

Intellectual property and access to medicines: an analysis of legislation in Central America

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Abstract Globalization of intellectual property (IP) protection for medicines has been advancing during the past decade. Countries are obliged to adapt their legislation as a requirement of their membership to the World Trade Organization or as a condition of being part of international trade agreements. There is a growing recognition that, in low-income countries, stronger IP protection is a barrier to access to medicines. At the same time, the number of low-income countries writing national legislation to protect IP for pharmaceutical products is growing worldwide, but little research has been done on the ways in which this process is happening at the national level.

This paper aims to contribute to the understanding of the implementation of IP legislation at the national level by providing a comparative analysis of the countries that are part of the United States–Dominican Republic–Central America Free Trade Agreement (DR-CAFTA). The analysis shows three trends. First, countries have often implemented stronger IP protection than required by trade agreements. Second, some countries have adopted IP protection before signing the trade agreements. Third, the process of ratification of DR-CAFTA increased public debate around these issues, which in some cases led to IP legislation that considers public health needs. These trends suggest that industrialized countries and the pharmaceutical industry are using more tactics than just trade agreements to push for increased IP protection and that the process of national legislation is a valid arena for confronting public health needs to those of the industry.

Une traduction en français de ce résumé figure à la fin de l'article. Al final del artículo se facilita una traducción al español. الترجمة العربية لهذه الخلاصة في نهاية النص الكامل لهذه المقالة.

Introduction

Much has been written about the impact of intellectual property (IP) provisions on access to medicines in the developing world.^{1–7} In recent years, this discussion has often centred on the impact of free trade agreements with the United States of America (USA) that contain elevated protection for pharmaceutical IP. Typically, views are deeply polarized: some decry the free trade agreements' provisions as inevitably disastrous for public health^{8–13} while others argue that IP protection does not constitute a significant obstacle to access to medicines.^{14–18} As countries contemplate ratification, the lack of available studies forecasting the impact of such regulations (or the lack of agreement on which studies to trust) has further hampered the discussion.

The United States–Dominican Republic–Central America Free Trade Agreement (DR-CAFTA) provides an important case study to examine the broader dynamics of national and international law and their public health impacts. DR-CAFTA is the largest free trade agreement to date to incorporate stronger IP provisions than those required by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. At the time of its drafting it was widely hailed by both supporters and opponents as heralding the dawn of a new era in IP protection. It also has served as a stepping stone to the Colombia and Peru agreements, and others under negotiation with other South American countries. Understanding the way DR-CAFTA's IP provisions may affect access to affordable medicines in Central America and the Dominican Republic can help predict the impact of

other related agreements still under negotiation, such as those with Malaysia, Thailand and the United Arab Emirates.

Assessing DR-CAFTA's current impact on access to medicines is a complex undertaking, beyond the scope of the present study. As a first step towards that end, however, we seek to determine which legislative changes have been implemented in each Central American country as a result of its adherence to DR-CAFTA. This study draws on analysis of the text of international agreements (DR-CAFTA and the TRIPS Agreement), analysis of national legislation in Central American countries and in the Dominican Republic, and interviews with public health and trade officials and representatives of civil society in Costa Rica, El Salvador and Guatemala.

Our research documents a dramatic tightening of Central American IP regulation in the wake of DR-CAFTA. At the same time, however, our findings suggest that the relationship between the text of international agreements (both DR-CAFTA and TRIPS) and the "public health sensitivity" of legislation^{19,20} is not as direct as many assume. First, in some cases restrictive reforms were adopted *prior* to the ratification of the agreements themselves. Second, in many cases countries have implemented more restrictive standards than those required in these agreements. Third, in some cases, the DR-CAFTA ratification process actually led to the implementation of legislation sensitive to public health. Our purpose is not to argue that trade agreements like DR-CAFTA are not important in determining IP policy, but rather to emphasize continuities between these agreements and broader trends in IP policymaking, which are often eclipsed by the intense

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(Submitted: 21 June 2008 – Revised version received: 17 December 2008 – Accepted: 12 January 2009 – Published online: 20 August 2009)

Table 1. Changes in pharmaceutical IP legislation in Central America and the Dominican Republic^{21–26}

| Legislation | Patent period (years) | Patent extension | Test Data Exclusivity Period, in years | “New product” definition | Linkage |
|---|-----------------------|------------------|--|--------------------------|---------|
| Costa Rica | | | | | |
| Law 6867 (1983). Invention Patents Law | | | | | |
| Law 7979 (2000). Modifications to Patents Law | 20 | no | 0 | n/a | no |
| Law 7975–2000. Undisclosed Information Law | n/a | n/a | unspecified | restrictive | no |
| Law 8632 (2008). Modifications to Patents Law | 20 | yes | n/a | n/a | yes |
| Dominican Republic | | | | | |
| Law 20 (2000). Industrial Property Law | 20 | no | unspecified | restrictive | no |
| Law 424 (2006). CAFTA Implementation Law | 20 | yes | 5 | broad | yes |
| El Salvador | | | | | |
| Decree 604 (1993). IP Law | 15 | no | unspecified | restrictive | no |
| Decree 35 (1994). IP Law’s Code | | | | | |
| Decree 912 (2005). Modification to IP Law | 20 | yes | 5 | broad | yes |
| Guatemala | | | | | |
| Decree 57 (2000). Industrial Property Law | 20 | no | 15 | restrictive | no |
| Decree 76 (2002). Modifications to Industrial Property Law | 20 | no | unspecified | restrictive | no |
| Decree 9 (2003). Modifications to Industrial Property Law | 20 | no | 5 | broad | no |
| Decree 34 (2004). Modifications to Industrial Property Law | 20 | no | unspecified | restrictive | no |
| Decree 30 (2005). Modifications to Industrial Property Law | 20 | no | 5 | broad | yes |
| Decree 11 (2006). CAFTA Implementation Law | 20 | yes | 5 | broad | yes |
| Government Decree 351 (2006). Regulation of Pharmaceuticals | n/a | n/a | n/a | broad | yes |
| Honduras | | | | | |
| Decree 12 (1999). Industrial Property Law | 20 | no | unspecified | restrictive | no |
| Decree 16 (2006). CAFTA Implementation Law | 20 | no | 5 | broad | yes |
| Nicaragua | | | | | |
| Law 354–2000. Patent Law for Inventions | 20 | no | unspecified | restrictive | no |
| Law 579 (2006). Modifications to Patent Law | 20 | no | 5 | restrictive | no |
| Health Ministry Regulation 115 (2006) | n/a | n/a | 5 | restrictive | yes |
| Law 634 (2007). Modifications to Patent Law | 20 | yes | n/a | n/a | n/a |

CAFTA, Central America Free Trade Agreement; IP, intellectual property; n/a, not applicable.

focus on trade agreements and their ratification. We explain the reasoning for these arguments here, using the examples of new IP provisions imported by DR-CAFTA to Central America, and conclude with a discussion of their broader implications.

IP in Central America

All of the CAFTA countries are members of the World Trade Organization (WTO). To comply with the TRIPS Agreement, El Salvador passed its first IP legislation in 1993–94; the remaining countries of the region passed legislation in 1999–2000. Prior to this time, effective IP protection was not applied to pharmaceutical products in the region, as in much of the rest of the world. Although the new IP legislation was motivated by pressures common

to all the Central American countries, both its content and the political will to enforce it have varied widely from country to country, and within countries across time.

DR-CAFTA was ratified by a slim margin in the Congress of the USA in August 2005, after having been ratified by the Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua earlier that year. Costa Rica approved it through a referendum in late 2007. While many of the IP provisions DR-CAFTA requires were anticipated by TRIPS, there are several key points where the agreement imposes a more stringent standard, and on which its implementation has therefore required “TRIPS-plus” reforms to existing legislation. Yet as Table 1 reveals, in some cases these provisions were implemented well before DR-CAFTA.

In other cases, laws were passed as late as 2007 but regulations had yet to be devised for their implementation.

As Table 1 shows, both the content of legislation and the dates of its passage vary widely from country to country. In many cases – that of Guatemala in particular – IP restrictive legislation was passed before the ratification of DR-CAFTA, and the political controversies associated with the ratification process led to the eventual repeal of such legislation in favour of alternatives more sensitive to public health.^{27,28} Guatemala is not the only country in which this occurred.

In Table 2, we analyse the legislation in force in Central America both before and after the passage of DR-CAFTA. We note the presence of “opportunities” and “threats” to public health, using a framework for

Table 2. Public health sensitivity in IP legislation in Central American countries and the Dominican Republic

| | Opportunities | | | | | | Threats | | | | | |
|---------------------------|--------------------------|----------------------|-----------------------------------|-----------------|--------------------------------|----------------------------|------------------|---------|-----------------|--------------------------|--------------|-----------------------|
| | Patentability exemptions | Bolar-type exception | Other exceptions to patent rights | Parallel import | Grounds for compulsory licence | Grounds for government use | Patent extension | Linkage | Data protection | “New product” definition | Grace period | “New uses” protection |
| Costa Rica | | | | | | | | | | | | |
| Pre-DR-CAFTA | + | + | + | 0 | + | + | 0 | 0 | + | 0 | 0 | 0 |
| Post-DR-CAFTA | + | 0 | 0 | 0 | + | + | - | - | - | - | 0 | 0 |
| Dominican Republic | | | | | | | | | | | | |
| Pre-DR-CAFTA | + | + | - | 0 | + | + | 0 | 0 | + | 0 | 0 | 0 |
| Post-DR-CAFTA | + | + | - | 0 | + | + | - | 0 | - | - | - | 0 |
| El Salvador | | | | | | | | | | | | |
| Pre-DR-CAFTA | + | 0 | - | 0 | + | 0 | 0 | 0 | + | 0 | 0 | 0 |
| Post-DR-CAFTA | + | + | - | 0 | + | 0 | - | - | - | - | - | 0 |
| Guatemala | | | | | | | | | | | | |
| Pre-DR-CAFTA | + | 0 | + | 0 | + | + | 0 | 0 | - | 0 | 0 | 0 |
| Post-DR-CAFTA | + | + | + | 0 | + | + | - | - | - | - | - | + |
| Honduras | | | | | | | | | | | | |
| Pre-DR-CAFTA | - | 0 | - | 0 | + | + | 0 | 0 | 0 | 0 | 0 | 0 |
| Post-DR-CAFTA | - | + | - | 0 | + | + | 0 | - | - | - | - | 0 |
| Nicaragua | | | | | | | | | | | | |
| Pre-DR-CAFTA | + | 0 | - | 0 | + | + | 0 | 0 | + | - | 0 | 0 |
| Post-DR-CAFTA | + | + | - | 0 | + | + | 0 | - | - | - | - | 0 |

DR-CAFTA, United States–Dominican Republic–Central America Free Trade Agreement; IP, intellectual property; TRIPS, Trade-Related Aspects of Intellectual Property Rights.

+ TRIPS flexibility or the TRIPS Plus provision allows an interpretation that privileges breaking the IP protection for public health needs.

0 TRIPS flexibility or TRIPS Plus provision is not explicitly included in the legislation.

- TRIPS flexibility or the TRIPS Plus provision privileges the IP protection even if it confronts public health needs.

Source: based on data from Central American legislative assemblies^{5,20–26}.

analysing the public health impact of IP developed by Chaves & Oliveira.²⁰ “Opportunities” include mechanisms that harmonize IP protection with public health objectives, such as specifications to limit patents, exceptions to patent rights that offer opportunities for timely generic drug production, and provisions for parallel importation, compulsory licensing and government use. “Threats” include patent term extension, mandated linkage between health safety requirements and patent protection, and test data exclusivity that delay the availability of generic drugs. More detailed analysis of these opportunities and threats can be found elsewhere.^{5,29–32}

A detailed discussion of all the specific provisions detailed above would occupy more space than this paper permits. To illustrate the broad trend, therefore, we discuss two of the TRIPS-plus provisions and their application

in contemporary Central America in greater depth: (i) patent extensions, and (ii) the definition of a new product subject to test data protection. Both of these provisions provide clear illustrations of what Peter Drahos³³ has called “the global intellectual property ratchet”, whereby the USA and European Union have used a combination of multilateral and bilateral strategies to push in concerted fashion for ever higher IP standards. As Table 3 and Table 4 show, in both of these provisions, TRIPS imposed a standard which was subsequently superseded by DR-CAFTA, which many Central American countries chose to interpret in ways that raise the bar even higher for IP protection.

TRIPS established, for the first time, a 20-year patent term. Yet DR-CAFTA mandates the extension of patents beyond 20 years to compensate for “unreasonable” delays in the grant-

ing of the patent or marketing approval for the drug, when such delays have been caused by the government. In Central America, there is considerable variation in how this requirement is interpreted in national law. First, what constitutes an “unreasonable” delay? And how much time should be granted as compensation? As Table 3 shows, in El Salvador and Nicaragua, national implementing legislation establishes a 550 day limit to the extension of patents (El Salvador’s Decree 912–2005, Art. 57, Nicaragua’s Law 634, Art. 1). In the Dominican Republic, the limit is set at 3 years (Law 424–06, Art. 2). In Guatemala, no limit is established (Decree 11–2006, Art. 61). In Costa Rica, the limit is set at 18 months (Law 8632, Art. 2) while in Honduras there is still no legislation extending patent protection. This clearly illustrates how a drug could be off-patent in one country, yet still protected in another,

Table 3. Patent extension in Central American countries

| | TRIPS | CAFTA | Costa Rica | Dominican Republic | El Salvador | Guatemala | Honduras | Nicaragua |
|---------------------------|-------|------------|------------|--------------------|-------------|-----------|--------------|-----------|
| Limit to patent extension | – | [No limit] | 18 months | 3 years | 550 days | No limit | No extension | 550 days |

CAFTA, Central America Free Trade Agreement; IP, intellectual property; TRIPS, Trade-Related Aspects of Intellectual Property Rights.

despite both countries sharing the same international obligations.

The definition of which products receive test data protection provides a second illustration. During the period of test data exclusivity, generic manufacturers cannot demonstrate the safety and efficacy of their product to the drug regulatory authority merely by proving bioequivalence to an existing drug. TRIPS mandates the protection of test data for products using *new chemical entities*, but DR-CAFTA requires test data exclusivity for *new products*. CAFTA defines new products by their novelty in the market in question, such that a product that had been registered elsewhere in the world, yet not in the specific DR-CAFTA country, could still demand test data exclusivity under this standard.

As shown in Table 4, several Central American countries, in specifying what constitutes a new product, go beyond DR-CAFTA's requirements, defining compound products that include a new substance as an entirely new product. For example, under current Salvadoran regulations, if one ingredient in a compound product has not been registered previously, the entire product is considered new. By contrast, in Honduras, a compound product including elements that were not previously registered would not be considered new and hence would not receive test data protection.

These concerns about what constitutes a new product are particularly

important in the case of the newer antiretroviral drugs, most of which are compounds that include at least one previously known substance. Depending on the definition adopted, these may or may not be eligible for test data protection. Because brand-name antiretrovirals are extremely expensive, and in the Central American cases their costs are primarily borne by governments, just a few months' delay in a generic alternative's entry to market can mean millions of dollars spent, often at the expense of other public health priorities.

Discussion

In the DR-CAFTA region, while all countries are bound by the same international laws, specific provisions in national law as well as varying levels of political will and resources to implement such laws lead to dramatically different consequences among countries. This complicates the task of assessing the impact of international trends, for most often the aspects which most decisively determine the extent of their application are found in national laws, regulations and practices. These forms of IP lawmaking typically fly "below the radar screen" for those engaged in debates about trade and access to medicines, but they are a critically important site for attention in determining the impact of the current trade regime on health.

Our analysis of the implementation of the transnational IP norms yields

some surprising findings. First, sometimes IP legislation was passed before ratification of the agreement (Table 1). Second, IP legislation often imposes a stricter standard than that required by the agreement itself (Table 2). And third, in some cases, specific aspects of national legislation became *more* public health sensitive over the course of treaty implementation (Table 2, Table 3 and Table 4).

How do we make sense of these findings? First, the passage of trade agreements with strong IP provisions is just one of the most visible of many related tactics that, taken together, constitute a sustained campaign. While debates over ratification capture the most attention, it is not only through formal ratification that these processes advance the "global IP ratchet". In the case of Central America, interviews suggest that some countries passed more-restrictive-than-necessary IP legislation at a time when TRIPS did not yet warrant such measures because of their eagerness to curry favour with the USA by demonstrating readiness for inclusion in an eventual DR-CAFTA. In this sense, although this early legislation preceded the passage of DR-CAFTA, it was still influenced by the prospect of its eventual passage.

Furthermore, the actual text of these agreements is just one of the ways in which trade deals determine policy. In the Dominican Republic and Guatemala, media reports indicate that the USA continued to push for

Table 4. Definition of new product for test data protection in Central American countries

| | Definition of new product | Interpretation |
|---|---|-----------------|
| TRIPS | n/a | n/a |
| CAFTA | A new product <i>does not contain</i> chemical entities previously approved in the country. | old + new = old |
| Costa Rica | Products using new chemical entities. | old + new = new |
| Dominican Republic, El Salvador, Honduras | Product <i>does not contain</i> chemical entities previously approved in the country. | old + new = old |
| Guatemala, Nicaragua | Product <i>contains</i> a chemical entity not previously approved in the country. | old + new = new |

CAFTA, Central America Free Trade Agreement; IP, intellectual property; n/a, not applicable; TRIPS, Trade-Related Aspects of Intellectual Property Rights.

higher IP standards in excess of what the agreement required, even after ratification. In Guatemala, in the context of intense debates over IP and access to medicines, the American ambassador published an editorial in a major daily newspaper threatening the country's exclusion from the benefits of the trade deal if the country was perceived as failing to "take seriously" its international commitments;³⁴ in other countries, similar messages may have been relayed in private meetings. The fact that countries imposed higher IP standards upon themselves following ratification may reflect lack of sophistication in the drafting of national legislation, but it may also speak to the persistence of pressures from powerful trade partners.

Finally, although the openings for democratic participation are limited, the ratification process does afford some positive opportunities for political mobilization around the right to health. In Central America, the passage of DR-CAFTA created more controversy than the passage of TRIPS-compliant legislation somewhat earlier; in some limited cases, the discussion prompted by DR-CAFTA led to re-examination of previous laws that had been passed with little debate. The best example of this is Guatemala, where civil society's engagement with the ratification process led to the overturning of more restrictive IP legislation in favour of more public health sensitive alternatives, when they reduced the test data protection period from 15 to 5 years (Table 1). Although focusing on the ratification process exclusively may obscure the multifaceted ways in which IP policy is determined, public health advocates should not lose sight of the opportunities that it affords.

Conclusion

During the process of trade agreement ratification, attention is often focused on the implications of IP for public health. This public scrutiny can have positive effects. At the same time, our findings show that more sustained attention to these issues is needed: not only did most Central American countries pass laws mandating the bulk of DR-CAFTA's IP provisions well before the signing of the agreement, but they continued to implement these provisions much later than the agreement's ratification. The window of opportunity for public health intervention in policy discussions therefore cannot afford to be limited to the period immediately surrounding treaty ratification.

Similarly, the topics under scrutiny must extend beyond the text of these agreements alone. National implementing legislation varies greatly from country to country, and is affected by conditions external to the negotiations of the agreement. Both before and following DR-CAFTA's ratification, the Central American countries responded to pressure from such forces by tightening their IP norms. This suggests the importance of understanding trade agreements as part of a broader, longer-term strategy on the part of the transnational pharmaceutical industry and its allies. Our purpose is not to suggest that the treaty's impact is negligible, but rather that these changes must be understood in broader perspective as, overall, contributing to a tightening of IP norms in the region, the impact of which has yet to be fully understood.

Further study is required to determine the extent to which these laws, once widely implemented, limit access

to medicines in Central America. Also, while the country-by-country analysis undertaken here is absolutely necessary to understand the impacts of regional free trade agreements on the ground, given the global market in medicines, national analyses alone provide insufficient measures of the impacts of these norms. In Central America, for example, many generic medicines are imported from countries outside the region, including Colombia and India. In reaction to the rising IP demands of American free trade agreements (in the case of Colombia), direct challenges from American pharmaceutical companies (as in India), and political pressures from the American and other governments, these countries tighten their national IP legislation, which inevitably impacts the drugs they export. In Central America and other areas without major drug production capacity, the availability of generic medications is not only influenced by local legislation but by decisions made in far-away courts and congresses, which may cut off the flow of affordable medications at its source. As the public health community strives to better understand the impact of IP norms on access to affordable drugs, it is imperative that we undertake research that is both rooted in national particularities and sensitive to the crosscutting effects of changes at the international and transnational level. ■

Funding: This work was funded by the Puget Sound Partners for Global Health and by a grant from the National Science Foundation (award number: 0617374).

Competing interests: None declared.

Résumé

Propriété intellectuelle et accès aux médicaments : analyse de la législation en Amérique centrale

La protection de la propriété intellectuelle (PI) concernant les médicaments a progressé vers la mondialisation au cours de la dernière décennie. Les pays membres de l'Organisation mondiale du Commerce ou parties à des accords commerciaux internationaux ont été dans l'obligation d'adapter leur législation. Il est de plus en plus reconnu que, dans les pays à faible revenu, le renforcement de la PI est un obstacle à l'accès aux médicaments. Dans le même temps, le nombre de pays à faible revenu qui se dotent d'une législation nationale en faveur de la PI pour les produits pharmaceutiques est en augmentation partout dans le monde, mais peu de recherches ont été menées sur la façon dont ce processus s'opère au niveau national.

Le présent article vise à faire comprendre comment la législation sur la PI est mise en œuvre au niveau national par une analyse comparative de la situation dans les pays signataires de l'Accord de libre-échange entre l'Amérique centrale, les États-Unis d'Amérique et la République Dominicaine (DR-CAFTA). Cette analyse fait apparaître trois tendances. Premièrement, les pays ont souvent mis en place une PI plus forte que celle requise par les accords commerciaux. Deuxièmement, certains pays ont adopté une protection de ce type avant d'avoir signé ces accords. Troisièmement, le processus de ratification du DR-CAFTA a intensifié le débat public autour de ces questions, ce qui, dans certains cas, a conduit à la prise en

compte des besoins de la santé publique dans la législation sur la PI. Ces tendances laissent à penser que les pays industrialisés et l'industrie pharmaceutique utilisent des moyens tactiques autres que les accords internationaux pour promouvoir un renforcement

de la PI et que le processus d'élaboration d'une législation nationale est une arène valide pour confronter les besoins de la santé publique à ceux de l'industrie.

Resumen

Propiedad intelectual y acceso a los medicamentos: análisis de la legislación en América Central

Durante la última década ha avanzado la globalización de la protección de la propiedad intelectual (PI) de los medicamentos. Los países están obligados a adaptar su legislación como requisito de su pertenencia a la Organización Mundial del Comercio o como condición para participar en acuerdos comerciales internacionales. Una idea cada vez más aceptada es que en los países de ingresos bajos esa mayor protección obstaculiza el acceso a los medicamentos. Al mismo tiempo, crece en todo el mundo el número de países de ingresos bajos que promulgan legislación nacional para garantizar la PI de productos farmacéuticos, pero son escasas las investigaciones realizadas sobre la manera en que se está llevando a cabo ese proceso en cada país.

Este artículo pretende ayudar a comprender mejor la aplicación de la legislación sobre PI a nivel nacional, ofreciendo para ello un análisis comparativo de los países que forman

parte del Tratado de Libre Comercio entre los Estados Unidos, la República Dominicana y América Central (DR-CAFTA). El análisis pone de relieve tres tendencias: en primer lugar, los países han aplicado a menudo medidas de PI más enérgicas que las exigidas por los acuerdos comerciales; segundo, algunos países han adoptado medidas de PI antes de firmar los acuerdos comerciales; y, tercero, el proceso de ratificación del DR-CAFTA estimuló el debate público sobre esas cuestiones, debate que en algunos casos desembocó en legislación de PI que tiene en cuenta las necesidades de salud pública. Estas tendencias llevan a pensar que los países industrializados y las empresas farmacéuticas están empleando otras tácticas aparte de los acuerdos comerciales justos para intentar conseguir un mayor nivel de PI, y que la legislación nacional es un terreno válido para confrontar las necesidades de salud pública y los intereses de la industria.

ملخص

الملكية الفكرية والحصول على الأدوية: تحليل للتشريعات في أمريكا الوسطى

الأول لبلدان يغلب أن تنفذ حماية للملكية الفكرية بصورة أقوى مما تتطلبه الاتفاقات التجارية. والاتجاه الثاني لبلدان تبنت حماية الملكية الفكرية قبل توقيعها على الاتفاقات التجارية، والاتجاه الثالث لبلدان زاد فيها الجدل على الصعيد الشعبي حول هذه القضايا لدى تصديقها على اتفاق التجارة الحرة بين الولايات المتحدة الأمريكية وجمهورية الدومينيكان وأمريكا الوسطى، وقد أدى ذلك في بعض الحالات إلى ظهور تشريعات حول الملكية الفكرية تأخذ بالاعتبار الاحتياجات في الصحة العمومية. وتشير هذه الاتجاهات إلى أن البلدان الصناعية وشركات صناعة المستحضرات الصيدلانية تستخدم أساليب مختلفة ولا تقتصر على ما ورد في الاتفاقات التجارية وذلك للدفع باتجاه زيادة حماية الملكية الفكرية. وتمثل عملية التشريع الوطني حلبة حقيقية للمواجهة بين الاحتياجات التي تتطلبها الصحة العمومية وبين تلك الخاصة بالشركات الصناعية.

حققت عولمة حماية الملكية الفكرية للأدوية تقدماً مطرداً خلال العقد المنصرم. فالبلدان ملتزمة بتكثيف تشريعاتها كشرط للحصول على العضوية في منظمة التجارة العالمية، أو كشرط لتكون جزءاً من الاتفاقات الدولية الخاصة بالتجارة. ويزداد الإدراك بأنه في البلدان المنخفضة الدخل تمثل الحماية الأقوى للملكية الفكرية حاجزاً أمام الحصول على الأدوية. وفي الوقت نفسه، يتزايد عدد البلدان المنخفضة الدخل التي تضع تشريعات وطنية لحماية الملكية الفكرية للمنتجات الصيدلانية في جميع أرجاء العالم، إلا أن الأبحاث التي تجرى حول الطرق التي تتم فيها هذه العملية على الصعيد الوطني قليلة. وتهدف هذه الورقة إلى الإسهام في فهم تطبيق تشريعات الملكية الفكرية على الصعيد الوطني، من خلال إجراء تحليل مقارنة بين البلدان التي هي جزء من الاتفاق الخاص بالتجارة الحرة بين الولايات المتحدة الأمريكية وجمهورية الدومينيكان وأمريكا الوسطى. وقد أوضح التحليل ثلاثة اتجاهات، الاتجاه

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