DOWNLOAD PDF INTELLECTUAL PROPERTY RIGHTS, THE WTO, AND DEVELOPING COUNTRIES

Chapter 1 : Intellectual Property Rights in the WTO and Developing Countries - Jayashree Watal - Google

This book cuts through the daunting technicalities of one of the most important of the WTO (World Trade Organization) agreements, that dealing with Intellectual Property Rights (hitherto primarily the preserve of national patent legislation) and their treatment as internationally tradeable commodities.

Please help improve this article by adding citations to reliable sources. Unsourced material may be challenged and removed. Its inclusion was the culmination of a program of intense lobbying by the United States , supported by the European Union , Japan and other developed nations. Campaigns of unilateral economic encouragement under the Generalized System of Preferences and coercion under Section of the Trade Act played an important role in defeating competing policy positions that were favored by developing countries like Brazil, but also including Thailand, India and Caribbean Basin states. In turn, the United States strategy of linking trade policy to intellectual property standards can be traced back to the entrepreneurship of senior management at Pfizer in the early s, who mobilized corporations in the United States and made maximizing intellectual property privileges the number one priority of trade policy in the United States Braithwaite and Drahos, , Chapter 7. For this reason, TRIPS is the most important multilateral instrument for the globalization of intellectual property laws. States like Russia and China [4] that were very unlikely to join the Berne Convention have found the prospect of WTO membership a powerful enticement. Furthermore, unlike other agreements on intellectual property, TRIPS has a powerful enforcement mechanism. Copyright terms must extend at least 50 years, unless based on the life of the author. National exceptions to copyright such as " fair use " in the United States are constrained by the Berne three-step test Patents must be granted for "inventions" in all "fields of technology" provided they meet all other patentability requirements although exceptions for certain public interests are allowed Art. Exceptions to exclusive rights must be limited, provided that a normal exploitation of the work Art. No unreasonable prejudice to the legitimate interests of the right holders of computer programs and patents is allowed. In each state, intellectual property laws may not offer any benefits to local citizens which are not available to citizens of other TRIPS signatories under the principle of national treatment with certain limited exceptions, Art. It is the case of the protection of software and database. Article 10 of the treaty stipulates: Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention Compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself. Despite the role that patents have played in maintaining higher drug costs for public health programs across Africa, this controversy has not led to a revision of TRIPS. Instead, an interpretive statement, the Doha Declaration , was issued in November , which indicated that TRIPS should not prevent states from dealing with public health crises. After Doha, PhRMA , the United States and to a lesser extent other developed nations began working to minimize the effect of the declaration. In , the Bush administration also changed its position, concluding that generic treatments might in fact be a component of an effective strategy to combat HIV. Software and business method patents[edit] Main article: According to article 10 of the TRIPS Agreement the appropriate instrument to protect software protection is author right. Implementation in developing countries[edit] The obligations under TRIPS apply equally to all member states, however developing countries were allowed extra time to implement the applicable changes to their national laws, in two tiers of transition according to their level of development. The transition period for developing countries expired in The transition period for least developed countries to implement TRIPS was extended to , and until 1 January for pharmaceutical patents, with the possibility of further extension. A report by the WHO found that many developing countries have not incorporated TRIPS flexibilities compulsory licensing, parallel importation, limits on data protection, use of broad research and other exceptions to patentability, etc. Post-TRIPS expansion[edit] In addition to the

baseline intellectual property standards created by the TRIPS agreement, many nations have engaged in bilateral agreements to adopt a higher standard of protection. The creation of anti-circumvention laws to protect Digital Rights Management systems. More stringent restrictions on compulsory licenses for patents. More aggressive patent enforcement. This effort has been observed more broadly in proposals for WIPO and European Union rules on intellectual property enforcement. The campaign for the creation of a WIPO Broadcasting Treaty that would give broadcasters and possibly webcasters exclusive rights over the copies of works they have distributed. Panel reports[edit] According to WTO 10th Anniversary, Highlights of the first decade, Annual Report page , [19] in the first ten years, 25 complaints have been lodged leading to the panel reports and appellate body reports on TRIPS listed below. Statements by the World Bank indicate that TRIPS has not led to a demonstrable acceleration of investment to low-income countries, though it may have done so for middle-income countries. In particular, the illegality of pre-clinical trials or submission of samples for approval until a patent expires have been blamed for driving the growth of a few multinationals, rather than developing country producers. Daniele Archibugi and Andrea Filippetti [32] argue that the importance of TRIPS in the process of generation and diffusion of knowledge and innovation has been overestimated by its supporters. This point has been supported by United Nations findings indicating many countries with weak protection routinely benefit from strong levels of foreign direct investment FDI. The Doha Declaration affirmed that the TRIPS agreement should not prevent members from taking measures necessary to protect public health. The United States Free Trade Agreements with Australia, Morocco and Bahrain have extended patentability by requiring patents be available for new uses of known products.

Chapter 2 : The WTO, Intellectual Property Rights, and the Access to Medicines Controversy - www.nxgvis

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), negotiated during the Uruguay Round, introduced intellectual property rules into the multilateral trading system for the first time.

The highest decision-making body of the WTO, the Ministerial Conference , usually meets every two years. The Ministerial Conference can take decisions on all matters under any of the multilateral trade agreements. Some meetings, such as the inaugural ministerial conference in Singapore and the Cancun conference in [37] involved arguments between developed and developing economies referred to as the " Singapore issues " such as agricultural subsidies ; while others such as the Seattle conference in provoked large demonstrations. The decision was taken by consensus at the General Council meeting on 26 July and marks the first time a Ministerial Conference is to be organized in Central Asia. As a result, there have been an increasing number of bilateral free trade agreements between governments. It oversees the implementation, administration and operation of the covered agreements. The WTO shall provide the forum for negotiations among its members concerning their multilateral trade relations in matters dealt with under the Agreement in the Annexes to this Agreement. As the trade volume increases, issues such as protectionism, trade barriers, subsidies, violation of intellectual property arise due to the differences in the trading rules of every nation. The World Trade Organization serves as the mediator between the nations when such problems arise. The WTO is also a centre of economic research and analysis: That is, it is concerned with setting the rules of the trade policy games. It has two major components: Both are embedded in the main WTO rules on goods, services, and intellectual property, but their precise scope and nature differ across these areas. It reflects both a desire to limit the scope of free-riding that may arise because of the MFN rule, and a desire to obtain better access to foreign markets. A related point is that for a nation to negotiate, it is necessary that the gain from doing so be greater than the gain available from unilateral liberalization; reciprocal concessions intend to ensure that such gains will materialise. The tariff commitments made by WTO members in a multilateral trade negotiation and on accession are enumerated in a schedule list of concessions. These schedules establish "ceiling bindings": If satisfaction is not obtained, the complaining country may invoke the WTO dispute settlement procedures. The WTO members are required to publish their trade regulations, to maintain institutions allowing for the review of administrative decisions affecting trade, to respond to requests for information by other members, and to notify changes in trade policies to the WTO. These internal transparency requirements are supplemented and facilitated by periodic country-specific reports trade policy reviews through the Trade Policy Review Mechanism TPRM. In specific circumstances, governments are able to restrict trade.

Chapter 3 : TRIPS and its impact on developing countries

Fatoumata Jawara and Aileen Kwa The economic prospects of developing and developed countries alike are being shaped by the policies of the World Trade Organization (WTO) on trade, services, investment and intellectual property rights.

The agreement requires all WTO member states to establish minimum standards of legal protection and enforcement for a number of different forms of intellectual property rights IPRs. Many developing countries hold that the TRIPS agreement â€" which came into force in â€" is unbalanced in that it favours developed countries and transnational corporations, and at the same time is unhelpful or even harmful to their own interests. In addition, concerns have been raised about the moves to ensure that developing countries accept higher standards of intellectual property protection than the WTO requires, even before they have determined how best to implement the TRIPS agreement in ways that support economic development and poverty alleviation. Non-governmental organisations have criticised TRIPS on the grounds that it imposes various costs on developing countries â€" such as more expensive drugs, agricultural inputs and foreign-owned technologies â€" without producing sufficient longer-term gains in areas like trade and investment. Developed countries tend to counter that strong IPR protection will attract investment to developing countries and stimulate local innovation and creativity. The development of TRIPS The rights covered by TRIPS include copyright and related rights; trademarks; geographical indications; industrial designs; patents; layout-designs of integrated circuits; protection of undisclosed information trade secrets ; and control of anti-competitive practices in contractual licences. The standards of protection and enforcement required of WTO member states are very high, in that they are essentially those that developed countries themselves have only recently reached. In that sense, TRIPS marks a coming together of three trends in international IPR law whose beginnings date back to the end of the nineteenth century but that have become especially apparent in the last two decades. Common examples of the latter, some of which are required by TRIPS, include the extension of copyright protection to computer programs, which are now treated as literary works, and the application of patent protection to plants, animals, micro-organisms, DNA sequences, and pharmaceuticals. In many countries drugs had been excluded from patent protection on the grounds of public interest. The third is the progressive international standardisation of the basic features of IPRs. For instance, patent regulations increasingly provide protection for a period of 20 years from the date of application. Until recently there was wide variation in timescales between countries. Also, patent applications in almost all countries must now be subjected to literature searches and examinations to ensure that what they describe is genuinely new, inventive and industrially applicable. Moreover, patent rights are now almost universally assigned to the first applicant rather than the first inventor except in the United States where it is the opposite. Intellectual property and development The precise nature of the link between IPRs and economic development is unclear. The main issue is not whether or not IPRs can further economic development. In fact most governments agree that they can and do. History suggests that well-functioning IPR systems have contributed â€" some argue significantly â€" to the industrial revolutions that took place in nineteenth century Europe, North America and Japan, and continue to do so today, as indicated for example by the rapid growth of the modern pharmaceutical industry. More controversial is the extent to which IPR systems should be allowed â€" as they were prior to TRIPS â€" to vary according to the levels of development and technological self-sufficiency that individual developing countries have reached. The issue here is whether a relatively stringent IPR regime as embodied by TRIPS will best encourage economic growth in all countries, or whether a more flexible one may be more appropriate for some of them. Developed countries and business associations, whose members benefit directly from effective IPR regimes, tend to adopt the first position. They argue that strong IPR legislation will enable developing countries to attract more investment â€" since foreign companies will be reluctant to invest in a country where their technology might be copied with little recompense â€" and will thereby gain improved

access to new technologies introduced from outside. Developing countries would also be encouraged to generate more innovations of their own, because of the rewards to inventors and innovators offered by the IPR system. But many developing country governments are concerned that the legal standards required by TRIPS, especially for patents, may simply be too high for their countries at the present time. For example, they worry that having to extend IPR protection to advanced industrial fields such as biotechnology and information and communications technology will only benefit foreign businesses, since their domestic firms lack the capacity to innovate in this field. Overall, the Commission expresses serious doubts that the international IPR regime in its present form, and current processes to further strengthen IPR protection, are in the interests of the poor. The Commission presents well-documented historical evidence to support the view that at certain stages of development, weak levels of IPR protection are more likely to stimulate economic development and poverty alleviation than strong levels. Present-day empirical data is, as the Commission reveals, somewhat lacking. But what there is, points to the same conclusion. Due to their different scientific and technological capacities and social and economic structures, an optimal IPR system is bound to vary widely from one developing country to another. For example, those countries with relatively advanced scientific and technological capacities like India and China may well benefit from high levels of IPR protection in some areas, whereas the least-developed countries almost certainly will not. Among the specific recommendations relating to particularly controversial matters are that developing countries should establish workable laws and procedures to allow them to use compulsory licensing in order to improve access to urgently needed medicines. As for the patenting of life, the Commission recommends that developing countries should not provide patent protection for plants and animals, and should be permitted to develop sui generis systems for plant varieties that suit their agricultural systems. With respect to traditional knowledge and genetic resources, the Commission recommends that all countries should require patent applications to disclose the geographical source of genetic resources from which the invention is derived. As a result, there is currently strong pressure coming from some of these groups â€” together with a number of developing country governments â€” for TRIPS to be revised. In recent years several developing countries have indicated an interest in lowering some of the agreed standards. For example, some African countries such as Kenya have proposed to the WTO that both the ability to patent plants and animals which is optional at present, although allowed in the United States, Europe and Japan and micro-organisms which is obligatory be prohibited. In addition, a number of Latin American countries â€” including Peru and Bolivia â€” have proposed that the WTO establish new IPR regulations aimed at protecting traditional knowledge to further their specific development priorities. Any revisions of the text of TRIPS can take place either immediately following one of these reviews or, more likely, at the conclusion of a new round of trade negotiations. So far there have been no revisions at all. Nonetheless, given the growing attention being given to the issues that the agreement raises, future reviews are likely to become even more contentious.

Chapter 4 : Intellectual Property Rights, the WTO and Developing Countries

Intellectual property rights, the WTO and developing countries: the TRIPS agreement and policy options. [Carlos M Correa;] -- The Limits of the TRIPS AgreementThe TRIPS Agreemeni as a CeilingII: IMPLICATIONS FOR DEVELOPING COUNTRIESImpact on Domestic MarketsIi) The case of pharmaceuticalsIII: IMPLEMENTING THE.

During the Uruguay Round negotiations, members considered that the standards for copyright protection in the Berne Convention for the Protection of Literary and Artistic Works were largely satisfactory. The TRIPS Agreement ensures that computer programs will be protected as literary works under the Berne Convention and outlines how databases must be protected under copyright; It also expands international copyright rules to cover rental rights. Authors of computer programs and producers of sound recordings must have the right to prohibit the commercial rental of their works to the public. Producers of sound recordings must have the right to prevent the unauthorized reproduction of recordings for a period of 50 years. The TRIPS Agreement defines what types of signs must be eligible for protection as trademarks, and what the minimum rights conferred on their owners must be. It says that service marks must be protected in the same way as trademarks used for goods. Marks that have become well-known in a particular country enjoy additional protection. Using the indication when the product was made elsewhere or when it does not have the usual characteristics can mislead consumers, and can lead to unfair competition. Some exceptions are allowed, for example if the term in question is already protected as a trademark or if it has become a generic term. The TRIPS Agreement provides for further negotiations in the WTO to establish a multilateral system of notification and registration of geographical indications for wines, which was subsequently extended to include spirits. The question of whether to negotiate extending this higher level of protection beyond wines and spirits is also being discussed in the WTO. Owners of protected designs must be able to prevent the manufacture, sale or importation of articles bearing or embodying a design which is a copy or substantially a copy of the protected design for commercial purposes. Eligible inventions includee both products and processes. They must be protected for at least 20 years. However, governments can refuse to issue a patent for an invention if its sale needs to be prohibited for reasons of public order or morality. They can also exclude diagnostic, therapeutic and surgical methods, plants and animals other than micro-organisms , and biological processes for their production other than microbiological processes from patent protection. The TRIPS Agreement describes the minimum rights that a patent owner must enjoy, and defines the conditions under which exceptions to these rights are permitted. But this can only be done under specific conditions set out in the TRIPS Agreement aimed at safeguarding the interests of the patent-holder. If a patent is issued for a process invention, then the rights must extend to the product directly obtained from the process. Under certain conditions alleged infringers may be ordered by a court to prove that they have not used the patented process. In practice, layout designs of integrated circuits are commonly protected under patents. Trade secrets must be protected against unauthorized use, including through breach of contract or confidence or other acts contrary to honest commercial practices. Test data submitted to governments in order to obtain marketing approval for new pharmaceutical or agricultural chemicals must also be protected against unfair commercial use and disclosure. Extended transition periods continue to apply to least developed country members see section below on transitional arrangements. Recognizing the possibility that right holders might include conditions that are anti-competitive, the TRIPS Agreement says that under certain conditions, governments have the right to take action to prevent anti-competitive licensing practices. It also says governments must be prepared to consult each other on controlling anti-competitive licensing practices. More generally, the TRIPS Agreement recognizes that right holders could use their rights to restrict competition or impede technology transfer. The Agreement gives governments the right to take action against anti-competitive practices. In certain situations, the TRIPS Agreement also waives some conditions required for the compulsory licence of a patent in cases where the government grants the compulsory licence in order to remedy a practice determined to be

anti-competitive. The Agreement says governments have to ensure that intellectual property rights can be enforced to prevent or deter violations. The procedures must be fair and equitable, and not unnecessarily complicated or costly. They must not entail unreasonable time-limits or unwarranted delays. The TRIPS Agreement is the only international agreement that describes intellectual property rights enforcement in detail, including rules for obtaining evidence, provisional measures, injunctions, damages and other penalties. It says courts must have the right, under certain conditions, to order the disposal or destruction of goods infringing intellectual property rights. Wilful trademark counterfeiting or copyright piracy on a commercial scale must be subject to criminal offences. Governments also have to make sure that intellectual property rights owners can receive the assistance of customs authorities to prevent imports of counterfeit and pirated goods. The TRIPS Agreement aims for the transfer of technology see above and requires developed country members to provide incentives for their companies to promote the transfer of technology to least-developed countries in order to enable them to create a sound and viable technological base. More on technology transfer. Developing country members and under certain conditions transition economies were given five years, until Least-developed countries initially had 11 years, until â€" now extended to 1 July in general. In November , the TRIPS Council agreed to further extend exemptions on pharmaceutical patent and undisclosed information protection for least-developed countries until 1 January or until such date when they cease to be a least-developed country member, whichever date is earlier. They are also exempted from the otherwise applicable obligations to accept the filing of patent applications and to grant exclusive marketing rights during the transition period. In particular, it monitors the operation of the Agreement. These are for negotiations on a multilateral system for notifying and registering geographical indications for wines and spirits. The WTO also coordinates with a wide range of other international organizations, in particular as regards the organization of symposia, training activities and other events on intellectual property and trade and how these relate to other policy dimensions, such as public health and climate change.

Chapter 5 : WTO | Understanding the WTO - Intellectual property: protection and enforcement

Although it is common knowledge that the compliance of developing countries with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has become a serious stumbling block in the WTO agenda, the underlying reasons why this is.

Compare that with the 5, patents issued by the US patent office in a single week in July this year. An even scarier statistic is that, of the 50 or so patents granted in Kenya each year, between zero and five on average are granted to local Kenyan organisations or individuals. The remaining patents are granted to foreign firms, most of which are pharmaceutical companies. The minimal number of issued patents is not due to a lack of innovation or entrepreneurship in Kenya. Instead, the lack of patents is due to a lack of patent expertise in the private sector, and a lack of funds available to hire expensive patent drafting services from firms in Europe, South Africa , or India. Without access to proper patent drafting, it is difficult for the Kenyan patent office to find applications that are suitable for granting as patents, and the ability of local inventors to obtain patents is severely diminished. Subsequently, without patents, the ability of local inventors to attract foreign investment and partnerships, and to build companies that are based on intellectual property IP assets, are also severely diminished. In patent-laden countries such as the US, Japan and blocs like the EU, it is common for patent lawyers to have science and law degrees. Patent lawyers with similar qualifications are found only in South Africa, in Africa. Accordingly, the skills needed to protect innovations via well-drafted patents are scarce, almost non-existent. One way to solve this problem is to train more people in Kenya and other countries in Africa in the skill of drafting and obtaining patents. I spend much of my time offering such skills-training but it is a long-term commitment it can take a year or more and with very little to show in the short term, there seems little incentive to acquire these skills. Is it reasonable to expect Kenyan entrepreneurs, businesses, and inventors to play in the same patent system with corporate giants such as Google, IBM, and Pfizer? These are questions that not only apply to Kenya but also to much of the developing world. It comes as no surprise that the less privileged would have stronger tendencies toward the illegal. Here, the need for novel business models that balance the needs of knowledge creators and users becomes evident, especially given the vast development of enabling technologies. Trips â€" Trade-Related Aspects of Intellectual Property Rights â€" is a framework that applies to all World Trade Organisation member countries and compliance requires IP laws that largely resemble those of developed countries. So although there are minor variations from country to country, the IP laws of developing countries look or will someday look like those in the US or Europe. What this means is that there is very little opportunity for countries to tailor their IP laws to meet their individual needs, unless they wish to withdraw from the WTO. It is often argued that the existence of IP laws incentivises innovation as the monopolisation of knowledge or products create profits for those who own the IP rights but considering the low number of patents in Kenya, the current high level of innovation cannot be attributed to incentives offered by the western-style patent regime that is in place. Copycat businesses are a way of life here, and while they are fatal to some businesses, they are not always or even usually an insurmountable hurdle. Consider that M-Pesa , the most successful mobile money transfer system in the world and hugely profitable, must compete with at least three other nearly identical systems. The day may come when this is no longer the case, and in the meantime there is no doubt that more Africans should be exploiting the existing system. Still, the dream is for the day when foreign investment in African-owned patent assets will exceed foreign aid. He tweets as iruten This content is brought to you by Guardian Professional. To get more articles like this direct to your inbox, sign up free to become a member of the Global Development Professionals Network Topics.

Chapter 6 : TRIPS Agreement - Wikipedia

*Intellectual Property Rights in the Wto and Developing Countries [Jayashree Watal] on www.nxgvision.com *FREE* shipping on qualifying offers. Although it is common knowledge that the compliance of developing countries with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has become a serious stumbling block in the WTO agenda.*

Policy Implications Summary In August , the World Trade Organization WTO reached an agreement on the use of compulsory licenses by developing countries without manufacturing capacity to access life-sustaining medicines. Some developing countries have viewed the TRIPS agreement as an impediment in their attempts to combat such public health emergencies by restricting drug availability and by transferring scarce resources from developing countries to developed country manufacturers. For the developing world, the issue of compulsory licenses is an important test as to whether the WTO can meet the development needs of its members, and conversely, whether the developing world can influence the actions of the world trading system. Developed country pharmaceutical industries view the TRIPS agreement as essential to encourage innovation in the pharmaceutical sector by assuring international compensation for their intellectual property. Without such protection, industry claims it could not recoup the high costs of developing new medicines. The United States has been forceful in defending the interest of the U. In December , the United States blocked a compromise on the compulsory licensing issue to which all other nations had agreed; however, it was also the first nation to ratify the December amendment. In the th Congress, legislation was introduced S. This legislation was not acted upon in the th Congress, and has not been reintroduced in the th Congress. The system of compulsory licensing may have a relatively modest effect on the availability of medicines in the developing world. Compulsory licenses have rarely been used by developing countries because many patent regimes did not protect pharmaceuticals before Countries providing patent protection to pharmaceuticals have used the threat of compulsory licensing as a method to negotiate lower drug prices. Although some countries have amended their national laws to allow compulsory licensing for pharmaceutical exports, there may be little economic incentive for a supplier to manufacture the product in the case of an LDC issuing a compulsory license. It sets minimum standards of protection for patents, copyrights, trademarks and other forms of intellectual property based on three core commitments of the WTO: It delayed the implementation of patent system provisions for pharmaceutical products for least developed countries LDCs until The declaration committed member states to interpret and implement the agreement to support public health and to promote access to medicines for all. The declaration reiterated that each member has the right to grant compulsory licenses and to determine the terms and circumstances in which they are issued. Compulsory licenses are issued by governments to authorize the use or production of a patented item by a domestic party other than a patent holder. They are authorized by Article 31 of TRIPS, which generally limits their issuance to cases in which the government has made efforts to obtain authorization on reasonable commercial terms or in a circumstance of extreme urgency or national emergency. In addition, Article 31 limits the scope and duration of a compulsory license to address the circumstances for which the license is authorized, grants the rights-holder adequate remuneration for use of the patent covered by compulsory license, and restricts production authorized by compulsory license predominantly to the domestic market. It is this last provision that was the focus of the Paragraph 6 negotiations because it, in effect, conveys the right of compulsory licensing only to countries with the capability to manufacture a given product. That text previously was approved by all WTO members save the United States, which blocked its passage in December due to concerns of the U. The Decision provided for a waiver of Article 31 f of the TRIPS agreement, the language which stipulates that compulsory licenses are to be used predominantly for the supply of the domestic market. The Decision waived 31 f for exports of pharmaceutical products to least developed countries LDCs and countries with insufficient manufacturing capacity. Canada, China, India, Korea, Norway, and the European

Union have incorporated into their domestic or community law, although Canada and China have not, as yet, ratified the agreement. The European Parliament approved the amendments on October 24, , and if approved by the European Council of Ministers, the amendments can be ratified by the EU member states. The Decision allowed compulsory licensing for medicines based on the scope of the language in the Doha ministerial declaration: Developing countries were adamant that the language in the Ministerial Declaration on the scope of diseases should form the basis for the agreement, and this position eventually prevailed. During negotiations in the spring and summer of , the U. As stated above, TRIPS grants each nation the ability to assign compulsory licenses to their domestic manufacturers. However, there is a broad range of technical sophistication among the pharmaceutical industries of the developing countries. A country that can make aspirin may not be able to reengineer or reformulate sophisticated drugs in order to utilize the existing compulsory license language of the agreement. The question became whether a country that has some manufacturing capability, but not necessarily a specialized expertise, would be able to use a Paragraph 6 mechanism to issue a compulsory license to a more sophisticated industry in another country to produce a medicine. The Decision set out certain criteria for determining whether a country lacks domestic manufacturing capacity, but essentially countries would self-declare their eligibility by notification to the TRIPS council. This position reflected the rejection by developing countries of any restrictions on their ability to self-determine eligibility. The Decision clarified that eligibility notification would include information on the manner in which a country determined it had no manufacturing capability. However, no formal reviewing mechanism to assess the self-determination of eligibility by developing countries, as the United States proposed, was incorporated into the statement. This statement reflects industry concerns that the system could serve to aid the expansion of generic pharmaceutical industries in developing nations. In addition, several groups also indicated they would not avail themselves of the new compulsory license system. The Decision referred to 23 developed countries that would refrain from using the system as an importer. Until that time, they pledged to use the mechanism only "in situations of national emergency or other circumstances of extreme urgency. This list reflected U. The Decision called for the drugs to be specially marketed or packaged with identifiable characteristics, such as distinguishable colors or shapes "provided that such distinction is feasible and does not have a significant impact on price. It clarified that specialized marking and characteristics should apply to active ingredients and final products, not just to formulated pharmaceuticals. It also adopted a U. However, the statement did not incorporate a U. An eligible importing member, other than a least developed member, must notify the WTO that it intends to use the system to import medicines under compulsory license. For each instance, the importing country must disclose the name and expected quantities of the medicine sought, affirm that it has insufficient manufacturing capability to produce the medicine itself, and provide confirmation that it has granted a compulsory license to obtain the medicine from a third-country manufacturer. Conversely, an exporting country must provide information on the conditions attached to the compulsory license it approves, the name and address of the licensee, the products involved, the quantities produced, the designated import countries, and the duration of the license. This legislation was not acted upon in the th Congress, and it has not been reintroduced in the th Congress. The legislation would have authorized the Director of the U. Patent and Trademark Office PTO to issue compulsory licenses for the export of generic pharmaceuticals to least developed countries and other developing countries without sufficient manufacturing capability. The legislation explicitly would have permitted using non-governmental organizations to assist in distributing the medicines to the eligible country. It stipulated the content for license applications, established an office within PTO to assist applicants in filing applications, and placed certain conditions on the granted license. Among the latter, the legislation specified that the licensed product be distinguishable from product manufactured by the patent holder in terms of size, shape, color, packaging or other distinguishing characteristics to prevent reexportation of the product. The normal term for the compulsory license under the bill was set at seven years, and the bill provided for renewal under certain conditions. The Director would have determined the royalty payment by using a formula provided by the bill and by taking into account

certain enumerated considerations. The legislation provided for expedited approval of license applications for emergency situations. It also would have established a national advisory board to provide advice and guidance on the implementation of the compulsory licensing program and authorized appropriations for this entity. However, a system of compulsory licensing may have a relatively modest effect on the availability of medicines in the developing world. He cited other issues such as inadequate distribution systems for medicines in poor countries and the lack of trained personnel to administer the drugs as factors that could hinder the effectiveness of the new policy. This situation can be attributed to lack of patent protection in many countries. Developing countries were not required to enforce a TRIPS compliant patent system before , and the compliance date for LDCs was extended until for pharmaceutical patents by the Doha Ministerial Declaration. However, some developing countries do have patent regimes that cover some pharmaceuticals. In these countries, the threat of compulsory licensing can be used to negotiate better prices from developed-world pharmaceutical manufacturers. In Brazil, a presidential decree issued September 5, , granted the government the authority to import generic medicines without the consent of the patent holder in cases of national emergency or public interest. This language did not appear in the final version of the bill passed into law P. On the export side, several countries are considering legislation to provide patent waivers to allow their generic pharmaceutical companies to manufacture drugs for compulsory license under the WTO system. As noted earlier, Canada, China, India, Korea, Norway, have enacted legislation amending their patent laws and the European Union has adopted regulations to this effect in June Switzerland and France have also proposed regulations or legislation to comply with the agreement. There may be little economic incentive for a supplier to manufacture the product in the case of an LDC issuing a compulsory license. Under the Decision, a developing country with no manufacturing capability may use a compulsory license to obtain a product for a generic manufacturer in another country. However, the generic manufacturer in the second country may have no incentive to do so, especially in limited quantities to poor countries. In addition, under many of the proposals the product would have to use special packaging or distinctive shapes to avoid diversion. Under such restrictions, it is not certain that a generic producer would undertake the development and formulation costs for such a limited market. According to some non-governmental organizations and AIDS activists, this is precisely the result being sought by patent-holders. One activist claimed that restrictions, such as special packaging and notification requirements, create "a watertight system so that no generic drugs ever get through to the patients in developing countries who desperately need them.

Chapter 7 : WTO | intellectual property (TRIPS) - frequently-asked questions

Although it is common knowledge that the compliance of developing countries with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has become a serious stumbling block in the WTO agenda, the underlying reasons why this is so have not been dispassionately analyzed until the appearance of this book.

Chapter 8 : World Trade Organization - Wikipedia

Trips - Trade-Related Aspects of Intellectual Property Rights - is a framework that applies to all World Trade Organisation member countries and compliance requires IP laws that largely.