

Costa Rica: Strengthening Patent Laws, Weakening Human Rights¹

February 2008²

Introduction

1. Costa Rica, as a State party to the International Covenant on Economic, Social and Cultural Rights (ICESCR), is legally bound to respect, protect and fulfil the "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."³

2. The right to health is guaranteed by the Constitution of Costa Rica.⁴ The country's social security program, the Caja Costarricense de Seguro Social (CCSS), has long provided the vast majority of Costa Ricans with affordable or free health services, ensuring that cost has not constituted a barrier to access to health care in Costa Rica.⁵ This may all be about to change though, with the strengthening of intellectual property laws, that are likely to cause a substantial increase in the cost of medicines. (Although projections about the average price rise are contested, some sources cite an increase of up to 800 % in the coming years.⁶)

3. Since its inception, one of the principal aims of the CCSS has been to provide affordable medicines through national production⁷ and import of generic drugs, as well as through State subsidization of patented drugs.⁸ Until 2000, patents in Costa Rica were only granted for one year; such a short patent term meant that it was simply not worth it for patent-holders to seek access to Costa Rica's market. The absence of patents (and thus the absence of restrictions on copying and producing cheaper versions of brand-name drugs) enabled the development of a national generics industry. The resulting availability of cheap generic medicines has enabled Costa Rica to provide access to medicines to its population, and thus fulfil its public health and related human rights obligations.

CAFTA-DR and the strengthening of the intellectual property regime

4. On 7 October 2007, following the largest public debate in the country's history, Costa Rica narrowly voted in favour of ratifying the Central American-Dominican Republic-United States Free Trade Agreement (hereafter CAFTA-DR), with a tiny majority of 51.6% of the population voting "Sí".⁹

¹ The comments in this country briefing pertain to the following request of the Committee on Economic, Social and Cultural Rights to the Government of Costa Rica: '1.3. Please indicate the extent [to which] the Covenant is incorporated in the State party's economic policies and practices on economic development and to what extent the Covenant is taken into consideration in the State party's bilateral and multilateral trade policies.'

² This is a revised version of the country briefing with the same title published in November 2007.

³ *International Covenant on Economic, Social and Cultural Rights*, Article 12.1.

⁴ c.f. Articles 21, 50, 73, and 74 - Comisión Especial sobre Roces Constitucionales del TLC, *Roces Constitucionales del Tratado del Libre Comercio entre Republica Dominicana, Centroamérica y Estados Unidos*, San José, p.19

⁵ L. Rosero Bixby, *Acceso y disponibilidad de servicios de salud en Costa Rica 2000*, Centro Centroamericano de Población (CCP) de la Universidad de Costa Rica, available at <http://ccp.ucr.ac.cr/bvp/pdf/salud/Rosero-Acceso-2004.pdf>

⁶ Mora Jiménez, H. *101 Razones para Oponerse al Tratado del Libre Comercio entre Centroamérica y Estados Unidos*, San José: Escuela de Economía Universidad Nacional, 2004.

⁷ At public pharmacies – A. Guadamuz Gonzalez, 'The drugs don't work : Access to medicines in the developing world,' *AR: Revista de Derecho Informático*, November 2005, available at www.alfa-redi.org/rdi-articulo.shtml?x=3620

⁸ A. Guadamuz Gonzalez, op. cit.

⁹ 'Los costarricenses aprueban TLC con EEUU, pero oposición no lo reconoce,' *La Nación*, 8 October 2007, available at www.nacion.com/ln_ee/2007/octubre/08/latinoamericaya-071008160046.dxgh33g6.html

5. Although the public referendum on this trade agreement must be commended, the narrow result cannot be said to give the government a popular mandate in favour of ratification.¹⁰

6. Thus, lobbying efforts from both sides are now focused on the parliament which must approve thirteen laws¹¹ relating to the implementation of CAFTA-DR before the deadline for ratification, originally set at March 2008 and recently extended for another seven months.¹²

7. If CAFTA-DR is ratified, the change in policies that the agreement will require has serious implications for the ability of the State party to fulfil its human rights obligations, for a number of reasons. Areas of concern include the effect of agricultural liberalization on rural livelihoods and the right to food, the potential negative consequences, particularly for the poorest sections of Costa Rican society, of the liberalization of the telecommunications, insurance, water,¹³ electricity, and education industries, as well as the impacts of intellectual property laws on rural populations (for example, in terms of the potential negative consequences regarding access to seeds) and on access to medicines for people throughout the country.

8. This briefing focuses on access to medicines, and specifically on the way that the intellectual property provisions of CAFTA-DR can affect enjoyment of the right to health. Chapter 15 of the Agreement, which pertains to Intellectual Property Rights, includes numerous “TRIPS-plus”¹⁴ clauses with serious implications on the right to health:

- **Extension of the patent term for unreasonable delays:** Art. 15.9.6 of CAFTA-DR allows the extension of the patent term for pharmaceuticals beyond the twenty years required by the TRIPS Agreement by allowing an ‘adjustment’ for “unreasonable delays”¹⁵ experienced during the granting of a patent. If the Registro Público (the government body which awards patents) does not grant a patent within five years of the initial application or within three years of the request for examination of the application, the patent term can be extended. In Costa Rica, an eighteen month extension will be granted for such delays.¹⁶ In practice, this is tantamount to extending the patent term to up to twenty one and a half years, allowing a patent-holder to maintain its monopoly over a drug and ensuring prices remain artificially high due to the lack of generic competition.¹⁷
- **Marketing authorization:** Currently, drugs can be authorized for sale in Costa Rica if the Ministry of Health is satisfied with the results of tests regarding their safety and efficacy. Until now, the Ministry of Health has been concerned solely with issues relating to the usefulness and harmlessness of a drug, with no regard for its patent status. Patents have been dealt with by the Registro Público. With CAFTA-DR the Registro Público will remain responsible for granting patents, but the Ministry of Health will no longer be able to register a generic version of a drug that is under patent, even if the generic version of the drug is proven by the Ministry to be safe and useful. In other words, the Ministry of Health will no longer be allowed to authorize the sale of a generic version of a medicine if a patent on it is still in force, and this will limit the availability of generic versions of patented medicines in Costa Rica.

¹⁰ In addition, there have been highly vocal cries of fraud in the referendum. *La Nación*, op. cit.

¹¹ *La Nación*, op. cit. – these laws include those that approve the opening of the state telecommunications and insurance monopolies.

¹² ‘Gobierno negoció prórroga de siete meses para TLC,’ *La Nación*, 25 February 2008, available at www.nacion.com/lm_ee/2008/febrero/26/pais1439940.html

¹³ Latinamerica Press, *Costa Rica: CAFTA threatens to turn water into merchandise*, 4 November 2007, available at www.bilaterals.org/article.php3?id_article=10204&var_recherche=Costa+Rica

¹⁴ For an explanation of this, and other trade-related terms in this briefing, please refer to 3D’s Glossary of Trade Terms, available at www.3dthree.org/en/pages.php?IDcat=12

¹⁵ United State Trade Representative, *CAFTA-DR: Full Text*, available at www.ustr.gov/Trade_Agreements/Regional/CAFTA/CAFTA-DR_Final_Texts/Section_Index.html

¹⁶ Costa Rican pharmaceutical industry spokesperson, personal communication 18 December 2007.

¹⁷ MSF, *Access to Medicines at Risk Across the Globe: What to Watch Out for in Free Trade Agreements with the United States*, Geneva: MSF, 2004.

This transforms the Ministry of Health into an “effective enforcer of patents,”¹⁸ as it will block generic versions of patented drugs from being sold in the country. This provision goes far beyond the TRIPS Agreement, which stipulates that only the patent-holder can enforce a patent (by suing alleged patent violators through national courts). It is questionable whether it is for a public body, the Ministry of Health, to protect the private rights of patent-holders.¹⁹ From a public interest point of view, it is a matter of concern that CAFTA-DR’s marketing authorization provisions will undoubtedly save pharmaceutical patent-holders considerable time and money (since the Ministry will save them from having to sue infringers), but will place a heavier work burden on the Ministry. Analyzing the patent status of drugs waiting for marketing authorization is yet another job for an already overstretched and under-funded public institution, and could divert resources from its health-promotion mandate.

- **Exclusive rights over test data:** Art.15.10.1(b) allows owners of medicines that contain a chemical entity that has not yet been registered in Costa Rica exclusive rights, again granted by the Ministry of Health, over test data on safety and efficacy for a period of “at least five years.”²⁰ Although a patent-holder will have to publish the test data in order to be awarded the patent, this information will be protected by “industrial secret” legislation for at least five years. This provision of CAFTA gives companies registering “new”²¹ drugs in Costa Rica rights over data that requires costly and extensive tests. It thus has the damaging effect of delaying the manufacture of cheaper generic versions by at least five years (due to the limited capacities of generics companies to conduct such tests) even if the patent of the drug has already expired and generics could have been produced.²² Especially in a country like Costa Rica, where drugs will often enter the market a number of years after they have already been registered somewhere else (and thus, proven their market/patient success and likely been scrutinized by generics companies) this marks a serious impediment to the rapid development of generics.

Strengthening Patent Laws and Weakening Human Rights

9. Economic consequences for the CCSS – forced to compromise health?

Prices of medicines are a result of a combination of market size and the level of intellectual property protection within that market. In a situation with little or no intellectual property laws economics tells us that the bigger the demand, the cheaper the price. However, if stringent intellectual property laws are imposed, prices can (and usually do) remain very high for the duration of the patent, regardless of the size of the market.

The absence of intellectual property laws and the large size of CCSS purchases have fostered a large generics industry and kept prices of medicines very low in Costa Rica. The availability of inexpensive generic drugs has been crucial to the realization of the right to health in the country. For example, in 2005 more than 98% of the medicines used or supplied by the CCSS,²³ were

In 2005 the CCSS bought a year’s supply of amlodipina, a generic version of a medication used to treat hypertension. If purchased from the patent-holder (Pfizer), the same quantity of medication would have cost the CCSS 20 million US dollars more, the equivalent of one third of the CCSS’s annual budget.

G. Saenz Valverde, *Genéricos fueron mal negociados*, available at www.hacienda.go.cr/.../datos/Noticia/Genéricos%20fuerón%20mal%20negociados-Diario%20extra-10Febr2003.doc

¹⁸ MSF, op. cit.

¹⁹ MSF, op. cit.

²⁰ CAFTA-DR: Full Text, op.cit.

²¹ According to CAFTA-DR, “a new product is one that does not contain a chemical entity that has been previously approved in the territory of the Party.” In other words, data exclusivity rights will be awarded to all products that contain a chemical entity that has not yet been registered in Costa Rica, *even if the patent on the product has already expired*.

²² Comisión Especial sobre Roces Constitucionales del TLC, op. cit, p. 23

²³ Comisión Especial sobre Roces Constitucionales del TLC, op. cit, p.19 – data from the Caja Costarricense Social, Departamento de Farmacoterapia. NB: “3 national generics companies provide 28.44% of medicines purchased by the health service” in A. Guadamuz Gonzalez, op. cit

generic medicines. As a result of the intellectual property laws in CAFTA, all new drugs entering Costa Rica will be patented and the CCSS will thus be forced to buy increasingly greater quantities of patented medicines – medicines that will almost definitely be more expensive and which, without radical changes in budgeting, the CCSS simply cannot afford. This will prevent the CCSS from maintaining current levels of free and subsidized prescription programmes, with serious health implications, especially for the poorest segments of Costa Rican society.²⁴

Pharmaceutical industry analysts argue that, in many cases, different drugs exist for the treatment of the same disease, and the CCSS will be able to continue buying cheap, non-patented drugs.²⁵ What this argument fails to acknowledge is the fact that the availability in Costa Rica of a wide range of drugs for the same disease is in part a result of the lenient patent legislation in the past. Especially as time goes by and the percentage of patented drugs on the Costa Rican market increases, the CCSS will need to spend significantly greater sums of money on medicines. In addition, new drugs, which should either work better than their older counterparts or treat previously incurable symptoms and diseases, will be subject to patents and the option of non-patented versions will simply not exist.

It should also be noted that medicines in the same therapeutic category are not interchangeable, one version may have worse side effects or be unsuitable for a large segment of the population (for example, for reasons of blood type). However, the CCSS will be increasingly forced to assess medicines based on their price, rather than choosing the best options in terms of health for the Costa Rican population.

10. Legal restraints to the CCSS:

In addition to being constrained economically, the CCSS will simply not have legal access to certain medicines. For example, in 2001 the CCSS bought a nationally produced generic version of the anti-retroviral drug nelfinavir, which had been registered in Costa Rica in 1997. If CAFTA-DR had been ratified at the time, a generic version of the drug would not have been able to be produced until at least 2002, due to data exclusivity rights. Even if the CCSS had an unlimited source of funds, it would have been legally blocked from supplying HIV/AIDS victims with the generic version of this crucial anti-retroviral.²⁶

In essence, as a result of CAFTA, it will become “economically unsustainable”²⁷ and legally impossible to ensure universal coverage and access to medicines in the same manner that has served the population so well until now.

11. Poor priced out of health care:

In Costa Rica, about 23% of the population (one fifth of households) live below the poverty line.²⁸ Particularly vulnerable sectors include the rural population, households headed by females, indigenous people, and those living in the frontier states.²⁹ Even if the price rises are much lower than the 800 % estimated by some observers,³⁰ many Costa Ricans will be priced out of the medicine market.³¹ If it were possible for the Costa Rican State to massively increase the budget of the CCSS without raising taxes or the price of medicines nationwide, the CAFTA-DR would not necessarily affect the right to health in Costa Rica. However, given the unlikelihood of, for example, a programme that would fund

²⁴ G. Saenz Valverde, *Genéricos fueron mal negociados*, available at www.hacienda.go.cr/.../datos/Noticia/Genéricos%20fuerón%20mal%20negociados-Diario%20extra-10Febr2003.doc

²⁵ In addition, the CCSS may, in some cases, be able to negotiate cost-reductions on expensive patented drugs, given the size of the market it represents.

²⁶ R. Macaya, *El TLC, las medicinas y los argumentos utilizados*, Unidad de Formación, Información y Comunicación UFIC- ANEP, available at www.anep.or.cr/leer.php/1629

²⁷ Comisión Especial sobre Roces Constitucionales del TLC, op. cit., p.19

²⁸ V.H. Cespedes and R. Jiménez (eds.) ‘Pobreza en Costa Rica,’ *III Jornada Anual de la Académica de Centroamérica*, San José, 2006.

²⁹ V.H. Cespedes and R. Jiménez (eds.) op. cit.

³⁰ Mora Jiménez, H. op. cit.

³¹ R. Macaya, op.cit.

public health through elite taxation, it is to be expected that the changes in intellectual property rules will have serious human rights implications, especially for the poorest sectors of Costa Rican society. As a result of CAFTA-DR, the ability of the State to fulfil its obligations in relation to the right to health of the Costa Rican population could be constrained.

Questions and Recommendations

What measures is the Costa Rican government planning to take, in adopting the legislation for ratification of CAFTA, to ensure that it does not commit itself to intellectual property provisions that would make medicines more expensive and harder to access?

What steps has the Costa Rican government taken to assess the likely impacts of CAFTA-DR on the rights set out in the ICESCR, in particular on the rights to health, the right to food and the right to water?

If the Costa Rican government has not yet carried out such assessments, we encourage the Committee to recommend that the government undertake independent impact assessments of the effect of CAFTA-DR on access to medicines, access to health insurance and the enjoyment of the right to health, as well as on the effects on the right to an adequate standard of living, particularly on the rights to food and water.³²

*Zoe Goodman
Programme Assistant*

© 2008 3D → Trade - Human Rights - Equitable Economy. We encourage copying, distributing and quoting from 3D publications for non-commercial purposes, as long as the source is acknowledged. This Country Briefing is made available under an Attribution-NonCommercial-ShareAlike Creative Commons License. See <http://creativecommons.org/licenses/by-nc-sa/3.0>

³² To read the recommendations of the Committee on Economic, Social and Cultural Rights to the government of Costa Rica, see *Costa Rica: Draft concluding observations of the Committee on Economic, Social and Cultural Rights*, 8 January 2008, available at <http://daccessdds.un.org/doc/UNDOC/GEN/G08/400/25/PDF/G0840025.pdf?OpenElement>