

Costa Rica: Strengthening Patent Laws, Weakening Human Rights¹

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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 fulfill the "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."²
2. The right to health is guaranteed by the Constitution of Costa Rica.³ The country's social security program, 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.⁴ This may all be about to change though, with the strengthening of intellectual property laws that may, according to the national pharmaceutical industry, cause an 800% price rise in the cost of medicines.⁵
3. Since its inception, one of the principal aims of the CCSS has been to provide affordable medicines through the national production⁶ and import of generic drugs, as well as through State subsidization of patented drugs.⁷ Patent legislation has enabled Costa Rica to provide generic medicines to its population, and thus fulfill its public health obligations, by authorizing the State to grant compulsory licences⁸ and patents for public use.⁹

CAFTA-DR and the strengthening of the intellectual property regime

4. Following the largest public debate in the country's history, on 7 October 2007 Costa Rica narrowly voted in favor of ratification of 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".¹⁰

¹ The comments in this country briefing pertain to the following request of the ESCR Committee:

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

³ 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

⁴ 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>

⁵ 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.

⁶ 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 <http://www.alfa-redi.org/rdi-articulo.shtml?x=3620>

⁷ A. Guadamuz Gonzalez, op. cit.

⁸ Ley No. 6867 Art. 18. de Patentes de invención, dibujos y modelos industriales y modelos de utilidad. Costa Rica, L. Soley, *Plazo de Protección de las Patentes en la Legislación Costarricense*, available at <http://www.uned.ac.cr/redti/quinta/5laura.pdf>

⁹ Ley No. 6867, Art. 20, "which means that the government can grant, by executive decree, a public licence for the exploitation of a patent by the State or any other parties specifically named in cases of public interest, emergency or national security" L. Soley, op. cit.

¹⁰ 'Los costarricenses aprueban TLC con EEUU, pero oposición no lo reconoce,' *La Nación*, 8 October 2007, available at www.nacion.com/in_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.¹¹ And ratification of CAFTA-DR could have adverse effects on enjoyment of the right to health in Costa Rica.

6. Thus, lobbying efforts from both sides are now focused on the parliament which must approve thirteen laws relating to the implementation of CAFTA-DR before the deadline for ratification, set at March 2008.¹²

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 fulfill 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 populations¹⁴ and on access to medicines.

8. This briefing focuses on access to medicines, and specifically on the way that the Intellectual Property provisions can affect enjoyment of the right to health. Chapter 15 of CAFTA-DR, which pertains to Intellectual Property Rights, includes numerous “TRIPS-plus” 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” of three to five years experienced during the granting of a patent. In practice, this is tantamount to extending the patent term to up to twenty five years,¹⁵ allowing a patent-holder to maintain its monopoly over a drug and ensuring prices remain artificially high due to the lack of generic competition.¹⁶
- **Marketing authorization:** Art. 15.10.1(a) gives patent owners the right to prohibit the marketing of a generic medicine for a period of five years. This is effectively an outright ban on generic versions of patented medicines which blocks compulsory licenses¹⁷ and is another method by which patent owners can achieve a *de facto* extension of the patent term to twenty-five years. In addition, this clause transforms the national drug registration authority from a body exclusively concerned with the quality and safety of drugs to an “effective enforcer of patents.”¹⁸ It also removes a crucial safeguard through which the validity of a patent can be publicly questioned and scrutinized.¹⁹
- **Exclusive rights over test data:** Art. 15.10.1(b) allows owners of medicines that have not yet been registered in Costa Rica exclusive rights over test data on safety and efficacy for a period of five years. This provision of CAFTA gives patent holders rights over data that requires costly and extensive tests. It thus has the damaging effect of delaying the manufacture of cheaper generic versions by five years (due to the limited capacities of

¹¹ In addition, there have been highly vocal cries of fraud in the referendum. *La Nación*, op. cit.

¹² *La Nación*, op. cit. – these laws include those that approve the opening of the state telecommunications and insurance monopolies.

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 Prensa Latina, *Costa Rican Lawmakers Debate FTA Law*, 31 October 2007, available at www.bilaterals.org/article.php3?id_article=10159&var_recherche=Costa+Rica

¹⁵ Devandas, M. ‘The Population’s Universal Right to Medicines’, in *Why We Say No to CAFTA: Analysis of the Official Text*, Bloque Popular Centroamericano Alliance for Responsible Trade, San Jose, 2004, p.25

¹⁶ MSF, *Access to Medicines at Risk Across the Globe: What to Watch Out for in Free Trade Agreements with the United States*, Geneva, 2004.

¹⁷ MSF, op. cit.

¹⁸ MSF, op. cit. - the national drug registration authority will be prevented from registering generic versions of drugs for five years after their registration in Costa Rica, upholding patent-holder’s monopoly

¹⁹ MSF, op. cit. - with the job being completed behind the scenes by the national drug registration authority, patent-holders will no longer be compelled to sue through public courts to enforce a patent

generics companies to conduct tests) even if the patent of the drug has already expired and generics could have been produced.²⁰ In addition, even if a company is awarded a compulsory license, data exclusivity would prevent them from registering the generic version.²¹

- **Patents awarded to new uses of existing substances:** By defining a new product as “one that does not contain a chemical entity that has been previously approved in the territory of the Party” Article 15.10.1(c) will potentially lead to patent extensions by legalizing a new twenty year monopoly for each new therapeutic use of a known compound.²²

Strengthening Patent Laws and Weakening Human Rights

9. Economic consequences for the CCSS:

The availability of generic drugs has been crucial to the realization of the right to health in Costa Rica. For example, in 2005 more than 98% of medicines used or supplied by the CCSS, which provides medical care for the vast majority of the population, were generic medicines.²³ As a result of the IP laws in CAFTA, the CCSS will be forced to buy far greater quantities of patented medicines – medicines which, without radical changes in budgeting, the CCSS simply cannot afford. For example, 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, for one year’s supply of one medicine.²⁴ Price rises of the magnitude estimated by the Costa Rican pharmaceutical industry (800%)²⁵ will make it impossible for the CCSS to support its free and highly subsidized prescription programs.²⁶

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. 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.²⁷

In essence, as a result of CAFTA, it will become “economically unsustainable”²⁸ 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:

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

21 MSF, op. cit.

22 MSF, op. cit.

23 Comisión Especial sobre Roces Constitucionales del TLC, op. cit, p.19 – from Caja Costarricense Social, Departamento de Farmacoterapia. Citadao en presentación de la Asociación de la Industria Farmacéutica Nacional (ASIFAN) ante la Asamblea Legislativa: *Efectos negativos de la OMC y TLC en el Sector Salud z la Industria Nacional, Necesidad inmediata de una agenda complementaria* (sin fecha). NB: “3 national generics companies provide 28.44% of medicines purchased by the health service” in A. Guadamuz Gonzalez, op. cit.

24 R. Macaya, *En que afecta el TLC a la CCSS?*, Cámara de Empresarios Pro Costa Rica, available at <http://www.concostarica.com/en-qu-afecta-el-tlc-la-ccss>

25 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.

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

27 R. Macaya, *En que afecta el TLC a la CCSS?*, Cámara de Empresarios Pro Costa Rica, available at <http://www.concostarica.com/en-qu-afecta-el-tlc-la-ccss>

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

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 program that would fund 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.

12. In Costa Rica, about 23% of the population (one fifth of households) live below the poverty line.²⁹ Particularly vulnerable sectors include the rural population, households headed by females, indigenous people, and those living in the frontier states.³⁰ If the Costa Rican pharmaceutical industry estimates of an 800% price rise in the cost of medicines as a result of the changes in patent laws³¹ are correct, many Costa Ricans will be priced out of the medicine market.³² As a result of CAFTA-DR, the ability of the State to fulfill its obligations in relation to the right to health of the Costa Rican population could seriously be put into question.

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.

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

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

31 Mora Jiménez, H. op. cit.

32 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