

**AUTOMATIC LICENSE SYSTEM FOR PHARMACEUTICAL PATENTS IN DEVELOPING AND
LEAST-DEVELOPED COUNTRIES**
REVISING TRIPS FOR PUBLIC HEALTH: AN IDEAS CONTEST FROM MSF

I. Introduction

TRIPs Agreement contains a great degree of flexibility that allows WTO Members to structure their Intellectual Property Rights (IPR) and to adapt them to their national economic, political, social and cultural identity. However, WTO members have not generally used such flexibilities. This scenario is explained by the unprecedented expansion of IPR¹.

The Doha Declaration on TRIPs Agreement and Public Health has led the way in implementing TRIPs Agreement according to the needs of developing and least-developed countries. Therefore, in order to foster the exploitation of TRIPs flexibilities, we consider that TRIPs Agreement should be reformed introducing specific exceptions to patent rights. For this purpose, we support an Automatic License System (ALS) for prescription medicines in developing and least developed countries. The ALS allows exploiting the patented product or process related to a prescription drug by paying a reasonable royalty.

The main axes of this proposal are two. First, that developing and least-developed countries help to finance the R&D costs required to invent and approve new drugs. Those countries would make a contribution that equals the world market share of a specific country for such new drug². In addition to this, people from developing and least-developed countries will have more access to prescription medicines, improving competition and preventing that patentees fix monopolistic prices.

¹ The expansion of IPR has been bolstered by developed world governments and multinational companies lobbying, global advocacy and, in several cases, by strategic litigation grounded on certain interpretation of TRIPs provisions. See Correa, Carlos M. “*The Role of Intellectual Property Rights in Global Economic Governance*”, The Initiative for Policy Dialogue at Columbia University, The United Nations Development Program, Paper Series: Development Dimensions of Global Economic Governance, First draft March 2009, revised April 2011), http://policydialogue.org/files/publications/Correa_IPRs1.pdf; and “*Instrumentación del Acuerdo TRIPs en Latinoamérica. Armonización vs. Diferenciación de los sistemas de Propiedad Intelectual*”, Temas de Derecho Industrial y de la Competencia N° 1, Ediciones Ciudad Argentina, Buenos Aires, 1997, p. 97; Vaver, David and Basheer, Shamnad, *El consumo de pastillas patentadas: Europa y una dosis de TRIPS durante una década*, “Propiedad Intelectual y Tecnología. El Acuerdo ADPIC diez años después: visiones europea y latinoamericana”, Bernard Remiche and Jorge Kors, Buenos Aires, La Ley, 2006, p. 94.

² The United States, Europe and Japan represent approximately 84.7% of the pharmaceutical world market share. See IMS Health, MIDAS, 2009. Thus, the ALS would only affect the 15.3% of the world pharmaceutical market.

II. ALS main characteristics

The main characteristics of our proposal are:

- Developing and least-developed countries shall be authorized to establish an ALS for patents related to prescription medicines. Anyone willing to use, manufacture, import or export a prescription medicine will receive an automatic license.
- Patentees and licensees shall negotiate and mutually agree on the royalty. If they do not reach an agreement, licensees shall be entitled to exploit the patent according to the ALS, and the royalty rate shall be calculated using the following formula:

$$R = [(C^{R+D} / MS^C) / PT] / MS^L \text{ where}$$

R represents the royalty rate

C^{R&D} represents the cost of the research and development (R&D) investment for the patented invention

MS^C represents the specific country world market share for the prescription medicine,

PT represents the remaining patent protection term in such specific country, and

MS^L represents the licensee market share for the patented invention.

For instance, if (i) the R&D costs are USD 1 billion; (ii) a specific developing country has 0.5% of the world market share for a prescription medicine; (iii) there are 8 years of remaining patent protection; and (iv) the proposed licensee has 15% of market share in such country; the annual royalty rate should be USD 93,750³.

- Members shall be entitled to determine the administrative or judicial authority which shall establish the royalty.
- The royalty rate may be duplicated if the prescription medicine represents a major therapeutic improvement.
- The licensee must pay the royalty until the patent expiration.

³ USD 93,750 = [(USD 1 billion / 0,5% country world market share) / 8 years of remaining patent protection] / 15% market share of the proposed licensee.

III. ALS legal Coherence

It should be highlighted that the ALS is coherent with other TRIPs Agreement's objectives, principles and provisions. In particular, the proposed ALS is a measure directed to protect public health and foster technological development in the pharmaceutical sector in developing and least developed-countries⁴.

The proposed ALS also fulfills TRIPs Agreement's Article 30 requirements:

- i. It constitutes a limited exception to prescription medicines in developing and least-developed countries and it shall be considered a reasonably buttressed exception. It could not be alleged that the ALS represents an illegitimate discrimination. Treating different cases differently is not discrimination. On the contrary, the principle of non-discrimination requires differentiating between different situations, providing a specific solution and a rule suitable for each case⁵.
- ii. The ALS does not unreasonably conflict with the normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patentee. The patentee can continue with his exploitation, and, because of the royalties to be collected, he will obtain a profit. It should be highlighted that legal monopoly provided by patents is not a goal by itself⁶. Patent legal monopoly represents an economic incentive to grant innovators revenue for their innovation efforts. If such revenue is granted by an equivalent economic incentive, patent holder interests are not prejudiced⁷.
- iii. The ALS takes into account the legitimate interest of third parties. Furthermore, the proposal encourages innovation, but with less social and economic costs. As explained by the economic theory, legal monopolies cause a loss of revenue and social welfare, with

⁴ See TRIPs Agreement, Article 8.

⁵ Dinwoodie, Graeme B., "One Size Fits All. Consolidation and Difference in Intellectual Property Law", ATRIP Congress, Munich, July 21, 2008, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1601225. In the context of our proposal, it is self-evident that health public issues in developing and least-developed countries require different solutions than in developed countries.

⁶ See, *Declaración de la Asociación Internacional de Derecho Económico (AIDE)*, "Propiedad Intelectual y Tecnología. El Acuerdo ADPIC diez años después: visiones europea y latinoamericana", Bernard Remiche and Jorge Kors, Buenos Aires, La Ley, 2006, p. XVI.

⁷Challú, Pablo M., "Un método alternativo de compensación a las empresas innovadoras que minimiza los costos asociados a la exclusividad de la patente de producto", *Revista del Derecho Industrial*, Buenos Aires, Depalma, Separata, N° 42, September-December 1992; and "The consequences of pharmaceutical product patenting", *World Competition*, vol. 15, n° 2, 1992.

more costs to consumers and production factors⁸. Such losses and costs will be diminished by adopting the ALS, increasing social welfare.

IV. Implementation

This proposal could be implemented adding a new Article to TRIPs Agreement (Article 31 *ter*). The proposed wording is:

Article 31 *ter*

Automatic Licenses for Prescription Medicines

- 1. Developing and least-developed Members shall introduce automatic licenses for patented products or processes related to prescription medicines.*
- 2. The proposed licensee shall request a voluntary license to the right holder. The right holder and the licensee shall negotiate and mutually agree on the royalty rate within a 30-day period of receiving a notification by the proposed licensee. If they do not reach an agreement within a 30-day period, the proposed licensee shall be automatically authorized to exploit the patented product or process. In this case, Each Member shall determine the administrative or judicial process to establish the royalty rate.*
- 3. The royalty rate shall be determined following this formula:*

$$R = [(C^{R+D} / MS^C) / PT] / MS^L \quad \text{where}$$

R represents the royalty rate

C^{R+D} represents the cost of the research and development investment for the patented invention

MS^C represents the specific country world market share for the prescription medicine

PT represents the remaining patent protection term in such country, and

⁸ See, Challú, Pablo M., “Un método alternativo de compensación a las empresas innovadoras que minimiza los costos asociados a la exclusividad de la patente de producto”, Revista del Derecho Industrial, Depalma, Separata, N° 42, September-December 1992; “The consequences of pharmaceutical product patenting”, World Competition, vol. 15, n° 2, 1992; Penrose, Edith, “La Economía del sistema internacional de patentes”, 1° ed., Siglo Veintiuno Editores, México, 1974; Correa, Carlos M. “The Role of Intellectual Property Rights in Global Economic Governance”, The Initiative for Policy Dialogue at Columbia University, The United Nations Development Program, Paper Series: Development Dimensions of Global Economic Governance, First draft March 2009, revised April 2011), available at http://policydialogue.org/files/publications/Correa_IPRs1.pdf; MSF (Médecins Sans Frontieres), HAI (Health Action Internacional) and CPT (Consumer Project on Technology), “Open letter to the WTO members countries on TRIPS an access to health care technologies”, Geneva, November 12, 1999, available at <http://www.twinside.org.sg/title/twr120d.htm>; Reis, Renata – Viegas Neves da Silva, Francisco, “Licencias obligatorias: ¿cómo acceder a tecnología patentada?”, Temas de Derecho Industrial y de la Competencia N° 9 – Patentes de Invención e Interés Público, Ediciones Ciudad Argentina, Buenos Aires, 2010, p. 169-178, among others.

MS^L represents the licensee market share for the patented invention, including the patentee market.

4. The judicial or administrative authority shall be authorized to duplicate the royalty rate if the medicine represents a major therapeutic improvement.

References

- Arrow, Kenneth, “*Economic welfare and the allocation of resources for invention*”, The Rate and Direction of Inventive Activity, R. Nelson, National Bureau of Economic Research, 1962.
- Challú, Pablo M., “*Un método alternativo de compensación a las empresas innovadoras que minimiza los costos asociados a la exclusividad de la patente de producto*”, Revista del Derecho Industrial, Depalma, Separata, N° 42, September-December 1992.
- Challú, Pablo, “*The consequences of pharmaceutical product patenting*”, World Competition, vol. 15, n° 2, 1992.
- Correa, Carlos M., “*Instrumentación del Acuerdo TRIPs en Latinoamérica. Armonización vs. Diferenciación de los sistemas de Propiedad Intelectual*”, Temas de Derecho Industrial y de la Competencia N° 1, Ediciones Ciudad Argentina, Buenos Aires, 1997, p. 95-130
- Correa, Carlos M., “*Propiedad Intelectual y Salud Pública*”, 1° ed., Buenos Aires, La Ley, 2006.
- Correa, Carlos M. “*The Role of Intellectual Property Rights in Global Economic Governance*”, The Initiative for Policy Dialogue at Columbia University, The United Nations Development Program, Paper Series: Development Dimensions of Global Economic Governance, First draft March 2009, revised April 2011), http://policydialogue.org/files/publications/Correa_IPRs1.pdf
- Correa, Carlos M., “*Licencias obligatorias: ¿cómo acceder a tecnología patentada?*”, Temas de Derecho Industrial y de la Competencia N° 9 – Patentes de Invención e Interés Público, Ediciones Ciudad Argentina, Buenos Aires, 2010, ps. 179-191.
- Dinwoodie, Graeme B., “*One Size Fits All. Consolidation and Difference in Intellectual Property Law*”, Atrip Congress, Munich, July 21, 2008, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1601225
- Klein Vieira, Luciane, “*Licencias obligatorias: el derecho del titular de la patente versus el derecho del estado brasileño de protección a sus intereses nacionales*”, Temas de Derecho Industrial y de la Competencia N° 9 – Patentes de Invención e Interés Público, Ediciones Ciudad Argentina, Buenos Aires, 2010, p. 129-168.

- Mackielo, Andrea Laura, “*Las flexibilidades del acuerdo sobre los ADPIC, su recepción en los casos planteados en el ámbito de la OMC y la aplicación ulterior por los estados*”, Temas de Derecho Industrial y de la Competencia N° 9 – Patentes de Invención e Interés Público, Ediciones Ciudad Argentina, Buenos Aires, 2010, ps. 15-71.
- MSF (Médecins Sans Frontières), HAI (Health Action Internacional) and CPT (Consumer Project on Technology), “*Open letter to the WTO members countries on TRIPS an access to health care technologies*”, Geneva, November 12, 1999, <http://www.twinside.org.sg/title/twr120d.htm>
- Oh, Cecilia, “*Licencias obligatorias: Experiencias recientes en países en desarrollo*”, Temas de Derecho Industrial y de la Competencia N° 9 – Patentes de Invención e Interés Público, Ediciones Ciudad Argentina, Buenos Aires, 2010, ps. 13-93.
- Penrose, Edith, “*La Economía del sistema internacional de patentes*”, 1° ed., Siglo Veintiuno Editores, México, 1974.
- Remiche, Bernard and Kors, Jorge, *Propiedad Intelectual y Tecnología. El Acuerdo ADPIC diez años después: visiones europea y latinoamericana*”, Buenos Aires, La Ley, 2006.
- Reis, Renata – Viegas Neves da Silva, Francisco, “*Licencias obligatorias: ¿cómo acceder a tecnología patentada?*”, Temas de Derecho Industrial y de la Competencia N° 9 – Patentes de Invención e Interés Público, Ediciones Ciudad Argentina, Buenos Aires, 2010, ps. 169-178.
- Seuba Hernández, Xavier, “*Licencias obligatorias para uso público no comercial. El caso de Tailandia a la luz del acuerdo sobre los ADPIC*”, Temas de Derecho Industrial y de la Competencia N° 9 – Patentes de Invención e Interés Público, Ediciones Ciudad Argentina, Buenos Aires, 2010, ps. 95-128.
- World Bank, *Global Economic Prospects and the Developing Countries: Making Trade Work for the Worlds Poor*, 2002, Washington D.C., available at http://www-wds.worldbank.org/external/default/WDSContentServer/IW3P/IB/2002/02/16/000094946_0202020411334/Rendered/PDF/multi0page.pdf