

# A proposal for measuring the degree of public health–sensitivity of patent legislation in the context of the WTO TRIPS Agreement

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**Objective** This study aims to propose a framework for measuring the degree of public health-sensitivity of patent legislation reformed after the World Trade Organization's TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement entered into force.

**Methods** The methodology for establishing and testing the proposed framework involved three main steps: (1) a literature review on TRIPS flexibilities related to the protection of public health and provisions considered "TRIPS-plus"; (2) content validation through consensus techniques (an adaptation of Delphi method); and (3) an analysis of patent legislation from nineteen Latin American and Caribbean countries.

**Findings** The results show that the framework detected relevant differences in countries' patent legislation, allowing for country comparisons.

**Conclusion** The framework's potential usefulness in monitoring patent legislation changes arises from its clear parameters for measuring patent legislation's degree of health sensitivity. Nevertheless, it can be improved by including indicators related to government and organized society initiatives that minimize free-trade agreements' negative effects on access to medicines.

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Voir page 55 le résumé en français. En la página 55 figura un resumen en español.

يمكن الاطلاع على الملخص بالعربية في صفحة 55.

## Introduction

In April 1994, the General Agreement on Tariffs and Trade (GATT) Uruguay Round negotiations culminated with the creation of the World Trade Organization (WTO) and the signing of a series of multilateral agreements, including the Trade Related Aspects of the Intellectual Property Rights (TRIPS) Agreement.<sup>1</sup> Since that time, issues relating to intellectual property rights (IPR) have acquired greater importance in the international trade environment. All WTO Members are obligated to grant intellectual property protection in all technological fields, including patents for pharmaceutical products and processes.

Science-based companies consider patent protection one of the main forms of expanding their powers of appropriation.<sup>2</sup> Powers of appropriation are those mechanisms, including legal rights and entitlements, which allow individuals or entities to control the distribution of value created.<sup>3</sup>

However, as the monopoly conferred by the patent delays market competition,

it enables the patent holder to set high prices for the protected product.<sup>4-7</sup>

The high price of patented products has been pointed out as one of the most important barriers to their widespread adoption, in particular hindering access to medicines in low- and middle-income countries.<sup>8-10</sup> One example is provided by Brazil's National Programme on Sexually Transmitted Infections/HIV/AIDS, which guarantees universal and free access to treatment for all persons infected with human immunodeficiency virus (HIV). The programme provides 17 antiretroviral (ARV) medicines, but is currently facing serious financial problems because the cost of three patented ARVs (Efavirenz, Lopinavir/Ritonavir and Tenofovir) consumes over 60% of the Ministry of Health's budget for HIV/AIDS medicines.<sup>11-14</sup>

TRIPS challenges countries to identify strategies that enable them to abide by international trade agreements while allowing for national policies that promote economic, technological and social development. Correa recommends that developing countries strive to integrate

IPR-related policies and policies for national development, targeting industrial development, public health, food safety, education and other areas.<sup>15</sup> In addition, he argues that public health can best be protected through "health-sensitive" patent legislation incorporating all TRIPS flexibilities that enable governments to act efficiently in the public health sector, including those that augment access to medicines.<sup>16,17</sup>

Studies conducted from the public health perspective have analysed the TRIPS Agreement implementation process.<sup>16,18-24</sup> These studies adopted a descriptive approach, so they do not discuss or propose different degrees of importance for each of the TRIPS flexibilities related to public health protection. Therefore, they do not measure the degree of health sensitivity in legislation, nor perform country comparisons.

In a previous study, we showed that developing countries from Latin America and the Caribbean (LAC) had not incorporated into their patent legislation all the TRIPS flexibilities.<sup>16</sup> The present paper proposes to advance the

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Table 1. Definitions of the framework's TRIPS flexibilities and their corresponding articles

Flexibilities of public health interest	TRIPS Agreement articles	Definition
Transition period for granting pharmaceutical patents	65, 66 and paragraph 7 of the Declaration on the TRIPS Agreement and Public Health (Doha Declaration)	A transition period of ten years (until 2005) is specified for a developing country that did not grant patents for pharmaceutical products and processes before January 1995; least-developed countries that did not grant such patents before January 1995 have until 2016 to make this transition.
Parallel imports	6	Products imported into a country without the authorization of the patent holder in that country when the product is put on the market abroad by the patent holder or a third party with the patent holder's consent.
Experimental use	30	Use of the patented invention for scientific purposes.
Bolar exception (early working)	30	This allows a company to complete all procedures and tests required to register a generic product before the original patent expires.
Compulsory licensing	31	This refers to 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.
Health ministry participation in analysing pharmaceutical patent claims	8 (implicit)	Pharmaceutical patent claims are submitted to health ministry professionals for analysis and approval.

Source: ref. 16, 17.

discussion by answering the following questions: How important is each of the TRIPS flexibilities to health-sensitive patent legislation? How health-sensitive is LAC countries' patent legislation that has been modified to comply with international trade agreements?

To answer these questions, a framework to measure health sensitivity in patent legislation was developed, tested and validated. It is, however, important to point out that the LAC countries' use of the TRIPS flexibilities was not within the study's scope.

From an academic perspective, a framework's development contributes to advancing the scarce existing knowledge in this field. Additionally, this type of study generates new questions and academic challenges to be explored in future studies. In this sense, the country comparison provides researchers with baseline information about patent legislation in LAC countries, allowing them to identify new issues and questions to be explored.

From a political perspective, country comparison results might provide health sector stakeholders with information to improve their knowledge and ability to act regarding government decisions. Furthermore, data on one country may promote exchanges of experiences between countries, which can assist health sector decision-makers who negotiate and implement free trade agreements (FTAs).

## Materials and methods

### Developing the patent legislation framework and content validation

Content validation consisted of verifying that the framework incorporated all aspects related to the concepts used in the study.<sup>28, 29</sup> Consensus by selected professionals provided the framework with content validation, which was performed through a sequential process with feedback. This back-and-forth procedure allowed participants to include and/or exclude legal provisions and attribute scores for each, as well as to reach a consensus on incorporating all aspects relating to the concept of health-sensitive patent legislation.

The framework was developed by adapting the Delphi method. This consensus technique does not require all participants to meet face-to-face; instead, each responds to e-mailed questionnaires.<sup>25</sup>

The first step was selecting participants. The study sought graduate professionals (lawyers, medical doctors, economists and activists) who had experience dealing with patent legislation and access to medicines. To better identify these professionals, we used other criteria, seeking individuals who had published scientific and/or technical papers, documents and books discussing the implications of the WTO TRIPS implementation for public health policies; staff members or temporary consultants

of a United Nations organization who coordinated efforts to provide Members with relevant information; activists from international public-interest nongovernmental organizations (NGOs) who produced documents and/or provided recommendations for middle- and low-income country representatives; and health ministry professionals who coordinated activities relating to patents and access to medicines, and who represented their agencies in national and international arenas where this issue was discussed.

Once participants were identified, the second step was identifying the public health-related TRIPS flexibilities through analysis of scientific literature and documents. The initial proposal was that the consensus participants would score the identified flexibilities according to a scale to quantify their importance in protecting public health.<sup>24</sup>

The first questionnaire, comprising one closed-ended and two open-ended questions, was developed and tested on five pharmaceutical policy professionals who had prior knowledge on the theme of IPR and access to medicines. The objectives were to verify that the questionnaire was concise, that it used clear and understandable language, that it was directly connected to the issue being studied and that the format encouraged participants to respond.<sup>26, 27</sup>

A second questionnaire included three open-ended and two closed-ended

Table 2. Definition of framework's TRIPS-plus provisions

TRIPS-plus provision	Definition
Extension of patent term (beyond 20 years)	FTAs propose patent term extension as established in TRIPS Agreement article 33.
Linkage between drug marketing approval and patent status	Establishes a link between market approval for generic medicines and patent status, making it impossible for manufacturers to obtain market approval for generic versions of patented products.
Exclusivity of data submitted for registration of pharmaceuticals	This provision makes it impossible to obtain market approval for generic medicines based on safety and efficacy data the originating company submits to the Drug Regulatory Authority. Tests that prove safety and efficacy of a new molecular entity are performed in phase I, II and III clinical trials on humans. The presentation of clinical trial data is mandatory to request marketing approval for a product composed of a new molecular entity.

Source: ref. 30–35. FTAS = free-trade agreements.

questions. One of the open-ended questions allowed participants to cite their priorities for incorporating TRIPS flexibilities into national legislation, as well as to cite legal provisions that limit access-to-medicines policies.

Participants ranked grounds for issuing a compulsory licence according to perceived importance. Instead of asking each individual to list the flexibilities and then rank them, some examples were given. To not limit the scope of these flexibilities, participants were able to include others that they felt were important. If none of the flexibilities listed was considered important, participants were to score them as zero.

After the second questionnaire was returned and the responses analysed, measurements were calculated to determine overall response averages. A summary of these results and a third questionnaire based on the participants' input were produced and resubmitted for appraisal.

### Country selection and legislative analysis

LAC countries were selected if they reformed patent legislation after the TRIPS Agreement entered into force and published this legislation in an online version.

The selected legislation was analysed by reading and identifying each legal provision included in the framework. These values were then consolidated into a Microsoft Excel spreadsheet.

## Results and discussion

### Content validation

The consensus process was carried out in two rounds. In the first, 11 participants received the questionnaire and 7 responded. In the second round only

these 7 participants were sent the questionnaire, and all responded to it.

The resulting framework included the following flexibilities: transition period to grant patents for pharmaceuticals, exhaustion of rights and parallel imports, experimental use, the Bolar exception, compulsory licensing and health ministry participation in the analysis of pharmaceutical industry patent claims. Experts considered this participation as a flexibility implicit in article 8 of the TRIPS Agreement, which permits Members to adopt necessary measures to protect public health. Table 1 presents the proposed flexibilities and their definitions.

Even though the framework's initial objective was to incorporate only flexibilities related to public health, one participant proposed that it should consider including TRIPS-plus provisions.

Many authors have discussed FTAs' potential negative effects on access to medicines.<sup>30–34</sup> These agreements generally include provisions considered to be TRIPS-plus, which challenge the implementation of flexibilities related to

health. For this reason, the participants suggested including three of these provisions in the framework: patent term longer than 20 years, linkage between drug marketing approval and patent status, and protection of data submitted for registration of pharmaceuticals.

With the inclusion of the TRIPS-plus provisions, some adjustments had to be made in the framework. Legislation received the established scores in cases where flexibilities related to public health protection existed and TRIPS-plus provisions were not present, while legislation received zero scores for each TRIPS-plus provision included. These terms are defined in Table 2; Table 3 presents the framework used to analyse legislation and the scores each legal provision received. The framework does not include grounds for issuing a compulsory licence because consensus was not reached on this issue.

### Countries and selected legislation

Initially, the main source of data for analysis was patent legislation from each country. However, the inclusion of

Table 3. Framework to analyse degree of health-sensitivity of patent legislation

Legal provision	Score
<b>Flexibilities related to public health</b>	
Compulsory licensing	14.7
Health ministry participation in analysing pharmaceutical patent claims	13.1
Parallel imports	12.4
Bolar exception (early working)	11.1
Experimental use	7.5
Transition period for granting pharmaceutical patents	5.3
<b>TRIPS-plus provisions</b>	
Does not include extension of the patent term (beyond 20 years)	13.2
Does not include linkage between drug marketing approval and patent status	13.2
Does not include exclusivity of data submitted for registration of pharmaceuticals	9.5
<b>Total</b>	<b>100</b>

Table 4. Selected legislation analysed by country

Country	Legislation
Argentina	Law 24.572 (1996) – Patent Laws for Invention and Utility Model Law 24.766 (1996) – Confidentiality Law
Barbados	Law 18 (2001) – Patent Law
Belize	Chapter 253 (2000) – Patent Law
Brazil	Law 9.279 (1996) – Industrial Property Law Law 10.196 (2001) – Amendment to Law 9.279 (1996) Law 10.603 (2000) – Confidentiality Law
The Andean Community (Bolivia, Colombia, Peru, Ecuador and Venezuela)	Decision 486 (2000) – Common Regime of Industrial Property
Costa Rica	Law 6.867/ 2000 – Patent Law for Inventions, Designs and Utility Models Law 7.979 (2000) – Modification of Law 6.867 (2000) Law 7.975 (1999) – Undisclosed Information Law
Guatemala	Decree 57 (2000) – Industrial Property Law Decree 9 (2003) – Reform of Industrial Property Law, Decree 57 (2000) of the Congress of the Republic of Guatemala and its Reforms
Honduras	Industrial Property Law (1999)
Mexico	Industrial Property Law (1999)
Nicaragua	Law 354 (2001) – Patent Law for Inventions, Designs and Utility Models
Panama	Law 35 (1996) – Industrial Property Law Executive Decree 7 (1998) – Regulations of the 1996 Law 35 1996 on Industrial Property
Paraguay	Law 1630 (2000) – Patent Law for Inventions, Designs and Utility Models Law 2.593(2005) – Amendment to Patent Law
Dominican Republic	Law 20 (2000) – Industrial Property Law
Trinidad and Tobago	Law 21 (1996) – Patent Law Law 18 (2000) – Modification to Patent Law
Uruguay	Law 17.164 (1999) – Patent Law for Inventions, Utility Models and Industrial Designs

Source: ref. 36,37.

TRIPS-plus provisions in the framework created the need to identify these in legislation. This study was limited by the difficulties researchers faced in verifying a country's entire IPR legislation via the Internet. For this reason, it is not possible to state categorically that a country does not have any of the legal provisions presented in the framework. Table 4 presents the legislation analysed from each country. Only in some countries (Argentina, Brazil and Costa Rica) was it possible to identify legislation related to protection of data submitted for pharmaceutical registration.

### Analysis of patent legislation's health-sensitivity

This legislation was analysed focusing specifically on parameters established by the framework, as shown in Table 5. The transition period for granting pharmaceutical patents was excluded because

this provision expired in January 2005 for all developing countries. Therefore, the maximum score that each country could obtain was 94.7%.

It is important to highlight that in some cases the provisions existed in the legislation, but disagreed with the definitions in Table 1. Brazilian patent legislation (Law 279/96), for example, includes "parallel imports," but is limited to one year and is only applied in situations in which imports are necessary to implement a compulsory license (articles 68 and 74).

Paraguayan and Uruguayan legislation (articles 34 and 39, respectively) contain the Bolar exception. In Paraguay, the use of patented invention information necessary to obtain market approval for generic medicines is limited to the 30 days before the patent expires, in Uruguay it is limited to one year before patent expiration. Therefore this study

accorded Brazilian patent legislation a score of zero for parallel imports, and scored Paraguay and Uruguay zero for the Bolar exception. As shown in Fig. 1, Paraguay has the most health-sensitive patent legislation (83.6%) among LAC countries in 2005. Amended patent legislation (Law 2.593) that included health ministry participation in pharmaceutical industry patent claim analysis (article 25) contributed heavily to this result. The consensus survey participants considered this the second most important element of patent legislation health-sensitivity. This received a score of 13.1, probably because it can block patents to products that do not fulfil patentability requirements and that may impact pharmaceutical prices by preventing competition.<sup>38</sup>

Brazil has the second most health-sensitive patent legislation (82.3%), because Law 10.196/01 (article 229c) states

Table 5. Analysis of selected countries' patent legislation<sup>a</sup>

Legal provision	AR	BAR	BZ	BR	CA	CR	GUA	HON	MEX	NIC	PAN	PG	DR	TRI	URU
<b>Flexibilities related to public health protection</b>															
Compulsory licence	+	+	+	+	+	+	+	+	+	+	-	+	+	+	+
Health ministry participation in analysing pharmaceutical patent claims	-	-	-	+	-	-	-	-	-	-	-	+	-	-	-
Parallel imports	+	-	-	+	+	+	+	+	-	+	-	+	+	-	+
Bolar exception (early working)	+	-	-	+	-	+	-	-	-	-	-	+	+	-	+
Experimental use	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Transition period for granting pharmaceutical patents	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
<b>TRIPS-plus provisions</b>															
Does not include extension of patent term (beyond 20 years)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Does not include linkage between drug marketing approval and patent status	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Does not include exclusivity of data submitted for registration of pharmaceuticals	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-

Label: + when the provision is in the legislation; - when the provision is not in the legislation; NA when does not apply.

<sup>a</sup> Country abbreviations: AR – Argentina; BAR – Barbados; BZ – Belize; BR – Brazil; CA – Andean Community; CR – Costa Rica; GUA – Guatemala; HON – Honduras; MEX – Mexico; NIC – Nicaragua; PAN – Panama; PG – Paraguay; DR – Dominican Republic; TRI – Trinidad and Tobago; URU – Uruguay.

that pharmaceutical patents require National Health Surveillance Agency (ANVISA) consent.

Argentina, Costa Rica and the Dominican Republic presented less health-sensitive patent legislation (81.6%), mainly because their health ministries do not have a role in the pharmaceutical patenting process.

The legislation of Uruguay, the Andean Community, Honduras and Nicaragua received similar scores of around 70% because they included the same three flexibilities (compulsory licence, parallel imports and experimental use). Guatemala's patent legislation received a general score of 61% and was the only country to include a TRIPS-plus provision (data exclusivity).

Barbados, Belize, Mexico, and Trinidad and Tobago comprised the fourth group with a total score of 58.1%, and only included compulsory licence and experimental use.

Panama scored only 43.4%, because experimental use is the only TRIPS flexibility included in its patent legislation.

The analysis of the degree of health-sensitivity in patent legislation is limited because it might not include all TRIPS flexibilities and TRIPS-plus provisions stated in the framework. For example, the Bolar exception exists in Argentina's

Confidentiality Law, not in its patent legislation. Mexico's patent legislation does not include data exclusivity, yet the country protects data for 5 years as established in the North America Free Trade Agreement involving Mexico, Canada and USA (Article 1711, Trade Secrets).<sup>39</sup> Colombia also has data exclusivity, but this is established not in patent legislation but in Decrees 677 (1995) and 2085 (2002).

This analysis shows that none of these countries is taking full advantage of the right to incorporate all TRIPS flexibilities to protect public health as stated in Doha Declaration.<sup>16</sup>

When considering countries that have already signed FTAs with chapters on IPR, the scenario changes. The Dominican Republic, Central America and United States Free Trade Agreement (DR-CAFTA) involving the Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua, Costa Rica and the USA will make its signatory countries' patent legislation less health-sensitive, as shown in Fig. 2.<sup>40</sup>

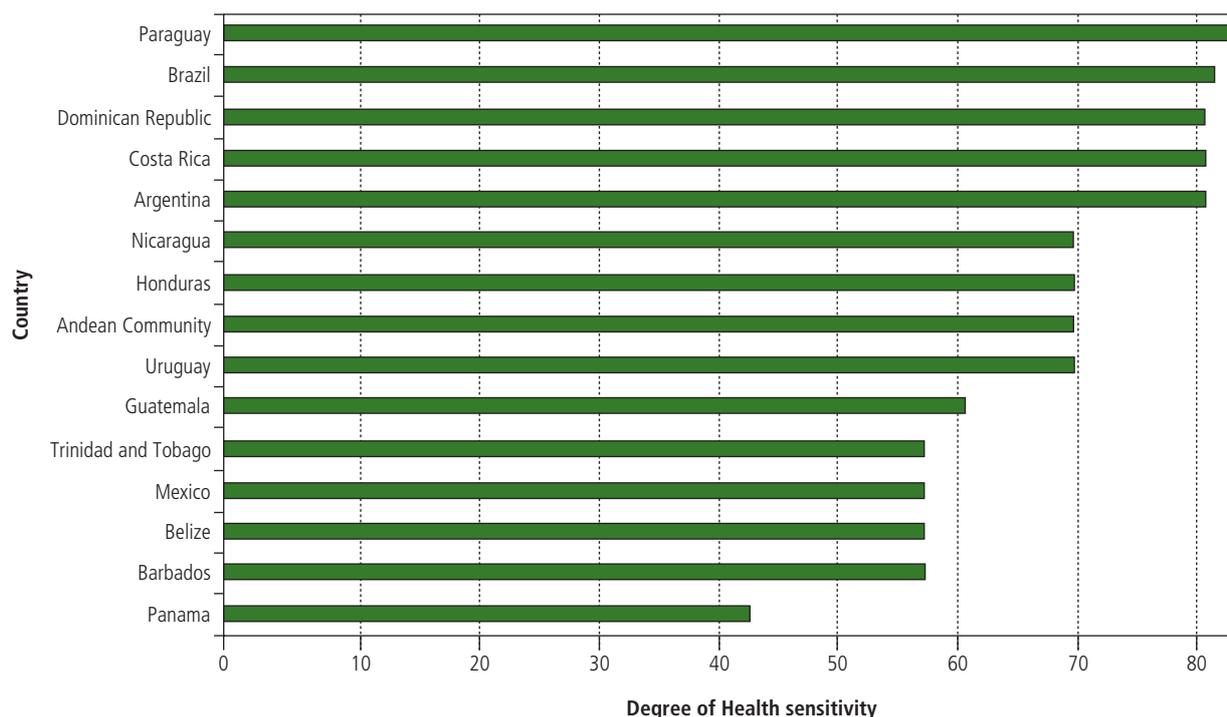
The potential negative impact of TRIPS-plus provisions on patent legislation is due to three mechanisms: the inclusion of additional provisions that hinder competition by generic medicines, limitations on the use of

existing flexibilities and the annulment of certain flexibilities by other provisions. An example of the latter is the inclusion of the linkage between drug marketing approval and patent status that makes the Bolar exception void. The framework developed in this study is significant because it represents the first time researchers have sought to measure the importance of each TRIPS flexibility that adds to patent legislation health-sensitivity. This framework defines clear parameters for performing country comparisons and for monitoring patent legislation changes, and reveals relevant differences between countries.

However, it is important to mention that the existence of flexibilities does not guarantee their use whenever it is necessary to protect public health, such as the provision of life-saving medicines. Threats of retaliation, lack of local production capacity and of political will are examples of barriers that developing countries must overcome to fully use TRIPS flexibilities.<sup>16</sup>

The case of Paraguay is emblematic because, despite this nation having the most health-sensitive patent legislation, its government cannot afford to provide regular access to medicines for people with HIV. Paraguay has depended on Brazilian donations for this purpose since

Fig. 1. Health-sensitivity of patent legislation in selected countries, 1996–2005



2004 through the Brazil–Paraguay International Cooperation Program (PCI).<sup>41</sup>

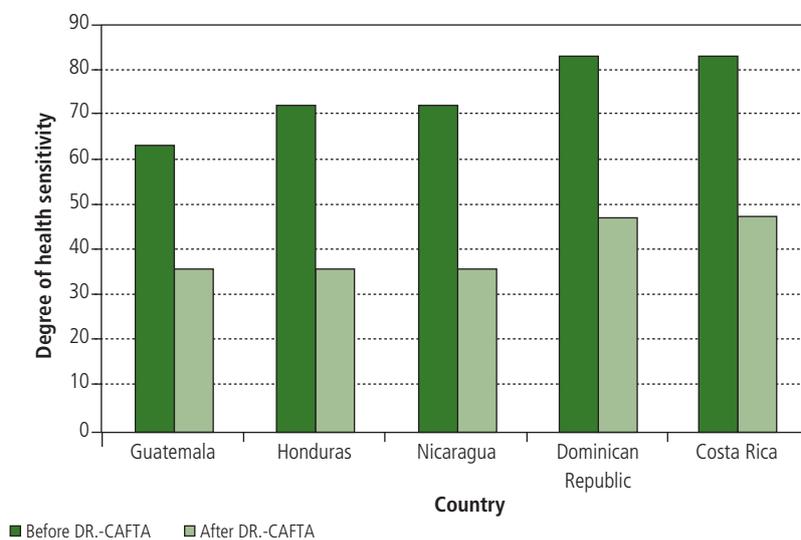
Civil society in countries such as Brazil and India is proposing alternative ways to overcome barriers imposed on patent legislation by TRIPS and TRIPS-plus. The Brazilian Working Group on Intellectual Property (GTPI) from the Brazilian Network for the Integration of Peoples (Rebrip) filed a civil action suit against Abbott Laboratories and the Brazilian government in the Brazilian Federal Justice Court, demanding the issuing of a compulsory licence for Lopinavir/Ritonavir.<sup>42</sup> The Indian NGO Lawyers Collective HIV/AIDS Unit is using a pre-grant opposition strategy to avoid granting unjustifiable patents.<sup>43</sup>

It is important to improve this framework in future studies by including government and organized society initiatives that minimize FTAs' negative effects on access to medicines. ■

### Ethical approval

The first questionnaire sent to the consensus participants was approved by the Ethics Committee on Research of the Sérgio Arouca School of Public Health, part of the Oswaldo Cruz Foundation.

Fig. 2. Degree of health-sensitivity of patent legislation in the Dominican Republic, Honduras, Guatemala, Costa Rica and Nicaragua, before and after the DR-CAFTA



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**Competing interests:** none declared

**Résumé****Proposition pour mesurer dans quelle mesure la législation sur les brevets dans le contexte de l'Accord de l'OMC sur les ADPIC répond aux impératifs de la santé publique**

**Objectif** La présente étude vise à proposer un cadre pour mesurer dans quelle mesure la législation sur les brevets modifiée après l'entrée en vigueur de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) de l'Organisation mondiale du Commerce répond aux impératifs de la santé publique.

**Méthodes** La méthodologie pour établir et éprouver le cadre proposé comporte trois étapes : 1) un examen de la littérature sur les flexibilités ménagées par l'Accord sur les ADPIC en matière de protection de la santé publique et les dispositions « ADPIC-plus » ; 2) la validation du contenu par des techniques fondées sur le consensus (adaptation de la méthode Delphi) ; et 3) une analyse de la législation sur les brevets de 19 pays d'Amérique latine et des Caraïbes.

**Résultats** Les résultats montrent que le cadre parvient à relever les différences pertinentes entre les législations sur les brevets des différents pays, ce qui permet des comparaisons entre les pays.

**Conclusion** L'utilité éventuelle du cadre pour suivre les modifications apportées à la législation sur les brevets tient à la clarté des paramètres permettant de mesurer dans quelle mesure cette législation répond aux impératifs de santé. Néanmoins, le cadre pourrait être amélioré si l'on ajoutait des indicateurs liés aux initiatives du secteur public et de la société civile qui réduisent dans la mesure du possible les effets néfastes des accords de libre échange sur l'accès aux médicaments.

**Resumen****Propuesta para medir el grado de sensibilidad a la salud pública de la legislación sobre patentes en el contexto del Acuerdo sobre los ADPIC de la OMC**

**Objetivo** La finalidad de este estudio es proponer un sistema para medir el grado de sensibilidad a la salud pública de las leyes sobre patentes reformadas después de la entrada en vigor del Acuerdo sobre los ADPIC (Derechos de Propiedad Intelectual relacionados con el Comercio) de la Organización Mundial del Comercio.

**Métodos** La metodología para establecer y ensayar el sistema propuesto incluyó los tres pasos siguientes: (1) una revisión de la bibliografía sobre las flexibilidades de los ADPIC relacionadas con la protección de la salud pública y las disposiciones consideradas «ADPIC plus»; (2) la validación del contenido mediante técnicas de consenso (una adaptación del método Delphi); y (3) un análisis de la legislación sobre patentes de diecinueve países de América Latina y el Caribe.

**Resultados** Los resultados muestran que el sistema detectó diferencias importantes entre las legislaciones de los países, lo que permite realizar comparaciones entre ellos.

**Conclusión** Las posibilidades que brinda el sistema para seguir de cerca los cambios de las leyes sobre patentes son atribuibles a la claridad de los parámetros que utiliza para medir el grado de sensibilidad a la salud de esa legislación. No obstante, es posible mejorarlo incluyendo indicadores relacionados con las iniciativas gubernamentales y de la sociedad organizada que reduzcan al mínimo los efectos negativos de los acuerdos de libre comercio sobre el acceso a los medicamentos.

**ملخص****قياس حساسية الصحة العمومية للتشريعات المتعلقة ببراءات الاختراع**

في الآراء. واستُخدم هذا الإطار لتحليل تشريعات براءات الاختراع في بلدان أمريكا اللاتينية والكاريبي. وبين هذا التحليل قدرة الإطار المقترح على رصد التغيرات التشريعية في سياق تنفيذ الاتفاقات الثنائية والإقليمية المتعلقة بالتجارة الحرة. كما بين التحليل أنه لا يوجد بلد واحد من البلدان المنتقاة للمشاركة في الدراسة يستفيد استفادة كاملة من الحق في إدخال جميع البنود المرنة لحماية الصحة العمومية، على النحو المنصوص عليه في إعلان الدوحة.

استهدفت هذه الدراسة إعداد واختبار وتطبيق إطار جديد لقياس درجة الحساسية الصحية للتشريعات المتعلقة ببراءات الاختراع، والتي أعيدت صياغتها بعد بدء تنفيذ اتفاق منظمة التجارة العالمية المتعلق بالجوانب التجارية لحقوق الملكية الفكرية (تربس). وقد أدخلت البنود المرنة والأحكام المعروفة باسم (( ما بعد التربس ))، والمتعلقة بسياسات الحصول على الأدوية في هذا الإطار، وتم التحقق من سلامتها من خلال عملية توافق

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