

Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health?

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Objective The World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement establishes minimum standards for intellectual property rights, including patent protection for pharmaceuticals; therefore, it may make it difficult for developing countries to gain access to medicines, especially those countries that are the least developed. This study aims to determine whether implementation of the TRIPS Agreement in Latin American and Caribbean countries has generated patent legislation that is sensitive to public health needs.

Methods Legislation in 11 Latin American and Caribbean countries was analysed. The variables considered in the analysis were: the term of patents issued, patentable subject matter, transition periods (that is, time until legislation was enacted), reversal of the burden of proof of patent infringement, exhaustion of rights, compulsory licensing and the early working exception (which allows a country to complete all procedures necessary to register a generic product before the original patent expires).

Findings By 2000, all of the countries studied had reformed their legislation to conform to the agreement. Brazil and Argentina used the transition period until 2005 to grant patents in the pharmaceutical industry. All countries, except Panama, made use of the safeguards and flexibilities available through the agreement by including mechanisms for compulsory licensing in their legislation. Argentina; Bolivia, Colombia, Ecuador, Peru and Venezuela (countries that represented the Andean community); the Dominican Republic; and Panama included mechanisms to allow parallel importation. Mexico did not. Brazil only permits parallel importation after a compulsory licence has been issued. The early working exception is included in legislation in Brazil and the Dominican Republic.

Conclusion The countries in this study did not incorporate all of the mechanisms allowed for by the Agreement and are not adequately using the provisions that enable World Trade Organization (WTO) members to obtain better health for the public, particularly in regard to gaining access to medicines. This situation may deteriorate in future if other agreements establish more restrictive rules for intellectual property rights.

Keywords Pharmaceutical preparations/supply and distribution; Patents/legislation; Treaties; Licensure/legislation; Drug industry; Drugs, Generic/supply and distribution; Drug and narcotic control/methods; Policy making; Developing countries; Latin America; Caribbean region (*source: MeSH, NLM*).

Mots clés Préparations pharmaceutiques/ressources et distribution; Brevet/législation; Traités; Autorisation exercer/législation; Industrie pharmaceutique; Produits génériques/ressources et distribution; Contrôle drogues et stupéfiants/méthodes; Choix d'une politique; Pays en développement; Amérique latine; Caraïbes (*source: MeSH, INSERM*).

Palabras clave Preparaciones farmacéuticas/provisión y distribución; Patentes/legislación; Tratados; Licencias/legislación; Industria farmacéutica; Medicamentos genéricos/provisión y distribución; Control de medicamentos y narcóticos/métodos Formulación de políticas; Países en desarrollo; América Latina; Región del Caribe (*fuentes: DeCS, BIREME*).

الكلمات المفتاحية: الإمداد بالمستحضرات الصيدلانية وتوزيعها؛ تشريعات براءات الاختراع؛ المعاهدات؛ تشريعات الترخيص؛ صناعة الأدوية؛ الإمداد بالأدوية الجنيسة وتوزيعها؛ طرق مكافحة تعاطي المخدرات؛ رسم السياسات؛ البلدان النامية، أمريكا اللاتينية؛ منطقة البحر الكاريبي. (المصدر: رؤوس الموضوعات الطبية - المكتب الإقليمي لشرق المتوسط)

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يمكن الاطلاع على الملخص بالعربية في صفحة 820.

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Introduction

All Member States of the World Trade Organization (WTO) must abide by a series of multilateral agreements. Among these, the Trade-Related Aspects of Intellectual Property Rights Agreement (known as the TRIPS Agreement), signed in April 1994 in Marrakesh, came into force in January 1995 (1).

The Agreement establishes minimum standards for intellectual property rights; for example, patent protection on pharmaceutical products must last for a minimum of 20 years. Member States must incorporate these standards into their legislation. Developed countries had one year (until 1996) to become TRIPS-compliant, while developing countries had five years (until 2000), and countries designated as “least-developed countries” had 11 years (until 2006) (1, 2). Under Article 66.1, developing countries and least-developed countries that had not previously recognized pharmaceutical patents, have 10 years to become compliant (until 2005). In November 2001, this period was extended to 2016 for least-developed countries (3). Box 1 describes the provisions and mechanisms of intellectual property rights covered by the Agreement.

Under the terms of the Agreement, life-saving products are treated in the same way as any other merchandise or commodity. Therefore, the Agreement may prevent governments, representatives of nongovernmental and international organizations, and experts from gaining appropriate access to medicines and other health-care products (4–7). The granting of patents may encourage innovation, but by their nature, they create

monopolies that allow pharmaceutical companies to set and maintain high prices for a minimum of 20 years. In addition to hampering competition, patents also delay the release of low-cost generic equivalents onto the market; these lower cost medicines traditionally meet the needs of developing countries (8).

Over the past two decades, a worldwide phenomenon of increasing national expenditures in health care, caused by increasing drug costs, has disproportionately affected those countries that are the least developed. The proportion of drug expenditures in relation to total health spending varies from 10–20% in developed countries to up to 50% in the least developed countries (9–11). This phenomenon has been linked to various factors such as the ageing of populations, overprescribing, and the introduction of new products (12–14). Large parts of the world’s population have been denied regular access to essential medicines. People in developing countries, where the majority of the population does not have any type of governmental subsidy to buy medicines, have been particularly badly affected (11).

For these reasons, countries that wish to optimize the protection of public health would need to make full use of Article 8 of the Agreement. This article states that “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this

Box 1. Description of the provisions and mechanisms of the TRIPS Agreement included in this study

Provisions and mechanisms	Description (Article no.)
Term of protection (the lifetime of a patent)	Under the Agreement, patents for products and processes last for a minimum of 20 years; this term is measured from the date on which the patent application was filed (Article 33)
Patentable subject matter	The Agreement states that patents are available for all inventions regardless of whether they are products or processes, and they are available for all technologies provided that they are new, involve a new step and are capable of being used in industry (Article 27)
Transition periods	1 year (until 1996) for developed countries 5 years (until 2000) for developing countries 11 years (until 2006) for least-developed countries (Articles 65 and 66)
Transition periods for pharmaceutical products and processes	An additional five years (until 2005) is allowed for a developing country that did not grant patents for pharmaceutical products and processes before signing the Agreement (Article 65.4) Member States are required to start to grant patent protection to areas of technology not previously protected (Article 65.4) The Declaration on the Trips Agreement and Public Health (2001) establishes an additional period (until 2016) for countries designated as least developed (Article 7)
Reversal of the burden of proof	If a person is suspected of having infringed the patent for a process, then he or she must prove his or her innocence (Article 34)
Exhaustion of intellectual property rights	According to Article 6, the exclusive right of the patent holder to import the protected product is exhausted, and thus ends, when the product is first launched onto the market. When a state or group of states applies the principle of exhaustion of intellectual property rights within a given territory, parallel importation is authorized for all residents of the state in question (2)
Parallel imports	Products imported into a country without the authorization of the right holder in that country, which have been put on the market in another country by that person or with his consent (Article 6)
Compulsory licensing	This refers to the authorization given by a judicial or administrative authority to a third party for the use of a patented invention, without the consent of the patent holder (Article 31)
Early working exception (the Bolar provision)	This exception allows a country to complete all of the procedures and tests that are necessary to register a generic product before the original patent expires (Article 30) (15)

Agreement". In other words, to protect public health countries should incorporate all of the flexibilities and safeguards available within the Agreement into their legislation, so that they can improve access to medicines.

This study aims to analyse the implementation process of the TRIPS Agreement in Latin America and the Caribbean, focusing on the incorporation into national intellectual property legislation the mechanisms and provisions that have the potential to affect access to medicines. We investigate whether incorporating the flexibilities and safeguards of the Agreement has generated patent policies for medicines that are sensitive to public health needs (15).

Methods

In 2002 we studied intellectual property legislation related to patent protection in 11 Latin American and Caribbean countries. Countries were selected according to the size of their pharmaceutical market (the three largest markets were included) and their geographical location (so that different subregions were included). Argentina, Brazil and Mexico represent 82.4% of the total Latin American market for pharmaceutical products (16), so they met the first criterion. To meet the geographical criterion, Bolivia, Colombia, Ecuador, Peru and Venezuela were selected to represent the Andean community; Honduras and Panama were selected to represent Central America; and the Dominican Republic was selected to represent the Caribbean.

Articles by Velasquez & Boulet (2) and Correa (15) were reviewed to formulate the conceptual framework of the study. The web site of the World Intellectual Property Organization (<http://www.wipo.int/>) and the national patent offices of the countries studied were consulted to gather information on legislation.

Findings

The main results are summarized in Box 2 and Table 1 and Table 2. Table 1 shows the date each country joined WTO and the year in which patent legislation was modified. All of the countries studied were members who had reformed their legislation by 2000 in order to conform to the Agreement.

Table 1. Countries by World Trade Organization (WTO) entry date and year patent legislation was modified

Country	Date of entry into WTO ^a	Year IPR legislation modified ^b
Argentina	1 January 1995	1996
Bolivia	12 September 1995	2000
Brazil	1 January 1995	1996
Colombia	30 April 1995	2000
Ecuador	21 January 1996	2000
Honduras	1 January 1995	1999
Mexico	1 January 1995	1999
Panama	6 September 1997	1996; amended 1997
Peru	1 January 1995	2000
Dominican Republic	9 March 1995	2000
Venezuela	1 January 1995	2000

^a Source: (17).

^b IPR = Intellectual property rights.

Box 2 summarizes the main results of the analysis of intellectual property rights legislation by country. Brazil and Argentina partially used the transition period (1 year and 5 years, respectively) to grant patents in the pharmaceutical industry.

All countries except Panama included mechanisms for compulsory licensing in their legislation. The conditions required to issue a compulsory licence are described in Table 2 (see also 18). All 10 of the countries that included compulsory licensing in their intellectual property legislation permitted its use in the case of national emergencies. Nine of the 10 countries allowed compulsory licensing in cases of public interest; 8 of them allowed it to be used to remedy anticompetitive practices; and 9 allowed it to be used when a patent cannot be exploited without using another patent (when it is a dependent patent). Mexico's decision not to utilize the provision for dependent patents is of concern because it may make it possible to invalidate a compulsory licence if the licenced product depends on the production of a patented product.

Argentina, the countries representing the Andean community, the Dominican Republic and Panama all included mechanisms to allow parallel importation; Mexico, however, did not. Brazil only permits parallel imports after a compulsory licence has been issued. The early working exception (also known as the Bolar Provision) is included in legislation in Brazil and the Dominican Republic.

Discussion

Transition periods for pharmaceuticals

The transition period (until 2005) for pharmaceuticals that is allowed under the TRIPS Agreement, could have been utilized by Argentina and Brazil. During this time, these countries could have increased their domestic capacity to produce pharmaceuticals. This would have increased competition while also decreasing their dependence on external suppliers; this dependence is a characteristic of the pharmaceutical sector in developing countries (19). Many developed countries, such as, Italy, Japan and Switzerland only began granting patents in the pharmaceutical industry after their national industry developed, thus ensuring exclusive market rights to the patent holders (20). India used the entire transitional period to increase its technological capacity. This permitted it to develop and consolidate its domestic pharmaceutical industry. It also stimulated the market for generic products that can be used to treat diseases such as HIV/AIDS so that these products became available at much lower prices than those set by patent holders from multinational pharmaceutical companies (C. Morrison, unpublished data presented at the Second Forum on HIV/AIDS and STIs in Latin America and the Caribbean, Havana, Cuba, April 2003).

Flexibilities that enable price reductions for medicines

Article 6 of the TRIPS Agreement states that members may adopt the principle of exhaustion of rights at national, regional or international levels. Brazil is an interesting example in that Brazilian legislation permits exhaustion of rights only at the national level, which in practice means that it is impossible to have parallel importation. However, parallel importation is permitted under the mechanism of compulsory licensing (21). It is also important to highlight the absence of the parallel importation mechanism under Mexican intellectual property legislation.

Box 2. Description of patent legislation by country

Provisions and mechanisms

Transition period of 5 years to comply with TRIPS Agreement

Transition period (until 2005) to grant patents for pharmaceutical products and processes

Patentable subject matter

Term of protection (time-limit for patent protection)

Burden of proof

Flexibilities and safeguards included into legislation

Implemented?

Partially implemented: Argentina, Brazil, Honduras, Mexico, Panama

Implemented: Andean community,^a Dominican Republic

Partially implemented: Brazil and Argentina. Brazil used 1 year (1996–1997). Argentina used 5 years (1996–2001)

All countries studied presented as patentable, products or processes that were new, or included a new step, and could be used in industry

All countries established 20 years as the time-limit for patent protection

All countries adopted the reversal of the burden of proof. Argentina was the last country to adopt this provision; it became effective 1 January 2000

Exhaustion of rights

- National exhaustion: Brazil
- International exhaustion (allowing parallel imports): Argentina, countries representing the Andean community, Dominican Republic, Honduras, Panama
- No exhaustion provision: Mexico

Compulsory licensing

Adopted by all countries except Panama

Early Working Exception ("Bolar" Provision)

Defined in legislation only in Brazil and the Dominican Republic

^a The countries representing the Andean community in this study were Bolivia, Colombia, Ecuador, Peru and Venezuela.

The Commission on Intellectual Property Rights (CIPR) was created by the United Kingdom's Department for International Development to study how national intellectual property rights laws could be best designed to benefit developing countries within the context of international agreements, including TRIPS. The commission states that the absence of an allowance for parallel imports in national legislation eliminates an effective pro-competition measure that is capable of promoting access to cheaper medicines. Parallel importation can be carried out without violating TRIPS, once the rights of the patent holder are exhausted in the exporting country (4, 10, 22).

Another important flexibility is the early working exception; this permits the use of an invention without the patent holder's authorization. This exception allows a country to complete all of the procedures and tests that are necessary to register a generic product before the original patent expires (15). This allows generic drugs to enter the market as soon as the patent expires which promotes competition and thus reduces prices. As stated by Creese & Quick (23): "Competition is perhaps the most powerful policy instrument to bring down drug prices for off-patent drugs. In the United States, when a patent expires the average wholesale price falls to 60% of the branded drug's price when there is just one generic competitor, and to 29% with 10 competitors". However, only two of the countries studied have included this mechanism in their legislation. The amendment made to Brazilian law in 2001 was fundamental to negotiations for lower prices for patented antiretrovirals. In Canada, the early working provision has been used extensively over the past decades to promote and enhance access to drugs. This provision also strengthened the Canadian generic drug industry (24).

Compulsory licensing: potential benefits and constraints

Compulsory licensing is considered to be a crucial element in intellectual property legislation because it provides a mechanism

for addressing public health concerns, especially if a country does not have strong antitrust legislation. It is an important public policy tool for all WTO members because promoting competition has an impact on prices while at the same time compensating the patent holder.

- Previous studies have found that developing countries are not using the compulsory licensing mechanism (4, 15) because:
- 1) the necessary legal and administrative structure is lacking in many developing countries. For example, Panama has no compulsory licensing mechanism, and in Brazil and Mexico its use is limited;
 - 2) there are risks to the country of bilateral and multilateral commercial sanctions caused by the power imbalance between countries;
 - 3) the local manufacturing capability is limited. Article 31(f) of TRIPS limits the possibility of issuing a compulsory licence for exportation of a product. In August 2003, the TRIPS Council decided that poorer countries that do not have their own manufacturing capability may import cheaper copies of patented drugs (25). As stated by Fleck, this decision created additional mechanisms for countries to use to prove they are incapable of manufacturing the product as well as requirements that they not export the product (26);
 - 4) they are having problems with technology transfer. Although compulsory licensing permits an invention to be used without the consent of the patent holder, it does not guarantee that the appropriate technology will be available. Thus the licensee must be technologically self-sufficient, and a country must have manufacturing facilities as well as facilities for research and development. For this reason, it is better for countries to negotiate to obtain a voluntary licence from the patent holder before issuing a compulsory licence;
 - 5) the investment involved is high risk. The processes involved in research and development are both time-consuming and

Table 2. Grounds for issuing compulsory licence, by country

Grounds for issuing compulsory licence	Countries using these grounds
Failure to exploit patent (the patented product or process is not marketed in the country after a period of 3 years)	Andean community, ^a Argentina, Brazil, Dominican Republic, Honduras, Mexico
Public interest (for example, to protect public health)	Andean community, Brazil, Dominican Republic, Honduras, Mexico
National emergency	Andean community, Argentina, Brazil, Dominican Republic, Honduras, Mexico
Remedy for anticompetitive practices or unfair competition	Andean community, Argentina, Brazil, Dominican Republic
Failure to obtain licence under reasonable terms (such as when negotiations between a government and a patent holder reach a deadlock)	Andean community, Argentina, Dominican Republic, Honduras
Failure of patent holder to produce locally	Brazil
Dependent patents (when a patent cannot be exploited without using another patent)	Andean community, Argentina, Brazil, Dominican Republic, Honduras
No provision for issuing compulsory licence	Panama

^a The countries representing the Andean community in this study were Bolivia, Colombia, Ecuador, Peru and Venezuela.

expensive (19). The licensee must have some guarantee of a return on investment. This condition is limited by the fact that according to Article 31(d), a compulsory licence will always be issued without exclusivity, so it is a high-risk investment for the licensee.

In view of these restrictions, countries designated as least-developed countries or developing countries who intend to issue a compulsory licence must implement policies to improve technological capacity, and they must also introduce strategies to compensate the private sector for investment risk.

In Brazil, a network composed of 16 public pharmaceutical laboratories has been an important component of the national drug policy (<http://www.alfob.org>). The Institute for Pharmaceutical Technology (Farmanguinhos/Fundação Oswaldo Cruz/Ministério da Saúde) played a major part in the price negotiations between the Brazilian Government and three multinational pharmaceutical companies (Merck, Roche and Abbott) regarding four patented antiretrovirals in 2001. Farmanguinhos provided the Brazilian Ministry of Health with guidelines that could be used to establish an acceptable price. In addition, their capacity to develop generic versions of the medicines by reverse-engineering techniques also had a role, as did the mechanism of compulsory licensing. (Reverse engineering is a way of discovering how a product is manufactured starting from the finished product.) The negotiation resulted in significant price reductions in indinavir (a 64.8% reduction), efavirenz (59% reduction), nelfinavir (40% reduction) and lopinavir (46% reduction). These new prices ensured the sustainability of Brazil's programme to provide universal access to antiretrovirals (27). Negotiations to allow Brazil to produce

generic versions of patented antiretrovirals or reduce prices were under way between the Brazilian Ministry of Health and the same three pharmaceutical companies in late 2003.

The United States of America and Canada have frequently used compulsory licensing for different areas of technology, including medicines. Canada has an extensive history of using compulsory licensing for medicines as a mechanism for building local technological capacity (27).

Conclusion

The countries included in this study have not been incorporating into their legislation all of the advantages that the TRIPS Agreement can provide. This means that these countries are not making full use of the mechanisms that may enable them to ensure better health for the public, particularly in regard to gaining access to medicines. This situation is likely to deteriorate further when the Free Trade Area of the Americas is enacted (<http://www.ftaa-alca.org>), potentially as early as January 2005, and if other bilateral agreements establish more restrictive rules for intellectual property rights (28).

Therefore, the following approaches should be considered to ensure that consistent, sustainable and equity-based policies are implemented in the developing world: countries should be given technical support to enable them to take public health into account in negotiations of trade issues; there should be an interaction between the health sector and patent offices; and there must be a better balance between the need for innovation and the need for medicines. ■

Conflicts of interest: none declared.

Résumé

La mise en œuvre de l'accord sur les ADPIC en Amérique latine et dans les Caraïbes a-t-elle conduit à une législation de la propriété intellectuelle favorable à la santé publique ?

Objectif L'accord sur les ADPIC (Aspects des droits de propriété intellectuelle qui touchent au commerce) de l'Organisation mondiale du Commerce fixe les normes minimales en matière de droits de propriété intellectuelle, y compris la protection des

produits pharmaceutiques par des brevets ; il peut par conséquent être difficile pour les pays en développement, en particulier les pays les moins développés, d'avoir accès aux médicaments. La présente étude cherche à déterminer si la mise en œuvre de l'accord

sur les ADPIC dans les pays d'Amérique latine et des Caraïbes a abouti à un droit des brevets qui tienne compte des besoins de la santé publique.

Méthodes Nous avons analysé la législation de 11 pays d'Amérique latine et des Caraïbes. Les variables retenues étaient : la durée de la protection conférée par les brevets, les objets brevetables, la période de transition (délai avant l'entrée en vigueur de la législation), l'attribution de la charge de la preuve au contrevenant présumé en cas d'infraction au droit des brevets, l'épuisement des droits de propriété intellectuelle, les licences obligatoires et l'exception pour travaux anticipés (qui permet à un pays d'effectuer toutes les démarches nécessaires à l'enregistrement d'un produit générique avant l'expiration du brevet original).

Résultats En 2000, tous les pays étudiés avaient réformé leur législation pour se conformer à l'accord. Le Brésil et l'Argentine ont adopté une période de transition allant jusqu'à 2005 pour accorder des brevets dans l'industrie pharmaceutique. Tous les pays, à l'exception du Panama, ont utilisé les sauvegardes et flexibilités

prévues par l'accord en inscrivant des mécanismes de licence obligatoire dans leur législation. La Bolivie, la Colombie, l'Équateur, le Pérou et le Venezuela (ces cinq pays représentant la communauté andine), l'Argentine, la République dominicaine et le Panama ont prévu des mécanismes autorisant les importations parallèles. Le Mexique ne l'a pas fait. Le Brésil n'autorise les importations parallèles qu'après délivrance d'une licence obligatoire. L'exception pour travaux anticipés (exception « Bolar ») figure dans la législation du Brésil et de la République dominicaine.

Conclusion Les pays étudiés n'ont pas incorporé tous les mécanismes prévus par l'accord et n'utilisent pas suffisamment les dispositions qui permettent aux membres de l'Organisation mondiale du Commerce (OMC) d'offrir les moyens d'une meilleure santé à leur population, notamment en ce qui concerne l'accès aux médicaments. Cette situation pourrait s'aggraver à l'avenir si d'autres accords établissent des règles plus restrictives en matière de droits de propriété intellectuelle.

Resumen

Aplicación del Acuerdo sobre los ADPIC en América Latina y el Caribe: ¿se ha traducido ello en una legislación sobre propiedad intelectual favorable a la salud pública?

Objetivo El Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC), de la Organización Mundial del Comercio, establece unas normas mínimas para los derechos de propiedad intelectual, incluida la protección de preparaciones farmacéuticas mediante patente; eso puede dificultar el acceso de los países en desarrollo a los medicamentos, sobre todo en el caso de los países menos adelantados. El objetivo de este estudio es determinar si la aplicación del Acuerdo sobre los ADPIC en los países de América Latina y el Caribe ha generado una legislación sobre patentes que responda a las necesidades de salud pública.

Métodos Se analizó la legislación existente en 11 países de América Latina y el Caribe. Las variables consideradas en el análisis fueron: el plazo de las patentes concedidas, la materia patentable, los periodos de transición (esto es, el tiempo transcurrido hasta la aprobación de la legislación), la inversión de la carga de la prueba en los casos de violación de patente, el agotamiento de los derechos, la concesión obligatoria de licencias y la excepción motivada por el proceso de aprobación reglamentario (que permite a un país llevar a término todos los procedimientos necesarios para registrar un producto genérico antes de que expire la patente original).

Resultados En el año 2000, todos los países estudiados habían reformado su legislación para adaptarla al acuerdo. El Brasil y la Argentina usaron el periodo de transición hasta 2005 para conceder patentes en la industria farmacéutica. Todos los países, excepto Panamá, hicieron uso de las salvaguardias y las flexibilidades previstas en el acuerdo incorporando a su legislación mecanismos de concesión obligatoria de licencias. La Argentina; Bolivia, Colombia, el Ecuador, el Perú y Venezuela (representantes de la Comunidad Andina); la República Dominicana, y Panamá incluyeron mecanismos para posibilitar las importaciones paralelas. México no lo hizo. El Brasil sólo permite las importaciones paralelas una vez que se ha concedido una licencia obligatoria. La legislación del Brasil y la República Dominicana incluye la excepción motivada por el proceso de aprobación reglamentario.

Conclusión Los países considerados en este estudio no incorporaron todos los mecanismos contemplados en el Acuerdo y no están usando suficientemente las disposiciones que permiten a los miembros de la Organización Mundial del Comercio (OMC) mejorar la salud de su población, en particular por lo que se refiere al acceso a los medicamentos. La situación puede deteriorarse en el futuro si otros acuerdos establecen normas más restrictivas para los derechos de propiedad intelectual.

ملخص

اتفاقية التريبس والصحة العمومية

هل أدى تنفيذ اتفاقية تريبس في بلدان أمريكا اللاتينية والبحر الكاريبي إلى صدور تشريعات لحماية الملكية الفكرية في مجال الصحة العمومية؟

والبحر الكاريبي. وشمل التحليل المتغيرات التالية: مدة براءات الاختراع، المواضيع القابلة للحماية ببراءات الاختراع، المدة الانتقالية، انعكاس عبء ما تم التثبت منه من انتهاك حقوق براءات الاختراع، فترة انتهاء الحقوق، الترخيص الإجباري والاستثناء من العمل المبكر (الذي يتيح للبلد استكمال الإجراءات اللازمة لتسجيل منتج جنيس (غير محدد الملكية) قبل انتهاء مدة التمتع ببراءة الاختراع الأصلية).

الموجودات: بحلول عام ٢٠٠٠ أتمت جميع البلدان التي شملتها الدراسة إصلاح تشريعاتها لتتوافق أحكام الاتفاقية. وقد حددت الأرجنتين والبرازيل فترة انتقالية لمنح براءات الاختراع في مجال صناعة المستحضرات الدوائية حتى عام ٢٠٠٥.

الغرض: توطد اتفاقية جوانب حقوق الملكية الفكرية المتعلقة بالتجارة في اتفاقية منظمة التجارة العالمية (تريبس) أبسط معايير حقوق الملكية الفكرية، والتي تشمل في ما تشمل حماية براءات اختراع المستحضرات الصيدلانية؛ ومن ثمّ قد يؤدي ذلك إلى صعوبة حصول البلدان النامية، ولاسيما أقل البلدان نمواً، على الأدوية. وتستهدف هذه الدراسة الإجابة عن السؤال التالي: هل أدى تنفيذ اتفاقية جوانب حقوق الملكية الفكرية المتعلقة بالتجارة في اتفاقية منظمة التجارة العالمية (تريبس) في بلدان أمريكا اللاتينية والبحر الكاريبي إلى صدور تشريعات، تنسجم بالحساسية لمتطلبات الصحة العمومية، لحماية براءات الاختراع؟

الطريقة: تم تحليل التشريعات المعمول بها في ١١ بلداً من بلدان أمريكا اللاتينية

تشريعات البرازيل وجمهورية الدومينيكان على استثناء من العمل المبكر. **الخصيلة:** لم تدمج البلدان التي شملتها هذه الدراسة في تشريعاتها جميع الآليات التي تسمح بها اتفاقية ترينس، كما أنها لا تستفيد بشكل مناسب من الأحكام التي تمكن البلدان الأعضاء في منظمة التجارة العالمية من توفير صحة أفضل للجمهور، ولا سيما في ما يتعلق بالحصول على الأدوية. وقد يتدهور هذا الوضع أكثر في المستقبل إذا وضعت اتفاقيات أخرى قواعد لتقييد حقوق الملكية الفكرية.

واستفادات جميع البلدان، ما عدا بنما، من الضمانات وعناصر المرونة التي تتيحها الاتفاقية، وذلك بإدماج آليات الترخيص الإجباري في تشريعاتها. وقد قامت كل من الأرجنتين؛ والإكوادور وبوليفيا وبيرو وفنزويلا وكولومبيا (وهي البلدان التي تمثل المجتمع الإندي)؛ وجمهورية الدومينيكان؛ وبنما، بإدخال الآليات التي تسمح بالاستيراد المتوازي في تشريعاتها، فيما لم تفعل المكسيك ذلك. وأما البرازيل فسمح فقط بالاستيراد المتوازي بعد صدور ترخيص إجباري. وتشتمل

References

- World Trade Organization. *Agreement on trade-related aspects of intellectual property rights*. Geneva: World Trade Organization; 1995. (Also available from: http://www.wto.org/english/docs_e/legal_e/27-trips.pdf)
- Velásquez G, Boulet P. *Globalization and access to drugs: implications of the WTO/TRIPS agreement*. Geneva: World Health Organization; 1999. (Also available from: <http://www.who.int/medicines/library/dap/who-dap-98-9-rev/who-dap-98-9-rev.pdf>)
- World Trade Organization. *Doha WTO ministerial: ministerial declaration 2001*. Geneva: WTO; 2001 (Document No. WT/MIN(01)/DEC/2(2001)). (Also available from: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm)
- Commission on Intellectual Property Rights. *Integrating intellectual property rights and development policy*. London: Commission on Intellectual Property Rights; 2002.
- T'Hoen E. TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha. *Chicago Journal International of Law* 2002;3:27-48.
- Bermudez JAZ, Epsztejn R, Oliveira MA, Hasenclever L. *The WTO TRIPS Agreement and patent protection in Brazil: recent changes and implications for local production and access to medicines*. Rio de Janeiro: Fiocruz; 2000.
- Supakankunti S, Janjaroen WS, Tangphao O, Ratanawijitrasin S, Kraipornsak P, Pradithavanij P. Impact of the World Trade Organization TRIPS Agreement on the pharmaceutical industry in Thailand. *Bulletin of the World Health Organization* 2001;79:461-70.
- Bailey M, Mayne R. *Priced out of reach: how WTO patent policies will reduce access to medicines in the developing world*. Washington (DC): Oxfam International; 2001 (Briefing paper No. 4). (Also available from: http://www.oxfam.org.uk/what_we_do/issues/health/bp04_priced.htm)
- Management Sciences for Health, World Health Organization. *Managing drug supply*. West Hartford (CT): Kumarian Press; 1997.
- National Institute for Health Care Management. *Changing patterns of pharmaceutical innovation*. Washington (DC): National Institute for Health Care Management; 2002. (Also available from: <http://www.nihcm.org/innovations.pdf>)
- Health Action International, World Health Organization. *Medicines prices: a new approach to measurement*. Geneva: World Health Organization; 2003. WHO document WHO/EDM/PAR/2003.2.
- Henry D, Lexchin J. The pharmaceutical industry as a medicines provider. *Lancet* 2002;360:1590-5.
- Hunt M. *Prescription drugs and intellectual property protection: finding the right balance between access and innovation*. Washington (DC): National Institute for Health Care Management; 2000. (Also available from: <http://www.nihcm.org/pharm.html>)
- National Institute for Health Care Management. *Prescription drug expenditures in 2001: another year of escalating costs*. Washington (DC): National Institute for Health Care Management; 2002. (Also available from: <http://www.nihcm.org/spending2001.pdf>)
- Correa C. *Integrating public health concerns into patent legislation in developing countries*. Geneva: South Centre; 2001. (Also available from: <http://www.southcentre.org/publications/publichealth/publichealth.pdf>)
- International Marketing Service. *Improved outlook for Latin America, 1999–2004*. London: International Marketing Service; 2003. (Also available from: http://www.ims-global.com/insight/news_story/news_story_0002015.htm)
- World Trade Organization. *Understanding the WTO: the organization. Members and observers*, 2002. Available from: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm
- Thorpe P. *Study on the implementation of the TRIPS Agreement by developing countries*. London: Commission on Intellectual Property Rights; 2001 (Study Paper No. 7).
- Bermudez JAZ. [Pharmaceutical industry, state and society: critical approach to the Medicines Policy in Brazil]. São Paulo: HUCITEC; 1995. In Portuguese.
- Bermudez JAZ. [Medicines: health or industry? The production of medicines in Brazil]. Rio de Janeiro: Relume Dumará; 1992. In Portuguese.
- [Decree No. 4.830, 4th September 2003. Changes to articles 1, 2, 5, 9 and 10 of Decree No. 3.201, 6th October 1999, regarding issuing of compulsory licences in cases of national emergency and public interest]. Brasília, DF: Diário Oficial [da] República Federativa do Brasil; 5th September 2003. In Portuguese.
- Abbott FM. *Compulsory licensing for public health needs: the TRIPS agenda at the WTO after the Doha declaration on public health*. Geneva: Friends World Committee for Consultation, Quaker United Nations Office; 2002 (Occasional Paper No. 9). (Also available from: <http://www.geneva.quino.info/pdf/OP9.Abbott.pdf>)
- Creece A, Quick J. *Working paper on differential pricing arrangements and feasibility: context setting paper*. Geneva: World Health Organization; 2001.
- Reichman JH, Hasenzahl C. *Non-voluntary licensing of patented inventions: historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the USA*. Geneva: International Centre for Trade and Sustainable Development, United Nations Conference on Trade and Development; 2003 (Issue Paper No. 5). (Also available from: http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf)
- World Trade Organization. *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, 2003. Available from: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm
- Fleck F. Drugs could still be costly under World Trade Organization deal. *BMJ* 2003; 327:639.
- Bermudez JAZ, Oliveira MA. Essential medicines and AIDS care in Brazil: recent lessons learnt. In: Hammer S, Moati JP, N'Doye I, Binswanger H, Cahn P, Hira S, et al, editors. *Improving access to care in developing countries: lessons from practice, research, resources and partnerships*. Geneva: UNAIDS, WHO, Ministry of Foreign Affairs, France; 2002. p. 79-87.
- Drahos P. *Bilateralism in intellectual property*. Washington (DC): Oxfam International; 2001. (Also available from: http://www.oxfam.org.uk/what_we_do/issues/trade/bilateralism_ip.htm)