

Developments under the TRIPS Agreement

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Introduction

Although there were multilateral conventions on intellectual property like the Paris Convention for the protection of Industrial property and the Berne Convention for the Protection of Literary and Artistic Works that preceded the Trade Related Aspect of Intellectual Property Rights Agreement (TRIPS) by many years, it was the TRIPS Agreement that first linked intellectual property with trade issues.

The linkage between IP and trade was based on two points: First, widespread piracy, counterfeiting and infringement of IP rights constitutes a barrier to trade in that the availability of such goods diminishes market access for legitimately traded goods. This premise appeals to developed countries, which will benefit from this linkage but it may not necessarily appeal to developing countries. Second, there is a link between such trade and Intellectual Property Rights (IPRs) through IP rights transfer or licensing agreements. National regulation of such agreements is common and is generally of two types: (1) notification and (2) registration and approval. U.S. negotiators were concerned that burdensome registration and approval requirements in certain countries inhibited investment and IPR licensing, and therefore, restricted trade. The negotiation of the TRIPS Agreement was primarily one between developed and developing countries of the GATT. The latter accepted the TRIPS Agreement reluctantly as part of the Uruguay Round package deal.

Two considerations led to the creation of the TRIPS Agreement. First, the United States and other developed countries failed in their attempts to increase normative standards of protection for IP through the WIPO and the Paris and Berne Convention. Second, these two conventions leave enforcement of IP through judicial and administrative remedies to local decisions rather than through uniform normative standards of protection. Traditionally, IP protection is restricted to national standards and may differ from one country to another based on

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their governing statutes. With the coming globalization, higher standards of IP protection and international enforcement became increasingly important.

The innovation that TRIPS introduced is that it is established rights and obligations among WTO member countries rather than private individuals or companies. In a sense, TRIPS may be important for the following reasons: (1) it establishes an international law of substantive minimum standards for national IP laws; (2) it establishes minimum international criteria for national enforcement of IPRs through civil, criminal and administrative proceedings; (3) it subjects national IP standards and enforcement to the WTO dispute settlement system, thereby providing an international forum for enforcement of rights and resolution of disputes; and (4) it establishes certain common procedural requirements that each national government must meet concerning the administration and maintenance of IPRs. Essentially, although TRIPS does not unify IP laws, it does stipulate a certain level of harmonization on a worldwide basis.

Types of IP Rights under TRIPS

The TRIPS Agreement addresses seven categories of intellectual property rights: (1) copyright and related rights; (2) patents; (3) trademarks and service marks; (4) geographical indication; (5) undisclosed information or trade secrets (6) industrial designs and (7) layouts of integrated circuits.

Substantive requirements of the TRIPS Agreement

The TRIPS Agreement contains two types of substantive requirements regarding IPRs that WTO members must meet. First, each Member must extend a national treatment obligation for WTO members to afford nationals of all members the opportunity to protect IP rights to the same extent as a Member's own nationals. There is also a most-favored nation obligation to accord these same rights to nationals of WTO members.

Our Congress has implemented this requirement in Section 3 and 231 of the IP Code, which provides:

SECTION 3. International Conventions and Reciprocity. – Any person who is a national or who is domiciled or has an effective industrial establishment in a country which is a party to any convention, treaty or agreement relating to intellectual property rights or the repression of unfair competition, to which the Philippines is also a party, or extends reciprocal rights to nationals of the Philippines by law, shall be entitled to benefits to the extent necessary to give effect to any provision of such convention, treaty or reciprocal law, in addition to the rights to which any owner of an intellectual property right is otherwise entitled by this Act. (n)

Prior to the IP Code, the Supreme Court held in *Philip Morris, Inc., Benson & Hedges (Canada), Inc. and Fabrique of Tabac Reunies, S.A. vs. Court of Appeals and Fortune Tobacco Corporation*¹ that the provisions of international treaties on IPRs like the Paris Convention must be subordinated for those of Philippine laws. Under Section 3 of the IP Code, it could be reasonably interpreted that international convention on IPRs have been incorporated as part of national law since nationals of member countries “shall be entitled to benefits to the extent necessary to give effect to any provision of such convention, treaty or reciprocal law, in addition to the rights to which any owner of an intellectual property right is otherwise entitled by this Act.” Our Congress also introduced a provision on reverse Reciprocity of Foreign Laws, to wit:

SECTION 231. Reverse Reciprocity of Foreign Laws. – Any condition, restriction, limitation, diminution, requirement, penalty or any similar burden imposed by the law of a foreign country on a Philippine national seeking protection of intellectual property rights in that country, shall reciprocally be enforceable upon nationals of said country, within Philippine jurisdiction. (n)

TRIPS also contains minimum substantive standards for IP protection for all categories of IP: copyright and neighboring rights, patents, trademarks, geographical indications, trade secrets, industrial designs and layout designs of integrated circuits. The TRIPS Agreement incorporates the substantive standards of IP conventions, such as the Berne Convention and the Paris Convention, but goes beyond them to establish even higher and more specific norms of IPR protection. Enforcement must be effective as well as fair and more equitable. There must be judicial review of final administrative decisions. Civil and administrative enforcement procedures must conform to certain standards

¹ GR. No. 91132, July 16, 1993.

regarding matters such as evidence and proof and due process and must adopt border procedures that allow IP rights holders to block the import of infringing goods. Parties must also provide appropriate criminal penalties for willful violation of IPRs.

The TRIPS Agreement requires WTO Members to establish an adequate IP Office and procedures to facilitate the acquisition and maintenance of IP rights. Procedures for the grant and registration of IP rights must operate within reasonable periods and the law must allow *inter partes* proceedings of opposition, revocation and cancellation. Final administrative decisions must be subject to judicial review.

Provisions relating to developing countries

The TRIPS Agreement makes relatively few concessions to developing countries. Developing countries were given until 2000 to comply with the Agreement, four years more than developed country members.² In addition, if a developing country is required by TRIPS to extend patent protections to new product and technology areas heretofore not covered by its IP laws, it can delay compliance until January 1, 2005.³ Least developed country members have until 2006 to comply with all of the TRIPS Agreement, with the exception of the general obligations of national treatment and MFN treatment.⁴

Developed country members are obliged to provide incentives for transfer of technology to least developed countries⁵; and (2) technical assistance and financial help to developing countries in preparing laws and regulations on protection and enforcement of IP rights.⁶

The case against IP protection is simply that the cost of protection simply outweighs the benefits. The traditional view is that developing countries receive little or nothing from the price they pay in granting foreign monopolies over technology and industry within their borders. Under this view, IP rights stifle domestic innovation and impede the diffusion of technology in poor countries. Using protected technology will involve higher prices and paying royalties to foreign companies. It

² TRIPS Agreement, Art. 65.2 and 3

³ Art. 65.4

⁴ Art. 66

⁵ Art. 66.2

⁶ Art 67

has been said that developing countries should not be made to spend for the procession of thousands of IP applications filed primarily by US, Japanese and European companies when patent statistics show that developing countries hold less than 1 percent of patents.⁷

Several benefits may be mentioned, but their effects may be hard to measure. There is evidence that IP protection will mean increased investment and technology transfer diffusion in developing countries, as well as increased investment, trade and opportunity for capital formation. There will also be positive benefits in the form of training, the productivity of research and international interactions with foreign business and universities.

Traditional knowledge and genetic resources

Although the TRIPS Agreement was originally concluded to govern traditional intellectual property rights, namely, patents, trademarks and copyright, there is now an emerging consensus at the WIPO and the TRIPS Council that the TRIPS Agreement should contain protection for traditional knowledge, culture, folklore and even genetic resources.

Traditional knowledge and genetic resources may be deemed a relevant subject matter under the TRIPS Agreement to the extent that its unauthorized appropriation may lead to the creation of intellectual property rights in favor of the appropriators of such traditional knowledge.

This use of genetic resources and traditional knowledge is referred to as biopiracy which means the appropriation by means of patents, of indigenous biomedical knowledge by foreign entities (including corporations, universities and governments) without compensatory payment. The classic case is that of the Rosy Periwinkle (Madagascar Periwinkle), a plant native to Madagascar. Research into that plant was prompted by the plant's traditional medicinal role and resulted in the discovery of a large number of biologically active chemicals, including the children's cancer cure vincristine. Vincristine is both highly effective in curing children's cancer and, as a result, an unusually lucrative drug. Vincristine was initially patented and marketed by a US pharmaceutical company.

⁷ OECD "Economic Agreements for Protecting IPR Effectively", TC WP (88) 1989, at 21.

In contrast to biopiracy, which is a judgmental term, is the concept of “bioprospecting”, which is considered a neutral or positive term. While biopiracy and bioprospecting are easily defined terms of each other (biopiracy is illegal or unethical; bioprospecting is legalized or ethical biopiracy), a United Nations University Institute of Advanced Studies report stated in 2005 that there was no agreed definition of bioprospecting.

The classic Rosy Periwinkle case is a good example for how biopiracy cases are rarely as simple as they seem. There are complicating factors in this case: First, the Rosy Periwinkle, while native to Madagascar, had been widely introduced into other tropical countries around the world well before the discovery of vincristine. This meant that researchers could obtain local knowledge from one country and plant samples from another. Second, the locally known medical properties of the plant were not the same as the medical properties discovered and commercially used by the US pharmaceutical company. The use of the plant as a cure for diabetes was the original stimulus for research but cures for cancer were the most important results. Third, different countries are reported as having acquired different beliefs about the medicinal properties of the plant.

The role of bioprospecting in pharmaceutical research

Theoretically, pharmaceutical researchers could simply take thousands of plant samples and conduct a battery of tests on them to establish any useful medicinal properties. In practice, this is a time-consuming and financially inefficient method. The discovery of useful medicines can be significantly accelerated by taking into account indigenous biomedical knowledge found in the communities where the plants are native. Shamans may be asked to point out potentially useful plants and list their known properties. Typically such local knowledge has been built up over centuries or millennia. Modern pharmaceutical research can build on that local knowledge and achieve faster results.

Media report about discoveries based on indigenous biomedical knowledge naturally focus on a few outstandingly successful cases. This draws attention away from the realities of pharmaceutical research, in which thousands of dead-ends may be investigated before a positive result is found. Pharmaceutical research has some of the economic properties of attempting to win the jackpot in a lottery. If the research is successful, the economic returns are unpredictable and can be wildly out of proportion to

the invested effort. The lobby group Rural Advancement Foundation International reports that random testing has a success rate of about 1:10000, but if testing is combined with local shamanic knowledge, the success rate can be to about 1:2.

Another example is the Neem tree which grows throughout India. In 1995 the U.S. Department of Agriculture and a pharmaceutical research firm received a patent on technique to extract an anti-fungal agent from the Neem tree (*Azadirachta indica*). Indian villagers have long understood the tree's medicinal value. Although the patent had been granted on the extraction technique, the Indian press described it as a patent on the Neem tree itself which of course is a non-patentable product; the result was widespread public outcry, which was echoed throughout the developing world. Legal action by the Indian government followed, with the patent eventually being overturned in 2005. Importantly, the pharmaceutical company involved in the Neem case argued that as traditional Indian knowledge of the properties of the Neem tree had never been published in an academic journal, such knowledge did not amount to "prior art" which is the term used when previously existing knowledge bars a patent because that knowledge is in the public domain.

In response to biopiracy threats such as this, India has been translating and publishing ancient manuscripts, containing old remedies in electronic form. The texts are being recorded from Sanskrit, Urdu, Persian and Arabic; they will be made available to patent offices in English, German, French, Japanese and Spanish in 2006. The aim is to protect India's heritage from being exploited by foreign companies since this voluntary disclosure is also prior and that has been criticised by a spokesman for the pharmaceutical industry as "a solution in search of a problem", which is a word play on the clarification of a patent as a technical solution to a protection in any field of human activity.

A large selection of African biopiracy cases are discussed at http://www.ghnaweb.com/public_agenda/article.php?ID=5062, including the following:

The following is a selection of 11 cases from the 36 cases in the Edmonds Institute anecdotal report on biopiracy in Africa:

- Diabetes Drug produced by a microbe from Kenya: *Acarbose* is a drug taken by Type II diabetics. The German company Bayer filed a

patent on a new way to manufacture the product. According to the 1995 application, an *actinoplanes sp. Bacteria* strain called SE50 has unique genes enabling the biosynthesis of acarbose in fermentors and the strain comes from Kenya's Lake Ruiru. The author found no evidence of benefit sharing this valuable microbe.

- Drug addiction treatment from *Iboga* plant that has long been used in Central and West Africa. In low dose, it serves as a stimulant to maintain alertness, for example, while hunting. In larger dose, it is a hallucinogen, traditionally used for religious purposes. But in recent years, it has drawn the interest of drug addiction researchers as *Iboga* reportedly has the effect of ending cravings for addictive substances, such as heroin and nicotine. There is thus great interest in *Iboga* to cure some drug addictions. Numerous patents have been taken out on *Iboga*, but the author could not find any evidence of benefit-sharing related to *Iboga*.
- Multipurpose *Kombo* Butter derived from Central and West Africa: Kombo butter, an extract of the African nutmeg (*Pycnanthus angolensis*), has been used in Europe and North America since at least the 1970s, when it was identified as the source of cetyl myristoleate, a 'dietary supplement' used to treat arthritis. The plant is native to Central Africa. As a vegetable-derived fatty acid, it is suitable for personal care products and because it is of plant origin, it can be used in products that are *Kosher*, *Halal* and 'non-animal'. As a result, a wave of intellectual property claims is being made on *kombo* butter. Although African exporters are presumably being paid as suppliers of raw or semi-processed *kombo* butter, there was no evidence of any benefit-sharing agreement related to use of *Pycnanthus angolensis* as a genetic resource.
- The cancer fighting agent of Bitterleaf from Sub-Saharan Africa: A scientist at Jackson State University in the US obtained a US patent in 2005 on extracts of *Vernonia amygdalina*, an African medicinal plant called Bitterleaf which is native to most of Sub-Saharan Africa and is used in many countries. According to the patent, the extracts are effective against cancer. The inventor obtained samples in Benin City, Nigeria. Questions arise as to whether the invention is new and if benefits derived from its use will be shared.
- Infection-fighting mycobacteria from Uganda: A mycobacteria collected in Uganda in the 1970s has been patented at least five times

in the US. It covers use of a *Mycobacterium vaccae* called R877R, against chronic viral infections, including HIV. According to the patent, R877R patents and commercialization may be coming soon but there is no mention of benefit sharing.

Legal aspects of Biopiracy

Patent Law

A frequent legal misunderstanding with respect to biopiracy is the belief that pharmaceutical companies patent the plants they collect. It is not possible to patent a previously known living organism on any product of nature. Patents are instead typically taken out on specific chemicals isolated or developed from plants, often in combination with a stated and researched use of those chemicals.

Convention on biological diversity

In the context of the proposed consideration of traditional knowledge and genetic resources as an appropriate subject matter for TRIPS, it is relevant to mention that the Convention on Biological Diversity (CBD) came into force in 1993 and the Philippines signed the CBD on June 12, 1992 and ratified it on October 8, 1993. It is explicitly directed to the protection of traditional knowledge associated with biological resources. It confirmed that rights to control access to biological resources belong to the countries in which those resources were located. One objective of the CBD is to enable lesser-developed countries to better benefit from their resources and traditional knowledge. Under the rules of the CBD, bioprospectors are required to obtain informed consent to access such resources, and must share any benefits with the biodiversity-rich country. However, some critics believe that the CBD had failed to establish regulations to prevent biopiracy.

There are key issues regarding the manner and scope of protection for traditional knowledge associated with the biological resources. First, should these items be protected in traditional IP categories or should a separate category be recognized? Second, traditional knowledge is often the creation of a group of unknown persons who should receive the

payment and how should the price be determined? Third, what should the scope of protection encompass?

The Philippine IPRA

Some of the above key issues, however, have been addressed in the Indigenous Peoples' Rights Act, Republic Act No. 8371, which was enacted by the Philippines Congress on October 29, 1997.

SECTION 34. Right to Indigenous Knowledge Systems and Practices and to develop own Sciences and Technologies. – ICCs/IPs are entitled to the recognition of the full ownership and control and protection of their cultural and intellectual rights. They shall have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, including derivatives of these resources, traditional medicines and health practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, knowledge of the properties of fauna and flora, oral traditions, literature, designs, and visual performing arts.

SECTION 35. Access to Biological and Genetic Resources. – Access to biological and genetic resources and to indigenous knowledge related to the conservation, utilization and enhancement of these resources, shall be allowed within ancestral lands and domains of the ICCs/IPs only with a free and prior informed consent of such communities, obtained in accordance with customary laws of the concerned community.

The IPRA established the legal rule that it is the local communities who possess the traditional biomedical knowledge who should benefit from the commercial use of such knowledge. Ownership rights should be attributed to these communities in order to safeguard their interests.

An argument against this is that patent and copyright laws have long been understood as merely temporary legal mechanisms for allowing inventors to recoup some profits – enough to motivate them to make their discoveries in the first place. The ethical basis of intellectual property law is that knowledge is a public good over which a monopoly is only temporarily granted to any specific possessor of that knowledge. Patents and copyrights expire, and rightly so, so that everyone can eventually benefit. If one applied this thinking to the ownership rights of local

communities, their intellectual property rights would have long expired for the benefit of the rest of humanity.

Some writers have explored the issue whether the TRIPS Agreement adequately protects “traditional knowledge and culture,” a concept that covers a lot of ground ranging from knowledge that certain plants have benefits, to stories, songs, music, dance, carvings, designs, pottery, sculpture, mosaics, costumes and metal wares. Although the literature on the subject suggests that there is a consensus at the WIPO and the TRIPS Council that TRIPS should contain protection for traditional knowledge, concrete steps have been taken to implement that consensus because key issues remain unresolved: since traditional knowledge or folklore is the creation of a group of unknown persons, who should receive payment for the use of traditional knowledge, how should the price be determined, and what scope or protection should be extended to it?

To a certain extent, the Philippines Indigenous People’s Rights Act has afforded protection to traditional knowledge even in the absence of an international consensus on the matter.

Exploitation of genetic resources

Access to and exploitation of genetic resources without adequate compensation to holders of traditional knowledge is called “biopiracy.” The biotechnology, pharmaceutical and agriculture industries are dependent on worldwide access to genetic resources. These industries use wild plants and animals in three basic ways: One, natural species can be used directly as a source of natural chemicals or compounds for the production of drugs, or other products. An example is the use of the Pacific *yew* tree to produce an anti-cancer drug. Two, natural species chemicals can provide information and ideas that can lead to the production of useful synthetic chemicals, drugs or other products. Three, a natural species can be the source of a gene or genetic sequence that can be used to develop new varieties through breeding or a genetically modified organism through implantation. Since crops and animals are susceptible to disease and adverse climatic conditions, it is important to have access to natural gene pools (germ plasm) to develop more productive and disease-resistant plants and animals.

Near-universal coverage

In this context, the TRIPS Agreement made great strides toward requiring that patent protection be available universally, for all technologies. Patents must be available for any inventions, whether products or processes, in all fields of technology, that meet the three general substantive requirements for patent protection, novelty, inventive step and industrial applicability.⁸ The Agreement also repudiates requirements for patent protection based upon the place of invention or place of production.⁹ These requirements are intended to make patent protection independent of national boundaries.

Specific exceptions are few. They are generally confined to health care methods, living things larger than microorganisms, and biological breeding methods. Members may exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals¹⁰ other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbial processes.¹¹ Members, however, must provide plant variety protection, whether under patent laws or *sui generis* laws.¹²

The exceptions' careful language leaves little doubt that pharmaceuticals, medical devices, and modern biotechnological method for their production must be eligible for protection. By negative implication, the exception in Article 27.3 (b) requires coverage of pharmaceutical, whether produced by non-biological or microbial processes, so drugs produced by chemicals and bioengineering means must be covered. Moreover, there is no general exception for products of any kind-except for plants and animals other than micro-organisms.

⁸ Art. 27.1

⁹ Subject to enumerated exceptions, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. Agreement on Trade-Related Aspects of Intellectual Property Rights, Art 27.1.

The requirement for nondiscrimination as to place of invention required amendment of Section 104 of the United States' patent statute.

¹⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights, Art. 27.3(a) Annex 1C to Agreement Establishing the World Trade Organization reprinted in H R Doc. 316 103d Cong., 2d Sess 1621, 1633 (Sept 27, 1994)

¹¹ Art. 27.3(b), Annex 1C to Agreement Establishing the World Trade Organization, reprinted in H.R. Doc.316, 103d Cong., 2d Sess. 1621, 1634 (Sept 27, 1994)

¹² The Philippine has enacted a Plant Varieties Protection Act.

Under Article 27.1 of TRIPS, patents must be available for both products and processes in all fields of technology. Article 8.1 permits measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to socioeconomic and technological development but requires that such measures must be consistent with this Agreement. Plants, animals and essential biological processes may also be excluded from patentability but micro-organisms; microbiological processes are all patentable. This formulation assures that most biotechnological, pharmaceutical and agricultural biotechnical inventions, genetically modified micro-organisms, microbiological processes, and non-biological processes are patentable. Although naturally occurring plants and animals are not patentable, genetically modified micro-organisms, animal genes, human DNA sequences, human proteins, and human genes have all been patented in the United States and Europe.¹³ Although transgenic animals such as the "Harvard mouse",¹⁴ an experimental animal developed for the study of breast cancer, would not be patentable under the TRIPS Agreement, the transgenic process by which such animals are developed would be, either as a microbiological or non-biological process.

Exclusive Rights

Article 28 of the TRIPS Agreement specifies the minimum level of exclusive rights that a patentee must have. A product patentee must have the right to prevent others, without authorization, from making, using, offering for sale, selling, or importing the patented product for the same purposes.¹⁵ A process patentee must also have the right to prevent others, without authorization, from using the process and from using, offering for

¹³ *Diamond vs. Chakrabarty*, 47 US 303 (1980)

¹⁴ Genetically altered animals such as a transgenic mouse with cancer-sensitive characteristics are patentable under US law.

¹⁵ Art. 28 (a), Annex 1C to Agreement Establishing the World Trade Organization, reprinted in H.R. Doc.316, 103d Cong.2d Sess.1621, 1634 (Sept.27, 1994) (Footnote omitted.) While the drafting is rather opaque, the words for these purposes appear to modify importing and to refer to sale or offering for sale. So construed, they would permit importation for personal use, study or research, but not for commercial purposes. The words cannot refer to making because an item is not usually remade, and the word making by itself would cover using an imported machine to manufacture new items in any event. Finally, they cannot also refer to using; if they did, they would be superfluous, because then all relevant acts after importation they would prohibit, including sale and offering for sale.

sale, selling, or importing for these purposes at least the product obtained directly by that process.¹⁶ In either case the rights must be capable of assignment, transfer by succession, and transfer by licensing.¹⁷

Four points regarding these minimum rights of exclusion are worth making. First, although they are based on the fundamental trilogy of making, using, and selling, they include two newer rights that may be less familiar to some practitioners. These are the rights of offering for sale and importation. The latter right, among other things, supports the use of border-enforcement measures, which the TRIPS Agreement also requires. Second, like the exclusive rights in the IP Code, the rights in the TRIPS Agreement are expressed in terms of the right to exclude others.¹⁸ They thus reflect the basic rule that a patent, by itself, provides no right to practice the patented invention, which may, for example, be dominated by a more fundamental patent held by another. Third, a process patent must confer exclusive rights at least with respect to products made directly by the patented process.¹⁹

Finally, it is worth noting that the exclusive rights of use, sale, offering for sale and importation are subject to exhaustion at each Member's discretion, as long as the basic principles of national treatment and most-favored-nation treatment are honored. Since the TRIPS Agreement does not impose any particular requirements with respect to exhaustion of intellectual property, each member is free to provide that the first authorized sale of a patent-protected article exhausts these rights with respect to that article-but not other rights, and not the same rights with respect to other articles.

¹⁶ Art. 28:1(b) Annex 1C to Agreement Establishing the World Trade Organization, reprinted in H.R. Doc.316, 103d Cong.2d Sess.1621, 1634 (Sept.27, 1994). Again, the words for these purposes appear to modify importing and to refer only to offering for sale or selling.

¹⁷ Art.28: 2 Annex 1C to Agreement Establishing the World Trade Organization, reprinted in H.R. Doc.316, 103d Cong.2d Sess.1621, 1634 (Sept.27, 1994).

¹⁸ Art. 28 (a), (b), Annex 1C to Agreement Establishing the World Trade Organization, reprinted in H.R. Doc.316, 103d Cong.2d Sess.1621, 1634 (Sept.27, 1994). (patent shall confer on its owner... [the right] to prevent third parties not having the owner's consent from taking specified acts).

¹⁹ See Agreement on Trade Related Aspects of Intellectual Property Rights, Art. 28:1 (b), Annex 1C to Agreement Establishing the World Trade Organization, reprinted in H.R. Doc.316, 103d Cong.2d Sess.1621, 1634 (Sept.27, 1994) quoted in the text at N.70 *supra*

Exhaustion or First-Sale Doctrine

There is a doctrine in intellectual property law called the doctrine of exhaustion of IP rights, or in US law the doctrine of first sale.

The doctrine of exhaustion of rights has long been a familiar one in copyright law and has been extended by the TRIPS Agreement to patented inventions, whether they are products or process. Under this doctrine in copyright law as classified by the U.S. Supreme Court in *Bobbs-Merill vs. Strauss*,²⁰ since the distribution right of the author is limited to the "first public distribution," the purchaser of a book, once sold by authority of the owner of the copyright, may sell it again, although he could not publish a new edition of it. The copyright owner's distribution right is therefore exhausted by the first authorized sale of the original or copies of the work. The owner of the lawfully acquired original or copies of the work may then dispose of the original or copies in any manner by sale, donation or destruction without any liability to the copyright proprietor. But the copyright author has in this situation only exhausted his right of first public distribution of his works; he does not exhaust his remaining exclusive rights under Section 177 of the IP code.

Unfortunately, the TRIPS Agreement does not define the issue of exhaustion to which Article 6 relates. The term generally refers to doctrines that extinguish certain exclusive rights of the holder of intellectual property with respect to a particular physical item embodying the intellectual property after the item has first been sold under the holder's authority.

The doctrine of exhaustion of rights or first sale intersects with the right of importation, which the TRIPS Agreement recognized in favor of a patent holder. Article 6 of the TRIPS Agreement explicitly disclaims an intention to impose any particular requirements regarding the issue of the exhaustion of intellectual property rights.²¹ As a result, Members of the WTO are free to implement exhaustion of intellectual property rights as they please. This means that each member country may adopt a rule of international, regional or national exhaustion.

In an international exhaustion regime, the first sale by the patent owner of a patented product such as pharmaceutical products anywhere in

²⁰ 210 US 339 (1908)

²¹ Article 6, TRIPS Agreement.

the world exhausts the patent holder's right of importation so that the patented products may be sold in or exported to any other country in the world without violating the patent holder's exclusive right to sell the product. In a regime of regional exhaustion, as for example in the European Union, the first sale of the patented product in any member of the Union exhausts the patent holder's right of importation in the other members of the union and he may not prevent the trading of his patented product in the other member's territories. In a national exhaustion regime, once the patented product is sold in one country by the patent holder, the product may be traded and sold only in that country without any further restriction but the patent holder retains his right of importation in other countries where the product has not yet been made available.

Although the TRIPS Agreement does not define the doctrine, it limits it by implication. Footnote 6 to Article 28: 1(a), which prescribes patentee's exclusive rights, implies that only rights... in respect of the use, sale, importation or other distribution of goods can be exhausted. It thus reflects a principle well-established in the laws of the United States: those exclusive rights to make or reproduce protected property, or to publicly perform copyrighted works, are not exhausted by the sale of any particular item embodying the intellectual property.

In a legal regime intended to encourage worldwide trade, it would seem incongruous to create an exclusive right of importation by patent holders since the more these products are traded without any restriction, the better is the financial gain for the patent holder. The exclusive right of importation by the patent holder in this situation therefore serves as a restriction on what otherwise would be lawful trade in patented products, which are in any case lawful products, manufactured by the patent holder.

Public Health

This is why a favorite argument against TRIPS is that it blocks developing country access to medicine. However, it has been pointed out that the TRIPS Agreement provides global patentability, which is part of the solution because it gives private pharmaceutical companies an incentive to develop medicines for diseases in topical and other developing areas.

At the 2001 WTO Ministerial conference in Doha, the Declaration on the TRIPS Agreement and Public Health addressed this issue among developing countries in the following ways:

1. It affirmed the TRIPS Agreement and the importance of IP protection for development of new medicines.
2. It agreed that the TRIPS Agreement does not and should not prevent Members from taking action to protect public health.
3. It recognized the freedom of Members to grant compulsory licenses and determine the grounds for such licenses.
4. It affirmed that each Member has the right to determine what disease conditions constitute a national emergency under TRIPS Article 31(b).
5. It reaffirmed TRIPS Article 6, which allows each member to establish a regime for exhaustion of IP rights "without challenge."
6. It recognized that some developing nations cannot use compulsory licensing effectively and called on the TRIPS Council to find an expeditious solution to this problem.
7. It agreed that least developed countries will not be obliged to comply with the patent and trade secret part of TRIPS until 2016 at the earliest.

Since the Philippines is a member of GATT-TRIPS Agreement, it had to recognize the exclusive right of importation of patent holders.

SECTION 71. Rights Conferred by Patent. – 71.1. A patent shall confer on its owner the following exclusive rights:

- (a) Where the subject matter of a patent is a product, to restrain, prohibit and prevent any unauthorized person or entity from making, using, offering for sale, selling or importing that product;
- (b) Where the subject matter of a patent is a process, to restrain, prevent or prohibit any unauthorized person or entity from using the process, and from manufacturing, dealing in, using, selling or offering for sale, or importing any product obtained directly or indirectly from such process.

71.2. Patent owners shall also have the right to assign, or transfer by succession the patent, and to conclude licensing contracts for the same. (Sec.37, R.A. No. 165a)

SECTION 72. Limitations of patent rights. - The **owner of a patent** has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances:

72.1. Using a patented product which has been put on the market in the Philippines by **the owner of the product, or with his express consent**, insofar as such use is performed after that product has been so put on the said market;

Section 72 speaks of the owner of the patent, while Section 72.1 speaks of the owner of the product who put the patented product on the market in the Philippines. While the owner of the patent has the exclusive right of importation under this provision, it is clear that after the owner of the product - who presumably may have purchased the patented product elsewhere - does not infringe the patent if he subsequently resells the product in the Philippines. This provision suggests that we have adopted the rule of international exhaustion so that patented products, over which the patent holder has exhausted his right by reason of sale anywhere in the world, may be lawfully sold and traded in the Philippines without infringing the patent holder's right of exclusive importation.

Roxas Bill on Patent Liberalization

A patentable invention is defined as "any technical solution of a problem in any field of human activity which is new, involves an inventive step and is industrially applicable. It may be, or may relate to, a product, a process, or an improvement of any of the foregoing."

The proposed amendment to this definition in Sec.21 of the Intellectual Property Code ("IP Code") seeks to clarify the exclusions of patentable extensions to "new use, molecule or compound" of a patented invention.

This proposed amendment is consistent with jurisprudence defining a patented invention. For example, as to the exclusion of "new use", it has been held that a new application of an old device may not be patented if the result claimed as new is the same in character as the

original result, even though the new result had not before been contemplated.²² As to a molecule or compound of a patented invention, jurisprudence describing the patentability of a combination of a patented invention, jurisprudence describing the patentability of a combination of the elements of a machine may be applied. In this regard, it has been held that the mere combination of a number of old parts or elements which, in combination, perform or produce no new or different function or operation than that theretofore performed or produced by them, is not patentable invention.²³ As to new use from the combination, it has likewise been held that the combination of elements may result in an effect greater than the sum of several effects taken separately. Where no such synergistic result was achieved, the fact that the combination filled a long felt want and has enjoyed commercial success will not justify patentability.²⁴

The reference to "new use" is intended to cover so-called Swiss claims, which covers a new use or activity of a known pharmaceutical substance. Even if that substance is known, that knowledge does not prevent the compound from being regarded as new, if the use of that substance or composition in any such method does not form part of the state of the art. In other words, it is possible to patent a known chemical compound as a pharmaceutical provided that it has not been previously known to have any pharmaceutical activity.²⁵

International Exhaustion

The proposed amendment of Section 72.1 of the IP Code under the Roxas Bill seeks to adopt the matter of "international exhaustion" as it relates to drugs and medicine. Under the amendment, one who has obtained a drug or medicine subject to a patent can use the product in the Philippines as long as the patent owner has put the product in the market - or exhausted the product - anywhere in the world.

The Doha Declaration allows States the discretion to use the principle of exhaustion for the protection of public health. The discretion

²² Cuno Engineering Corp. v. Automatic Devices Corp., 314 US 84, 10 November 1941.

²³ Lincoln Engineering Co. v. Stewart-Warner, 303 US 545, 28 March 1938, cited in Amador, Patents under the Intellectual Property Code 44, 2001.

²⁴ Anderson's- Black Rock, Inc. v. Pavement Salvage Co., Inc., 396 US 57, 8 December 1969.

²⁵ www.steporgkatharak, 2nd_pharmaceutica_usc.doc, accessed on November 6, 2005

is broadly given, such that the term "public health" is not limited to pharmaceuticals, but could involve other health-related patents.²⁶

The right to use the product is consistent with the principle that the patent right is separate from the product that embodies the right. A buyer of the product can therefore obtain title to the product without owning the patent to the product. The proposed language appears to be based on Section 72.1 of the IP Code, which provides that it is not considered patent infringement to use "a patented product which has been put on the market in the Philippines by the owner of the product or with his express consent, insofar as such use is performed after that product has been so put in the said market."

However, the proposed amendment, as with the present law, leaves unclear the rights of third persons to use a patented product upon the exhaustion by a patent owner of his right to import the patented product.

Although the term "use" is a right enumerated separately from manufacture, sale, or importation, the term "use" as a principle of exhaustion under TRIPS relates to "consumption" of the product.²⁷ But since the patent holder has other exclusive rights aside from "use," including the exclusive right to "make, sell, offer for sale or import" the patented product, a regime of exhaustion that rights only to the right to "use" means that the buyer of the patented product has the right to "condone" only, but does not have the right to sell, offer for sale and much less import the patented product.

This result is in sharp context with Section 72.1 of the IP Code. Under this provision, once a patent owner has put the product on the Philippine market, a third person who may have purchased the products elsewhere may import the products into the Philippines. Here, the purchaser of the product also has the legitimate right of use of the product in the Philippines.

The principle of international exhaustion proposed to be adopted by the Bill is not necessarily prejudicial in economic terms to the patent owner. The reason is that the patent owner is not deprived of the right to continue to market the patented product in the market at the instance of the patent owner. He only loses the right of exclusive importation and sale of

²⁶ *Id.*

²⁷ *Id.* at 98

his product but clearly will benefit financially from sale of his product in a broader economic market.

Bolar Exception

The proposed amendments to Sections 72.3 and 72.4 relate to the introduction of the "Bolar exception" - sometimes called the "early working exception" - that was first introduced in 1984 by the U.S. Drug Price Competition and Patent Term Restoration Act.²⁸

Under the proposed amendment, a person would be allowed to make or use a patented product without the consent of the owner if it is used exclusively for experimental purposes "including commercial purposes" that "do not unreasonably conflict with a normal exploitation of the patent..." However, to include "commercial purposes" under this exception would cause undue confusion as to the extent of that commercial purpose.

The Bolar exception was upheld by a WTO dispute ruling adopted on 7 April 2000.²⁹ The purpose of the Bolar exception was to allow the introduction of generic drugs to enter the market as soon as a patent expires. But it should not be used as a justification for the "commercial exploitation" of the patented product during the last year of the letter's patent since this would clearly be an actionable infringement. The amendment should only allow early experimentation by generic manufacturers with the patent to allow the public the benefit of a generic equivalent of the patented product as soon as the letter patent expires.

To assist with the immediate distribution of generic drugs, manufacturers are allowed to begin with the process of obtaining government approvals for production as well as marketing of the product. To lessen the time for development of much needed generic drugs, manufacturers and marketers were allowed a reasonable time to begin with such experimentation and approvals before the patent expired. The WTO dispute panel upheld this exception as within the right of WTO members under the TRIPS Agreement under Article 30 thereof to "provide limited exceptions to the exclusive rights conferred by a patent" that does not unreasonably conflict with the normal exploitation of the patent..."

²⁸ 35 USC 271(e)(1)

²⁹ Canada - Patent Protection for Pharmaceutical Products, WTDS114R[Canada Panel Decision]; see also WTO OMC Fact Sheet, September 2003.

The concept of "commercial exploitation" within the Bolar exception, however, contemplates regulations of countries like the United States that require production runs of the product on a commercial scale.³⁰ Wherever this is required by government as a condition for approval, what would otherwise be deemed commercial activity or exploitation would be allowed. It was Canada's submission that even if this requirement was not present in Canada, it could be required if other Territories imposed such a requirement.

Compulsory Licensing

Article 31 of the TRIPS Agreement provides the conditions that must be observed when a Member provides for the mechanism of compulsory licensing.³¹ As long as these conditions are met, a Member

³⁰ Canada panel Decision 147 (Position paper of Canada).

³¹ Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) Authorization of such use shall be considered on its individual merits;
- (b) Such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) The scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) Such use shall be non-exclusive;
- (e) Such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) Authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The

satisfies its treaty obligations. In the Philippines, these conditions are sufficiently addressed in Sections 95-97, and 100-102 of the IP Code.

Article 31 of the TRIPS Agreement provides the conditions that must be observed when a Member provides for the mechanism of compulsory licensing.³² We have implemented our compulsory licensing regime in Sections 93 to 102 of our IP Code. We have observed the TRIPS conditions by providing for (i) allowing the filing of petitions for compulsory license only after the petitioner has made efforts to obtain authorization from the patent owner on reasonable commercial terms but failed to obtain it (ii) when granted, the scope and duration of the license shall be limited to the purpose for which it was authorized; the license shall be non-exclusive; (iii) the license shall be non-assignable and (iv) such use of shall be authorized predominantly for the supply of the domestic market, (v) the license may be terminated upon proper showing that the

competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances.

³² Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provision shall be respected:

- a) authorization of such use shall be considered on its individual merits;
- b) such use may only be permitted if, prior to such use, the propose user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be use by or for the government, the right holder shall be informed promptly;
- c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- d) such use shall be non-exclusive;
- e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- f) any such use shall be authorized predominantly to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances.

corrections which led to its grant have ceased to exist and are unlikely to recur; and (vi) the license shall be paid adequate remuneration taking into account the grant or authorization.

The proposed amendment to the IP Code under the Roxas Bill only seeks to amend the procedure for the grant of compulsory licenses to the government. Congress would be deemed to have merely designated the administrative agency to determine the public health emergency, grant the license, supervise the use of the license, including the venue for disputes arising from such determination, grant or supervision.

Under the proposed Bill, the Philippine Government may import drugs or medicine manufactured or sold through a compulsory license granted abroad. In fact, members have waived condition 31(f) of the TRIPS Agreement so that persons in possession of compulsory licenses need not limit distribution within the territory of the licensor.³³

Compulsory Licensing Under TRIPS and the IP Code

However, it should be mentioned here that the TRIPS Council has already liberalized the rules on compulsory licensing. It used to be that under Article 31(f) of TRIPS Agreement production under compulsory licensing must be predominantly for the domestic market. This effectively limited the ability of countries that cannot make pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are patented. Although governments can issue compulsory licenses to allow local companies to make a patented product or use a patented process under license without the consent of the patent owner, we have seen that this can be accomplished only under certain conditions aimed at safeguarding the legitimate interests of the patent holder.

In the main Doha Ministerial Declaration of 14 November 2001, ministers recognized that it is important to implement and interpret the TRIPS Agreement in a way that supports public health -- by promoting both access to existing medicines and the creation of new medicines. They therefore adopted a separate declaration on TRIPS and Public Health. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.

³³ Decision of the WTO General Council of 30 August 2003.

Article 31(f) of the TRIPS Agreement says products made under compulsory licensing must be "predominantly for the supply of the domestic market". This applies directly to countries that can manufacture drugs -- it limits the amount they can export when the drug is made under compulsory license. And it has an indirect impact on countries unable to make medicines and therefore wanting to import generics. They would find it difficult to find countries that can supply them with drugs made under compulsory licensing.

An agreement on 30 August 2003 allows any member country to export pharmaceutical products made under compulsory licenses within the terms set out in the decision (text below). All WTO member countries are eligible to import under this decision, but 23 developed countries are listed in the decision as announcing voluntarily that they use the system to import.

Geographical indication

Article 22 of the TRIPS Agreement requires the protection of geographical indications.

A **geographical indication** (sometimes abbreviated to *GI*) is a name or sign used on certain products or which corresponds to a specific geographical location or origin (e.g. a town, region, or country). The use of a GI may act as a certification that the product possesses certain qualities, or enjoys a certain reputation, due to its geographical origin.

In many countries the protection afforded to geographical indications by law is similar to the protection afforded to trademarks, and in particular, certification marks. Geographical indications law restricts the use of the GI for the purpose of identifying a particular type of product, unless the product or its constituent materials originate from a particular area and/or meet certain quality tests that are administered by an association that owns the exclusive right to the use of the indication. Although a GI is not strictly a type of trademark as it does not serve to exclusively identify a specific commercial enterprise, there are usually prohibitions against registration of a trademark which constitutes a geographical indication. In countries that do not specifically recognize GIs, regional trade associations may implement them in terms of certification marks.

Geographical indications are particularly important in Europe, where there has been a long tradition of associating certain food products with particular regions.

The consumer-benefit purpose of the monopoly rights granted to the owner of the GI also applies to the trademark monopoly right. Geographical indications have other similarities with trademarks. For example, they must be registered in order to qualify for protection. And they must meet certain conditions in order to qualify for registration. One of the most important conditions that most governments have required before registering a name as a GI is that the name must not already be in widespread use as the generic name for a similar product. Of course, what is considered a very specific term for a well-known local specialty in one country may constitute a generic term or genericized trademark for that type of product. For example, *parmigiano* cheese in Italy is generically known as *parmesan* cheese in Australia and the United States.

Like trademarks, geographical indications are regulated locally by each country because conditions of registration such as differences in the generic use of terms vary from country to country.

Provisions of TRIPS

In 1994, when negotiations on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") were concluded, governments of all WTO member countries (148 countries as of September 2003) had agreed to certain basic standards for the protection of GIs in all member countries. There are, in effect, two basic obligations on the WTO member governments relating to GIs in the TRIPS Agreement:

1. **Article 22 of the TRIPS Agreement** says that all governments must provide legal opportunities in their own laws for the owner of a GI registered in that country to prevent the use of marks that mislead the public as to the geographical origin of the goods. This includes prevention of use of geographical name which, although literally true, "falsely represents" that the product comes from somewhere else. Article 22 of TRIPS also says that governments may refuse to register a trademark or may invalidate an existing trademark (if their legislation permits or at the request of another government) if it misleads the public as to the true origin of the goods.

2. **Article 23 of the TRIPS Agreement** says that all government must provide the owners of GI the right, under their laws, to prevent the use of a geographical indication identifying wines not originating in the place indicated by the geographical indication. This applies *even where the public is not being misled*, where there is no unfair competition and where the true origin of the goods is indicated or the geographical indication is accompanied by expressions such as "kind", "type", "style", "imitation" or the like. Similar protection must be given to geographical indications identifying spirits. Article 23 says governments may refuse to register or may invalidate a trademark that conflicts with a wine or spirits GI whether the trademark misleads or not.
3. **Article 24 of TRIPS** provides a number of exceptions to the protection of geographical indications that are particularly relevant for geographical indications for wines and spirits (Article 23). For example, Members are not obliged to bring a geographical indication under protection where it has become a generic term for describing the product in question. Measures to implement these provisions should not prejudice trademark rights that have been acquired in good faith; and, under certain circumstances -- including long-established use -- continued use of a geographical indication for wines or spirits may be allowed on a scale and nature as before.

In the Doha Development Round of WTO negotiations, launched 1 December 2002, WTO member governments have begun negotiating on the creation of a 'multilateral register' of geographical indications.

Two issues are debated under the Doha mandate, both related in different ways to the higher (Article 23) level of protection: creating a multilateral register for wines and spirits. The governments that want to negotiate the inclusion of GIs on products other than wines and spirits under Article 23 of TRIPS argue that extending Article 23 will increase the protection of these marks in international trade. This is opposed by other governments including the United States and the Philippines who question the need to extend the stronger protection of Article 23 to other products. They are concerned that Article 23 protection is greater than required, in most cases, to deliver the consumer benefit that is the fundamental GI laws. Both are as contentious as any other subject on the Doha agenda. Although they are discussed separately, some delegations see a relation between the two.

Three sets of proposals have been submitted over the years, representing the two mainlines of argument in the negotiations and some proposed compromises. The latest are (documents downloadable from Documents Online <http://docsonline.wto.org> on the WTO website):

- The EU's detailed proposal (TN IP/W/11) circulated in June 2005 calls for the TRIPS Agreement to be amended (by adding an annex to Article 23.4).

The paper proposes that when a geographical indication is registered, this would establish a "rebuttable presumption" that the term is to be protected in other WTO members -- except in a country that has lodged a reservation within a specified period (for example, 18 months). A reservation would have to be on permitted grounds. These include when a term has become generic or when it does not fit the definition of a geographical indication. If it does not make a reservation, a country would not be able to refuse protection on these grounds after the term has been registered.

- A "joint proposal", document TN/IP/W/10, has been put forward by Argentina, Australia, Canada, Chile, Costa Rica, Dominican Republic, Ecuador, El Salvador, Honduras, Japan, Mexico, New Zealand, Chinese Taipei and the US.

This group does not want to amend the TRIPS Agreement. Instead, it proposes a decision by the TRIPS Council to set up a voluntary system where notified geographical indications would be registered in a database. Those governments choosing to participate in the system would have to consult the database when taking decisions on protection in their own countries. Non-participating members would be "encouraged" but "not obliged" to consult the database.

- Hong Kong, China has proposed a compromise (document TN/IP/W/8). Here, a registered term would enjoy a more limited "presumption" than under the EU proposal, and only in those countries choosing to participate in the system.

These three proposals have been laid out side by side so that they can be compared easily, in a Secretariat paper (document TN/IP/W/12 of 14 September 2005). An earlier compilation is in document TN/IP/W/7/Rev.1, dated 23 May 2003 (with a correction, TN/IP/W/7/Rev.1/Corr.1 dated 20 June 2003). All of these are available on Documents Online <http://docsonline.wto.org>.

At the heart of the debate are a number of key questions. When a geographical indication is registered in the system, what legal effect, if any, would that need have within member countries, if the register is to serve the purpose of "facilitating protection" (the phrase used in Article 23.4)? And to what extent, if at all, should the effect apply to countries choosing not to participate in the system? There is also the question of the administrative and financial costs for individual governments and whether they outweigh the possible benefits.

The IP Code does not explicitly refer to the registrability of a "geographical indication." However, Section 123.1(g), precludes the registration of a mark if it is likely to mislead the public, particularly as to the geographical origin of the goods or services. Similarly, Section 123.1(j) precludes the registration of a mark that consists exclusively of signs or of indications that may serve in trade to designate geographical origin of the goods or services. Under Section 169.1 (b) misrepresentation regarding geographic origin of his or her or another person's goods, services, or commercial activities subjects the trader to a civil action for damages and injunction provided in Sections 156 and 157 of the IP Code Act by any person who believes that he or she is or is likely to be damaged by such act. Although there is no explicit provision allowing the registration of geographical indications, it is reasonable to maintain in prohibiting the registration of a mark that is likely to mislead the public, particularly as to the geographical origin of the goods or services, the IP Code impliedly allows that marks that serve to accurately designate the geographical origin of products or services as well as their quality due to their origin may be registrable in the register.