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*Compulsory licensing in Peru regarding right to health: Defining public interest
in light of the Andean Community legal framework*

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Abstract

Decision 486 of the Commission of the Andean Community, establishing the Common Industrial Property Regime, provides for the competence that its Country Members (Peru, Ecuador, Colombia and Bolivia) have in order to grant compulsory licences on patents, being the public interest one of the reasons for the adoption of this measure. However, there is not any harmonization between the Country Members regarding the criteria on the determination of the referred public interest reason. Moreover, the Peruvian government has no experience regarding the issuance of a compulsory licence on the basis of this particular reason.

This situation has brought too much uncertainty to the Peruvian government, which had its most critical moment in 2015 when a draft of Supreme Decree for the declaration of the public interest on a patented antiretroviral drug was presented by the Minister of Health before the Council of Ministers in order to make possible the use of the compulsory licensing system. Ultimately this draft was not approved because the arguments were not strong enough in view of the other Ministers, who thought that the adoption of such a measure would breach the obligations which arise from the international trade agreements subscribed by Peru.

This thesis aims to construe the content of the public interest reason needed for the issuance of a compulsory licence under the light of the Andean Community normativity, particularly addressed to the right to health and its application in Peru. For this purpose, an analysis on the particular wording of Article 65 of the Decision 486 is conducted and also whether there is any additional consideration deductible from Peruvian national legislation. Additionally, it is carried out an assessment over the consistency of the studied public interest reason with the Agreement on Trade-Related Aspects of Intellectual Property, in order to provide a meaning to this reason which is coherent with the obligations under such international instrument. Throughout the analysis it is taken into account how the public interest reason is applied in the other Country Members of the Andean Community.

Acronyms and Abbreviations

AB = Appellate Body

ALAFARPE = National Association of Pharmaceutical Laboratories

Art. 31(b)/TRIPS = Article 31(b) of the Agreement on Trade-Related Aspects of Intellectual Property

Art. 40/LD1075 = Article 40 of the Legislative Decree 1075, approving complementary provisions to the Decision 486

Art. 65/D486 = Article 65 of the Decision 486 of the Commission of the Andean Community

Bristol = Bristol-Myers Squibb

CAN Member Countries = Member Countries of the Andean Community

Doha Declaration on TRIPS = Doha Declaration on the TRIPS Agreement and Public Health

EsSalud = Social Health Insurance - Peru

GATT = General Agreement on Tariffs and Trade

HIV/AIDS = Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome

IEPI = Ecuadorian Institute of Intellectual Property

INDECOPI = National Institute for the Defense of Competition and the Protection of Intellectual Property - Peru

IPR = Intellectual property rights

MEF = Ministry of Economy - Peru

MINCETUR = Ministry of Foreign Trade and Tourism - Peru

MINJUS = Ministry of Justice - Peru

MINSA = Ministry of Health - Peru

PEN = Peruvian Soles

POS = Mandatory Health Plan - Colombia

R&D = Research and development

SENAPI = National Service of Intellectual Property - Bolivia

SIS = Comprehensive Health Insurance - Peru

TARGA = Highly Active Antiretroviral Treatment - Peru

TARV = Antiretroviral treatment

TPA = Peru-United States Trade Promotion Agreement

TRIPS Agreement = Agreement on Trade-Related Aspects of Intellectual Property

UNIMED = Unit of Drugs and Technology in Health - Bolivia

USD = United States Dollars

USTR = United States Trade Representative

WHO = World Health Organization

WTO = World Trade Organization

CHAPTER I. Introduction

Under the light of Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement),¹ the Andean Community, formed by Peru, Ecuador, Colombia and Bolivia, has adopted a compulsory licensing regime on patents within its common industrial property legislation, which is established by Decision 486.² In particular, Article 65 of the Decision 486 sets forth that compulsory licensing may be available under considerations of public interest, emergency or national security, however the content and scope of these reasons have not been provided by such norm nor have been construed by the Court of Justice of the Andean Community. By 2015 there was a great debate within the official spheres of the Peruvian government before a request from the Ministry of Health to declare the public interest on Atazanavir, a patented antiretroviral drug, for the issuance of a compulsory licence.

The aforementioned request was ultimately unsuccessful, but it exposed that there is great uncertainty as to when a circumstance of public interest for the granting of a compulsory licence may arise. According to this situation the purpose of this thesis is to construe the content and scope of the public interest consideration provided by Article 65 of Decision 486 and its application in the Republic of Peru under the light of its domestic legal context. In particular, this thesis will focus on the public interest consideration regarding the right to health.

Chapter II introduces the fundamentals on patent protection and its potential conflict with the essential right of access to health as well as how this situation is intended to be controlled by the World Trade Organization (WTO) through the flexibilities provided in the TRIPS Agreement, doing emphasis in the compulsory licensing regime and the leeway with that Member States count in order to determine the reasons on which they may

¹ Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

² Decision 486 of the Commission of the Andean Community Establishing the Common Industrial Property Regime, 14 September 2000, published in the Official Gazette of the Cartagena Agreement 600 on 19 September 2000.

apply this system, subsequently confirmed by the Doha Declaration on the TRIPS Agreement and Public Health. It is further presented how the Andean Community has implemented the compulsory licensing regime in its common industrial property legislation, particularly addressing the reason of public interest provided by it and how each of CAN Member Countries have locally applied such a reason.

Chapter III gives a general overview on the access to pharmaceutical products in Peru, doing emphasis in the provisioning of the antiretroviral drug Atazanavir by the government and the economic issues that surround the acquisition of this product as a consequence of its protection provided by a Peruvian patent. In this context subsequent attention is given to the main aspects regarding the request made by the Ministry of Health for the declaration of public interest on the referred patented drug to enable the use of compulsory licensing, including the reasons supporting this measure and the counterarguments provided by the guild from which the patentee is member.

Chapter IV addresses the interpretation on the content of the public interest reason provided by Article 65 of Decision 486 and its application to the republic of Peru, for which the particularities surrounding the Peruvian national legislation complementary to the Andean compulsory licensing regime are analyzed in the first place. Then it is carried out the construction of the public interest reason provided by Article 65 in attention to the singular drafting of this norm. Finally it is analyzed whether there is any further exigency stipulated by the TRIPS Agreement as to the adoption of a compulsory licence in order to determine the consistency of the reasons that lead to the adoption of a compulsory licence with the TRIPS standards.

CHAPTER II. Compulsory Licensing on Patents

A. Fundamentals on the Protection of New Technologies in the Pharmaceutical Field and its Repercussion on Access to Health

The patent regime is, as recognized in every country where it is applied, a trade-off between the person who develops a new technology and a government which confers to such person a limited period of exclusivity over the use of that technology, which regularly amounts to twenty years since the filing date of the patent application. By conferring this period of exclusivity the patent holder is able to exploit the protected creation without concurring competitors, finding a relevant condition to recoup the investment made in the achievement of the patented invention. Thus, it is expected that those who benefit from a patent right may feel encouraged to keep on bringing new solutions to existing technical needs and, therefore, to contribute to mankind's technological progress.

Indeed, in order to accomplish policies fostering technology development within fields such as pharmacy and biotechnology, the patent system is currently acknowledged as one of the main legal instruments that provide undertakings the necessary incentives to innovate,³ alongside with other more recent instruments such as data exclusivity protection.⁴ This assertion is founded in the general fact that once the knowledge is diffused it becomes a public-good and hence there is non-rivalry over its use, which eventually enables free imitation, depriving inventors of the complete capturing of the returns made in investment, reason why the existence of a patent regime becomes significantly important, mainly in the fields of technology where

³ Walter García-Fontes, "Incentivos para Innovar: Una Revisión" in Vicente Ortún (ed), *Incentivos a la I+D+i de Medicamentos* (Springer 2012) 12.

⁴ Charles Clift, 'Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals', in A Krattiger, R T Mahoney, L Nelsen and others. (eds) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR/PIPRA 2007) 431, 435, data exclusivity is described as 'a time-bound form of intellectual property protection that seeks to allow companies to recoup the cost of investment in producing data required by the regulatory authority. The effect of data exclusivity is to prevent the entry of generic competitors, independent of the patent status of the product in question'.

such investment is considerably high and the cost of producing copies is significantly low.

In particular, the pharmaceutical sector is amongst the most research-intensive industries,⁵ accounting high costs in the development of new products. For instance, in 2012 the development of a new drug (whether chemical or biological entity) amounted to approximately USD 1,506 million in 2011 prices.⁶ Moreover, the research and development (R&D) of a medicinal product take almost ten years, which includes the pre-clinical development and the clinical trials, and if the process is successful the product will be introduced into the market only after two or three more years.⁷

Whereas developing an innovative synthetic drug is onerous,⁸ its manufacturing is relatively cheap (close to marginal costs of production), and so free imitation would have great impact in the innovators' projected recoupment of investment if it were not for the protection provided by patent law. Therefore, there are valid reasons to assert that R&D activities in the pharmaceutical industry are very sensitive to the existence of a system which protects intellectual property. Then, the incentivisation of the investment in the extremely costly and time-intensive process of medicine development through the guaranteeing of exclusivity rights may be seen as a policy of public interest.⁹

Without prejudice to the above mentioned, it also has to be pointed out that safeguarding intellectual property on pharmaceuticals implies a social cost, because, taking advantage of its exclusivity in the market, patentees will

⁵ For instance, in the United States the pharmaceutical industry invests almost five times more in R&D, relative to their sales, than the other industries, as referred in The Congress of the United States, *Research and Development in the Pharmaceutical Industry* (Pub. 2589, CBO 2006) 9.

⁶ Jorge Mestre-Ferrandiz, Jon Sussex and Adrian Towse, *The R&D Cost of a New Medicine* (OHE 2012) 11.

⁷ European Federation of Pharmaceutical Industries and Associations, *The Pharmaceutical Industry in Figures* (EFPIA 2016) 6.

⁸ According to Interfarma - Associação da Indústria Farmacêutica de Pesquisa, *Entendendo os Medicamentos Biológicos* (2012) 7, 'Traditional synthetic drugs are generally small molecules, consisting of a few tens or a few hundreds of atoms and have well known chemical structure. They are stable molecules and, given its nature, can be identically replicated.'

⁹ Wayne Winegarden, *Improving the Incentive to Innovate: An important benefit of the 21st Century Cures bill* (PRI 2015) 1.

usually charge prices that are higher than those that would be charged under competition (prices well above marginal costs).¹⁰ Studies like the one conducted by the International Monetary Fund in 2004 suggest that the price of pharmaceuticals may increase from 25% to 50% due to the existence of patent protection.¹¹ In these conditions there will be price-sensitive consumers that will not be able to afford the price charged by the patentee, which ultimately will represent a welfare loss, situation which is generally referred in economics as dead weight loss.¹² The impossibility of affording medicines constitutes one of the main reasons of the lack of access to these products and may become a serious health problem when it comes to drugs that are essential to life-saving, which is also a matter of public interest, especially for developing countries, where demand for health care is elastic.¹³ Furthermore, in many developing countries the encouragement to innovate may be not as transcendent as the deadweight loss existing as a cause of high prices.¹⁴

In order to alleviate the difficulties regarding access to health, the patent system itself conceives some flexibilities, such as the compulsory licensing regime, which will be studied below.

B. Compulsory Licensing and Public Interest

¹⁰ Owen Gehrett, 'Innovation, Parallel Trade, and the Pharmaceutical Industry' (2007) Duke University <<https://econ.duke.edu/uploads/assets/dje/2007/Gehrett.pdf>> accessed 3 September 2016.

¹¹ According to Arvind Subramanian, 'Medicinas, patentes y ADPIC' in International Monetary Fund (ed), Finanzas y Desarrollo (IMF 2004) 23, '[A]fter a comparison between the price of triple combination antiretroviral drugs against AIDS in countries where patent protection exists and where it does not, it is asserted that the prices varies greatly between ones and others in approximately 4,000 %'.

¹² 'Understanding Patents on Pharmaceuticals' <<http://individual.utoronto.ca/adamlewinberg/Access/Box2.htm>> accessed 3 September 2016.

¹³ According to Mor Bakhoun, 'Trips, Patent Rights and Right to Health: 'Price' or 'Prize' for better Access to Medicine?' (2009) Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper No. 10-07, 33 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1619215> accessed 3 September 2009, 'Given the low income of consumers in most developing countries, a raise in the price of pharmaceuticals renders the pharmaceuticals unaffordable'.

¹⁴ Aidan Hollis, 'An Efficient Reward System for Pharmaceutical Innovation' (2004) 6 <<http://www.who.int/intellectualproperty/news/Submission-Hollis6-Oct.pdf>> accessed 3 September 2016.

I. World Trade Organization Standards on Compulsory Licensing

1. The Trade Related Aspects of Intellectual Property Rights Agreement and the Leeway for National Adoption of Grounds on Compulsory Licensing

From 1986 to 1994 the Contracting Parties of the General Agreement on Tariffs and Trade (GATT) carried out the Uruguay Round, an ambitious series of international negotiations that, looking to expand regulations beyond trade in goods, included intellectual property amongst the novel matters that needed to be implemented. The end of the referred negotiations led to the creation of the WTO, an international organization established on 1 January 1995 which deals with the liberalizing of trade and for this purpose operates as a forum for the negotiation of trade agreements and the settlement of disputes related with its rules.

The conclusion of the discussions on intellectual property matters gave rise to the TRIPS Agreement, which came into effect since 1 January 1995, being one of the pillars on which rests the WTO¹⁵ and a transcendental global milestone as to the substantive harmonization of these rights.^{16,17} Specifically, the TRIPS Agreement sets minimum standards for the protection of intellectual property rights (IPR), including those related to patents.

It is relevant to refer that the TRIPS Agreement introduced IPR standards that would inevitably have a tremendous impact on Member States' health policies, especially in developing and least-developed countries. For instance, before the entry into force of the TRIPS Agreement forty countries did not include pharmaceutical products as patentable subject matter, and therefore generic versions, either locally manufactured or imported, could

¹⁵ '¿Qué es la OMC?' <https://www.wto.org/spanish/thewto_s/whatis_s/whatis_s.htm> accessed 3 September 2016.

¹⁶ Subhasis Saha, 'Patent Law and Trips: Compulsory Licensing of Patents and Pharmaceuticals', *Journal of the Patent and Trademark Office Society* (2009) 365.

¹⁷ As seen in Jayashree Watal and Antony Taubman, 'Revisiting the TRIPS negotiations: Genesis and structure of this book' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement Personal insights from the Uruguay Round negotiations* (WTO 2015) 15, where it is said that the TRIPS Agreement signifies 'a turning point for multilateral governance and a catalyst for transformation of law, policy and international relations in IP and in a host of related policy fields'.

be easily introduced into their markets at affordable prices.^{18,19} Now, under the TRIPS Agreement, patents shall be available for any invention, whether product or process, in all fields of technology,²⁰ which implies that pharmaceutical products must inevitably be part of the subject matters that are patentable.²¹ Plus, the term of patent protection, which before the TRIPS Agreement ranged from 15 to 17 years amongst developing and developed countries, was set to be no less than 20 years counted from the application filing date.^{22,23}

Notwithstanding, due to the pressure of developing countries it was possible to include provisions that aimed to enable Member States to safeguard sensitive national interests, such as those related to health policies²⁴, which are known as TRIPS flexibilities.²⁵ The referred flexibilities are embodied in Article 30, which provides for the option to apply limited exceptions to patent rights,²⁶ and Article 31, which provides for other uses without the authorization of the right holder.²⁷ Moreover, these flexibilities seem to be

¹⁸ P. Boulet and others, *Pharmaceuticals and the WTO TRIPS Agreement: Questions and answers* (UNAIDS/WHO 2000) 3.

¹⁹ For instance, before the adoption of the TRIPS Agreement the Andean Community (Bolivia, Colombia, Ecuador, Peru and, by that time, Venezuela) established that inventions related to pharmaceutical products listed in the essential drug list of the World Health Organization were not patentable, that according to Decision 344 of the Cartagena Agreement, Common Regime on Industrial Property, art 7(e).

²⁰ TRIPS Agreement, art 27(1).

²¹ According to Piragibe dos Santos Tarragô, 'Negotiating for Brazil' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement Personal insights from the Uruguay Round negotiations* (WTO 2015) 245, 'The developing countries were unable to retain the possibility of invoking reasons of public health to exclude inventions from patentability. If that carried, they would have been able to continue not to grant patents to pharmaceutical products and processes, which, for many demandeurs, was their critical objective in the TRIPS negotiations. The 14 developing countries, with the possible exception of India, agreed not to insist on the issue as they were already in the process of changing their national laws to grant patent protection to pharmaceutical products'.

²² World Health Organization, 'Intellectual Property Protection: Impact on Public Health' (2005) 19/3 Drug Information 199, 238.

²³ TRIPS Agreement, art 33.

²⁴ According to Antony Taubman, 'Thematic review: Negotiating 'Trade Related Aspects' of Intellectual Property Rights' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement Personal insights from the Uruguay Round negotiations* (WTO 2015) 44, 'Unquestionably, if TRIPS does have legitimacy and balance as a legal and policy instrument today, this is a consequence of the give-and-take of the negotiations and the efforts, well documented in this volume, of developing country negotiators to include effective policy safeguards which have since been shown to be effective in practice, for instance in the sensitive policy area of public health'.

²⁵ Saha (n 1616) 366, 'TRIPS included some concessions to address the concerns of developing nations regarding policies of economic development and the need to take protective measures'.

²⁶ TRIPS Agreement, art 30.

²⁷ *Ibid* art 31.

supported by the objectives and principles contemplated in the text of the TRIPS Agreement itself. According to the mentioned objectives the harnessing of the benefits provided by the intellectual property system should be done in a manner that is consistent with the achievement of social and economic welfare.²⁸ Furthermore, according to the provided principles, while implementing national legislation consistent with the TRIPS Agreement, Member States may not find obstacles as to the adoption of measures consistent with the safeguard of public health or which are needed to prevent any abuse from the intellectual property holders.²⁹

It has to be noted that even when Article 31 of the TRIPS Agreement does not mention expressly that it is addressed to regulate compulsory licences on patents, the scope of its text is clearly related to these kind of measures.³⁰ A compulsory licence is an authorization given by a national authority to a person for the exploitation of the subject matter protected by a patent or other IPR without the consent of the right-holder.³¹ Normally when a government issues a compulsory licence, prices experience a relevant decrease, compared to the existence of competition conditions in which generic drugs are introduced into the market.³²

The text of Article 31 of the TRIPS Agreement does not specify the grounds on which a compulsory licence may be issued, instead it constitutes an open clause for Member States to determine by themselves on what circumstances it is necessary to use this legal mechanism.³³ In this sense, it

²⁸ Ibid art 7.

²⁹ Ibid art 8.

³⁰ Saha (n 16) 369, 'TRIPS does not expressly provide for compulsory licensing. Article 31 of TRIPS, however, effectively provides for compulsory licensing by allowing "other use of [patents] without the authorization of the right holder"'.
³¹ Ibid 365.

³¹ Ibid 365.

³² Sara M. Ford, 'Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents' (2000) 15/4 Am. U. Int'l L. Rev. 941, 946.

³³ According to Peter Roderick, 'Do India's Compulsory Licences violate TRIPs?' (2012-13) 225 *Managing Intell. Prop.* 47, 'The TRIPs Agreement allows for [compulsory licences], does not restrict them to a public health emergency, and does not set out the grounds upon which they can be granted'; Also as referred to in Jayashree Watal, 'Patents: An Indian Perspective' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement Personal insights from the Uruguay Round negotiations* (WTO 2015) 304-306, in which it is stated that there are no restrictions on grounds for compulsory licences because India submitted a non-paper that was accepted for further negotiations on this matter and that merged the previous draftings as to compulsory licences and government use into only one general provision with the title "Use without authorization of the right holder", which embodied an approach that was too close to the United States'

may be said that Member States enjoy broad discretion as to the issuance of compulsory licences.³⁴ Nevertheless, Article 31 of the TRIPS Agreement provides for compliance of certain conditions for the issuance and maintenance of a compulsory licence. For instance, the non-authorized use may only be allowed if previously the proposed user has made unsuccessful efforts to get a voluntary licence on reasonable commercial terms.³⁵ Also, consistent with Article 31, there are terms that must be set at the granting and be fulfilled at the execution of a compulsory licence, such as the payment of an adequate remuneration to the right holder³⁶ and the scope and duration of the use according to the purpose of the authorization³⁷. Furthermore, this use must be non-exclusive³⁸, non-assignable³⁹ and predominantly addressed to supply the domestic market of the authorizing Member State.⁴⁰

Article 31 of the TRIPS Agreement makes reference to some specific grounds on which a government may justify the issuance of a compulsory licence, such as national emergencies or other circumstances of extreme urgency and cases of public non-commercial use. Nevertheless, according to what has been referred before, these circumstances may be seen only as referential reasons and not as the unique causes on which a government can rely on to authorize a non-consented use of a patented invention. As a matter of fact, these grounds respond to the decision of negotiators to provide some flexibility in these cases and make it possible for Member States to waive the requirement related to the seeking of a voluntary

submission and that at the same time shared the nature of the United States' existing use without authorization established in 28 USC Section 1498(a). It is said that consequently the US delegation could no longer insist on restriction on the grounds for compulsory licences, rather it only pushed to make some weakening arrangements on the text.

³⁴ Donald Harris, 'TRIPS after fifteen years: success or failure, as measured by compulsory licensing' (2010-11) 18 J. Intell. Prop. L. 367, 383; see also Mohammed K El Said, *Public Health Related TRIPS-plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiators and Implementers in the WHO Eastern Mediterranean Region* (WHO/ICTSD 2010) 161, 'TRIPS does not stipulate the circumstances under which compulsory licences must be issued but rather leaves the door open for individual member states to determine such grounds'.

³⁵ TRIPS Agreement, art 31(b).

³⁶ Ibid art 31(h).

³⁷ Ibid art 31(c).

³⁸ Ibid art 31(d).

³⁹ Ibid art 31(e).

⁴⁰ Ibid art 31(f).

licence.⁴¹ In the same way, there are specific allusions to the granting of compulsory licences on the basis of anti-competitive practices committed by the patentee⁴² and the dependence of a patent to another patent owned by a third party,⁴³ but again these are only referential reasons.

According to Article 2 of the TRIPS Agreement, intellectual property is also governed by the Paris Convention (1967),⁴⁴ and hence compulsory licensing comes to be ruled too by this legal body, which provides for the grant of these measures in order to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, such as failure to work.⁴⁵ Therefore, the rules of the Paris Convention do not limit Member States to establish the basis for compulsory licensing, although the grant must be associated to any abuse committed by the patentee.

Notwithstanding the above and in attention to the authorizing clauses of the TRIPS Agreement, some authors have asserted that the grounds provided by the Member States may attend two implicit justifications: whether the patentee does not utilize or does not properly utilize the patented invention within the country (corrective justification) and whether there is a special situation in the country that justifies the adoption of this measure (social or humanitarian justification).⁴⁶ Thereby, apparently the compulsory licensing rules provided by the TRIPS Agreement would imply a reconciliation between the patent system and the need that Member States have regarding the protection of the health of their people whenever it is required, however a later event revealed the lack of uniform understanding amongst the Member States on the application of these measures.

In 1997 the government of South Africa enacted the Medicines and Related Substances Control Amendment Act (the Act), in an attempt to control the AIDS pandemic existing in that country. The Act provided measures for the

⁴¹ Catherine Field, 'Negotiating for the United States' in Jayashree Watal and Antony Taubman (eds), *The Making of the TRIPS Agreement Personal insights from the Uruguay Round negotiations* (WTO 2015) 143.

⁴² TRIPS Agreement, arts 31(c) and 31(k).

⁴³ Ibid art 31(l).

⁴⁴ Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as last revised at Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305.

⁴⁵ Ibid art 5(A)(2).

⁴⁶ Aditi Bagchi, 'Compulsory Licensing and the Duty of Good Faith in TRIPS' (2002-03) 55 Stan. L. Rev. 1529, 1532-1533.

supplying of more affordable antiretroviral agents,⁴⁷ such as the amendment of Section 15c of Act 101, whose language allowed the Minister of Health to prescribe the conditions to adopt compulsory licences on medicines. The Act was, nevertheless, subject to criticism from the potentially affected patentees, who predominantly were from the United States and Europe, and soon their respective governments took some measures as retaliation. For instance, the United States Trade Representative (USTR) included this case in the Special 301 Report of 1998^{48,49} and in October 1998 the Congress of the United States decided to cut off economical assistance to the government of South Africa until the disputed provision were repealed, suspended or terminated.⁵⁰ It was only after many months of meetings that the South African representatives and the USTR settled, so in September 1999 the latter expressed its conformity with the use of compulsory licensing by South Africa to attend its problem with the access to medicines, consistent with the TRIPS Agreement.

Notwithstanding the referred settlement agreement, there was a widespread incertitude regarding the TRIPS Agreement flexibilities panorama and, particularly, on the grounds upon which a Member might rely on for the issuance of a compulsory licence,⁵¹ which eventually boosted the emergence of an apparent solution: The Doha Declaration on the TRIPS Agreement and Public Health, which will be the object of next section.

2. Doha Declaration on the TRIPS Agreement and Public Health: Ratification of the Freedom in the Domestic Determining of Reasons for Compulsory Licensing

⁴⁷ Medicines and Related Substances Control Amendment Act No. 90 (ZA).

⁴⁸ USTR Special 301 Report (1998) 21
<<https://ustr.gov/sites/default/files/1998%20Special%20301%20Report.pdf>> accessed 4 September 2016.

⁴⁹ The USTR Special 301 Report is a US governmental system created to monitor every year the economic policies adopted by other nations and their adequacy to WTO rules.

⁵⁰ On October 21, 1998 the US government passed the law PL 105-277, which contained a provision that cutted off aid to the government of South Africa, pending a Department of State report outlining its efforts to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Act No. 90.

⁵¹ According to Pier DeRoo, 'Public Non-Commercial Use Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs' (2011) 32 Mich. J. Int'l L. 347, 358, 'The South Africa confrontation permanently altered the TRIPS flexibilities landscape'.

Concerns regarding threats on the application of the TRIPS Agreement flexibilities led developing countries to pursue the reaffirmation of the right that WTO Member States have in order to use these measures. This matter was approached in the fourth WTO Ministerial Conference, which was celebrated in Doha from 9 to 14 November 2001. It has to be pointed out that the objective of the participant developing countries was not the clarification of the text related to the flexibilities, which they understood was very clear indeed, but the ratification of the compromise from WTO Member States to respect a Member's adoption of flexible measures to safeguard health.⁵² The outcome was the Doha Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 (Doha Declaration on TRIPS),⁵³ which expressly reaffirmed the right of WTO Member States to use the flexibilities provided in the TRIPS Agreement in order to safeguard public health, emphasizing that it might consist of the full use of such flexibilities.⁵⁴

Thus, recognizing the seriousness of the existing problems on public health in developing countries and least-developed countries⁵⁵ and the repercussion of intellectual property protection on prices,⁵⁶ it was highlighted that the TRIPS Agreement should be considered as an instrument to tackle such matters, through its designation as a component of the ampler domestic and international practices on these issues.⁵⁷ In this context, it was agreed that none of the provisions of the TRIPS Agreement could impede the adoption of measures issued to safeguard public health, rather they would have to be interpreted and implemented in a way consistent with this purpose, particularly for the promotion of access to medicines.⁵⁸

To overcome any doubt regarding the application of the flexibilities, it was pointed out that the interpretation of any provision of the TRIPS Agreement

⁵² Ibid.

⁵³ See World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002).

⁵⁴ Doha Declaration on TRIPS, para 5.

⁵⁵ Ibid para 1.

⁵⁶ Ibid para 3.

⁵⁷ Ibid para 2.

⁵⁸ Ibid para 4.

should be done taking into account the express object and purpose of the Agreement, and particularly the established objectives and principles.⁵⁹ Moreover, making explicit the content of Article 31 of the TRIPS Agreement, it was recognized the right of Member States to grant compulsory licences and, even more, that they are free to determine the corresponding grounds of granting,⁶⁰ thus conferring them an important discretion in the adoption of these measures.⁶¹

The following years to the Doha Declaration on TRIPS seem to reflect its success. According to Public Citizen,⁶² from 2002 many countries have granted compulsory licences in order to control their health troubles. Thus, Zimbabwe (2002), Malasya (2003), Mozambique (2004), Zambia (2004), Indonesia (2004), Eritrea (2005), Ghana (2005), Thailand (2006, 2007), and Brazil (2007), among others, granted compulsory licences on medicines, predominantly for the treatment of HIV/AIDS and mostly on the basis of national emergency. The CAN Member Countries are also Member States of the WTO, so it corresponds to analyze whether they are using the special regime of compulsory licences, which will be made in the following section.

II. Andean Community Legal Framework on Compulsory Licensing

1. Decision 486 of the Commission of the Andean Community: The public Interest for the Issuance of Compulsory Licensing

The Andean Community is the result of the seeking of the balanced and harmonious development of Bolivia, Chile, Colombia, Ecuador and Peru,

⁵⁹ Ibid para 5(a).

⁶⁰ Ibid para 5(b).

⁶¹ As noted in Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (WHO 2002) 15, ‘Sub-paragraph 5(b) of the Doha Declaration deals with an issue central to the interests of developing countries. It simply states what is apparent: Article 31 sets forth a number of conditions for the granting of compulsory licences (case-by-case determination; prior negotiation, in certain cases, with the patent owner; remuneration, etc.), but it does not limit the grounds on which such licences can be granted. Though Article 31 refers to some of the possible grounds (such as emergency and anti-competitive practices) for issuing compulsory licences, it leaves Members full freedom to stipulate other grounds, such as non-working, public health or public interest’.

⁶² Public Citizen, ‘Ejemplos Mundiales de Licencias Obligatorias por Farmacéuticas después de ADPIC’ <<http://www.citizen.org/documents/compulsory-licenses-chart-short-version-spanish.pdf>> accessed 4 September 2016.

which in May 26, 1969 signed the Cartagena Agreement, laying the groundwork for the creation of a subregional community that since then was known as Andean Pact and that from 1996 was renamed as Andean Community.⁶³ In order to achieve the said objective, the Andean Community promotes a continuous process of integration and economic and social cooperation.⁶⁴ In particular, this process of integration involves the need of having common rules as to matters that foster the unification of the market, such as industrial property rights, including patent rights.⁶⁵

Patent rights in the Andean Community are regulated through the Decision 486, establishing the Common Industrial Property Regime, which was issued on September 14, 2000 by the Commission of the Andean Community. As well as the rest of regulations provided by the Andean Community, Decision 486 is subjected to two fundamental principles enshrined in Article 4 of the Treaty establishing the Court of the Andean Community: Direct application and preeminence of the legal system of the Cartagena Agreement.

The patent regime established in Decision 486 includes a section providing for a compulsory licensing regime.⁶⁶ According to the content of the referred section, the Andean legislation sets forth that compulsory licensing may be used due to causes attributed directly to the patent holder (lack of exploitation of the patented invention in the country where the licence is requested⁶⁷ or the commission of practices affecting free competition)⁶⁸ and to external causes (existence of public interest, emergency or national security considerations⁶⁹ or the exploitation of an invention owned by a third party and protected by a dependent patent).⁷⁰ Article 65 of Decision 486 (Art. 65/D486), establishing compulsory licensing on the basis of public

⁶³ Chile left the Cartagena Agreement in 1976, and then returned in 2006 as an associate member.

⁶⁴ '¿Qué es la CAN?' <<http://www.comunidadandina.org/Seccion.aspx?id=189&tipo=QU&title=somos-comunidad-andina>> accessed 4 September 2016.

⁶⁵ Carlos Lugo Silva, 'Propiedad Industrial e Integración Económica en la Comunidad Andina de Naciones: Obstáculos para una Patente Andina' (2012) 5/1 ArtefaCToS 123, 124.

⁶⁶ Decision 486, Title II, Chapter VII.

⁶⁷ Ibid, art 61.

⁶⁸ Ibid, art 66.

⁶⁹ Ibid, art 65.

⁷⁰ Ibid, art 67.

interest reasons does not further develop the content of this specific justification and so far there is not any interpretation made by the Andean Community Court of Justice on this respect, reason why it is up to each country to give internally a meaning and content to such causes in application of the principle of indispensable complement existing in the Andean Community.⁷¹ In spite of that it should be stressed that when it comes to the development of national normativity, the constituent countries of the Andean Community enact rules that are not uniform and that, instead, reflect the existence of different dynamics in the treatment of patent rights.⁷²

Despite the fact that the Andean Community has not brought a definitive pronouncement on the public interest as a reason for the granting of a compulsory licence, it has to be noted that on February 6, 2015 Sugen Inc. filed a non-compliance claim against the Republic of Ecuador before the General Secretariat due to the issuance of a compulsory licence on a patent owned by such undertaking. On May 29, 2015, the General Secretariat issued the Opinion No. 006-2015 by which made emphasis in the fact that the compulsory licence subject of the claim was still being disputed in the Ecuadorian Institute of Intellectual Property (IEPI) due to the administrative appeal brought by Sugen Inc. against such measure. Thereby, the General Secretariat asserted that being pending the referred appeal it did not correspond to make any comment about the state of compliance of the community obligations by Ecuador. Later on, on August 5, 2015, the General Secretariat issued a Clarification on the Opinion No. 006-2015 in response to a request made by the Ecuadorian government. This Clarification stated that it could be counterproductive to make a pronouncement on the debated merits because there had not been issued yet a decision on the pending appeal. To the date there is no evidence that IEPI

⁷¹ In the case of a loophole within the Andean Community legislation, Member Countries are able to implement national rules in order to give operability to such common legislation. On this principle the Andean Court has said: "(...) It is not possible the issuance of national standards on the same subject, except when they are necessary for the proper application of those." (Process 10-IP-94. Prejudicial Interpretation of March 17, 1995, published in Official Gazette of the Cartagena Agreement No. 177 of April 20, 1995)". Also "(...) Thus, the Member Country could only have regulated that case where Community law itself explicitly had foreseen, or when on such matter had been silent." (Process 115-IP- 2009. Prejudicial interpretation of February 25, 2010, published in the Official Gazette of the Cartagena Agreement No. 1828 of April 30, 2010)."

⁷² Lugo Silva (n 65) 127.

has issued a final decision on the referred appeal or that the General Secretariat has issued a further statement on this case.

However, it is relevant to comment that the Clarification issued by the General Secretariat includes a brief reference in relation to the reason of public interest required to issue a compulsory licence, albeit without specifically defining such ground. In this context it was said as follows:

[T]he Andean Community rules on compulsory licensing do not delimit the grounds of public interest which can justify the granting of such licences. However, with respect to the relationship between industrial property rights and the right to health, experts in these areas have pointed out that right to moral and economic protection resulting from scientific research constitutes a human right subjected to limitations of public interest. Such limitations, only regulated as provided in Article 68 of Decision 486, do not cease to be difficult to define nor ensure certainty in the scope. The General Secretariat, in the light of the various existing positions worldwide on these dilemma, recognizes that the right to health includes a series of minimum and interrelated elements such as availability, accessibility, acceptability and quality (of goods/services and health programs).⁷³ (translation made by the author)

Chapter 4 will deepen on how this clarification may be helpful on the task of construing the meaning of the public interest reason needed for the issuance of a compulsory licence in the Andean Community. For the moment it corresponds to take a look at how each CAN Member Country has implemented the compulsory licensing regime in its internal regulations as well as the casuistry generated around it.

2. National Case Law: The Experience of the Andean Community Member Countries

a) Peru: A Panorama of Uncertainty

⁷³ *Sugen Inc v Ecuador* 011-FP-2015 (Clarification on the Opinion No. 006-2015, 5 August 2015).

In Peru complementary provisions to Decision 486 are established by Legislative Decree 1075, which has been in force since February 1, 2009, having been implemented as a result of the obligations assumed by the Peruvian government under the Peru-United States Trade Promotion Agreement (TPA).⁷⁴ Legislative Decree 1075 only incorporates one provision regarding the compulsory licensing regime, namely Article 40 (Art. 40/LD1075),⁷⁵ which reads as follows:

Previa declaratoria, mediante decreto supremo, de la existencia de razones de interés público, de emergencia o de seguridad nacional; esto es, emergencia nacional u otras circunstancias de extrema urgencia o en casos de uso público no comercial; y solo mientras estas razones permanezcan, en cualquier momento se podrá someter la patente a licencia obligatoria. En tal caso, se otorgarán las licencias que se soliciten. El titular de la patente objeto de la licencia será notificado cuando sea razonablemente posible [*Following a declaration, by Supreme Decree, of the existence of reasons of public interest, emergency or national security; that is, national emergency or other circumstances of extreme urgency or in cases of public non-commercial use; and only for as long as those reasons subsist, the patent may be subjected to compulsory licensing at any time. In such a case, the licences will be granted upon request. The holder of the patent subjected to the compulsory licence will be notified when it is reasonable possible*] (translation made by the author).

Art. 40/LD1075 establishes that compulsory licences on the grounds of public interest, emergency or national security shall be granted only when previously a Supreme Decree has declared the existence of these reasons. It

⁷⁴ Peru-United States Trade Promotion Agreement was signed on 12 April 2006, approved by Congress through Legislative Resolution No. 28766, published in the official gazette El Peruano on June 29, 2006 and ratified by Supreme Decree No. 030-2006-RE, published in the official gazette El Peruano on June 30, 2006. it was implemented by Supreme Decree No. 009-2009-MINCETUR, published in the official gazette El Peruano on January 17, 2009. Date of entry into force on February 1, 2009.

⁷⁵ This article was modified by Law No. 29316, amending, incorporating and regulating various provisions in order to implement the Trade Promotion Agreement signed between Peru and the United States of America, published in the official gazette El Peruano on January 14, 2009.

is implicit that this rule is addressed to complement the rule contained in Art. 65/D486. Moreover, Art. 40/LD1075 sets forth that the above referred reasons are linked necessarily to national emergency considerations or other circumstances of extreme urgency or cases of public non-commercial use by stating: “[f]ollowing a declaration (...) of the existence of public interest, emergency or national security; that is, national emergency or other circumstances of extreme urgency or in cases of public non-commercial use (...)”. Additionally, Art. 40/LD1075 regulates certain further conditions for the issuance of a compulsory licence under the indicated reasons, such as the notification to the patentee when it is reasonably possible, but not any other considerations regarding the corresponding grounds of issuance.

Later on, a Directive Draft regarding compulsory licensing was made available for public scrutiny in accordance to Resolution of the Presidency of the Board of Indecopi No. 059-2015-INDECOPI/COD, published on April 10, 2015 in the official gazette El Peruano. This Draft Directive sought to provide the rules applicable to the proceeding of compulsory licensing before the national authority in charge of processing it, that is to say the Directorate of Inventions and New Technologies.⁷⁶ This Draft Directive did not provide any substantive clarification as to the public interest, emergency or national security grounds, only a relevant procedural provision that stipulated that in these cases it should not be necessary to have tried to obtain a prior authorization from the patent holder. Up to date this Draft has not been officially approved.

Finally, it is relevant to assert that up to date the Peruvian authorities have not granted any compulsory licence on the basis of the public interest ground or, in general, on any of the other grounds provided by the Andean common legislation.

b) Ecuador: Lax Definitions for a Broad Scope

⁷⁶ The Directorate of Inventions and New Technologies is the administrative competent body to process and resolve the patent applications filed in Peru according to article 37 of Legislative Decree 1033, approving the Law of Organization and Functions of the National Institute for the Defense of Competition and the Protection of Intellectual Property (INDECOPI).

Ecuador complements its intellectual property legislation through the Intellectual Property Law (Consolidation No. 2006-013), in force as from May 19, 1998, whose chapter on patents (Chapter II of Book II) includes a section which provides for the compulsory licensing regime. Particularly Article 154 provides some details regarding the compulsory licensing grounds established in Art. 65/D486, and reads as follows:

Previa declaratoria del Presidente de la República acerca de la existencia de razones de interés público de emergencia o de seguridad nacional y, sólo mientras estas razones permanezcan, el Estado podrá someter la patente a licencia obligatoria en cualquier momento y en tal caso, la Dirección Nacional de Propiedad Industrial podrá otorgar las licencias que se soliciten, sin perjuicio de los derechos del titular de la patente a ser remunerado conforme lo dispone esta Sección. El titular de la patente será notificado en forma previa a la concesión de la licencia, a fin de que pueda hacer valer sus derechos [*Following a declaration by the President of the Republic as to the existence of reasons of public interest of emergency or national security and, only for as long as these reasons subsist, the State may subject a patent to compulsory licensing at any time and in such a case, the National Directorate of Industrial Property may grant licences for which applications are filed, without prejudice to the rights of the patent owner to be remunerated in accordance to this Section. The patent owner will be notified prior to the granting of the licence, so that he may assert his rights*] (translation made by the author).

In the first place, it is important to point out that, as well as in the case of Peruvian legislation, the granting of a compulsory licence on the grounds provided by Art. 65/D486 is conditioned to the issuance of a prior declaration made by the Executive Power upon the existence of the considerations established in such Article. Nonetheless, the drafting of the Ecuadorian law has some singular aspects. From the text of Article 154 it can be read that there is a sole ground for the issuance of a compulsory

licence, namely the public interest consideration, which at the same time is divided into two specific categories: public interest on the basis of an emergency and public interest on the basis of national security.⁷⁷ Thereby, Article 154 could be interpreted in the sense that the public interest consideration shall only exist when an emergency or a national security arise, which could imply that the Ecuadorian law has narrowed the scope of such consideration.

On October 23, 2009, Rafael Correa Delgado, Constitutional President of the Republic of Ecuador, enacted the Presidential Decree 118, by which declared of public interest the access to medicines used for the treatment of diseases that affect Ecuadorian population and that are priorities for public health, for which compulsory licences on patents for medicines that may be necessary for treatment may be granted.⁷⁸ At the same time, it was established that the Ecuadorian Institute of Intellectual Property (IEPI), through the National directorate of Industrial Property, is the Competent National Office competent for the granting of compulsory licences to those who apply for them, and that the authorization of compulsory licences shall be considered in the light of their particular circumstances and shall be supported by factual basis in each case.⁷⁹

Contrary to the above-referred interpretation of Article 154 of the Intellectual Property Law, the Presidential Decree 118 sets forth that compulsory licences may be granted when a medicine for human use is necessary for the treatment of a disease and that, at the same time, is a priority for public health, which gives the access of such medicine a mantle of public interest. Thus, it is clear from the text of Presidential Decree 118 that the public interest reason is not linked inevitable to any consideration of urgency or national security, and so should be in accordance to Article 65 of Decision 486.

⁷⁷ According to Manuel Fernández de Córdoba, ‘Las Licencias Obligatorias de patentes en el Ecuador. Una breve referencia al caso de los medicamentos y al decreto presidencial 118’ (2013) 15 *Iuris Dictio* 205, 217, ‘Intellectual Property Law of Ecuador and Decision 486, keeping the fundamental dogmatic precepts, require (...) [r]easons of public interest resulting from an emergency or national security (...)’.

⁷⁸ Presidential Decree No. 188, art 1.

⁷⁹ *Ibid* art 2.

Later on, on January 15, 2010, the IEPI issued the Instructive for Compulsory Licensing on Drug Patents through Resolution No. 10-04-P-IEPI (the Instructive), which established the proceeding of compulsory licensing applications in accordance to Decision 486 and the Intellectual Property Law. It has to be said that the Instructive establishes the needed requirements for two kinds of compulsory licence applications, namely those applications for licences for public non-commercial use and those for commercial use.⁸⁰

On April 14, 2010 the IEPI granted the first compulsory licence under the light of the Presidential Decree 118 in response to the application made by the undertaking Eskegroup S.A. to obtain a licence on the patent No. PI-97-1142, which covered the active substance called Ritonavir.⁸¹ In order to grant this licence the Ministry of Health of Ecuador gave a technical opinion to the EIPI, by which it was asserted that Ritonavir is an active substance which is used alone or in combination for the manufacture of drugs used in the treatment scheme of people living with HIV/AIDS, thus being a priority for public health.⁸² This was only the first of several licences issued later. Between 2013 and 2014 the IEPI granted nine compulsory licences for drugs used in the treatment of HIV/AIDS, arthritis, cancer, diseases affecting the immune system and difficulties in patients due to kidney donation.^{83,84}

⁸⁰ Article 5 of the Instructive specifies that a “public non-commercial use” should be understood as a drug procurement process by any of the entities of the Ecuadorian public sector to cover their health programs.

⁸¹ The compulsory licence on the patent No. PI-97-1142 for “Retroviral protease inhibitor compounds, a process for repair and pharmaceutical compositions which include them”, owned by Abbott Laboratories, was granted through Resolution No. 1-DNPI-IEPI.

⁸² Resolution No. 1-DNPI-IEPI, para 10.

⁸³ According to Javier Llamaza, ‘Salvaguadas de Salud Pública. Licencias Obligatorias en Brasil, Ecuador’ (Lima, 7 July 2015) <<https://prezi.com/bgrlyghk956o/salvaguadas-de-salud-publica/>> accessed 4 September 2016, one more licence was granted as to the patent No. PI-97-1142, plus three licenses regarding Patent No. SP-98-2505 (covering ABC + 3TC for the treatment of HIV/AIDS), one for Patent No. SP-97-2190 (covering Etoricoxib for the treatment of arthritis), one for the patent PI-08- 1913 (covering Mycophenolate sodium for kidney transplant), one for patent No. SP-97-1383 (covering Sutinib for the treatment of cancer) and one for patent No. PI-2010-2027 (covering Cortolizumab for the treatment of rheumatoid arthritis).

⁸⁴ According to ‘Nueve Licencias Obligatorias para abaratar Medicamentos Estratégicos’ (Guayaquil, 29 July 2014) <<http://www.elcomercio.com/tendencias/medicinas-medicamentos-sida-iepi-licenciasobligatoria.html>> accessed 4 September 2016, the issuance of the referred compulsory licences represented savings of between 23% and 99% in the acquisition of the medicines subjected to such measures.

As it may be seen, in Ecuador it is the right of access to medicines a consideration of public interest consistent with Art. 65/D486, provided that such medicines are intended to treat diseases existing in Ecuador and that, at the same time, are considered priorities for public health. Thus, the determination of this ground reflects a State policy as it is stated in the preamble of the Presidential Decree 118, which bases its enacting on the obligation that the Ecuadorian government has regarding the ensuring of universal access to essential medicines according to the policy 3.3 of the 2007-10 National Development Plan.

Even when Article 2 of the Presidential Decree 118 states that the authorization of a compulsory licence shall be considered under the light of the particular circumstances and be supported by a factual basis in each case, the broadness of the conditions indicated in Article 1 denotes that the use of compulsory licensing is not subject to a rigid evaluation criteria. This is confirmed by the content of Resolution No. 1-DNPI-IEPI which just pointed out that the active substance subject to the evaluation is used for the production of medicines addressed to the treatment of people with HIV/AIDS, which entails its priority character for public health.

Therefore, it can be asserted that in Ecuador the determination on the existence of the needed conditions for the issuance of a compulsory licence is made on the basis of the nature of a disease rather than in the particular circumstances that affect a specific market. This interpretation might lead to conclude on the one hand that there is not any legal certainty as to the determination of the demanded conditions and on the other hand that such a measure might not have an exceptional character, which has brought much criticism.⁸⁵

c) Colombia: Contradiction of Decisions

⁸⁵ According to Fernández (n 77) 219, ‘Could the issuance of compulsory licences on patents be justified then under the general interest that underlies any State policy? We believe not. (...) [T]he public interest (...) that is inherent to all State policies which are permanent can not be itself a sufficient condition for the granting of [compulsory] licences, which are always temporary’. (translation made by the author); see also USTR Special 301 Report (2016) 63 <<https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf>> accessed 4 September 2016, by which Ecuador is encouraged to provide clarification on its processes related to the compulsory licensing of pharmaceuticals.

In Colombia, Art. 65/D486 is internally regulated through the Decree No. 1074 enacted on May 26, 2015 by the Ministry of Commerce, Industry and Tourism,⁸⁶ which establishes the procedure for the declaration on the existence of reasons of public interest. In order to seek the granting of a compulsory licence on the basis of a public interest, any interested person may apply for the declaration of this situation before the respective Ministry or the Administrative Department responsible for formulating and adopting policies and projects of the target sector,⁸⁷ which, by reasoned act, will decide to go forward or not with the administrative action and will communicate that order to the person concerned.⁸⁸ It has also been provided that the respective Ministry or Administrative Department shall have a Technical Committee, which, after the corresponding evaluation, will recommend to the respective Minister or Director of Administrative Department to take the decision of declaring or not the existence of public interest.⁸⁹ Particularly Article Art. 2.2.2.24.5. provides some specific aspects that the declaration on the existence of public interest has to include, and reads as follows:

La resolución expedida por el correspondiente Ministerio o Departamento Administrativo en la que se declare que existen razones de interés público que ameriten la expedición de licencia(s) obligatoria(s) deberá identificar la situación que afecta el interés general; establecer las circunstancias que llevaron a la declaratoria y los motivos por las cuales se debe licenciar la patente; además, indicará las medidas o mecanismos necesarios que se deban adoptar para conjurar dicha afectación

[The resolution issued by the corresponding Ministry or Administrative Department which declares the existence of reasons of public interest that support the issuance of compulsory licence(s) should identify the situation affecting the public interest; establish the circumstances that led to such

⁸⁶ This Decree includes the provisions contained in the Decree No. 4302 published on November 13, 2008, which established the proceeding for the declaration on the existence of reasons of public interest according to Article 65 of Decision 486.

⁸⁷ Decree No. 1074, art 2.2.2.24.3.

⁸⁸ Ibid art 2.2.2.24.4.

⁸⁹ Ibid art 2.2.2.24.6.

declaration and the reasons why the patent must be licensed; and also indicate the measures or mechanisms necessary to be taken to avert such affectation] (translation made by the author).

Finally, it is established that, following the publication of the corresponding declaration on the existence of public interest in the Official Gazette, the Superintendency of Industry and Commerce should go forward with the procedure for granting any compulsory licence for which applications are filed in accordance with the procedure established for such effect.⁹⁰

On July 16, 2008 the first Colombian application for the issuance of a compulsory licence attending to reasons of public interest was filed before the Ministry of Social Protection, the Superintendency of Companies and the Presidency of the Republic. The referred application was lodged by Mesa de Organizaciones con Trabajo en VIH/SIDA, Recolvih, Fundación Ifarma, Acción Esencial para la Salud AIS and Fundación Misión Social, seeking the declaration of the public interest over the combination Lopinavir/Ritonavir (an antiretroviral) protected by the Colombian patent No. 28.401 in force until December 12, 2016, owned by Abbott Laboratories, which commercializes such a product with the brand name Kaletra®.⁹¹

On May 8, 2009 the Ministry of Social Protection issued the Resolution 1444, by which the application was declared inadmissible, after stating that there were no reasons to declare that the access to the invention was of public interest. In this regard, the Ministry of Social Protection followed the recommendation made by the Technical Committee, which concluded that there was not a problem of access to the discussed antiretroviral because such a medicine was included in the Mandatory Health Plan (POS), which implied that, although high, the cost of the product was borne by the

⁹⁰ Ibid art 2.2.2.24.7.

⁹¹ When the application was filed there was not any regulation on the processing for the issuance of compulsory licences according to the public interest ground provided by Article 65 of Decision 486, reason why Decree No. 4302 was enacted, establishing the corresponding proceeding. Furthermore, through Presidential Resolution No. 5283 it was created the Technical Committee of Social Protection, in charge of the evaluation of the conditions for the declaration of public interest.

General Social Security System in Health of Colombia and not by the consumers.⁹²

Subsequently, on November 24, 2014, a new application for the declaration of public interest on a pharmaceutical product was lodged before the Ministry of Health and Social Protection. In this occasion Fundación Ifarma, Misión Salud Veeduría Ciudadana Coordinadora de la Alianza LAC Global por el Acceso a Medicamentos and Centro de Información de Medicamentos de la Universidad Nacional (Cimun) requested such a declaration as to the product Imatinib mesylate (polymorphic form β) protected by the Colombian patent No. 29270, owned by Novartis A.G., marketed with the brand name Glivec®. This request was based mainly on the high price of the pharmaceutical product and the constraints to the Budget of the Colombian government.

This time, the Ministry of Health and Social Protection declared the existence of reasons of public interest through Resolution No. 2475 issued on June 14, 2016, following the recommendation of the Technical Committee. Thereon, it was stated that this declaration was related with the need to preserve the savings in public health expenditure. Moreover, the Resolution No. 2475 refers that while it is true that Glivec® is included in the POS, the resources with which the drugs included in such a Plan are covered are of a public nature and therefore are not irrelevant, besides being limited.

Additionally Resolution No. 2475 indicated that even when there was another molecular form that is not patented (form α of Imatinib), there was insufficient evidence to establish that it was possible to obtain formulations of this form of Imatinib mesylate that are free of traces of form β , which would make their producers potential infringers of the patent. Finally, Resolution No. 2475 stated that there was no consensus on the fact that the active substances Dasatinib and Nilotinib are perfect therapeutic substitutes of Imatinib, since those are second-line treatments unlike the latter which is

⁹² The applicants took the case to court through a Popular Action demand. Through judgment of February 29, 2012, the Thirty-Seven Administrative Judge of the Judicial Circuit of Bogota rejected in first instance the arguments of the applicants. This latter decision was appealed by the applicants before the Administrative Court of Cundinamarca, which through judgment of September 27, 2012 confirmed the judgment of first instance.

frontline. In addition, it was considered that the value per recommended daily dose of those alternatives is considerably higher than that of Imatinib, with which it could not be achieved the goal of lowering prices and increasing the respective access.

As it may be noted, the legislation on compulsory licensing in Colombia does not further develop the needed conditions to determine the existence of a public interest. However, it has been the case law the one that has outlined some relevant considerations, which, although contradictory, reflect a position consistent with the existing problems in the access to health. Resolution No. 1444, which denied the application, emphasized that as long as the antiretroviral Kaletra® were funded by the Government it could not be alleged that there was a problem regarding the access of the population to such a medicine, regardless its high price.⁹³ Nevertheless, contrary to that position, Resolution No. 2475 established that it is of public interest alleviating the budgetary difficulties of the state in front of high prices of medicines on which rests a patent. These contradictory decisions generate uncertainty as to what position will prevail in the future, creating a negative impact on innovators. It is likely that if the latter interpretation prevails a greater number of requests for the declaration of public interest as to patented medicines may be boosted, because the adopted standard would be applicable to any other pharmaceutical product covered by a patent and funded by the government.⁹⁴

d) Bolivia: Choosing a Different Path

The internal regulation on industrial property in Bolivia is provided by the Law of December 2, 1916 on industrial privileges and rules for its application and use in the Republic and the Administrative Resolution No.

⁹³ David Francisco Franco Moreno and Angie Johanna Triana Aranda, 'La Viabilidad Jurídica de la Declaratoria de Razones de Interés Público para la Concesión de una Licencia Obligatoria para el Kaletra medicamento antirretroviral para el tratamiento del VIH-SIDA' (2009) 3 Escenarios Sociojurídicos 5 <<http://www.redsociojuridica.org/escenarios/edicion3/La%20viabilidad%20juridica%20de%20la%20declaratoria-%20Kaletra-VIH.pdf>> accessed 4 September 2016.

⁹⁴ Precisely this aspect has been subject of strong criticism by Novartis A.G., which in its closing allegations against the report of the Technical Committee (5 April 2016), affirmed that the Committee has not explained in this case why Glivec, compared to any other pharmaceutical product protected by a patent, is specially relevant for the financial sustainability of the health system.

017/2015 of June 16, 2015, establishing the internal procedure on industrial property of the National Service of Intellectual Property (SENAPI),⁹⁵ but only this latter includes provisions regarding compulsory licensing based on public interest reasons. Article 168 of Administrative Resolution No. 017/2015 establishes that in order to grant compulsory licence for reasons of public interest, emergency or national security, it should be accredited the declaration by the Plurinational State of Bolivia. It should be noted however that there is not any substantive provision regarding the interpretation on the existence of public interest reasons. Moreover, there is also no case law that has constructed the meaning of this ground.

Despite the above mentioned, it should be said that, pursuant to the provisions of the Supreme Decree No. 29004 of January 9, 2007, the granting of a patent for pharmaceutical products or processes depends on a Prior Consent issued by the Unit of Drugs and Technology in Health (UNIMED).⁹⁶ Thereby, it is relevant to consider that only when UNIMED determines that the content and scope of what is going to be patented does not interfere with the right to health and access to medicines, it is issued a positive Prior Consent and only then the corresponding patent may be granted by SENAPI.⁹⁷

Thus, it seems that Bolivia has adopted a preventive strategy in order to avoid any problem as to the population's access to medicines because of the exclusivity right that a patent confers, fulfilling a similar or maybe even more stringent role than that of the compulsory licensing regime. Notwithstanding, it has to be pointed out that it is likely that the alluded measure is not consistent with the Decision 486 since such a measure establishes a patentability requirement that is not provided by the Andean regulation, which may be subject to a possible non-compliance action before the Court of Justice of the Andean Community.

⁹⁵ SENAPI, created on September 16, 1997 under the 1788 Act, is the decentralized public institution in charge of administering the intellectual property regime in Bolivia.

⁹⁶ Supreme Decree No. 29004, art 3.

⁹⁷ Ibid arts 2 and 5.

CHAPTER III. Access to Health in Peru and Problems related to the Acquisition of the Antiretroviral Drug Atazanavir

A. Access to Pharmaceutical Products in Peru

The health system in Peru is conformed by providers from both, public and private sector, each of which counts with a set of funding mechanisms.⁹⁸ Private sector provides access to health services to those with ability to pay, either directly or indirectly through medical insurance.⁹⁹ The government provides access to health care to uninsured population through the Ministry of Health (MINSa) and regional governments, which by means of the Comprehensive Health Insurance (SIS) subsidize the provision of services to population in poverty.¹⁰⁰ The Social Health Insurance (EsSalud), attached to the Ministry of Labour and Employment Promotion, is destined to the treatment of the working population and their families and operates its own network of hospitals and health centers, constituting the second largest network of coverage in the country.^{101,102}

The distribution of drugs listed in the Single National Essential Drugs Request for patients in both SIS and EsSalud is free of charge.¹⁰³ Moreover, there are in Peru free health programs specifically designed to treat patients with tuberculosis, malaria, STDs and HIV/AIDS, who receive full treatment for such diseases at no cost.¹⁰⁴ During the last decade, MINSa has led the integration of the main processes of corporate drug supply in the Peruvian public sector.¹⁰⁵ Thus, the list of pharmaceutical products to be acquired

⁹⁸ Oscar Cetrángolo and others, *El Sistema de Salud del Perú: Situación Actual y Estrategias para orientar la Extensión de la Cobertura Contributiva* (OIT 2013) 43.

⁹⁹ José Félix Salazar Araujo, 'La Gestión de Abastecimiento de Medicamentos en el Sector Público Peruano: Nuevos Modelos de Gestión' (2014) 2 *Sinerg. innov.* 160, 178.

¹⁰⁰ Cetrángolo and others (n 98).

¹⁰¹ Salazar (n 99) 177.

¹⁰² To a lesser extent Peruvian government also provides health services through the Medical Services of the Armed Forces, under the Ministry of Defense, and the Health Services of the National Police of Peru (PNP), under the Ministry of Interior.

¹⁰³ Salazar (n 99).

¹⁰⁴ Peruvian Ministry of Health, *Republic of Peru: Pharmaceutical Country Profile* (PAHO/WHO 2012) 34.

¹⁰⁵ Salazar (n 99).

through corporate purchases for the supply of 2016 amounts to 474 drugs and the participating public entities are 34.¹⁰⁶

It has to be indicated that public spending by MINSA and regional governments on pharmaceuticals has experienced an evolution of 50.29% since 2005 (PEN 260.5 million -approximately USD 62.63 million-)¹⁰⁷ to 2012 (PEN 524 million -approximately USD 198.62-)¹⁰⁸. However, the public budget execution on such products has experienced a recoil of -13.85% in the same period (74.9% in 2005 to 65% in 2012).¹⁰⁹ On the other hand the availability of medicines in health facilities nationwide has been greatly increased, given that in 2005 it was only of 54.34% and in 2011 it reached 80.24%.¹¹⁰

B. Peruvian Antecedent regarding the Request of a Compulsory Licence. The Atazanavir Case

I. Case History

HIV/AIDS is a chronic disease that in early 2015 affected 65,000 people in Peru.¹¹¹ Taking that into account MINSA provides free antiretroviral treatment (TARV) for all people living with HIV/AIDS through the Highly Active Antiretroviral Treatment (TARGA).¹¹² By the end of 2013 26,332

¹⁰⁶ Ministerial Resolution No. 584-2015/MINSA, List of pharmaceutical products and participants entities for corporate purchase of pharmaceuticals regarding the supply of 2016.

¹⁰⁷ Conversion made under the bank nominal exchange rate (annual average sales) <<https://estadisticas.bcrp.gob.pe/estadisticas/series/anuales/resultados/P01274PRA/html>> accessed 3 September 2016.

¹⁰⁸ Ibid.

¹⁰⁹ Maruja Crisante N., 'Mercado Farmacéutico y Acceso a Medicamentos en el Perú' <http://www1.paho.org/per/images/stories/FtPage/2013/Mercado_farmaceutico-acceso_medicamentos-Peru.pdf> accessed 4 September 2016.

¹¹⁰ Maruja Crisante Núñez, 'Situación de los Medicamentos en el Perú' <http://www.digemid.minsa.gob.pe/UpLoad%5CUpLoaded%5CPDF/EURacMed/TrabSalud/ReuTec/RTM_Mayo2012/Potencias_01-Situacion_medicamentos_Peru.pdf> accessed 4 September 2016.

¹¹¹ Peruvian Ministry of Health, 'Minsa Actualiza Aspectos Preventivos y de Diagnóstico Temprano en atención de las personas con VIH' (19 January 2016) <<http://www.minsa.gob.pe/?op=51¬a=15995>> accessed 4 September 2016.

¹¹² According to 'Tratamiento Antiretroviral de Gran Actividad 'TARGA' Voluntario, Confidencial Gratuito y está a tu Alcance' <<http://www.minsa.gob.pe/portada/Especiales/2009/tuprevihenes/targa.html>> accessed 4 September 2016, 'TARGA is the combination of three types of antiretrovirales drugs that controls the amount of virus in the blood and improves the body's defense system'. (translation made by the author).

persons were receiving TARGA.¹¹³ Public investment in TARV has been increasing steadily over the years. Thus, it should be noted that while spending in 2005 was PEN 91.7 million -approximately USD 27.81 million-,^{114,115} by 2014 it was PEN 202.1 million -approximately USD 71.17 million-,^{116,117} which meant an increase of 54.63%.

The Peruvian Technical Standard for TARGA¹¹⁸ establishes that TARV schemes for new patients (first-line regimen) are based on the combination of two inhibitor drugs nucleoside/nucleotide of reverse transcriptase (INTR) plus a non-nucleoside inhibitor drug of reverse transcriptase (INNTR). The suggested scheme by the Peruvian Technical Standard consists of Tenofovir/Emtricitabine/Efavirenz.¹¹⁹ In cases where the first-line regime fails the patient is treated under a rescue scheme, for which the available drugs are Atazanavir, Lopinavir, Darunavir, Raltegravir, Etravirine and Maraviroc, although, except for Atazanavir, the use of these drugs requires the authorization of the Expert Committee on Comprehensive Care for the Adult with HIV Infection.¹²⁰ Atazanavir is the preferred drug in rescue schemes, having a favorable opinion on the maintaining of its use according to the Report of the Expert Committee on Comprehensive Care of Adults Infected with HIV / AIDS date don April 11, 2013 (Office 001-2014 CODEAVIS). However, there is so much discretion on the choice of a scheme, which might be induced by breakups of stocks of some drugs, circumstance that forces to use the ones that are available.¹²¹

Due to strong competition amongst generic producers and the increase of the corresponding demand, the price of the first generation of ARV drugs

¹¹³ Peruvian Ministry of Health, 'Informe Nacional sobre los Progresos realizados en el País' (2012-13). 60
<[http://www.unaids.org/sites/default/files/country/documents/file_94713.es..pdf](http://www.unaids.org/sites/default/files/country/documents/file_94713.es.pdf)> accessed 4 September 2016.

¹¹⁴ Acción Internacional para la Salud, 'Compras Públicas de Antirretrovirales en Perú' (2009) 27 AIS LAC Serie Investigaciones y Monografías 7 <<http://metaperu.org/wp-content/uploads/2016/03/compras-antirretrovirales-2009.pdf>> accessed 4 September 2016.

¹¹⁵ Conversion made under the bank nominal exchange rate (annual average sales) (n 107).

¹¹⁶ Peruvian Ministry of Health, 'Informe Nacional sobre los Progresos realizados en el País' (n 113) 64.

¹¹⁷ Conversion made under the bank nominal exchange rate (annual average sales) (n 107).

¹¹⁸ NTS N° 097 - MINS/DGSP-V.02, Technical Standard for the Comprehensive Health Care of the Adult infected by the Human Immunodeficiency Virus (HIV).

¹¹⁹ Ibid 16.

¹²⁰ Ibid 17.

¹²¹ Acción Internacional para la Salud (n 114) 9.

has been reduced by more than 99% since 2000; nonetheless, rescue scheme drugs are comparatively more expensive, mainly because they are protected by patents and also because the initial demand for these drugs is scarce.¹²² It is pertinent to note that between October 2007 and October 2008 EsSalud allocated 52% of its budget addressed for the purchasing of ARV drugs in the acquisition of Atazanavir.¹²³ Thus, the most expensive drug in that period was Atazanavir (weighted unit price of PEN 21.26 -approximately USD 7.26-¹²⁴ for the presentation of 150 mg and PEN 21.31 -approximately USD 7.28-¹²⁵ for the presentation of 200 mg), being estimated that the annual cost per person was over PEN 15,000 -approximately USD 5,127-^{126,127} . It should be pointed out that in the same period MINSA acquired Atazanavir at a price of PEN 14.85 -approximately USD 5-¹²⁸ per tablet, that is 30% less than the cost above, representing annual savings of PEN 5,000 -approximately USD 1,709-¹²⁹ per person in front of the acquisition made by EsSalud.¹³⁰

Moreover, the proportion of investment in Atazanavir contrasted a lot with the proportion of people who used that drug, since according to available statistics of MINSA, extrapolated to other sectors, Atazanavir was only consumed by 0.72% of users; notwithstanding it represented 15% of the overall investment in the referred period.¹³¹ By 2013 EsSalud bought a quantity of 147.220 units of Atazanavir 300 mg at a price of PEN 38.08 -approximately USD 14- per tablet,¹³² while MINSA acquired 559.980 units of the same product at a price of PEN 29.37 -approximately USD 11- per tablet.^{133,134} It is noted in this regard that there is a difference regarding the price at which Atazanavir is acquired by EsSalud and the one at which is

¹²² Ibid 11.

¹²³ Ibid 14.

¹²⁴ Conversion made under the bank nominal exchange rate (annual average sales) (n 107).

¹²⁵ Ibid.

¹²⁶ Acción Internacional para la Salud (n 114) 16.

¹²⁷ Conversion made under the bank nominal exchange rate (annual average sales) (n 107).

¹²⁸ Ibid.

¹²⁹ Ibid.

¹³⁰ Acción Internacional para la Salud (n 126).

¹³¹ Ibid 21.

¹³² Conversion made under the bank nominal exchange rate (annual average sales) (n 107).

¹³³ Ibid.

¹³⁴ Javier Llamaza, 'Patente en ARV: Caso Atazanavir' (Lima, June 2014) <<http://www.citizen.org/documents/patente-en-arv-caso-atazanavir-javier-llamaza-june-2014.pdf>> accessed 4 September 2016.

acquired by MINSA and that in view of the quantity purchased can be substantial, reflecting that one of the two institutions comes to get such drug in better conditions. As seen, the problem of acquisition of Atazanavir is not reduced only to the high price at which it is acquired but it could also be associated with the bifurcated purchases made by the governmental health national authorities, which results in a divergence of prices, which is seriously disadvantageous for the public expenditure. In this sense, it would be highly recommended to design a purchasing strategy which involves a common acquisition by these authorities.

Finally, it has to be said that in Peru the bisulfate salt of Atazanavir is protected by the patent No. 2380, granted to the Bristol-Myers Squibb (Bristol), being effective until January 2019 and marketed through the brand name Reyataz®.

II. The Arguments from the Involved Parties

1. Civil Society Organizations and Professional Associations

Since December 2013 civil society organizations and professional associations demanded to the Peruvian government the use of the compulsory licensing system on the ARV drug Atazanavir, based on the efficient use of the public resources.¹³⁵ According to various press releases and other relevant documentation issued before 2015, it may be asserted that the arguments supporting the claim previously mentioned are:

- *Compared to other countries in Latin America, Peru pays the highest price for Atazanavir.*¹³⁶

It was said that Peru paid 6.5 times more for Atazanavir than Brazil and almost twice as Argentina, Colombia and Mexico. Moreover, with the exception of Colombia, in all the mentioned countries there is patent protection for Atazanavir and the distribution is made by the same company:

¹³⁵ Ibid.

¹³⁶ RedGE and others, 'Urge una Licencia Obligatoria para Atazanavir y acabar con el Abuso Monopólico de este Medicamento' (31 March 2014) <<http://www.redge.org.pe/sites/default/files/20140331%20Pronunciamiento%20Caso%20Atazanavir.pdf>> accessed 4 September 2016.

Bristol.¹³⁷ Besides, in 2014 the average price per tablet acquired by MINSA and EsSalud was PEN 29.16 -approximately USD 10-,¹³⁸ price which was twenty times higher than the generic version available in Bolivia where the cost per tablet is equivalent to only PEN 1.4 -approximately USD 0.5-.^{139,140} Based on the latter data, it was emphasized that the overspending on the acquisition of Atazanavir in 2014 was of PEN 26,041,212.82 -approximately USD 9,171,439.7-.¹⁴¹

- *Only the acquisition of Atazanavir represents a cost which is close to half of the public budget for the purchase of ARV drugs:*¹⁴²

During the period 2004-14, the public sector entities have acquired Atazanavir for an approximate value of PEN 88 million -approximately USD 31 million-,¹⁴³ which constitutes 56.6% of the total public sector spending on medicines to treat HIV/AIDS. Having said this, it must be pointed out that Atazanavir is only one of the twelve drugs that the government buys to treat people with HIV/AIDS.

- *Given that the patent for Atazanavir owned by Bristol expires in 2019, acquiring Atazanavir (Reyataz®) under the same conditions would represent for the Peruvian government an overspending of PEN 130,206,064.10 -approximately USD 40,867,029.83-.^{144, 145}*
- *A compulsory licence is a viable and legitimate mechanism according to the flexibilities established by the TRIPS Agreement.*

¹³⁷ According to Public Citizen, 'Licencia Obligatoria para Atazanavir: Documento Técnico' (2014) 9 <<https://www.citizen.org/documents/atazanavir-technical-document.pdf>> accessed 4 September 2016, Argentina pays USD 8.91 per Tablet; Brasil, USD 2.90; Colombia, USD 9.54; Mexico, USD 10.55; and Peru, USD 18.60. Data corresponds to public purchases made in 2012 and the results are expressed in couplets dollars (PPA) to make them comparable.

¹³⁸ Conversion made under the bank nominal exchange rate (annual average sales) (n 107).

¹³⁹ Ibid.

¹⁴⁰ Public Citizen, 'Licencia Obligatoria para Atazanavir: Documento Técnico' (n 137) 10.

¹⁴¹ Conversion made under the bank nominal exchange rate (annual average sales) (n 107).

¹⁴² Public Citizen, 'Licencia Obligatoria para Atazanavir: Documento Técnico' (n 137) 8.

¹⁴³ Conversion made under the bank nominal exchange rate (annual average sales) (n 107).

¹⁴⁴ Ibid.

¹⁴⁵ Acción Internacional para la Salud and RedGE, 'Urge una Licencia Obligatoria para el Atazanavir'. (2014) <http://www.redge.org.pe/sites/default/files/alerta%20urgente%2022_atazanavir%20FINA.L.pdf> accessed 4 September 2016.

Based on the above considerations and noting that universal access to essential medicines is an enabling condition for the full exercise of the right to health, it was requested to the Peruvian government to make an efficient use of the public resources and, therefore, to use the compulsory licensing regime on Atazanavir, which would allow public entities to acquire such drug at a better price for the sake of the public interest.¹⁴⁶

2. National Association of Pharmaceutical Laboratories

In response to the referred request for the declaration of public interest, the National Association of Pharmaceutical Laboratories (ALAFARPE), of which Bristol is an associate, issued a press release in April 2015, by which highlighted the following arguments:

- *A compulsory licence is a temporary and exceptional mechanism:*

The compulsory licensing regime permits a government to face specific cases of extreme urgency or national emergency such as a pandemic; situation that currently does not exist in Peru, because the HIV prevalence is 0.4% according to the Analysis of Epidemiologic Situation of HIV/AIDS in Peru (MINSa 2013), which states that the affected population is serviced regularly and for free, reaching 97.1% of coverage.

- *A compulsory licence which does not comply with the legal requirements constitutes an expropriation:*

The expropriation of a patent through a compulsory licence without complying with the requirements of the Constitution, the national laws and the free trade agreements signed with the United States, Europe and other nations would represent a serious attack on intellectual property and exposes Peru to international sanctions.

- *A non-motivated compulsory licence discourages innovation on pharmaceuticals:*

As the Constitutional Court points out, the right to property is not absolute but is protected from direct and indirect expropriation. In this sense, the

¹⁴⁶ RedGE and others (n 136).

imposing of a compulsory licence arguing a public interest without proper motivation represents a legal and social nonsense, while discourages investment in a sector that requires constant innovation to improve the quality of life of patients.

III. Outcome

The request made by the civil society organizations and professional associations was echoed by MINSA, which in early 2015 presented a draft of a Supreme Decree before the Council of Ministers for the declaration of the public interest of Atazanavir.¹⁴⁷ However, it is known that after the corresponding discussions, the Ministry of Economy (MEF), the Ministry of Foreign Trade and Tourism (MINCETUR) and the Ministry of Justice (MINJUS) had an unfavorable opinion regarding the enacting of the alluded Supreme Decree arguing that it was not adequately supported and that it also could affect the TPA with the United States.¹⁴⁸

However, MINSA and Bristol held direct negotiations and in July 2015 Bristol agreed to reduce the price of Atazanavir 300 mg in 35% for the official supplying corresponding to August of such year.¹⁴⁹ Thus, while in 2013 it was paid PEN 29.17 -approximately USD 11-¹⁵⁰ per unit, the new price was PEN 18.96 -approximately USD 7-.^{151,152} MINSA emphasized that the price reduction would also favour other institutions of the sector such as EsSalud, the National Penitentiary Institute, the Armed Forces, the National Police, among others. In this sense, the Peruvian government

¹⁴⁷ Alexandra Hernandez Muro, 'Monopolio de Medicina contra VIH costará a peruanos 130 millones de soles' Sophimania (7 March 2015) <<http://www.sophimania.pe/ciencia/medicina-salud-y-alimentos/monopolio-de-medicina-contra-vih-costara-a-peruanos-130-millones-de-soles-video/>> accessed 4 September 2016.

¹⁴⁸ 'Patentes dadas por Indecopi a Fármacos afectan a la Salud Pública' La República (9 April 2015) <<http://larepublica.pe/09-04-2015/patentes-dadas-por-indecopi-a-farmacos-afectan-la-salud-publica-y-causan-sobrecostos>> accessed 4 September 2016.

¹⁴⁹ Peruvian Ministry of Health, 'Minsa logra reducción del 35% en precio del Atazanavir' (13 July 2015) <<http://www.minsa.gob.pe/?op=51¬a=16730>> accessed 4 September 2016.

¹⁵⁰ Conversion made under the bank nominal exchange rate (annual average sales) (n 107).

¹⁵¹ Ibid.

¹⁵² Peruvian Ministry of Health, 'Minsa logra reducción del 35% en precio del Atazanavir' (n 149).

reached a price below countries like Chile, Colombia and Mexico, which at that time paid USD 9.22, USD 7.75 and USD 7.18, respectively.¹⁵³

This result brought mixed reactions by the involved actors. Thus, while MINSA affirmed that this was a positive measure that implies important savings to the national treasury and which particularly benefits patients with HIV/AIDS,¹⁵⁴ organizations such as Foro Salud expressed their dissatisfaction with the fact that the request made to make possible the use of the compulsory licensing regime had failed because, in its opinion, that mechanism would have allowed savings for 75%, instead of savings for only 35%.¹⁵⁵ Beyond the results achieved by MINSA, it can be seen that there is not any clarity regarding the considerations that the Peruvian government should analyze in order to determine the existence of a situation of public interest which enables the expedition of a compulsory licence under the Andean legislation, circumstance that creates a great uncertainty as to what will happen to future requests on this matter and that, at the same time, motivates the making of this work, which in the next chapter will develop the corresponding analysis.

¹⁵³ Ibid.

¹⁵⁴ Ibid.

¹⁵⁵ 'Licencia Obligatoria hubiera permitido 75% de ahorro en Atazanavir' La República (14 July 2015) <<http://larepublica.pe/impres/politica/15202-licencia-obligatoria-hubiera-permitido-75-de-ahorro-en-atazanavir>> accessed 4 September 2016.

CHAPTER IV. Interpretation of the Public Interest Ground for Compulsory Licensing in the Andean Community

A. Extent of the Peruvian Legislation regarding Compulsory Licensing on Public Interest Reasons

As it was stated in Chapter 2, Art. 40/LD1075 complements Art. 65/D486 under the principle of indispensable complement existing in the Andean Community regime. It was noted that just as Art. 65/D486 does, Art. 40/LD1075 refers to public interest, emergency and national security reasons as grounds for compulsory licensing. Furthermore, Art. 40/LD1075 sets forth that the above-mentioned grounds are directly related to national emergency considerations or other circumstances of extreme urgency or cases of public non-commercial use, by stating the following: ‘*Previa declaratoria (...) de la existencia de razones de interés público, de emergencia o de seguridad nacional; esto es, emergencia nacional u otras circunstancias de extrema urgencia o en casos de uso público no comercial (...)*’/[f]ollowing a declaration (...) of the existence of public interest, emergency or national security; that is, national emergency or other circumstances of extreme urgency or in cases of public non-commercial use (...).’ (emphasis added).

In order to make a clear analysis, this thesis will further refer to the text prior the conjunction "that is" (existence of public interest, emergency or national security) as “the first statement” and to the text found after such conjunction (national emergency or other circumstances of extreme urgency or in cases of public non-commercial use) as “the subsequent statement”.

By including the conjunction “that is”, Art. 40/LD1075 expressly indicates that the grounds provided by Art. 65/D486 do materialize in some specific circumstances. Moreover, it can be noticed that the specific circumstances referred by Art. 40/LD1075 in the subsequent statement are those mentioned by Art. 31(b)/TRIPS, namely national emergency or other circumstances of extreme urgency or cases of public non-commercial use. In light of the above it can be noted that there are two aspects that would require further

clarification: a) whether the express reference made by Art. 40/LD1075 to the specific circumstances that are also contemplated by Art. 31(b)/TRIPS has only an exemplifying nature or whether rather it has a limiting character, and b) if having a limiting character, how the public interest reason should be construed under the extent of such specific circumstances.

In the first place it is pertinent to point out that the locution “that is” constitutes a transition connector used when a subsequent statement is destined to explain wholly or partly what has been expressed in one or more prior statements.¹⁵⁶ Within language there are various transition connectors that have an exemplifying nature, however “that is” is not one of them.¹⁵⁷ Instead, the use of the locution “that is” has a clarifying intention within language. Having said that, it is clear that the subsequent statement in Art. 40/LD1075 has the purpose of clarifying the circumstances under which the public interest, emergency and national security reasons recited in the first statement will manifest. In other words, such clarification has a manifest limiting effect, by which the grounds proposed in the first statement must be aligned solely to the circumstances referred in the subsequent statement. Thereby, by defining the specific circumstances by which the grounds set out in Art. 65/D486 arise, Art. 40/LD1075 has circumscribed the whole scope thereof to the referential reasons provided by Art. 31(b)/TRIPS.

It must be recalled that the Legislative Decree No. 1075 was enacted as a result of the obligations assumed by the Peruvian government under the TPA with the United States, which led to the inclusion and modification of several industrial property standards. However, as noted in chapter 2, the intellectual property provisions of such TPA do not contain any exigency related to compulsory licensing aspects, much less their delimitation to some specific circumstances.

Having determined that the wording of Art. 40/LD1075 has a limiting effect over Art. 65/D486 it corresponds to assess how the public interest reason

¹⁵⁶ Webster’s New World College Dictionary (4th edn, 2001) 1483, ‘-that is 1 to be specific 2 in other words’.

¹⁵⁷ Such as “for example” and “for instance” as referred to in ‘Connectors: Usage and Meaning’.
<<https://www.douglascollege.ca/~media/620D1295C1E6452C9AAB4344DFD037B7.ash>> accessed 7 September 2016.

should be construed under the extent of the circumstances specified in the subsequent statement. It should be said in the first place that by alluding in the subsequent statement to national emergency reasons or other circumstances of extreme urgency, Art. 40/LD1075 is reciting a species and a genus, respectively. Thus, when making allusion to "other circumstances of extreme urgency", Art. 40/LD1075 declares that a national emergency is considered one situation of extreme urgency. On the basis of this aspect, hereinafter the analysis made in this thesis shall refer only to circumstances of extreme urgency on the understanding that it encompasses a national emergency.¹⁵⁸ Consequently, it is determined preliminarily that the subsequent statement in Art. 40/LD1075 alludes to two circumstances, that is extreme urgency and cases of public non-commercial use.

Additionally it must be discarded any interpretation which concludes that the set of circumstances included in the subsequent statement are cumulatively attributable to each of the grounds set out in the first statement, that due to the presence of the disjunctive conjunction "or", by which it will suffice that either one or another arise.¹⁵⁹ Therefore, in order to determine the existence of one of the grounds set forth in the first statement it is sufficient the arising of one of the two circumstances provided in the subsequent statement, without prejudice that all of them occur simultaneously according to the non-exclusive nature of the conditions provided in the subsequent statement, which gives to the aforementioned disjunction an inclusive character.¹⁶⁰

In consequence it could be said *prima facie* that according to the Peruvian standards the public interest ground required for the issuance of a compulsory licence would be conditioned to the existence of a circumstance of extreme urgency or to a case of public non-commercial use, or even both. Nonetheless, considering that the first statement includes a ground

¹⁵⁸ According to Nuno Pires de Carvalho, *The Trips Regime of Patents and Test Data* (4th edn, Kluwer Law International 2014) 405, 'The cases "of national emergency" are just an example of "circumstances of extreme urgency". This means that there are no emergencies where there is no extreme urgency. [...] In other words, Article 31(b) provides for two exceptions only, and not three, because the national emergency is mentioned merely as an example of circumstances of extreme urgency.'

¹⁵⁹ Webster's New World College Dictionary (n 156) 1013.

¹⁶⁰ 'Inclusive Disjunction' <<http://mathworld.wolfram.com/InclusiveDisjunction.html>> accessed 7 September 2016.

based on an emergency reason, that is, a case of extreme urgency, it is unlikely that a reason of public interest may be associated with the consideration of extreme urgency provided in the subsequent statement, otherwise the emergency justification provided in the first statement would be senseless. In other words, the public interest ground provided in the first statement of Art. 40/LD1075 must be associated only with the circumstance of public non-commercial use of the subsequent statement.

It should be noted in this regard that a case of public non-commercial use implies that the use of the invention covered by the patent shall be held by a public body or a private entity under the authorization and supervision of a public body. On the other hand, the non-commercial aspect implies that the purpose of the compulsory licence shall not involve profiting. However a non-commercial use does not preclude the involving of a lucrative element in its deployment, especially if there is the intervention of a private entity, provided that the ultimate goal of the licence does not have a commercial character.¹⁶¹ Along the lines of the above it is clear that the delimitation made by Art. 40/LD1075 entails significant consequences, such as, for instance, that the reason of public interest could not lead to the granting of a compulsory licence if this measure is associated to a commercial use, whether public or private. Thus, this fact constitutes a major difference with the other countries of the Andean Community, whose legislations do not provide for such a limitation.¹⁶²

Limiting the use of compulsory licensing under public interest reasons to solely non-commercial uses could have an enormous impact in cases where the access to medicines is not funded by the government. Furthermore, the inclusion of this limitation in the Peruvian internal legislation results incomprehensible if it is taken into account that the TPA with the United States does not provide for any obligation in this regard. In this sense, it

¹⁶¹ According to Pires de Carvalho (n 158) 406, '[I]t is not the existence of profits that qualifies the commercial nature of the use, but the fact that operation is eventual, non-regular, and that the government absorbs the costs of distribution'.

¹⁶² Ecuador has established in its Instructive for Compulsory Licensing on Drug Patents (Resolution No. 10-04-P-IEPI) that any licence can be issued for commercial use and non-commercial use.

would be advisable to amend Art. 40/LD1075 in order to modify or remove the subsequent statement.

Having established how to characterize the requirement of public interest under Peruvian law it is necessary to determine now how these considerations are aligned with Art. 65/D486, upon which the countries of the Andean Community rely their compulsory licensing regime.

B. Construing of the Public Interest Justification for Compulsory Licensing in the Andean Community

I. Public Interest as a Legal Concept

According to Art. 65/D486 compulsory licensing is available in front of reasons of public interest, emergency or national security and only as long as these reasons remain. It has to be noted that the public interest is an indeterminate legal concept since its content and extent are variable, being subject to a discretionary construction by the administration, based on the merits of specific decisions.¹⁶³ According to the Constitutional Tribunal of Peru, the public interest is simultaneously a political principle of the State organization and a legal concept, operating in the first case as an ethical and political fundamental proposition that informs all government decisions; while in the second case it acts as an idea that allows to determine under what circumstances the State must prohibit, restrict, coerce, license, permit or cancel something.¹⁶⁴

In any case the public interest is equivalent to the general interest of the community and its satisfaction is one of the goals of the State, justifying the existence of the administrative organization.¹⁶⁵ It should be noted that this interest is preserved in so far as its content is deemed necessary, primary or fundamental.¹⁶⁶ However, it is not necessary that those who benefit directly from a measure supported by the public interest are all the individuals who are part of the community, being possible that the immediate beneficiaries

¹⁶³ *Juan Carlos Callegari Herazo v Ministry of Defence* File No. 0090-2004-AA/TC (Sentence of the Constitutional Tribunal of Peru, 5 July 2004) 4-5.

¹⁶⁴ *Ibid.*

¹⁶⁵ *Ibid.*

¹⁶⁶ Nicolás López Calera, 'El Interés Público: Entre la Ideología y el Derecho' (2010) 44 *Anales de la Cátedra Francisco Suárez* 123, 129.

are part of a collective whose protection is important for the society in general under a spectrum of elementary justice.¹⁶⁷

It should be clear that whenever an administrative body makes a decision based on the public interest, it should be able to explain the objective that is sought through the invocation of that concept, so the mere reference to the public interest is not enough, instead it shall exist a proper justification only when a worthy goal for society is pursued.¹⁶⁸ As to the right to health and its recognition as a public interest issue, the General Secretariat has manifested that it is linked to the necessity of providing a minimum set of interrelated elements such as availability, accessibility, acceptability and quality regarding the goods and services. In this sense the General Secretariat noted among other things that essential drugs should be available within health systems in appropriate doses and at any time, in the appropriate form, with secure quality and information, and at a price that the community in general and the patient in particular can afford.¹⁶⁹

The General Secretariat indicated that the above-mentioned considerations would allow to delimit in a theoretical way the reasons of public order entitling a CAN Member Country to grant a compulsory licence over a patent for a drug, being essential for this purpose to make a constant verification and analysis of the corresponding constraints in order to achieve an appropriate balance between the authorized violation to industrial property rights and an adequate protection of public health.¹⁷⁰ From the point made by the General Secretariat it is possible to make some conclusions. It has been noted that the availability, access and quality of pharmaceutical products, whose assurance is of general interest, are within a conceptual framework, that is, they constitute precepts that will guide policies and administrative decisions. However a decision intending to safeguard the right to health should not only be based on a precept of public

¹⁶⁷ Ibid 128, 'Anyway the strictest or restricted public interest sense does not end in being the interest of a large audience, of many people, but especially an interest whose protection benefits the community in very fundamental aspects and consequently also to individual members who integrate it'. (translation made by the author).

¹⁶⁸ César Augusto Rodríguez G., '¿Qué es el Interés Público? a propósito de los "Conceptos Jurídicos Indeterminados' (1994) 5 Revista de Derecho Público 61, 72.

¹⁶⁹ *Sugen Inc v Ecuador* (n 73) 5.

¹⁷⁰ Ibid.

interest, which is something in itself inherent to all State action, but shall be made also as a response to an objective circumstance, such as the existence of a situation that affects or will potentially undermine such right.

In this sense, it could be said for example that the Decree No. 118 issued in Ecuador, by which it is declared of public interest the access to medicines used in the treatment of diseases affecting the Ecuadorian population and that are priorities for public health, only has a preceptual support inherent to a State policy. Even when Article 2 of such decree provides that the authorization of a licence shall be considered in the light of particular circumstances and should be supported by factual evidence in each case, the practice indicates that in Ecuador it is sufficient to indicate that the drug subject of the decision is a priority for public health and no more, as happened in Resolution No. 1-NCPA-IEPI, which gave place to the first compulsory licence granted in that country.

II. Extent of Public Interest Reasons according to the Drafting of Art. 65/D486

Given that the reasons of emergency and national security provided also by Art. 65/D486 are related somehow to the attention of a public interest, it could be assumed that this latter reason encompasses the other two. As indicated by Pires de Carvalho ‘After all it is the public interest that, in market-oriented economies, dictates government interference with private property, against payment of reasonable compensation’.¹⁷¹ Nonetheless, the legal technique used in the drafting of Art. 65/D486 leads to establish that, just as public interest, the reasons of emergency and national security respond individually to different considerations, given the use of the disjunctive conjunction "or" between such listed reasons. In this context it should be understood that Art. 65/D486 provides three different reasons for the issuance of a compulsory licence.

It also has to be taken into account that a broad interpretation of the public interest reason established by Art. 65/D486 would turn into inoperative the other two reasons included in such provision. An analysis under the *noscitur*

¹⁷¹ Pires de Carvalho (n 158) 398.

a sociis doctrine¹⁷² would suggest that a public interest reason for the issuance of a compulsory licence does not arise under the same circumstances that give rise to the reasons of emergency and national security, so it is convenient to analyze the content of these other two precepts.

By definition an emergency involves an unexpected state of danger or disaster which requires immediate action¹⁷³. As referred to by the World Health Organization (WHO), this specific state has to be declared by an authority and at a certain moment will have to be lifted.¹⁷⁴ In any case, the response to an state of emergency requires the adoption of extraordinary measures. It should be noted that the Doha Declaration on TRIPS provides that a public health crisis can represent a national emergency.¹⁷⁵ A health crisis may be decreed in front of the existence of two particular features, namely the state of emergency and the unprecedented nature of the risk which originates with such crisis.¹⁷⁶ A health crisis can be derived from an epidemic caused by pathogens or be drug-induced, foodborne or even have a natural origin, such as in cases of heat wave or tsunami agents.¹⁷⁷

As for the national security reasons, its delimitation can be carried out in accordance with normative instruments such as Article 163 of the Political Constitution of Peru, which provides that the State guarantees the security of the nation through the National Defense System. Ricardo Beaumont mentions that the comprehensive security, achieved through national defense, is defined as a situation in which the State ensures its existence and the integrity of its patrimony, as well as its ability to act with full autonomy

¹⁷² ‘What is Noscitur A Sociis?’ <<http://thelawdictionary.org/noscitur-a-sociis/>> accessed 7 September 2016, ‘A latin term for ‘it is known by the company it keeps’, it is the concept that the intended meaning of an ambiguous word depends on the context in which it is used’; Black’s Law Dictionary (8th ed. 2004) 1087, ‘canon of construction suggesting that “the meaning of an unclear Word or phrase should be determined by the words immediately surrounding it” -literally- “it is known by its associates’.

¹⁷³ Webster’s New World College Dictionary (n 156) 465.

¹⁷⁴ ‘Glossary of Humanitarian Terms’ (2008) <<http://www.who.int/hac/about/reliefweb-aug2008.pdf?ua=1>> accessed 5 September 2016.

¹⁷⁵ Doha Declaration on TRIPS, para 5(c).

¹⁷⁶ <<http://salud.ccm.net/faq/21447-crisis-sanitaria-definicion>> accessed 5 September 2016

¹⁷⁷ Ibid.

in the internal field and free from any subordination in the external field.¹⁷⁸ As such, national security has a predominantly military conception and seeks the prevention and control of the threats that may appear before a military attack or a war. Thus, considering the parameters surrounding the other two reasons established by Art. 65/D486, it could be justifiably asserted that the reason of public interest is associated with the reaction to the impairment or curtailment of a collective right, to the detriment of the general interest; albeit no addressing urgent and unpredictable concerns such as public health crises nor threats to the sovereignty and freedom of the nation. It should be noted that under the aforementioned considerations there is no restriction to appreciate that a reason of public interest may be associated with the need to address immediately a current or a potential situation that affects or will affect the common rights of society. Finally, it is pertinent to mention that contrary to what has been manifested by ALAFARPE, a compulsory licence consistent with Art. 65/D486 is not available only in cases of a national emergency or extreme urgency which, as it has been seen, is only one of the conditions established by such provision.

Having determined the meaning of the public interest reason which is required by Decision 486 to issue a compulsory licence, it corresponds to study the leeway that WTO Members have as to the determining of the grounds upon such a measure can be adopted under the light of the TRIPS Agreement.

C. Leeway for the Determination on Grounds for the Issuance of Compulsory Licences under the TRIPS Agreement: The Necessity Test

I. Compulsory Licences as Exceptional Measures

The TRIPS Agreement seeks to reduce distortions and impediments to international trade by promoting effective and adequate protection of intellectual property rights and ensuring at the same time that the

¹⁷⁸ Ricardo Beaumont Callirgos, 'El Tribunal Constitucional Peruano y los derechos fundamentales de las personas jurídicas' (2012) XVIII Anuario de Derecho Constitucional Latinoamericano 117, 131.

enforcement rules as to such rights do not represent a barrier to legitimate trade.¹⁷⁹ Furthermore, it is recognized in the TRIPS Agreement that intellectual property rights constitute private rights,¹⁸⁰ aspect which does not only enable a property owner to enforce his rights against any act of infringement committed by a third person but also to safeguard such rights from the interference of the government.

In view of the above it can be stated that a compulsory licence, whose object is to curtail the enforceability of intellectual property rights, must be seen as an exceptional measure.¹⁸¹ The exceptional nature of compulsory licensing is evident from the text of the TRIPS Agreement, which entitles Article 31 as "Other Use Without Authorization of the Right Holder" referring to uses that are not included in the scope of Article 30, but nevertheless share its exceptionality. This does not mean however that a compulsory licence shall be a residual measure, but rather that situations giving rise to the corresponding use of such measure must meet certain conditions that allow the authority to depart from its duty to protect intellectual property rights. Notwithstanding, Article 31 of the TRIPS Agreement does not establish itself the conditions that the motivating circumstances for such an exceptional measure must fulfill, so it turns imperative to establish whether those conditions are deducted from any of the other section of that Agreement.

Under the light of Paragraph 5(a) of the Doha Declaration on TRIPS the flexibilities provided by the TRIPS Agreement shall be read in the light of the object and purpose of this Agreement as expressed, in particular, in its objectives and principles, in accordance to the customary rules of interpretation of public international law. The TRIPS Agreement contains an Article entitled "objectives" (Article 7) and another entitled "principles" (Article 8), which, consistent with the above-referred context, should be

¹⁷⁹ TRIPS Agreement, preamble para 1.

¹⁸⁰ Ibid preamble para 4.

¹⁸¹ Pires de Carvalho (n 158) 203, 'Compulsory licenses have never been, and never will, relevant tools for accessing essential medicines. They may operate only in exceptional situations - and exceptional situations should be kept exceptional, they should not inform public health policies. As said above, it is not by systematically undermining the rights of those who invest in developing new pharmaceutical products that poor people will obtain easier or wider access to drugs'.

read to construe the leeway that WTO Members have as to the formulation and implementation of compulsory licensing on the basis of public policies. Moreover, there are other provisions which incorporate significant objectives and principles. Paragraph 1 of the Preamble provides for the most important objective of the TRIPS Agreement which, as previously stated, addresses to the reduction of distortions and impediments to international trade through the promotion and protection of intellectual property rights and their appropriate observance. On the other hand, Article 3 and Article 4 of the Agreement set forth principles such as National Treatment and Most-Favoured-Nation Treatment, respectively.

After analyzing the content of the aforementioned legal provisions, it is noted that Article 8.1 of the TRIPS Agreement is the one directly associated with the power provided to WTO Members to adopt legislative measures addressed to attend a public interest, especially those aimed to protect public health and nutrition. In this context, it is noted that Article 8.1 provides two important conditions that limit the spectrum of freedom enjoyed by WTO Members as to the implementation or amendment of their laws and regulations based on public policies of general interest; namely, that the adopted measures are necessary to safeguard the corresponding right and that such measures are consistent with the provisions of the TRIPS Agreement.

Alluding that the measure must be consistent with the provisions of the TRIPS Agreement is very vague since it is not specified to what particular provision it must be related to, however some authors have pointed out that such consistency is to be effected under the spectrum of Article 8.1 itself, that is, with the exigency of necessity.¹⁸² Thus it can be said that the relevant requirement for the purpose of implementing a measure whose purpose is to safeguard the health is its need. In other words, the TRIPS Agreement gives to the Member States the power to impair or curtail the enshrined intellectual property rights in order to protect a right for the public interest, provided that such impairment or curtailment is needed to be done. In this sense, it is extremely important to establish how this limitation

¹⁸² Pires de Carvalho (n 158) 117.

provided by Article 8.1 of the TRIPS Agreement affects the public interest declaration made by the Peruvian government under Art. 40/LD1075 and Art. 65/D486 with the purpose of granting a compulsory licence.

II. Necessity as a Requirement for the Issuance of a Compulsory Licence

The construction of the adjective "necessary" has already been made in the context of the WTO Dispute Settlement Mechanism, although not specifically in relation to Article 8.1 of the TRIPS Agreement but rather under the framework established in Article XX of the General Agreement on Tariffs and Trade (GATT 1994),¹⁸³ which *inter alia* provides that nothing in that Agreement shall be construed to prevent any contracting party from adopting or enforcing measures necessary to protect human life or health -Article XX(b)-, subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade.

The first thing that must be considered is that the Appellate Body (AB) has established that the necessary nature of a measure is not limited to the indispensability of its adoption, since a measure that makes a contribution to achieve the sought objective or value can also be considered necessary,¹⁸⁴ provided that such contribution is material, that is, other than marginal or insignificant, especially if the measure is trade-restrictive.¹⁸⁵ In other words, a measure whose adoption is indispensable or inevitable will be considered as necessary *per se*, while a measure which is contributory has to be duly analyzed in order to establish that is indeed "necessary". In order to determine whether a contributory measure is "necessary", the AB has developed a test which comprises two stages. First it should be carried out a judgment that weighs and balances the confronted interests, those from the Member who adopts the trade-restrictive measure and those from who is

¹⁸³ GATT was signed on October 30, 1947 and came into force from January 1, 1948 to April 14, 1994, when the Uruguay Round Agreements, which established the World Trade Organization, were signed. The original GATT text (GATT 1947) is still in force under the WTO framework, although subject to the modifications provided by GATT 1994.

¹⁸⁴ Appellate Body Report, *Korea - Measures Affecting Imports of Fresh, Chilled and Frozen Beef* WT/DS161/AB/R, WT/DS169/AB/R (11 December 2000) par 161.

¹⁸⁵ Appellate Body Report, *Brazil - Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R (3 December 2007) paras 210-211.

affected with such measure, consisting of: a) an assessment on the importance of the interest whose protection is sought, b) an assessment on the level of protection which is sought and the contribution that the disputed measure has as to its achievement and c) an assessment on the trade-restrictiveness of the disputed measure. The purpose of this first analysis is to verify whether the measure in question pursues a legitimate objective.

If after this first evaluation it is preliminarily concluded that the disputed measure is necessary, then it has to be conducted, at a second stage, an efficiency analysis to determine whether there is a less restrictive means as an alternative to the disputed measure, consisting of: a) the verification of whether there is not any less restrictive alternative that can achieve such level of protection and b) the verification of whether the found alternative is a reasonably available measure.¹⁸⁶ The AB has deepened the extent of each of the considerations required by the referred necessity test in many decisions, which are detailed out below in order to conduct the subsequent analysis:

➤ Weighing and Balancing

a) *assessment on the importance of the interest whose protection is sought*

Due consideration should be given to the relative importance of the general interest that motivates the adoption of the disputed measure. So, it will be more likely to estimate that the disputed measure is “necessary” if the general interest is more important or vital.¹⁸⁷

b) *assessment on the level of protection which is sought and the contribution that the disputed measure has as to its achievement*

The level of protection may be evaluated on the basis of quantitative or qualitative considerations, then its demonstration might be done through objective projections supported in data or a set of hypotheses supported by consistent evidence, respectively.¹⁸⁸ It is also relevant to determine the

¹⁸⁶ Ibid para 156.

¹⁸⁷ Appellate Body Report, *Korea - Measures Affecting Imports of Fresh, Chilled and Frozen Beef* (n 184) para 162.

¹⁸⁸ Appellate Body Report, *Brazil - Measures Affecting Imports of Retreaded Tyres* (n 185) paras 150-151 and fns 242-243.

degree of correlation between the disputed measure and the accomplishment of the value which is pursued. So, the more the measure contributes to the accomplishment of such value it will be most likely to determine that the measure is necessary.¹⁸⁹

c) *assessment on the trade-restrictiveness of the disputed measure*

It should be measured the negative impact that the contested measure has over the diminished right, being understood that a measure that has a smaller adverse impact would be deemed necessary against a measure with a broader restrictive scope.¹⁹⁰

➤ Least-Trade Restrictive Means

a) *verification of whether there is not any less restrictive alternative that can achieve the sought level of protection*

It should be checked whether there is an alternative measure that is consistent or at least the less inconsistent with the Agreement and that at the same time achieves the value which is pursued through the disputed measure.¹⁹¹ In this context, it should be noted that a measure will only be considered as an alternative if the same level of protection which is pursued by the Member State can be obtained.¹⁹²

b) *verification of whether the found alternative is a reasonably available measure*

It must be determined whether the adoption of the found alternative measure is reasonable or whether such measure is simply theoretical. So, it is relevant to know whether the found alternative does not imply an undue burden on the Member, such as prohibitive costs or substantial technical difficulties.¹⁹³ In any case, the reasonability of an available alternative

¹⁸⁹ Appellate Body Report, *Korea - Measures Affecting Imports of Fresh, Chilled and Frozen Beef* (n 184) para 163.

¹⁹⁰ Ibid.

¹⁹¹ Ibid paras 176, 180-181.

¹⁹² Appellate Body Report, *Brazil - Measures Affecting Imports of Retreaded Tyres* (n 185) para 170.

¹⁹³ Appellate Body Report, *China - Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products*, WT/DS363/AB/R (21 December 2009) paras 318-319.

measure can not be rejected only on the basis that it involves some administrative burden or cost, due to the fact that adopting a measure may necessarily entail costs, therefore it is not admissible to argue that a measure is not a reasonable alternative only because there are no cheaper alternatives.¹⁹⁴

Taking into account the judgement elements set out above it corresponds to conduct an analysis on how a health-related circumstance can fit into such elements for the purpose of determining that there is a necessary reason for the granting of a compulsory licence in Peru, considering in particular the events in Peru related to the drug Atazanavir and those ones in Colombia regarding the drug Imatinib.

➤ Weighing and Balancing

First, it is important to determine the value achieved through the intellectual property curtailment that will suppose the use of compulsory licensing as a result of the declaration of public interest. In the Atazanavir case the problem was associated with the high price of the drug, having been said that the persistence of that situation would affect the financial sustainability of the health sector.

Thereon, it has to be recalled that, as said in Chapter 3, the Peruvian State guarantees the free access to medicines to all people infected with HIV, so it could be argued that the problem is related to a matter of future sustainability and not to a current problem of lack of access to such medicine by the population or the incapacity to acquire the drug by the government, whose budget to purchase medicines for HIV treatment has met the needs since 2004, when Atazanavir began to be purchased. On this matter, due attention should be given to the point made by the Ministry of Health and Social Protection from Colombia under Resolution 2475 of 2016, which with the purpose of declaring the existence of a public interest on the drug Imatinib argued that even when such medication is given for free to the population, its acquisition is carried out with public resources, which are limited and are intended to serve the public interest of the

¹⁹⁴ Ibid paras 327-328.

Colombian population. Thus, in this case it was expressly recognized that the public interest is related to the need to preserve savings in public expenditure on health.¹⁹⁵

It is clear that as well as in the Imatinib case from Colombia, the request made in Peru for the declaration of public interest in relation to the drug Atazanavir was carried out with the aim of ensuring the future financial sustainability of the health sector through savings of an expenditure considered excessive. It could be argued that the final value which is sought to be protected is the accessibility to drugs, which is guaranteed by the State according to Article 3 of Law No. 29459 and that financial sustainability is only a means to achieve this purpose, nevertheless even in the case that this efficiency is achieved there is no guaranty that the produced savings will be used to get access to more drugs since the suppression of a budgetary credit in Peru may be used to enable the increase of the budget for other activities or projects in the health sector presenting a deficit in respect of its set goals, in accordance to Articles 40 and 41 of the General Law of the National Budget System (Law 28411), which is why it is concluded that indeed it is the financial sustainability of the sector itself the value which is sought to be safeguarded in this particular case. Taking into account that the AB opined that the term "necessary" is framed within a range of degrees,¹⁹⁶ it seems that it would be more valuable to ensure the financial sustainability of the sector in front of the existence or imminence of a deficit gap, than to merely secure the savings from the public treasury to achieve an administrative efficiency.

On the other hand, it should be noted that in cases like this, where the financial sustainability is involved, the protection level can be quantified using economic methods. In fact, as noted in the previous chapter, those who proposed the granting of a compulsory licence for Atazanavir suggested that this measure would have been allowed savings for an amount of PEN 130,206,064.10 -approximately USD 40,868,193.38-¹⁹⁷ by getting access to generic versions of such drug since 2015 until 2019, date in which

¹⁹⁵ Resolution 2475, 7.

¹⁹⁶ Appellate Body Report, *Korea - Measures Affecting Imports of Fresh, Chilled and Frozen Beef* (n 184).

¹⁹⁷ Conversion made under the bank nominal exchange rate (annual average sales) (n 107).

the corresponding patent expires. It is noted that the projected savings were made considering the level of annual overspending which would currently exist because of the purchasing of the patented drug Reyataz®,¹⁹⁸ which was deducted from the price per tablet of such branded medicine compared to the price of the generic drug distributed in Bolivia.

Regarding the level of contribution that savings like the referred above can produce in order to safeguard the future financial sustainability of the sector, it should be clear that there is not an absolute degree of certainty to assert that a measure such as a compulsory licence achieves better efficiencies over other possible measures. In this context, importance should be given to considerations such as that in most health systems the potential to improve the supply of pharmaceuticals is enormous, reflecting in part the magnitude of current administrative inefficiencies.¹⁹⁹ In particular, it has been noted that issues such as incorrect quantification, high prices, poor quality, improper storage, expiration of medicines, irrational prescribing, corruption, absence of careful selection, and the use of incorrect medicines by patients cause losses rising to 70% of annual expenditure.²⁰⁰ In the above sense, it is said that these losses can be controlled and reduced through a better management which takes into consideration the adoption of measures such as improving purchasing, quality assurance, the best storage, careful inventory control and improved medical prescriptions.²⁰¹

Moreover, relevant results may be achieved even with a moderate amount of know-how and relatively little additional funds, being understood that that improvements in pharmaceutical administration require an initial investment in systems development, training, physical infrastructure and other development initiatives, which result in dramatic cost reductions. Thus, it has to be borne in mind that the two biggest threats to the successful increase of access to medicines are the weak and vulnerable supply systems

¹⁹⁸ Givar Videos (21 January 2014) ‘Perú tiene sobregasto de 21 millones por compra de medicina de VIH/Sida’ [video file] retrieved from <<https://www.youtube.com/watch?v=nKXqcUPSkY8>> accessed 5 September 2016.

¹⁹⁹ Martha Embrey, ‘Toward Sustainable Access to Medicines’, *Managing Access to Medicines and Health Technologies* (MSH 2012) 1.6.

²⁰⁰ Ibid.

²⁰¹ Ibid 1.7.

and the worsening crisis in human resources.²⁰² While it is true that the entry into the market of generic drugs as a result of a compulsory licence would save the State spending under the aforementioned projections, it should be noted that its effect could be essentially contributive. In particular, this contributive effect should be measured in each case, since in theory the efficiency involved in solving other problems can have a greater impact.

Likewise, it has to be considered that high prices constitute a circumstance inherent to the intellectual property system. Even more, a claim on the existence of disproportionate prices in front of the prices existing in other countries should be made on the basis of similar conditions. Thus, it can not be made a fairly reasonable conclusion on the disproportion of a price by comparing the price of a generic drug with the price of an innovative drug. Additionally, it is important to note that the existence of different prices in different countries on the same innovative drug may respond to particular market conditions, such as the level of demand.

Finally, it should be noted that the savings that the purchasing of generic drugs mean to the public treasury represents at the same time an economic loss for the holder of the patent, whose ability to recover the investment made in the development of the patented invention is affected and ultimately implies a disincentive to continue developing new technologies, which is also a matter of public interest. Thus, the effect in these cases is significant because it deals directly with the right of excluding conferred by the intellectual property system. In this context, the restrictive impact of a compulsory licence for a patent that protects an invention in the pharmaceutical field can be absolute because even when the patentee is not impeded to participate in the market, low production costs of this kind of products will allow anyone who is beneficiary of such a licence to participate in the market with substantially lower prices.

In conclusion, the need to impose a compulsory licence shall be subject to the relevance of the target value, which may be better reflected when the financial sustainability of the sector is guaranteed in response to the existence or imminence of a worrying circumstance, such as a deficit gap,

²⁰² Ibid 1.14.

and not only when an administrative efficiency with no further specific purpose is tried to be achieved. Thus, while the target value is more relevant it is possible to consider that a measure with a lesser degree of contribution is indeed necessary, while a target with a minor value will force the degree of contribution to be higher. In any situation the degree of contribution should be analyzed case by case.

➤ Least-Trade Restrictive Means

Finding an alternative measure that ensures financial sustainability of the health sector requires in my view a search of two phases. In the first phase it has to be pursued the acquiring of the same product through other legally available channels or, alternatively, the acquiring of a product with the same active ingredient but which is not covered by any patent, or any other product with a different active ingredient not covered by any patent and that is a therapeutic substitute.

A non-restrictive option could be the parallel import of the same drug introduced by the patentee into foreign markets, that under the principle of exhaustion of rights provided by Article 54 of Decision 486, which states that a patent does not give the right to prevent third parties from engaging in acts of commerce in respect of a product protected by a patent after that product has been introduced into the market in any country by the patent owner or by another person with the consent of the patent owner or economically connected to him. Plus the exhaustion of rights adopted by the Andean Community is consistent with Article 6 of the TRIPS Agreement, which sets forth that nothing in the Agreement shall be used to address the issue of the exhaustion of intellectual property rights. However it can not be denied that this mechanism is of difficult use, since it is conditioned to the existence of sufficient stocks available abroad to satisfy the needs of Peru. Moreover, even if the selling price of the product placed abroad is significantly lower than the price with which it is marketed in Peru, it is possible that such lower price does not reach the level of savings pursued by the government.

Alternatively, the purchasing of a product that has the same active ingredient and that is not covered by any patent could be considered to achieve a similar level of contribution, although its commercialization should be viable.²⁰³ For instance, Resolution No. 2475 of 2016 issued in Colombia evaluated the possible use of the polymorph α of Imatinib (not patented) instead of Imatinib β (patented), notwithstanding it was said in this regard that there was insufficient evidence to demonstrate that a drug such as Imatinib mesylate always retains a single molecular form, which means that the molecular form α could eventually contain traces of form β , and therefore producers of form α could commit acts of infringement, reason why this alternative was rejected.

Regarding the Peruvian case of Atazanavir, the patent No. 2380 covers Atazanavir bisulfate salt, and although it could be considered that this is only one form of this principle (salt), it turns out to be the only commercially viable form. Furthermore, the possibility of accessing to an alternative also involves the evaluation on the scope of protection of the patent which covers the invention of interest. If such patent covers the compound or active ingredient itself there will be few chances of using an alternative product containing that compound. When a product that has the same active ingredient and that is not covered by any patent can not be found, the finding of a product with a different active ingredient not covered by a patent and constituting a therapeutic substitute should be considered. For example, Resolution No. 2475 of 2016 issued in Colombia said that although the active agents Dasatinib and Nilotinib could be considered as alternatives, there was no consensus on whether these drugs were perfect substitutes for Imatinib, due to the fact that they were included in the second-line treatment, while Imatinib was part of the first-line treatment. Moreover, it was added that the price per daily dose for the two aforementioned therapeutic alternatives was much higher than Imatinib, so the use of those options would not comply with the function of reducing prices.

²⁰³ Appellate Body Report, *Korea - Measures Affecting Imports of Fresh, Chilled and Frozen Beef* (n 184) paras 170, 172.

Regarding the Atazanavir case in Peru it should be considered that such drug corresponds to a second-line treatment, which is indicated when the patient fails to the treatment of first-line regime. However, the Peruvian Technical Standard for TARGA not only includes Atazanavir in the second-line regimen but also drugs such as Lopinavir, Darunavir, Raltegravir, Etravirine and Maraviroc, although unlike Atazanavir the use of these other drugs requires the authorization of the Expert Committee on Comprehensive Care Adult with HIV Infection and in the specific case of Maraviroc it is also necessary to previously count with a tropism test which indicates the presence of CCR5 co-receptor, issued by the National Institute of Health.

Thereby it is noted that according to Peruvian regulations there are other medications that can be used in the rescue scheme apart from Atazanavir. In fact there is evidence suggesting that Darunavir/Ritonavir combination presents a metabolic profile on adipocytes which is safer than Atazanavir/Ritonavir.²⁰⁴ Moreover, neither Darunavir or Lopinavir are covered in Peru by a patent for a compound or its particular forms (salt, crystal, isomer, among others) and up to date there are only patents that protect compositions comprising such compounds,²⁰⁵ so depending on the scope of protection conferred by such patents, it will be viable the comercialization of generic versions of these drugs. While it is true that unlike Atazanavir the acquisition of such drugs depends on an additional administrative procedure (the authorization of the Expert Committee on Comprehensive Care of Adults with HIV Infection), it is considered that such a charge is reasonable, being noted in this regard that according to the AB an alternative measure should not be seen as unreasonable only because it involves administrative costs.²⁰⁶

²⁰⁴ E. Capel and others, 'Effects of Ritonavir-boosted Darunavir, Atazanavir and Lopinavir on Adipose Functions and Insulin Sensitivity in Murine and Human Adipocytes', 17(3) *Antivir Ther* (2012) 549, 556; see also M Auclair and others, 'Impact of Darunavir, Atazanavir and Lopinavir boosted with Ritonavir on Cultured Human Endothelial Cells: Beneficial Effect of Pravastatin', 19(8) *Antivir Ther* (2014) 773, 782.

²⁰⁵ Email from Belén González (Executive in the Directorate of Inventions and New Technologies - INDECOPI) to author (24 August 2016).

²⁰⁶ Appellate Body Report, *China - Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products* (n 193) paras 327-328.

Nevertheless, if at the end none of the mentioned alternatives is feasible, it would correspond to evaluate in a second phase whether there are alternative mechanisms that, without seeking the acquisition of the discussed product at a lower price, tend to achieve the level of financial sustainability that the government looks for. After all, as noted above, the budget for the health sector is not only affected by the prices of medicines but also because of several variables including crisis with delivery systems and human resources. In any case, the level of contribution should be similar to that which is sought through the granting of the compulsory licence.

On the other hand, it should be noted that the necessity test developed by the AB does not only contemplate the possibility of using alternative measures which are not restrictive but also provides the possibility of using measures which, although restrictive, involve less impairment to the rights stipulated under the WTO legislation.²⁰⁷ For example, it was referred in Resolution No. 2475 that in Colombia drugs may be subject to a direct price control, however this possibility was ruled out because, as it was mentioned in that resolution, the international benchmarking methodology for prices which is used according to Circular 03 2013 of the National Commission for Prices of Drugs and Medical Devices only allows a referencing with the price of the branded product commercialized in other countries and not with all the medicines containing the active ingredient, which includes generics, so this method does not allow to capture the efficiencies required for the adequate sustainability of the health sector.

Unlike what happens in Colombia, in Peru there is no system for price control of pharmaceutical products or medical devices, so this type of measure is not legally feasible in Peru. In this regard, it can be said that, in theory, a price-control system over pharmaceutical products might be enough to overcome the problems associated to high prices, however the adoption of this system must find a balance between the right to health and the economic profitability of the R&D pharmaceutical companies, because if this latter is negatively affected, the launch of new products within the

²⁰⁷ Appellate Body Report, *Brazil - Measures Affecting Imports of Retreaded Tyres* (n 185) para 156.

health sector could be jeopardized and, by its effects, the access to products which improve the quality of life, which is also a matter of public interest. Perhaps, instead of adopting a price-control system it could be better to introduce a system which aims to the price fixing of a patented product as a result of the mandatory negotiation between the patent holder and the government. After all, it was by virtue of direct negotiations that the Peruvian government obtained a lower price for Atazanavir.

Additionally, although Art. 31(b)/TRIPS provides that Member States are not required to make efforts to obtain the authorization from the patentee before the issuance of a compulsory licence in cases of public non-commercial uses, it might be taken into account that negotiations between the patentee and the government in order to obtain a voluntary licence for exploiting the invention could be seen as a good non-invasive practice.

Given the above it is estimated that the verification of the existence of a condition of need regarding a situation of public interest for the issuance of a compulsory licence consistent with Article 31 of the TRIPS Agreement can be framed within the methodology that has been established by the WTO in various disputes and which seeks to achieve a balance between the interests of the parties by obtaining the level of protection sought by the Member State on the basis of measures that are necessary.

Finally, it should be concluded that a compulsory licence granted in accordance with the conditions set out in Article 31 of the TRIPS Agreement and, as developed in this thesis, under a foundation of necessity will be consistent with the said Agreement. In this regard there is nothing in the TRIPS Agreement which leads to establish that an expropriation arise whether a compulsory licence is granted, as suggested by ALAFARPE. Notwithstanding, it is relevant to mention that on this specific subject there is a pertinent provision incorporated to the TPA signed with the United States. Thereon, Article 10.7(5) of the TPA stipulates that Article 10.7 (Expropriation and Compensation) won't apply to the issuance of compulsory licences granted in accordance with the TRIPS Agreement, to the extent that such issuance is consistent with the chapter on Intellectual Property Rights (Chapter 16). It should be stressed, however, that Chapter

16 of TPA does not provide for any particular obligation regarding the issuance of compulsory licences. Therefore, it could be established that Article 10.7(5) of the TPA is essentially associated with the provisions of the TRIPS Agreement. In other words, the use of compulsory licensing without taking into account Article 8.1 (necessity test) and Article 31 of the TRIPS Agreement will constitute a breach to the Investment Chapter of the TPA, subject to a claim to arbitration.

Additionally, it is pertinent to say that there is another international agreement which could have an influence over the decision of the Peruvian government on the use of the compulsory licensing regime, namely the Trans-Pacific Partnership, also known as TPP.²⁰⁸ Similarly to the TPA, the TPP includes an Investment Chapter (Chapter 9). In particular, Article 9.8(5) provides that Article 9.8 (Expropriation and Compensation) is not applicable to compulsory licences provided that they are consistent with Chapter 18 (Intellectual property) and the TRIPS Agreement. Since there is not any provision regarding the use of compulsory licensing within Chapter 18 (Intellectual Property), Article 9.8(5) should be solely linked to the compliance of the pertinent provisions of the TRIPS Agreement, just as the TPA. Consequently, the issuance of a compulsory licence which does not comply with Article 8.1 (necessity test) and Article 31 of the TRIPS Agreement will also constitute a breach to the Investment Chapter of the TPP. However, it must be indicated that the ratification of this international instrument is still pending, and so the future of this agreement will depend on the final decisions that will adopt the signing countries, specially after the withdrawal of the United States of America on 23 January 2017.

²⁰⁸ The TPP is a multilateral trade agreement which was negotiated by Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States of America and Vietnam. The final text was signed on 4 February 2016, after seven years of negotiation, however it has to be ratified by all the countries to enter into force. Currently there is uncertainty as to the future of the TPP after the withdrawal of the United States on 23 January 2017.

CHAPTER V. Conclusions and Recommendations

The public interest established by Decision 486 as a reason for the issuance of a compulsory licence should motivate the protection of collective rights with fundamental content. Moreover, the national authorities which use this regime shall explain the specific objectives that are pursued on a case by case basis. However, taking into due account that the normal conditions of economic coexistence among Member States of the WTO involve the protection and effective enforcement of patent rights, these should only be curtailed as a reaction to a current or potential impairment on the rights of society, such as the right to health, which includes the right to access to medicines.

The content of the public interest reason which triggers the use of compulsory licensing according to Article 65 of Decision 486 must be construed under the light of the two other reasons provided by this rule, namely emergency and national security. A correct interpretation of the public interest reason will be done disregarding the meaning of the emergency and national security reasons, considering that each one of these three reasons respond to unique circumstances which give them full independence.

Thus, in cases addressed to protect health, the issuance of a compulsory licence based on the reason of public interest should respond to a situation that undermines the collective right to the availability, access and quality of products and services to health; albeit not addressing urgent and unpredictable concerns such as public health crises, which are inherent to emergency circumstances, nor the danger or threatening of the national sovereignty, which is an inherent aspect to national security circumstances. This interpretation allows to establish that the reasons of public interest which allow to adoption of compulsory licences in the Andean Community have a repairing character not associated with alarm situations.

It has to be taken into account that in the particular case of Peru, the public interest reason for compulsory licensing is associated solely to non-

commercial uses, according to the industrial property domestic legislation, which was amended after the signing and ratification of the TPA with the United States of America. Nonetheless, the linkage between public interest and non-commercial use was not part of the obligations arising from the TPA, reason why this norm should be revoked in order to facilitate the utilization of compulsory licensing before cases where the profit is an inevitably result of the use of this regime.

As an additional aspect, it should be considered that the reason of public interest provided by the Andean Community as a ground for the use of compulsory licensing is essentially consistent with the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health, which grant entire freedom to WTO Member States to establish the reasons upon which a compulsory licence can be issued. However, in view of its exceptional nature, compulsory licensing cannot be arbitrary, rather, under the light of the objectives pursued by the TRIPS Agreement and, specifically, as from what it is provided by Article 8.1 of the Agreement, the adoption of such a measure should be inextricably connected to the necessity on its implementation.

In accordance with the standards developed by the WTO, the analysis on the referred necessity should involve the assessment on the value of the rights whose protection is sought and the subsequent search of a less-restrictive means to the patent rights. In light of these standards, it would be more likely to determine the existence of a condition of necessity where the access to medicines is threatened than in those cases where the government only pursues a mere administrative efficiency.

As a final consideration, the author of this thesis would suggest an amendment of the Peruvian domestic legislation, permitting the patentee's participation whenever a draft concerning a Supreme Decree for the declaration of public interest on his/her patent is assessed, in the exercise of his/her right to defence. For this purpose it could be taken into account the Colombian model described in this work.

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