.
2. The Parties shall provide for extension of the duration of the rights conferred by the patent protection for a period that will be equal to the period referred to in paragraph 1 second sentence above, reduced by a period of five years.
3. Notwithstanding paragraph 2 and the extension for paediatric use for pharmaceutical products, the duration of the certificate may not exceed five years."

Similarly to US FTAs, the EC draft requires for data exclusivity of undisclosed information: "(…) during this period of protection, no person or entity (public or private), other than the person or entity who submitted such undisclosed data, will without the explicit consent of the person or entity who submitted this data, rely directly or indirectly on such data in support of an application for medicinal product approval/registration."

The article specifically mentions that no market authorization shall be granted during a certain period (which is not specified in the draft, and presumably is up for negotiations), and that subsequent applicants will have to provide their own data. The language is even clearer than the language in US FTAs. This can prevent the marketing of generic version of medicines that are not even protected by patents, or of generic version produced or imported under compulsory licensing.

Paragraph 10.4 provides an extension of the exclusivity in case of new indications for an already commercialized product, which "are considered of significant benefit in comparison with existing therapies". One can wonder how and by who the significance of the benefit will be evaluate. This type of provision opens the door to evergreening and abusive patent rights.

Note that the provision on data protection was not yet submitted in the CAN draft when the document was leaked.

By agreeing on data exclusivity protection provision countries are agreeing to an interpretation of article 39.3 of the TRIPs agreement being promoted by IP right holders. This also precludes their use of the flexibility available in TRIPS to interpret Article 39.3 in a way most favorable to their public health interests. While as HAI mentioned, "For countries that have not signed free trade agreements with the United States with TRIPs Extra provisions (exclusive, temporary data protection), the standard continues

to be from article 10 *bis* of the Paris Convention, namely, the protection of data against unfair competition." (Xavier Seube, 2009)

Article 10 – Protection of Data Submitted to Obtain a Marketing Authorisation

"1. The Parties will implement a comprehensive system to guarantee the confidentiality, undisclosed and non-reliance of data submitted for registration purpose of medicinal products.
2. The Parties will enact and implement legislation ensuring that any information submitted to obtain marketing approval, i.e., registration, of pharmaceutical products will remain undisclosed to third parties and benefit from a period of […] years of protection against unfair commercial use starting from the date of grant of marketing approval in the Parties, i.e. that during this period of protection, no person or entity (public or private), other than the person or entity who submitted such undisclosed data, will without the explicit consent of the person or entity who submitted this data, rely directly or indirectly on such data in support of an application for medicinal product approval/registration.
3. During this […]-year period, any subsequent application for marketing approval or registration would not be granted, unless the subsequent applicant submitted his/her own data (or data used with authorization of the right holder) meeting the same requirements as the first applicant. Products registered without submission of such data would be removed from the market until the requirements were met.
4. In addition, the […]-year period referred shall be extended to a maximum of […] years if, during the first […] years after obtaining the registration in the Parties, the registration holder obtains an authorization for one or more new therapeutic indications which are considered of significant clinical benefit in comparison with easting therapies."

While, the EC draft sets higher and broader standards of IPR protection it also mentions transfer of technology in its Article 3. However, since the article is written in very weak and general language and contains no mandatory obligations, one can expect it to be overlooked. In light of the weak language, enforcement of such and article will be problematic. Meanwhile, Article 3.2 emphasizing again the protection of IPR holders increases the impression of a clear imbalance between protection and technology transfer.

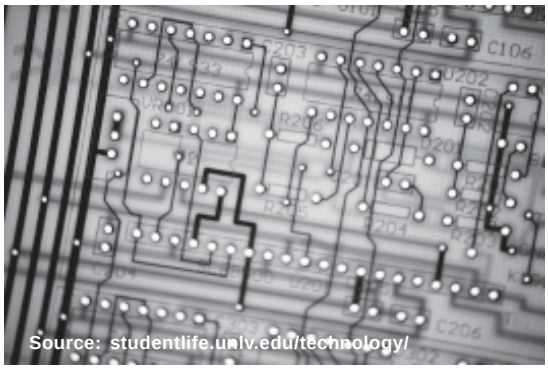
In comparison, the Article 142 of the EPA with CARIFORUM offers better language. It requires the parties to control possible abuses by intellectual property right holders – resulting for example in a license being granted when there is "an abuse of intellectual property rights by right holders or an abuse of obvious information asymmetries in the negotiation of licenses." The same article commits the EC to "facilitating and promoting" the use of incentives for transferring technology.

HAI suggests that the lack of provisions regarding technology transfer in the European draft can be mitigated, in the field of health, by referring and incorporating relevant sections of the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, which was adopted in May 2008 during the World Health Assembly – including "point 34 that offers the precision missing from the current EC proposal" (Xavier Seube, 2009).

Article 3 – Transfer of Technology

"1. The Parties agree to exchange views and information on their domestic and international practices and policies affecting transfer of technology. This shall in particular include measures to facilitate

information flows, business partnerships, licensing and subcontracting deals on a voluntary basis. Particular attention shall be paid to the conditions necessary to create an adequate enabling environment for technology transfer in the host countries, including issues such as the relevant legal framework and development of human capital.
2. The Parties shall ensure that the legitimate interests of the intellectual property right holders are protected."


Source: studentlife.unlv.edu/technology/

Meanwhile what is defined as 'Cooperation' in the Article 30 of the EC draft is limited to the legal development of provisions to protect intellectual property rights, as well as practices designed to guarantee IPR enforcement. This article also appear weak in comparison to the commitments made by the EC with other states. Within the specific scope of the relationship between technology transfer and public health, the EC recently made a commitment in the WHO to undertake much more interesting and practical activities. HAI suggested that the Andean countries should use *The Global Strategy and Plan of Action for Public Health, Innovation, and Intellectual Property* from which they can extract and incorporate provisions that seek to promote technology transfer (Xavier Seube, 2009).

Article 30 – Cooperation

"1. The Parties agree to co-operate with a view to supporting implementation of the commitments and obligations undertaken under this Chapter.
2. Subject to the provisions of Article [X, horizontal art. on assistance/co-operation issues] of this Agreement, areas of co-operation include, but are not limited to, the following activities:
(a). exchange of information on the legal framework concerning intellectual property rights and relevant rules of protection and enforcement; exchange of experiences on legislative progress;
(b). exchange of experiences on enforcement of intellectual property rights;
(c). exchange of experiences on central and sub-central enforcement by customs, police, administrative and judiciary bodies; co-ordination to prevent exports of counterfeit goods, including with other countries;
(d). capacity-building; exchange and training of personnel;
(e). promotion and dissemination of information on intellectual property rights in, inter alia, business circles and civil society; public awareness of consumers and right holders;
(f). enhancement of institutional co-operation, for example between intellectual property offices.
3. [Possible inclusion of a Dialogue mechanism to be launched at the request of one of the Parties]."

Strengthening enforcement of the rights of owners and protection of their interests

As in other EC agreements signed recently, enforcement of IP represents the most comprehensive part of the IP chapter. The EC is not only exporting the contents of European Directive 2004/48/EC and European Regulation 1383/2003, but also content of Proposed Directive 2005/0127(COD) – also called Directive IPRED2 – on criminal measures which approval by the Council of the European Union is still pending (Xavier Seube, 2009).

One of the major difference with the TRIPs agreement, is that provisions of the EC-ASEAN agreement, through was is defined as "complementary measures, procedures and remedies", prescribes the type of enforcement actions that should be undertaken, in detail, rather than only defining the expected results

of IP enforcement. On the other hand, in its Article 13, the agreement restates that what are considered IP rights includes plant variety, trade names, etc. which represents an extension of what should be included in the realm of IPR in comparison to what the TRIPs agreement says.

One problematic omission in the EC draft is the reference to article 41.5 of the TRIPs agreement, which states that "nothing in this part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general." When looking at the enforcement measures prescribed by the EC, one serious issue is indeed the resources it requires – whether it is the financial costs of reorganizing the management of IP in the countries, to increase police or custom action, to proceed litigations and charges, or the economic impact for populations who make a living out of the parallel economy of copying and to not have other financial resource or jobs. Countries that want to increase the enforcement of IPR protection standards (which themselves are increasing) should assess the economic impact of such policies, taking into account their overall effects, and having in mind not only the social cost of the enforcement of higher IPR protection standards but also the balance between these polices and other public spending.[8]

In the context of the negotiation of agreements with the EC, HAI suggests that the WIPO Development Agenda (point number 45) provides a general framework for enforcement that is more adapted to developing countries situation and other a better balance. (Xavier Seube, 2009)

On another note, we can see how Article 13.2 could lead to problems such as what recently took place with the Dutch custom that blocked Indian generic medicines shipped to Brazil and UNITAD's Abacavir shipped to Ravanda: enforcement measures in these cases are creating "barriers to legitimate trade", while impeding consumers' rights.[9] Later in the EC draft Article 18.2 is also typically the kind of language that would permit such incident.

Sub-Section 3 – Enforcement of IP
Article 13 – General Obligations

"1. Both Parties reaffirm their commitments under the TRIPS Agreement and in particular of its Part III, and shall provide for the following complementary measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights(1). Those measures, procedures and remedies shall be fair and equitable, and shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.
2. Those measures and remedies shall also be effective, proportionate and dissuasive and shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse."

Footnote:
(1) For the purposes of Article 13 to 25 the notion of "intellectual property rights" should at least cover the following rights; copyright; rights related to copyright; sui generis right of a database maker; rights of the creator of the topographies of a semi conductor product; trademark rights; design rights; patent rights, including rights derived from supplementary protection certificates; geographical indications; utility model

[8] See information provided by World Bank and UNCTAD about cost estimations mentioned in the HAI document about the EC-CAN agreement. (Xavier Seube, 2009)
[9] see Intervention made by Brazil at the WTO General Council (February 03 and 04, 2009).

rights; plant variety rights; trade names in so far as these are protected as exclusive rights in the national law concerned.

On many levels, the EC proposal increases means available to IPR owners to trigger action against potential generic medicine producers or competitors. Thus Article 14 increases the number of entitled applicants that can take action to defend an intellectual property right beside the "the holders of intellectual property rights", and includes among the list third parties legally authorized to exercise holder's rights (which was not included in TRIPs):

- "all other persons authorized to use those rights, in particular licensees",
- "professional defense bodies", and, in the event the parties so recognize them, "intellectual property collective rights management bodies."
- Intellectual property collective rights management bodies which are regularly recognized as having a right to represent holders of intellectual property rights, in so far as permitted by and in accordance with the provisions of the applicable law."

Again here, the right of interested third parties (consumers or users for example) is not mentioned. As HAI recommended the agreement should include the possibility for consumers or organizations representing them to take part to the administration of the IPR and theirs enforcement. (Xavier Seube, 2009)

Article 14 – Entitled applicants

"1. The Parties shall recognize as persons entitled to seek application of the measures, procedures and remedies referred to in this section and in Part III of the TRIPS Agreement:
a. the holders of intellectual property rights in accordance with the provisions o the applicable law,
b. all other persons authorized to use those rights, in particular licensees, in so far as permitted by and in accordance with the provisions of the applicable law,
c. professional defence bodies which are regularly recognized as having a right to represent holders of intellectual property rights, in so far as permitted by and in accordance with the provisions of the applicable law.
2. The Parties may recognise as persons entitles to seek application of the measures, procedures ad remedies referred to in this section and in Part III of the TRIPS Agreement, intellectual property collective rights management bodies which are regularly recognised as having a right to represent holders of intellectual property rights, in so far as permitted by and in accordance with the provisions of the applicable law."

Furthermore, article 15 and 16 contribute to substantially reduce the rights of supposed infringers, thus establishing a system where IP owners' interests overcome any other consideration – the presumption of guiltiness override the presumption of innocence. This is also set by Article 18 that establishes that actions can be undertaken even before any infringement is proven (Art. 18. 2. "An interlocutory injunction may also be issued to order the seizure or delivery up of the goods suspected of infringing an intellectual property right so as to prevent their entry into or movement within the channels of commerce"). The most striking examples being that "measures shall be taken, if necessary without the other party being heard" or that "[the] judicial authorities may… order prompt and effective provisional measures" even in the case where a right is not infringed yet, "is about to be infringed"… or thought so. Saying that "reasonably available evidence" is enough to trigger measures opens the door to any type of action dictated by the IP owners even in the absence of any proof.

In addition, because of the wording of the articles –"The party shall ensure" – the obligations contained in these provisions are imposed on the party and become an obligation of the state – when in the TRIPs agreement what was required was to the state to "empower its judicial authorities". Hence, the agreement not only alters deeply the balance between IPR owners and non IPR owners, but it provides the State with a role to act upon the interest of the formers and engage the means and resources to do so.

Article 15 – Evidence

"The Parties shall take such measures as are necessary, in the case of an infringement of an intellectual property right committed on a commercial scale to enable the competent judicial authorities to order, where appropriate and following an application, the communication of banking, financial or commercial documents under the control of the opposing entity, subject to the protection of confidential information."

Article 16 – Measures for Preserving Evidence

The Parties shall ensure that, even before the commencement of proceedings on the merits of the case, the competent judicial authorities may, on application by an entity who has presented reasonable available evidence to support his claims that his intellectual property right has been infringed or is about to be infringed, order prompt and effective provisional measures to preserve relevant evidence in respect of the alleged infringement, subject to the protection of confidential information. Such measures may include the detailed description, with or without the taking of samples, or the physical seizure of the infringing goods, and, in appropriate cases, the materials and implements used in the production and/or distribution of these goods and the documents relating thereto. Those measures shall be taken, if necessary without the other party being heard, in particular where any delay is likely to cause irreparable harm to the right holder or where there is a demonstrable risk of evidence being destroyed.

The actions and measures that entitled applicants can request to be applied are significantly broader and stronger in comparison to obligations in the TRIPs agreement. Significantly, as opposed to the TRIPs agreement, entitled applicants may not only file civil and administrative actions, but also criminal ones (Art 17.3.b).

Article 15 targets cases of infringements "committed on a commercial scale". However this opens the questions of how is defined the requirement of "commercial scale". As Heesob Nam from Ip Left commented, if the definition follows the one proposed in ACTA, "for purposes of commercial advantage or private financial gain", and if the "financial gain" is defined to include "receipt or expectation of anything of value", as in the US-Korea FTA, the range of infringements that can be considered as "committed on a commercial scale" is broad.[10] When "commercial scale" infringement is occurring or suspected very radical actions are allowed such as "blocking (…) bank accounts and other assets", which raises pragmatic and ethical issues considering the imbalance of rights between IP owners and suspected infringers. Moreover, the measures requested very often do not appear in the language of the FTA limited to infringement on "commercial scale".

[10] The case of South Korea provides us with a good example of how criminal enforcement of IPR laws can be used, misused and abused by IP right holders (letters sent to suspected individuals threatening them – abusively in many cases
– with criminal actions and asking for cash settlement for example) (Nam, 2009).

The EC draft expands the information to be reported related to the potential infringer. Under TRIPs the only information that is required to be supplied is the identity of the third parties who have participated in the "production and distribution" and of their channels of distribution. In the European proposal, the states have to order their judicial authorities to force the infringer to report the names and addresses of the producers, manufacturers, distributors, suppliers and other previous holders of the goods or services, as well as wholesalers and retailers, and also "on the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the goods or services in question." Moreover, The TRIPs agreement states that the infringer must be the one to provide the information, whereas in the European proposal information is provided by the infringer and any other person who was found in possession of, using, or providing the infringing goods or services on a commercial scale. The TRIPs agreement does not require infringing parties to inform on third parties or distribution channels if this "would be out of proportion to the seriousness of the infringement." That provision does not appear in the EC draft.

Article 17 – Right of Information

"1. The Parties shall ensure that, in the context of proceedings concerning an infringement of an intellectual property right and in response to a justified and proportionate request of the claimant, the competent judicial authorities may order that information on the origin and distribution networks of the goods or services which infringe an intellectual property right be provided by the infringer and/or any other person who;

a. was found in possession of the infringing goods on a commercial scale;
b. was found to be using the infringing services on a commercial scale;
c. was found to be providing on a commercial scale services used in infringing activities; or
d. was indicated by the person referred to in point (a), (b) or (c) as being involved in the production, manufacture or distribution of the goods or the provision of the services.

2. The information refereed to in paragraph 1 shall, as appropriate, comprise:

a. the names and addresses of the producers, manufactures, distributors, suppliers and other previous holders of the goods or services, as well as he intended wholesalers and retailers;
b. information on the quantities produced, manufactured, delivered, received or ordered, as well as the price obtained for the goods or services in question.

3. Paragraphs 1 and 2 shall apply without prejudice to other statutory provisions which;

a. grant the right holder rights to receive fuller information;
b. govern the use in civil or criminal proceedings of the information communicated pursuant to this Article;
c. govern responsibility for misuse of the right of information;
d. afford an opportunity for refusing to proved information which would force the person referred to in paragraph 1 to admit to his own participation or that of his close relatives in an infringement of an intellectual property right; or
e. govern the protection of confidentiality of information sources or the processing of personal data."

Article 18 – Provisional and Precautionary Measures

"1. The parties shall ensure that the judicial authorities may, at the request of the applicant issue an interlocutory injunction intended to prevent any imminent infringement of an intellectual property right, or to forbid, on a provisional basis and subject, where appropriate, to a recurring penalty payment where provided for by domestic law, the continuation of the alleged infringements

of that right, or to make such continuation subject to the lodging of the guarantees intended to ensure the compensation of the right holder. An interlocutory injunction may also be issued, under the same conditions, against an intermediary whose services are being used by a third party to infringe an intellectual property right.
2. An interlocutory injunction may also be issued to order the seizure or delivery up of the goods suspected of infringing an intellectual property right so as to prevent their entry into or movement within the channels of commerce.
3. In the case of an infringement committed on a commercial scale, the Parties shall ensure that, if the applicant demonstrates circumstances likely to endanger the recovery of damages, the judicial authorities may order the precautionary seizure of the movable and immovable property of the alleged infringer, including the blocking of his/her bank accounts and other assets. To that end, the competent authorities may order the communication of bank, financial or commercial documents, or appropriate access to the relevant information."

In article 19 again, measures such as the destruction of goods and of "materials and implements principally used in the creation or manufacture of those goods" raise concerns considering the biased balance of the system in favour of IP rights holders.

Article 19 – Corrective Measures

"1. The Parties shall ensure that the competent judicial authorities may order, at the request of the applicant and without prejudice to any damages due to the right holder by reason of the infringement, and without compensation of any sort, the recall, definitive removal from the channels of commerce or destruction of goods that they have found to be infringing an intellectual property right. If appropriate, the competent judicial authorities may also order destruction of materials and implements principally used in the creation or manufacture of those goods.
2. The judicial authorities shall order that those measures shall be carried out at the expense of the infringer, unless particular reasons are invoked for not doing so."

The TRIPs agreement merely states that the willful or negligent infringer must pay adequate damages to compensate for the injury the right holder has suffered. Requiring payment of the holder's legal expenses is at discretion of the courts, and it is a right of the member states to authorize the courts to grant reparation for benefits and/or damages in the event the infringer did not know he was carrying out unlawful activities. However, according to the European proposal, not only must there be "adequate" compensation, but this compensation must cover "all the relevant aspects", which include, no less than, damages caused to the holder, profits obtained by the infringing party, and even "moral prejudice" he has caused.

Article 22 – Damages

"1. The Parties shall ensure that when the judicial authorities set the damages:
a. they shall take into account all appropriate aspects, such as the negative economic consequences, including lost profits, which the injured party has suffered, any unfair profits made by the infringer and, in appropriate cases, elements other than economic factors, such as the moral prejudice caused to the right holder by the infringement ; or
b. as an alternative to (a), they may, in appropriate cases, set the damages as a lump sum on the basis of elements such as at least the amount of royalties or fees which would have been due if the infringer had requested authorization to use the intellectual property right in question.

2. Where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity, the Parties may lay down that the judicial authorities may order the recovery of profits or the payment of damages which may be pre-established."

While the TRIPs agreement only provides member states the power to authorize the *judicial authorities* to order the infringing party to pay the right holder's legal expenses, the European proposal demands that *the parties shall* ensure all legal fees and other expenses incurred by the successful claimant are paid for by the infringer. Thus what is considered as the authority of the courts has now turned into being the responsibility of the state.

Article 23 – Legal Cost

"The Parties shall ensure that reasonable and proportionate legal costs and other expenses incurred by the successful party shall as a general rule be borne by the unsuccessful party, unless equity does not allow this."

The EC did not submitted language yet regarding the criminal sanctions that can be undertaken. One can refer to the language it provided for the CAN agreement – taking into account that the EC mentioned that patents would be excluded from criminal section in the agreement with the ASEAN[11]:

EC-CAN draft:

"1. Without prejudice to the measures and procedures set out by the other provisions of this agreement, the parties shall take the necessary measures to ensure that any intentional infringement of an intellectual property right on a commercial scale, as well as attempting, aiding or abetting and inciting such infringements, are treated as criminal offences and subject to deterrent sanctions.

2. For the offences referred to in paragraph 1, the parties shall provide for the following sanctions:

a) for natural persons: custodial sentences;

b) for natural and legal persons:

(i) fines;

(ii) confiscation of the object, instruments, and products stemming from infringements or of goods whose value corresponds to those products.

3. For the offences referred to in paragraph 1, the parties shall provide that the following penalties are also available in appropriate cases:

a) destruction of the goods infringing an intellectual property right;

b) total or partial closure, on a permanent or temporary basis, of the establishment used primarily to commit the offence;

c) a permanent or temporary ban on engaging in commercial activities;

d) placing under judicial supervision;

e) judicial winding-up;

f) a ban on access to public assistance or subsidies;

g) publication of judicial decisions.

[11] **Article 26 – Criminal Sanctions**
"the proposal parallel Directive 2004/48/CE, which does not include criminal sanctions, and subsequent legal progress made in the area of EC law has placed special emphasis on excluding patent infringements from any criminalization."

This articles set forth a very detailed range of punishments for infringement against IPR, including imprisonment, fines, confiscation of materials and goods, destruction of goods, closure of involved establishments, disqualification from engaging in commercial activities, judicial supervision and winding up orders, banishment from public benefit or aid, and publication of judicial decisions. As HAI noted, it "even address penalties to be imposed on infringers, something rather uncommon to international public law and even less so when it comes to trade agreements" (Xavier Seube, 2009).

On the contrary, according to the TRIPs agreement imprisonment and monetary fines can be limited to two types of infringements: "willful trademark counterfeiting or copyright piracy on a commercial scale", while each state is left free to exclude the option of imprisonment (Article 61).

As HAI notes, we observe a paradoxical phenomenon: while European countries, the US and other developed countries have excluded most IPR infringements from the scope of their criminal law, these same countries pushes for developing nations to adopt criminal provisions for combating large scale infringements of intellectual property rights. (Xavier Seube, 2009)

Regarding border measures, The EC is putting pressure bilaterally, regionally and multilaterally to expand the scope and intensity of actions addressing IP issues in comparison to what is in the TRIPs agreement. The European proposal, for example, adds activities for which customs authorities must suspend the release of goods (adding to import control, exportation, re-exportation, entry or exit of the customs territory, placement under a suspended procedure or placement under a customs free zone or a customs free warehouse) and increases the number of intellectual property rights, whose alleged infringement can trigger custom measures. While, provisions in article 51 of the TRIPs agreement applied to counterfeit trademarks and copyright piracy, the European draft widened the scope of the infringements considered to any infringement to "an intellectual property right".

As the example with the recent transit seizure of Indian generic medicines by the Dutch custom shows, the expansion of border measures can have harmful effects on legitimate trade. This is part due to the fact that patent infringement is not as easy to establish that copyright or trademark infringement, and can be assessed of infringement in the origin and destination countries by the custom at once.

Article 28 – Border Measures

"1. The Parties shall, unless otherwise provided for in this section, adopt procedures(1) to enable a right holder, who has valid grounds for suspecting that the importation, exportation, re-exportation, entry or exit of the customs territory, placement under a suspensive procedure or placement under a free zone or a free warehouse of goods infringing an intellectual property right(2) may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation or the retain of such goods,
2. Any rights or duties established in Section 4 of the TRIPS Agreement concerning the importer shall be also applicable to the exporter or to the holder of the goods."

Footnotes:
(1) It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder.
(2) For the purposes of this provision, "goods infringing an intellectual property right" means:
(a). "counterfeit goods", namely:

(i) goods, including packaging, bearing without authorization a trademark identical to the trademark duly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the trademark holder's rights;
(ii) any trademark symbol (logo, label, sticker, brochure, instructions for use or guarantee document), even if presented separately, on the same conditions as the goods referred to in point (i);
(iii) packaging materials bearing the trademarks of counterfeit goods, presented separately, on the same conditions as the goods referred to in point (i);
(b). "pirated goods", namely goods which are or contain copies made without the consent of the holder, or of a person duly authorized by the holder in the country of production, of a copyright or related right or design right, regardless of whether it is registered in national law;
(c). goods which, according to the law of the Party in which the application for customs action is made, infringe:
(i) a patent;
(ii) a plant variety right;
(iii) a design;
(iv) a geographical indication

With its article on "Codes of Conduct and Forensic Co-operation" the EC draft again goes into the details of actions and resources that ASEAN countries should invest in the control of IPR protection. Here again, the innovative commitment to foster the development of codes of conduct aims only at facilitating enforcement of intellectual property rights.

Article 29 – Codes of Conduct and Forensic Co-operation

"1. Parties shall encourage:
(a). the development by trade or professional associations or organizations of codes of conduct aimed at contributing towards the enforcement of intellectual property rights, particularly by recommending the use on optical discs of a code enabling the identification of the origin of their manufacture;
(b). the submission to the competent authorities of the Parties of draft codes of conduct and of any evaluations of the application of these codes of conduct
2. Parties shall co-operate in order to identify forensically illegal optical discs which are produced by plants located in the ASEAN. The competent authorities shall collect and store samples for each production line in a database to which trade or professional associations or organizations shall have access, under the conditions defined by domestic law, to compare samples found on the market. In exchange, these associations or organizations may use, at the request of the competent authority, their international sample database to help that competent authority determine the source of the illegal product that it has reason to believe was produced outside the ASEAN."

Conclusion

The IP chapter draft tabled by the EC for negotiation with the ASEAN is very similar to the one introduced by the EC in the negotiation with the CAN countries. It contains detailed and specific provisions, at least as demanding as the one required by the US in its FTAs, which, if adopted, will impact access to medicines. The main potential types of barriers are:

- Increased IPR protection standards: expanding the scope of what falls in the realm of IP protection, extending the duration of exclusive rights, introducing marketing regulation rules that will favor monopolies and therefore high prices, independently of the existence of patent protection.

• A limitation of the scope of the Doha declaration on TRIPs and public health.
• Increased enforcement standards as well as a broad set of enforcement measures and actions which introduce a biased approach in favor of IP owners in the name of suspicion of infringements, while totally ignore consumers needs and interests or developing countries local situation and social and developmental imperatives.

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