

## Access to Medicines in Developing Countries and Free Trade Agreements: The Case of the US-DR-CAFTA with Focus on Costa Rica

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The scope of this paper is to provide an analysis of the impact of the IP provisions of a free trade agreement, the US-DR-CAFTA, in the context of access to medicines in developing countries. The paper appraises whether the said provisions depart from the framework set by TRIPS, to which extent they create a more stringent framework by the inclusion of TRIPS plus provisions, heavily criticised because of their repercussions on the fundamental right to health. There is also an assessment of whether these provisions have determined a change of the related IP law provisions in the CAFTA Member State, Costa Rica, and whether access to affordable or indispensable medicines has been affected or not. In conclusion, some improvements are recommended along with an overall assessment of the IP provision of the country, as a result of CAFTA implementation.

**Keywords:** Access to medicines, CAFTA, developing countries, free trade agreement, TRIPS plus

### **Access to Medicines, Free Trade Agreements and WTO: Relation and Purpose**

The intersection between the need to grant adequate access to health and the implementation of TRIPS (mandatory for WTO members), has created a situation where pharmaceutical companies enjoy more rights than before, while developing countries try to address the cure for diseases that can create health crises or emergencies. Such an issue has been also object of a consuming academic debate. Developing countries are today at crossroads, since some of them are experiencing a rapid growth in terms of GDP, as well as fast development in terms of implementation of fundamental rights. Health is without doubt a fundamental right,<sup>1</sup> and despite the fact that developing countries face high levels of poverty and inequalities, actions to remove barriers in accessing medicines have been the object of various initiatives. The climax was undoubtedly reached with the explosion of the AIDS crisis and the consequent intervention of many NGOs putting pressure for a reconsideration of the impact of TRIPS on access to health. These actions lead eventually to two further steps: the Doha declaration on TRIPS and Public Health and the WTO 2005 Ministerial Declaration, introducing TRIPS Article 31bis.

According to article XXIV of GATT, WTO Members may enter into a free trade agreement (FTA), which aims to increase freedom of trade by the development of closer ties between the economies of countries that are parties to such agreements.<sup>2</sup> An FTA is clearly an exception to the Most Favoured Nation (MFN) principle.

Unsurprisingly enough, trade does not mean only goods and services, but also intellectual property rights to be protected and enforced. Even though the third pillar of the WTO – TRIPS – does not contain a clause similar to Article XXIV of GATT, this has not prevented the US from providing for an IP chapter when negotiating an FTA, whose provisions usually modify the level of protection given by such rights. This is indeed logical as a premise but can hypothetically have profound consequences if put into practice. One may not disregard, as it will be shown in the following pages, that an FTA may be a means to bypass the flexibility provided in the TRIPS Agreement, as well as in the Doha Declaration on TRIPS and Public Health, by providing, on one hand, that the parties may implement more extensive IP rights protection, and, on the other hand, providing a ‘default’ set of rules that go directly beyond TRIPS flexibility.<sup>4</sup> When discussing access to medicines, this bypassing mechanism must be taken into account to make an appraisal of the impact of the provisions related to IP rights, patents in particular, contained in a FTA.

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The focus of this paper is on the IP provisions of the US-DR-CAFTA (hereinafter CAFTA)<sup>5</sup> between the US and the Dominican Republic, Nicaragua, Guatemala, Costa Rica, El Salvador and Honduras which entered into force in 2006. Further focus is on the implementation of CAFTA in Member Countries, dedicating attention to Costa Rica. The reason for choosing this country is related to the progressive amendments in its IP legislation after the entry into force of TRIPS and CAFTA, which offers a broad spectrum for the assessment of the effects of the IP provisions to be discussed. Its classification as a developing country has been made according to the UNDP Human Development Index and the Statistics data released by UNCTAD.<sup>6</sup>

### **CAFTA: An Assessment of Sensitive IP Provisions in Relation to Access to Medicines**

#### **IP Provisions in the CAFTA**

Intellectual property rights are contained in Chapter 15 (hereinafter, The Chapter) of CAFTA.<sup>7</sup> For the scope of this paper are relevant the 'General Provisions' contained in Article 15.1; the provisions on 'Patents' contained in Article 15.9; and Article 15.10, titled 'Measures related to certain regulated products'. The author only discusses provisions related to pharmaceutical products, the focus not being on research in agricultural chemical products.

Article 15.1 contains a set of obligations that Members have to meet as a result of being Parties to the CAFTA. It is compulsory for the Parties to give effect to 'The Chapter', wherein although not obliged to, but at the same time not prevented from, adopting more extensive protection of IP rights than required.<sup>8</sup> Parties shall also 'ratify or accede' the Patent Cooperation Treaty and 'make all reasonable efforts to ratify or accede to' the Patent Law Treaty;<sup>9</sup> commitments existing under the TRIPS and other Intellectual Property agreements concluded or administered under the auspices of WIPO are also affirmed [Article 15.1 (7)]. The principle of national treatment has an explicit provision, and can be derogated only in particular circumstances and provided that it does not create disguised restrictions to trade [Article 15.1.(8) & (9)]. Parties are also not prevented from adopting measures necessary to contrast anticompetitive practices deriving from the abuse of IP rights [Article 15.1 (15)]. Other provisions are related to the application of the Agreement, making clear that, while there is no obligation to restore matters that have fallen into the

public domain or to create rights in relation to acts that occurred before its entry into force, it will apply to all subject matter protected at the time of its entry into force, or that subsequently meets the requirement to be protected [Article 15.1 (12)-(13)]. Transparency is another important issue: laws of the Member States must be accessible and made publically available [Article 15.1 (14)]. Finally, the importance of cooperation in educational projects related to the importance of IP as a research and innovation tool is stressed; in the exchange of information between IP offices and other institutions of the Parties; and in the implementation of electronic systems to manage intellectual property issues [Article 15.1 (16)].

An invention that is new, involves an inventive step and is capable of industrial application (namely, having specific, substantial and credible utility) [Article 15.9 (11)] is the object of a patent,<sup>17</sup> although parties are free to exclude some inventions from patentability.<sup>11</sup> A clarification is also provided on the requirement of invention disclosure established in the TRIPS, setting a rule in order to consider when the disclosure of a claimed invention is sufficiently complete and clear [Article 15.9 (9)], as well as a presumption as to when to consider an invention sufficiently supported by its disclosure.<sup>12</sup>

Parties may also include limited exceptions to the exclusive rights conferred by a patent,<sup>13</sup> as well as set grounds to revoke or cancel it, including fraud, misrepresentation or inequitable conduct.<sup>14</sup> A 'bolar exception' is also contemplated under which a third party can use the subject matter of a patented invention to generate data needed for a particular use: no different use is allowed other than obtaining a marketing approval before the patent has expired [Article 15.9 (5)].

Last but not the least, it is provided that each Party shall adjust the term of a patent to compensate for unreasonable delays in the granting procedure (for a delay of more than five years from the date of filing an application or three years after filing a request for examination); in relation to pharmaceuticals products it is provided to make available a compensation for unreasonable curtailment of the patent term as a result of the marketing approval process, under the form of restoring or extending the patent term [Article 15.9 (6)].

Article 15.10 contains some (sensitive) provisions related to certain regulated pharmaceutical products,<sup>15</sup> imposing a set of obligations on the Parties, which compliance may entail amendments in the Members' legislation. The first set of provisions is related to

submission of undisclosed data related to safety or efficacy of a product necessary for its marketing approval: Parties must prohibit third persons from marketing a product on the basis of such information or on the basis of the approval obtained by the person that initially submitted the data, for a period of five years from the date of initial approval [Article 15.10 (1)(a)]. Moreover, Parties have an obligation to protect undisclosed information from disclosure, with the exception of actions necessary to protect the public; disclosed information must be protected against unfair commercial use [Article 15.10 (1)(d)].

A second set of provisions concerns the case where a Party permits, as condition for marketing approval of a new pharmaceutical product, submission of evidence concerning safety or efficacy of the product previously approved in another territory (bioequivalence test), or evidence of its marketing in another territory: third persons shall be prevented from marketing the product based on the aforementioned grounds for a period of at least five years starting from the date of granted approval in the Party's territory to the person who who obtained approval in another territory. To make effective such a protection, a Party may provide that a person obtained approval in another territory will have to seek approval in the Party's territory within five years [Article 15.10 (1)(b)].

On the other hand, where a Party permits, as condition for approving the marketing of a pharmaceutical product, third persons to rely on evidence or information concerning the safety and efficacy of a product that was previously approved in the Party's territory or in another country; that Party shall implement measures to prevent other persons from marketing a product covered by a patent during the term of patent validity. The Party, moreover, shall inform the person enjoying the patent of such a request and of the identity of the person asking approval to enter in the market during the term of patent validity and on the conditions set above [Article 15.10 (2)(a) & (b)].

A last provision states that a new product is one that does not contain a chemical entity that was previously approved in the territory of the Party.

#### **Do such Provisions Prejudice Access to Medicines?**

After the TRIPS Agreement came into force,<sup>16</sup> many concerns were raised about its impact on access to medicines. This situation led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health which stated the necessity of interpreting the TRIPS Agreement so as to grant Member's rights to

protect public health and promote access to medicines. The Declaration was the starting point for the Decision of August 2003, a waiver of TRIPS Article 31(f), and the amendment of the same provision through the introduction of Article 31bis.<sup>17</sup> This wave of good will, however, left a gap in turn filled with the discontent of developed countries, precisely countries where interests of pharmaceuticals companies are more evident. This feeling led to successive erosion of these flexibilities, with the negotiation and accomplishment of (an increasing number of) FTAs imposing additional obligations over TRIPS, thus creating a barrier to access to medicines.<sup>18</sup>

CAFTA is not an exception to this trend, since some provisions clearly introduce TRIPS plus standards. Object of this subparagraph will be the assessment of these provisions to understand their impact on access to medicines.

#### **Patent Extension**

As previously discussed, unlike TRIPS, which provides that patents last for 20 years from the date of application, CAFTA (as common for FTAs promoted by the USA)<sup>18</sup> also includes patent extension, providing for a term adjustment to compensate for unreasonable delays granting a patent and, in relation to pharmaceuticals products, restoration or extension of the patent term for unreasonable curtailment of the patent term in the marketing approval process. Such a provision has been generally advocated (and obtained) by the pharmaceutical industry, according to whom obtaining marketing approval of new chemical entities requires time, thereby reducing the effective term of enjoyment of the patent, as well as the possibility of recouping research and development costs.<sup>18</sup> The text of the CAFTA leaves open possible interpretative gaps because it is not specified whether the extension shall apply only to a delay in the country where the application is filed or also to the delay in the country where the first approval was obtained.<sup>19</sup> Moreover the definition of 'unreasonable' is object to elaboration at a national level, creating more differences than similarities.<sup>20</sup> Last, as far pharmaceutical products are concerned, a period of patent restoration or a minimum period that constitutes unreasonable curtailment is not suggested, thus leaving the question open for national legislators to decide, which, lacking coordination, might create a situation in which a patent that has expired in one country would be still live in another.<sup>21</sup>

The justification for patent extension on this basis is not convincing. It has been argued that R&D costs may

be easily recouped in several months of sales (in a regime of monopoly) of successful products.<sup>18</sup> Further, only a few patents usually relate to new active ingredients, while in most of the cases there is an attempt to protect a mere different use of a product, as well as minor changes that delay competition.<sup>22</sup> On another note, patent extension is not a solution to improve the efficiency of the patent issuing procedure, since it does not address a common problem in many developing countries, namely that 'patent offices are under-staffed and delays are common'.<sup>18</sup> It is foreseeable that such extensions will impact public health, delaying the availability of low-cost generic (and directly competing) products (for instance, beyond the date they are available in the US),<sup>23</sup> increasing barriers to access to medicines and generating loss for consumers.

The mechanism of patent extension, in the author's view, will externalize the economic risk related to the patenting process to the sole advantage of pharmaceutical companies. Since the community will bear the burden of paying for any administrative delay and no additional benefits will be given to patients in developing countries, in terms of lower prices; a defence for the mechanism should be based on other (and more cogent) grounds than recouping R&D costs.<sup>18</sup>

The same conclusion may be reached based on an economic analysis. Revenues generated in developing countries represent only a small portion of the total profits of drug companies.<sup>24</sup> In the scenario that there is a sufficient percentage of wealthy people that can afford to buy at a higher price in these countries, pharmaceutical companies will most likely set their target accordingly.<sup>25</sup> As such, it is not expected that there will be huge investments in R&D in relation to specific diseases<sup>26</sup> that affect the population in developing countries,<sup>18</sup> although these companies would invest in research for common diseases products that would target a bigger market share, as well as that R&D costs are logically going to be recouped for the major part in developed countries. Furthermore, there is no clear relation between longer patent rights and increment of foreign direct investments or transfer of technology, since the decision to invest is driven by other factors such as the potential for economic growth.<sup>27</sup>

#### *Test Data Exclusivity*

The TRIPS Agreement in its Article 39(3) requires that undisclosed test data be protected against unfair commercial use. This provision, however, does not create an obligation for Members to grant exclusive rights over test data. However, CAFTA, as do some

FTAs negotiated by the US, departs from this standard, obliging the Parties to grant exclusive rights for at least five years from the date of approval of the product, independent of whether the product is patented or not and whether data is undisclosed or not.<sup>18</sup>

Such exclusivity will apply irrespective of whether a Party requires the submission of the data (thus even to cases relying on approval given in a foreign country) and covers chemical entities that are not 'new', as they may have been previously approved in other territories. Moreover, CAFTA provides for a waiting period of five years. In fact, a Party may require that the person providing the information in another territory seek approval in the Party within five years of obtaining marketing approval in the other territory. Thus, the originator is likely to enjoy up to ten years of exclusivity during which time no one would be able to use the test data without her consent.

Implications of data exclusivity should be considered very carefully, since medicines that are off-patent may then become subject to exclusive rights. This prevents competition because even when a medicine is not protected by a patent, there is a period of market monopoly where higher prices would be still charged.<sup>18</sup> It goes without saying that generic medicine producers would face a barrier in entering in the market, since they need to replicate costly and time consuming tests in order to obtain a marketing approval instead of relying on bioequivalence tests. The consequences of these provisions are in open contrast with the Doha Declaration since those CAFTA Members that are developing economies will have to wait longer than their developed counterpart, United States, to access generic and less expensive medicines.<sup>23</sup>

#### *Linkage*

CAFTA entails a linkage between drug approval and patent protection, a measure not provided for in the TRIPS Agreement. This mechanism requires a Party to deny marketing approval to a generic version of a product if a patent is already in force, unless permitted by the patent owner. Moreover, a party is required to inform the patent owner about applications for the approval of a generic product.

The linkage system does not take into account that patents are private rights and puts a heavy burden on Members to prevent possible infringement, along with the risk of liabilities in case the generic product was improperly prevented from entering the market.<sup>18</sup> This system would overwork health authorities, specially considering the fact that these authorities do not have

knowledge and expertise to deal with patent claims.<sup>23</sup> This is a task best left to a Court, and more specialized venues that deal with rights protection and enforcement, while health authorities should carry out merely administrative tasks. Looking at some developed countries, patent-registration linkage is not a standard followed in the USA and the EU. In particular, the US Food and Drug Administration does not act as an enforcer of rights derived from a patent, but merely informs patent owners of the existence of another application on the same drug, hence leaving the issue for the patent owner to act before a Court to seek protection against third parties for alleged infringement. In the EU, the protection of a patent is completely independent of its registration, the role of the health authorities being merely to ensure compliance with standards of quality, safety and efficacy of medicines, without any action in the enforcement of patent rights.<sup>18</sup>

### **Impact of CAFTA on National Legislations: The Example of Costa Rica**

In the previous discussion, it has been made amply clear that the provisions of CAFTA threaten access to medicines. The following paragraphs will focus on the implementation of CAFTA in Member States. Its impact on national legislation is examined taking Costa Rica as example.

Costa Rica has been a member of the WTO since 1995 and decided to ratify CAFTA in 2007 after a referendum. As far as access to medicines in this country is concerned, two points are important. The first is that the constitution of Costa Rica recognizes the right to health [Article 46 (5)], and individuals denied access to essential medicines can seek relief before the Constitutional Court with a remedy called *amparo*.<sup>28</sup> Secondly, Costa Rican legislation can be segregated into three periods: pre TRIPS; post TRIPS; post CAFTA. The first patent law in Costa Rica was enacted in 1983 (Law n. 6867) and did not recognize any right in relation to the patentability of pharmaceutical products. This law was then amended in 2000 and 2008, this being necessary to adapt the legislation to the requirements of TRIPS and CAFTA. It is also noteworthy that in 2000, a law on undisclosed information was passed (Law 7975/2000), again amended in 2008.

For the purpose of this paper, those CAFTA provisions relevant to access to medicines are discussed in terms of their impact on legislation in Costa Rica.<sup>29</sup>

### ***Patents Extension***<sup>30</sup>

Patents protection still lasts 20 years but it is possible to extend its duration for delays in granting a patent [Article 17 (2), Costa Rica Patent Law] or marketing approval<sup>31</sup> (for pharmaceutical products, a delay of more than three years from the date of filing of the marketing application). Restoration cannot exceed a maximum period of 18 months [Article 17 (3) & (5)], Costa Rica Patent Law]. The extension of a patent may however, be theoretically more than 18 months (but no more than three years) in case of a delay in both granting the patent and marketing approval, leading to interpretation problems.<sup>32</sup>

### ***Test Data Exclusivity***

The provisions of CAFTA find implementation in Article 8 of the Law on Undisclosed Information (Law 7975/2000), as amended in 2008. If in order to obtain an approval to market a new pharmaceutical product the applicant is required to reveal undisclosed test data, including data on safety and effectiveness or other undisclosed information whose preparation has entailed considerable efforts; such data is protected for five years from the date of initial marketing approval<sup>33</sup> against unfair commercial use and any disclosure, except where the use of such data is necessary to protect the public. If such information is disclosed, measures are to be taken to guarantee protection against any unfair commercial use.

A new product is defined as one which does not contain a chemical entity that was previously approved in Costa Rica;<sup>34</sup> a chemical entity being defined as 'the functional group of the active ingredient which is responsible for the biocidal, physiological or pharmacological action. All polymorphs, isomers and other derivatives with parts joined to the chemical whole of which it is composed, such as ester, ether, salt, including salt with hydrogen or coordinated unions, complex or otherwise, shall be defined as a single chemical entity'. Besides, there is a stipulation that new uses or indications, changes in the route of administration, dosage, assumption form, formulation of a chemical entity, or those products constituting combinations of chemical entities previously registered in the country will not be considered new pharmaceuticals products.<sup>35</sup>

This definition is problematic because it protects chemical entities not previously approved in Costa Rica, but in other countries in the world (leaving the room open for opportunistic behaviour wherein the producer seeks approval of a 'new' product in Costa Rica at a later stage after having obtained protection

in another country, thus to the detriment of generic medicines production and the availability of more affordable products); and also restrictive since not all the products will receive such protection.

Exceptions to test data protection [(according to Article 15.10(1)(d) CAFTA)] are indeed few, for instance, use of test data by competent authorities to prevent practices that may mislead consumers or to protect lives, health or human safety, or animal or plant life or the environment, provided that said information is not disclosed.<sup>36</sup> Moreover, as discussed above, the time period of exclusivity provided by CAFTA has not been adequately defined, and it is likely that the originator may enjoy up to ten years of exclusivity.<sup>37</sup>

#### *Linkage*

In Costa Rica, the Ministry of Health is in charge of implementing appropriate measures in order to prevent third persons from commercializing a product covered by a patent.<sup>38</sup> Information related to applications for marketing products are made available on the web site of the Ministry of Health, so that each patent holder is adequately informed.<sup>39</sup>

#### *US-DR-CAFTA Flexibilities*

As an attempt at reaffirming the flexibilities aimed at protecting public health under CAFTA, the Parties signed on 5 August 2005 an 'Understanding regarding

certain Public Health measures', making clear that the obligations set in Article 15 of CAFTA, are not an impediment to adopt measures that are necessary to protect public health and access to medicines. As a result of this Understanding, Costa Rica is not obliged, for instance, to give retroactive effect to patents, or to grant patents whose exploitation may be contrary to public policy or morals.<sup>32</sup>

In implementing CAFTA, Costa Rica also kept some other important flexibilities. As far as patents are concerned, there is a deadline to submit the application to obtain restoration: 3 months following the grant of patent or the marketing approval. Costa Rica, moreover, follows a regime of international exhaustion, so it is possible to rely on parallel imports and it is also possible to issue compulsory licences where a patent has not been worked, for secondary patents, or to prevent anticompetitive practices and to protect the public interest (Articles 18-20, Costa Rica Patent Law).

For test data, flexibilities are also incorporated in the restrictive definition of 'new product', in the use of the bolar exception [Articles 16.2 (b) & (c), Costa Rica Patent Law] and in the use by the State of test data in a series of circumstances.<sup>40</sup> The change in the relevant laws in Costa Rica and its major provisions discussed in this article are depicted in Table 1.

Table 1 — Changes in IP law related to pharmaceutical products in Costa Rica<sup>41</sup>

Legislation	Patent period	Patent extension	Text data exclusivity period	Definition of new product	Linkage	Compulsory License	Parallel import
Patent Law (Law 6867/1983)							
Patent Law (as amended by law 7979/2000)	20 years <sup>42</sup>					Yes	
Patent Law (as amended by law 8686/2008)	20 years <sup>42</sup>	18 months <sup>43</sup>			Yes <sup>44</sup>	Yes	
Undisclosed Information Law (Law 7975/2000)			not specified				
Undisclosed Information Law (as amended by law 8686/2008)			not specified	Yes <sup>45</sup>			
Regulation of the Undisclosed Information Law <sup>46</sup>			5 years <sup>47</sup>	Yes <sup>48</sup>			
Trade Mark Law (Law 7978/2000)							Yes <sup>49</sup>
Trade Mark Law (as amended by law 8686/2008)							Yes <sup>49</sup>

## Conclusion

As demonstrated, CAFTA contains many provisions that represent a TRIPS plus standard. To evaluate whether these provisions represent a barrier to international trade and to access to medicines, one has to evaluate their impact on national legislation. As the case of Costa Rica shows, patent extension, test data exclusivity and linkage provisions may act as a threat in access to medicines, but facilitate international trade; for while giving powerful rights to patents owners, operates against lowering the price of medicines. The fact that the waiting period, as per Article 15.10 (1) (b) has not been shortened may really entail a ten year-protection for test data, is quite alarming, considering that such a protection is related to products that might not be even protected by a patent in Costa Rica.

In the opinion of the author, however, this threat is not yet actual. Not only there is a system that protects health at a constitutional level, which will grant access to medicines shifting the burden on State's budget (may be a problem in the future), but there are also other provisions such as parallel import and compulsory licensing that really focus on lowering the prices of medicines. Moreover the 2005 'Understanding' seems to bring back from the main door what went out of the window, namely the Doha Declaration, which will play a determinant role in the future, provided that it is exclusive right of the States to determine their health policies and which cases constitute an emergency.

The analysis shows that in Costa Rica there is some kind of balance between protection of IP right and access to medicines/production of generic drugs. However, it would be advisable for Costa Rica to review the waiting period in relation to data exclusivity, limiting the danger of opportunistic behaviours. Moreover, the country will have to take care of the budgetary consequences of access to health as a constitutional right.

## References

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- 2 Guzman A & Pauwelyn J, *International Trade Law*, 2<sup>nd</sup> edn (Wolter Kluwers/Aspen Law), 2012 p. 337. A similar exception is provided by Article V of GATS.
- 3 In the WTO system, countries cannot discriminate between their trading partners. The Most Favoured Nation Principle implies that if a particular favourable treatment is granted to one country, it has to be granted to all the WTO members. Such principle is a milestone in trade law, and is present in the GATT, GATS and TRIPS.
- 4 See Article 15.1.1 of US-DR-CAFTA, and for the second statement its Articles 15.9 and 15.10.
- 5 CAFTA has been a side product of an agreement between all countries in the Americas, the Free Trade Area Agreement (FTAA), that never become an actual treaty. As the FTAA negotiations stalled, CAFTA was introduced as an expansion of the NAFTA. It is also considered to be a step towards the FTAA concept, <http://globaledege.msu.edu/trade-blocs/cafta-dr/history> (3 February 2014).
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- 8 Article 15.1 (1). See also Article 1 of TRIPS, first sentence.
- 9 Article 15.1 (3) and (6). See also Article 3 of TRIPS.
- 10 Article 15.9 (1) and Article 27 of TRIPS, first sentence.
- 11 See also Article 15.9 (7) and 15.9 (8) for provisions granting a grace period of 12 months prior to the filing of a patent application in relation to information contained in public disclosures made to determine the novelty and the inventive step of the invention, as well as a chance of making amendments, corrections and observations in connection to the patent applications.
- 12 Article 15.9 (10) and Article 29 of TRIPS.
- 13 Article 15.9 (3) and Article 30 of TRIPS.
- 14 Article 15.9 (4). However, according to Article 32 of TRIPS, Parties have to make available an opportunity for judicial review.
- 15 As this paper focuses on access to medicine, references are made only to those provisions related to pharmaceutical products.
- 16 Developing countries accepted stringent norms of patent protection in exchange of having access to developed markets for traditional manufactured goods, as well as commitment of developed countries to stop unilateral trade sanctions for inadequate protection of foreign intellectual property rights, Reichman J H, Comment: Compulsory licensing of patented pharmaceutical inventions: Evaluating the options, *The Journal of Law, Medicine & Ethics*, 37 (2) (2009) 247.
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- 27 Maskus K, The role of intellectual property rights in encouraging foreign direct investment and technology transfer, in *Intellectual Property and Development. Lessons from Economic Research*, edited by C Fink & K Maskus (World Bank and Oxford University Press Washington DC), 2005, p. 66; do Amaral A Jr, Compulsory licensing and access to medicine in developing countries, SELA 2005, Panel 5: Poverty and the International Order, 2005, p. 13; Reichman J H, Comment: Compulsory licensing of patented pharmaceutical inventions: Evaluating the options, *The Journal of Law, Medicine & Ethics*, 37 (2) (2009) 256.
- 28 Generic drug entry prior to patent expiration, Federal Trade Commission, Washington DC, 2002, <http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study> (3 February 2014).
- 29 Walker S, The United States–Dominican Republic–Central American Free Trade Agreement and access to medicines in Costa Rica: A human rights impact assessment, *Journal of Human Rights Practice*, 3 (2) (2011) 196.
- 30 For a detailed discussion on the evolution of Costa Rica Legislation after TRIPS and CAFTA, see Hernández-González G, Evaluación del Impacto de las Disposiciones de ADPIC + en el Mercado Institucional de Medicamentos de Costa Rica, Programa de ICTSD sobre Propiedad Intelectual y Desarrollo Sostenible, Diciembre 2009 (Spanish).
- 31 Due to the parallelism with other patent extension/restoration systems, among others the Supplementary Protection Certificate (SPC) in the European Economic Area, a question that may trigger the interest of the reader is whether patent extension also applies to secondary patents. From the CAFTA text it is not possible to infer whether patent extension is available for secondary patents because the text itself is not detailed and leaves open more questions than answers. However, a close look at both the Costa Rican Patent Law and the regulation to the Law of Undisclosed Information may be a good starting point for providing an answer. Article 1 of the Costa Rican patent law, at paragraph 2, excludes from the notion of invention 'the juxtaposition of known inventions or mixtures of known goods, a change in their form or use, dimensions or materials, except where such combination or amalgamation cannot function separately or where the qualities or functions that are characteristic thereof are modified to obtain an industrial result which is not obvious for a person skilled in the art.' Under this provision it seems that a secondary patent cannot be protected, specially if we think of formulations, and hence there should not be ground for granting patent extension. However, the statement 'except where such combination or amalgamation cannot function separately or where the qualities or functions that are characteristic thereof are modified to obtain an industrial result which is not obvious for a person skilled in the art' will certainly cause judicial debate in the future. On the other hand, the protection of test data relies on a domestic sided notion of new product. The 'Reglamento a la Ley de Información no Divulgada', defines a new pharmaceutical product as 'Un producto farmacéutico que no contenga una entidad química presente en la formulación de un producto que haya obtenido un registro sanitario previamente en Costa Rica. No se considerarán productos farmacéuticos nuevos aquellos que constituyan nuevos usos o indicaciones, cambios en la vía de administración, en la posología, en la forma farmacéutica o en la formulación de una entidad química o aquellos productos que constituyan combinaciones de entidades químicas previamente registradas en el país.' [A pharmaceutical product that does not contain a chemical entity present in the formulation of a product that has previously obtained a sanitary registration in Costa Rica. Pharmaceuticals product constituting new uses or indications, changes in the way of administration, dosage,



- pharmaceutical form or in the formulation of a chemical entity or those products which constitute combinations of chemical entities previously registered in the country will not be considered new]. The issue, as presented, may create some distortions, in the sense that if a new product is patented outside Costa Rica, then the related test data can be protected in Costa Rica as well, provided that the product is new under the Costa Rican law on undisclosed information and its regulation. Although it is not a patent extension, test data protection may prevent the availability of data to third parties to develop generic medicines. Following these considerations, it is reasonable to infer that secondary patents do not enjoy protection in the CAFTA system, as implemented in Costa Rica. However, some level of protection can be obtained throughout the test data protection term, which is surely a subject of debate. From this realm, however, those secondary patents (namely, formulations) remain excluded from this debate, since the possibility of their protection is expressly excluded by the regulation to the law on undisclosed information.
- 32 Thus specifying an unreasonable curtailment requirement contained in CAFTA Article 15.9 (6) (b). There is a discrepancy in the Spanish and English versions in terms of the period: the Spanish version mentions three years from the date of submission of a marketing application, while the English translation mentions three months. However, the author goes with the Spanish version since it is the original.
- 33 Hernández-González G, Evaluación del Impacto de las Disposiciones de ADPIC + en el Mercado Institucional de Medicamentos de Costa Rica, Programa de ICTSD sobre Propiedad Intelectual y Desarrollo Sostenible, Diciembre 2009, p. 15, 17-18.
- 34 Article 15 of the Regulation of Law on Undisclosed Information (Decreto N° 34927-J-COMEX-S-MAG/2009).
- 35 Article 8 of Law on Undisclosed Information (7975/2000 as amended in 2008); see Article 4 of the Regulation of Law on Undisclosed Information (Decreto N° 34927-J-COMEX-S-MAG/2009).
- 36 Article 4 of the Regulation of Law on Undisclosed Information (Decreto N° 34927-J-COMEX-S-MAG/2009).
- 37 Article 8 of Law on Undisclosed Information (7975/2000 as amended in 2008); see however Hernández-González G, Evaluación del Impacto de las Disposiciones de ADPIC + en el Mercado Institucional de Medicamentos de Costa Rica, Programa de ICTSD sobre Propiedad Intelectual y Desarrollo Sostenible, Diciembre 2009, p. 16-17, discussing some amendments to Costa Rica Patent Law and Law on Undisclosed Information that, if adopted would have introduced a more articulate regime of exceptions.
- 38 Hernández-González G, Evaluación del Impacto de las Disposiciones de ADPIC + en el Mercado Institucional de Medicamentos de Costa Rica, Programa de ICTSD sobre Propiedad Intelectual y Desarrollo Sostenible, Diciembre 2009, p. 17-20, noting that other CAFTA Members also share the same vacuum.
- 39 Article 16 (4) of the Costa Rica Patent Law and Article 14 of the regulation to Undisclosed Information law (Decreto N° 34927-J-COMEX-S-MAG/2009).
- 40 Hernández-González G, Evaluación del Impacto de las Disposiciones de ADPIC + en el Mercado Institucional de Medicamentos de Costa Rica, Programa de ICTSD sobre Propiedad Intelectual y Desarrollo Sostenible, Diciembre 2009, p. 18; and Article 24, DECRETO N° 34925-S-COMEX DEL 27/11/2008, Modificaciones al Reglamento de Inscripción, Control, Importación y Publicidad de Medicamentos, Decreto Ejecutivo N° 28466-S del 08 de febrero de 2000.
- 41 To prevent practices that may mislead consumers, or to protect lives, health or human safety, animal, plant life or the environment.
- 42 See Cerón A & Snodgrass G A, Intellectual property and access to medicines: An analysis of legislation in Central America, *Bulletin of the World Health Organization*, 87 (10) (2009) 788 for a similar table. However, the present one has been updated with the provision of the 'Regulation of the Undisclosed Information law (2009)'. Furthermore, data on compulsory licence and parallel importation has been added. Spaces left blank are to be understood as no provision existing under the law in relation to a particular issue.
- 43 Article 17 (1).
- 44 Article 17 (2) and for pharmaceuticals, Article 17 (4).
- 45 Article 16 (4) and Article 24, DECRETO N° 34925-S-COMEX DEL 27/11/2008, Modificaciones al Reglamento de Inscripción, Control, Importación y Publicidad de Medicamentos, Decreto Ejecutivo N° 28466-S del 08 de febrero de 2000.
- 46 Article 8.
- 47 Decreto N° 34927-J-COMEX-S-MAG (2009).
- 48 Article 15.
- 49 Article 4.
- 50 Article 27.