Legislative background of the FTA between Colombia & the U.S: Intellectual property on the pharmaceutical market

By Elia B. Sampayo Meza **

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"With bilateral trade agreements (or FTAs), Latin America will export many more flowers, taking the risk of running out of a single flower to place on the graves of those who die because the lack of essential medicines"
German Velasquez[2]

Abstract

The Free Trade Agreement (FTA) between the U.S. and Colombia has been the subject of constant debate with respect to intellectual property. That is why through this article we will try to study the topic. In the first part of the text we will evaluate the historical development of the intellectual property up to the present or modern concept we have of it. After this, we will consider the most important elements in the negotiation of intellectual property given by the bilateral dialogue between the U.S. and Colombia. To achieve this goal, there will be a critique of how United States has imposed its own policy of intellectual property all around the world, therefore to shield their patents' power in the

1 **Researcher and Member of Seed Research in Private Law, attached to the line Heritage Research Affairs, Faculty of Law at the Pontificia Universidad Javeriana in Bogotá DC Contact: sampayoe@javeriana.edu.co / eliasampayo5@hotmail.com

2 German Velasquez, Bilateral trade agreements and access to essential drugs. In: Bermudez, J.A.Z., Oliveira, M.A.(Eds.). Intellectual property in the context of the WTO ADPIC agreement: Challenges for public health, WHO/PAHO Collaborating Center for Pharmaceutical Policies, National School of Public Health, Rio de Janeiro, September, 2004. pp. 63-69.

pharmaceutical drug industry that "coincidentally" is originated in the US country. This way, United States of America will have the ability to control the millionaire medicine market.

Keywords

Free Trade Agreement, FTAs, International law, United States, Colombia, Intellectual Property, Medicine, Trading, Pharmaceutical Industries.

Resumen

Es indudable que el Tratado de Libre Comercio (TLC) entre Estados Unidos y Colombia ha sido tema de debate constante y turbulento con respecto a la propiedad intelectual. Es por ello que por medio de este artículo se pretenderá estudiar a fondo la temática. En la primera parte del texto se evaluará el desarrollo histórico del derecho de propiedad intelectual hasta llegar al concepto actual o moderno que se tiene de ella. Posteriormente se analizará los elementos más importantes en la negociación de propiedad intelectual dado por el dialogo bilateral entre Estados Unidos y Colombia. Para lograr este objetivo, se hará una critica de cómo E.E.U.U ha tratado de imponer su política propia de propiedad intelectual para así blindar las patentes con más poderío en la industria de medicamentos farmacéuticos que "coincidencialmente" son originadas en su país; y de ésta manera tener la capacidad de controlar el millonario mercado de las medicinas.

Palabras Clave

Tratado Libre Comercio, TLC, Derecho Internacional, Estados Unidos, Colombia, Propiedad Intelectual, Medicamentos, Negociación, Industria Farmacéutica.

Introduction

Great scholars of the studies of science and other acquaintance areas have devoted much of their lives making deep investigations on topics of their interest. It is precisely because of them, that humanity has reached a high degree of knowledge and has been able to enjoy it. For this global society, creators have used different tools, in order to open the possibility of playing their innovations and represent the contents of their intellectual creations.

Nowadays, there are national regulations protecting this development knowledge, namely, based on the modern concept known as intellectual property rights. However, when one or more States decide to sign bilateral or multilateral agreements, where appropriate, these nationals' regulations are directly affected. The Free Trade Agreement involving the governments of the United States and Colombia is a good example of it.[3]

This consensual pact treats an entire chapter to address intellectual property issues. According to the Office of the U.S. Trade Representative (USTR), Colombia and United States established what is known as a "strong protections" system, among some topics in patent protection. Obviously this concordat includes some direct references to pharmaceutical medical products.[4]

In other words we can say that through these diplomatic agreements countries like Colombia and all those others who have signed FTAs with the U.S, have included intellectual property rules with a greater degree of restriction than what was normally established in the WTO, World Trade Organization.[5]

Through this paper we will analyze the FTA promoted by the North American country, that was signed with the Colombian state a couple of years ago. Undoubtedly, these agreements are a key of access to the economic monopolization strategy, global intellectual property of medical products by the United States.

It should be noted that those benefits mentioned above would be favorable to the interests of large medical corporations in order to maintain pharmaceutical empire. Through this progress they will eliminate from the market, the generic drugs species[6] that manages an exorbitant sum of money. The free trade agreements is a legal instrument with a supranational character, that through the imposition of barriers to access cheaper drugs threaten the health of all people, but especially those in the Third World.[7]

3 Office of the United States Trade Representative, United States and Colombia sign Trade Promotion Agreement. November 22, 2006 http://www.ustr.gov/Document_Library/Press_Releases/2006/November/United_States_Colombia_Sign_Trade_Promotion_Agreement.html

4 Office of the United States Trade Representative. 2006. Free Trade with Colombia. Brief summary of the agreement. Trade Facts. Febuary 27, 2006. http://www.ustr.gov/assets/Document_Library/Fact_Sheets/2006/asset_upload_file908_9024.pdf

5 C.M. Correa, "Implications of bilateral free trade agreements on access to medicines", in: *Bulletin of the World Health Organization*, May 2006, pp. 399-404.

6 According to the World Health Organization (WHO) a generic drug is sold under the name of the active ingredient incorporated, being equivalent to the original brand. With the same composition and dosage form. This means that a generic drug is made with the same active ingredients and has the same strength than the equivalent brand, because both of them contain the identical active ingredients. However, a generic medication compared to a brand name medicine has a costless considering that in the first one, does not incur in high manufacturing costs. (Research, promotion and development).

7 Bernardo Useche, "Colombia FTA United States. Intellectual property, patents and access to generic drugs", en: *Demarcation*, N. 41, May 2007.

The center of this research paper is to analyze how the United States has used this type of treatments' to impose their own regulations; this way they are shielding social and economic interest in foreign territories. This specific point will be analyzed in chapter sixteen of the official text of the FTA. I will treat intellectual property through a critical study, explaining the implications of this clauses, signed by the US and Colombian government, and may have a direct repercussion in Colombian population.[8]

Historical evolutionary aspects of intellectual property

1. The beginning

The Statute of Anne was the first legislation that enacted ideals of copyright around the world. United States of course, was not the exception, so they tried to attach this new English system to situations that developed in the North American country.[9]

The portrayal of the Statute of Anne, attempted to regulate the right of publication. It was a provision, close to an administrative act by which they were giving the creators or authors and their inventions immediate protection (previously referred only to the benefits of the editors).[10]

Through these official documents were introduced innumerable precepts for the protection and enforcement of civil rights. Among the most important ideas of this manuscript is the one that allowed the author use and reproduction of their works. Also, it gives the author the ability to freely choose the publisher to make the latter work. This occurred because under that regime publishing houses were punished when they printed authors' works without their permission. This new legislation will give the freedom to creators of reproduction and distribution of their work. In this order of ideas the regulations recognize him as the titular of his work, giving him for the first time what is now known as copyright, which affirm the importance of the fact that it was unprecedented to obtain protection under the Current provision known as Copyright.[11]

These regulations were the founded around the years of 1783 and 1789. Many states in the huge North American nation enact their internal legislation aiming to attribute great importance to the research and knowledge produced by men.

In 1787, for example, during the constitutional convention of the same year, James Madinson representing Virginias State and Charles Coreswoth coming from South Carolina, proposed to the U.S. Congress an empower arising under grant copyright for an unlimited period. This will

8 P. Drahos, Lokuge, B., Faunce, T., Godddard, M., Henry, D, "Pharmaceuticals, Intellectual Property and Free Trade: The case of the US-Australia Free Trade Agreement", in: Prometheus, Vol. 22, No 3, September 2004. pp. 243-257.

9 Horacio Potel, Argentinas Copyleft: the crisis of copyright and practices to democratize culture. Edit. Vía Libre Foundation. Buenos Aires, January 1, 2010.

10 Ibid.

11 Santiago Márquez Robledo, Principios Generales del Derecho de Autor, Pontificia Universidad Javeriana, Bogotá, 2004.

means the ability of the author to exercise their right without any external restrictions. Using and reproducing for a specific time.

These proposals, that were originated from the honorable representatives is known as the "Copyright Clause" stipulated in the Constitution of the United States. This constitutional appendix allows the granting of copyright and / or patents for an unlimited time, aiming to be a useful element in North American society. "It empowers the U.S. Congress to promote the progress of science and useful Arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries".[12]

In 1790, just three years after U.S. Constitution, a normative was created to regulate in detail the issue, named "The Copyright Act". It is considered the first American law who specifically defines themes of intellectual property. The law went back one more time to the influence of the Statute of Anne, since it takes from it some elements and copies them identically. Therefore among some prerogatives of the 1790 regulation, it was included a period of "fourteen years since the time of recording the title". Also a new possibility to extend this term for another fourteen additional years if he was still alive by the end of the first fourteen years.

It should be noted however, that this legislation Copyright is not only related to literary books or volumes because it also accepts maps, charts and other scientific works considered handiworks. This perspective of the Copyright Act 1790, however, walked away a bit of the Queen Anne set, because the last one only includes books. That was an amazing concept within the new North American regulation.[13]

Given it was a context that printed ideas of developing, with an intimate relation with intellectual property, this gives the countries the need of creating some international conventions that protects Intellectual property. In this way, countries that accept such agreements would be enforced to respect fulfill and be sanctioned in the case of non-compliance of the international pacts.

At this historical moment in Europe was created the intellectual property agreement of Paris (1883)[14] and among others, the Berne Convention of copyright. (1886).[15] Nowadays, almost all countries of the world are part of these two major international conventions. To do this, they had integrated national laws of each state with international treaties.

12 U.S. Constitution. Article 1, Section 8, Clause 8.

13 Santiago Márquez . Op. cit.

14 The Paris Convention of 1883 addresses issues as applicability of industrial property. This includes detailed regulations, trademarks, industrial designs, trade names among others. And in turn establishes the topics of practical use, its geographical denominations and repression of unfair competition. These provisions however are framed into three broad categories namely they are: First, national treaties, second right of priority and finally common rules. In this treatise are linked both the U.S. and Colombia.

15 On September 9, 1886 in Bern (Switzerland) was signed by the Berne Convention for the Protection of Literary and Artistic Works, usually known as the Berne Convention. This is an international treaty that regulates the protection of copyright in literary and artistic works. As the Paris agreement, this agreement in turn, is based on three major principles in order to protect such copyright integrated in lowest and highest form of expression.

It should be noted, that these settlements are administered by what is known as the World Intellectual Property Organization (WIPO).[16] Actually its United Nations official institution that has as the primary functions of ensuring all countries committed, to comply fully with all agreed clauses.

2. The Modern Concept.

From a modern perspective, intellectual property law is analyzed in its two components that form, "property" and "intellectual". If we refer to the Dictionary of the Royal Spanish Academy it is found that the word property is defined as follows: "Property: The right or power to hold and dispose of a thing to the exclusion of foreign arbitration and claim back her if in power of another. "[17] From the above property can be understood as a power that a person has, which through its ownership allows you the power to enjoy, enjoy and dispose of the thing in which lies their own right.[18]

The second item within the term is "intellectual", this concept affects the well in which rests the right, it is understood only as those who have material or intangible characteristics.[19]

Now, a property right is considered as a real right because from it you create a direct and immediate link between the holder and intangible thing, where the owner does not require a third party intermediary to exercise their right.

Simultaneously this relationship creates a duty of respect to follow any subject in society, because although not within the parties (Holder right thing), if the taxpayer tries to disrupt indeterminate nature of this right may be sanctioned.

The fact that intellectual property rests on intangible or immaterial not mean you have lower rank than the ordinary property, unless the contrary by express mandate of the law have been established in the same degree of importance.[20]

16 In 1970, following the entry into force of the WIPO Convention in 1967, was established the World Intellectual Property Organization (WIPO) with the mandate emanating from its Member States to promote intellectual property throughout the world promoting cooperation between different states and in collaboration with other international organizations. In 1974 he became a specialized agency of the United Nations system. It aims to develop a system of intellectual property (IP) and simple balanced encourages creativity, stimulates innovation and contributes to economic development while ensuring the public interest. As part of the United Nations, WIPO provides a forum in which its Member States develop and harmonize standards and practices to protect intellectual property rights. WIPO also administers systems international registration of marks, industrial designs and appellations of origin, and an international patent filings. In most industrialized countries the systems of intellectual property protection available are centuries old. However, other countries, which include developing countries, are establishing their own systems and rules on patent, trademark and copyright. With the acceleration of globalization of trade and the rapid evolution of technological innovation, it is essential the role of WIPO in the consolidation of these new systems, taking charge of negotiating treaties to strengthen the registration systems and the enforcement of IP, and to provide assistance and legal and technical training through various activities. Viewed online, April 4, 2013. http://www.wipo.int/about-wipo/es/faq.html

17 Royal Academy of Spanish Language, Dictionary of the Spanish Language, Madrid, Editorial Espasa-Calpe SA, 1970.

18 Luis Guillermo Velasquez Jaramillo, Bienes, Twelfth Edition, Bogotá, Temis, 2010.

19 Ibid.

20 Santiago Márquez Robledo, *Principios Generales del Derecho de Autor*, Bogotá, Pontificia Universidad Javeriana, 2004.

However, intellectual property is considered limited in certain cases, for example, in some cases in which interest should prevail over private interests. (Case also happens the same assumption for ordinary property). To do this, you have to have joined certain limits and exceptions to who is holding the property owner.

The best-known case is the citation, which showed higher so this limitation is copyrighted. If you understood that this was immaterial absolute right, the author could prevent the company from using fragments of his work and make him punish that person to make use of their knowledge.[21] But under the right to quote any person can transmit small portions of what the author has created, although this requires an appointment where expressly granted to the creator of his own. These limitations make intellectual property more like ordinary property, because who knows; the last also has some limitations.

Also it is important to note that the concept of intellectual property is a genre that has articulated its legal system of protection on many occasions, since it is continuously changing. This definition and inherent regime that follows it evolves rapidly and constantly, which many times is response developing national legislation or otherwise for the ratification of treaties or international agreements so modified.

The Colombian Civil Code in its article 671 establishes it, as "The productions of talent or wit are property of their authors this kind of property is governed by special laws".[22]

Under Colombian legislation, intellectual property law is treated with two great principles. The first one that touches the themes of temporality, which is responsible for the duration of the warranty and the immediate protection of intellectual property, which in turn can appeal it, can be renewed. The second element is based on territoriality considering that intellectual property is protected in the country where protection is recognized. This territory may coincide with a country or not.[23]

But intellectual property is considered as a genre because of that system of protection embodied in the Constitution and the law underlying two major fields: industrial property and copyright.[24]

21 Ibid.

22 Colombian Civil Code. Title II, Article 671.

23 Juan Pablo Canaval Palacios, *Manual de propiedad intelectual,* Bogotá, Editorial Universidad del Rosario, 2008.

24 The law number 23 of 1982 talks about copyright. In its Article 3 is expressed as "The copyright holders comprise to exclusive powers: ... to profit thereby for profit or without, by means of printing, engraving, copying, mold, sound recording, photography, motion picture , videograma, and the execution, recitation, representation, translation, adaptation, display, transmission, or other means of reproduction, multiplication or dissemination known or hereafter "Likewise in article 12 again refers to it as" the author of a protected work has the exclusive right to do or authorize any of the following acts: A. reproduce the work. B. Making a translation, adaptation, arrangement or other transformation of the work and C. Communication of the work to the public by proxy implementation, radio broadcasting or any other means.

Intellectual property is divided more broadly protecting innovations and is divided into two: patents and utility models. The latter also comprises industrial designs and logos, which in turn are divided into several types of distinctive signs as trademarks, slogans, etc. Copyright includes related rights are certain rights related to exercise without proper copyright as interpretation.[25]

In summary, the first legislation in the world that include elements of intellectual property and copyright was the Statute of Queen Anne United States, Anglo docked this regime in order to protect authors and their creations. It also granted a right to exploit the works and choose the publishers who want to do the work of reproduction of their works. Later, under social needs driven by the ideals of globalization the world's countries saw the need to implement international agreements to regulate intellectual property between states, and it was when they were born the Paris Convention and the Berne Convention. Currently, the concept of intellectual property rights in rem is divided into two elements. The first refers to the property that is the power to use, enjoy and dispose of a thing, and the second, that of intellectual refers to intangible or immaterial elements of the essence of this right. Furthermore, it is understood that modern intellectual property is composed of industrial property and copyright, and that in turn the first term is sub divided by a patent side and on the other by a utility model.

Relationship between intellectual property and TLC.

In the process of establishing the Free Trade Agreement between the U.S. and Colombia, intellectual property of course had a starring role. Undoubtedly, this would be one of the most debated issues in establishing the treaty. The counterpoint was born under the different factors, both economic and social, that arose when NAFTA was signed, which for obvious reasons would have repercussions on the exercise of the Colombian legal system.

In the Free Trade Agreement signed in the framework of negotiations between the U.S. and Colombia refers to copyright, industrial property and our main theme of the article which is that which refers to medicines and access to the thereof.

The inclusion of regulations on intellectual property in the FTA tabled some thoughts:

1. Undoubtedly regarding patent issues, the trend presenting a unique competition is part of the game where political, economic and social.
2. It was a very long discussion because the United States is to extend the protection of their inventions, however to achieve this end it's using a strategy harmful to Latin American countries such as Colombia.
3. This strategy is based on making countries agree through international treaties like

25 Juan Pablo Canaval Palacios. *Op. cit.*

NAFTA, some regulations that benefit large North American pharmaceutical companies. A reason for this, the profits of patents, which are held by the companies, will not be affected by the production of generic drugs in foreign territories, since these products are very limited equivalent production and marketing issues for these regulations.

Regarding the economic assumptions that are developed perfectly according to such policies employed by U.S. regulations, we find that the monopoly that revolves around the purchase and sales of pharmaceutical drugs. This model is cataloged within the micro and macro economic theory as an "Imperfect Competition Market". In this type of market, there is a huge power supply; however there is an opposite trend with respect to demand. "The protection of intellectual property helps to deepen this market imperfections, by subtracting what the competition is protected, allowing the innovative raise prices to recoup its investment" [26] Following this line of thought, the very high market prices have not doubt a direct influence on the impact of the population, because they become unaffordable drugs for people who have an average income.

Unfortunately, this has been a problem that has reached the gates of Colombian households. Well, there is a tendency proportional socially, which considering the price of the drug is high; the access of the population of the same is equally inaccessible. [27] [28] (Especially when internal factors influence this system gave very poor coverage in health systems).[29]

Manuel Ramirez, after making a critical and analytical study of the subject, according to the above in his "Health spending Colombian household" I quote the following: "The disease tends to behave inversely to income. This focuses on the poor".[30]

This is based on the resulting monopoly with the Free Trade agreement, implies that pharmaceutical drugs range, that of a generic or equivalent acquire absolute restriction. After signing the treaty, the Colombian state has been committed not to produce, market and establish relationships with such products for a period of 20 years. This tool within the bilateral agreement between the U.S. and Colombia, therefore will allow companies and companies that have millions in patent ownership, market fix super-inflated prices and thus acquire a utility with very low prices and huge profits.[31]
Large pharmaceutical companies that "coincidentally" found in the United States clearly have

26 Model prospective impact of intellectual property protection on access to medicines in Colombia. Prepared by: PAN AMERICAN HEALTH ORGANIZATION Regional Office of the World Health Organization, IFARMA, Foundation research institute for medicine in health systems. Bogotá, November 2004.

27 The Economist. Pharmaceuticals heartburn, The Economist, August 19th, 2006.

28 ME. Cortes, Zerda, D., Sarmiento, A., De la Hoz, GA. 2004. Model prospective impact of intellectual property protection on access to medicines in Colombia. Pan American Health Organization. Foundation Institute for Drug Research in Health Systems. Bogota: November, 2004.

29 Pan American Health Organization-PAHO-2005. Applying the model of impact of changes in IPR Colombia, Costa Rica and Guatemala. http://www.misionsalud.org/documentos.htm.

30 Manuel Ramírez, *El gasto en salud de los hogares Colombianos*, Bogotá, Universidad del Rosario, 2002; Citado en: Ministerio de Salud de Colombia, Política Farmacéutica Nacional, 2003.

31 Ibid.

arguments in their favor. Large industries in this market claim that patent protection that the North American State is offering them through these bilateral agreements, is the only way to raise capital, so you can engage in the necessary research to develop new products. (Research and Development, R & D).

"[...] In the case of consumers of pharmaceutical products in developing countries and the Andean Community, the granting of exclusive rights, for periods of time, may conflict with fundamental human rights and health life, since the consumption of drugs is related to its price, and the monopoly price can make it impossible to access the drug, which can lead to disease and death to their potential consumers. For test data, protection for a period of time has the effect of unduly extend the patent monopoly, thus prolonging seen the deferral of free competition in the market, the difficulty of access to medicine".[32]

Studies show that the most effective way to lower drug prices to facilitate access to them is to encourage generic production. When a patent runs out and generics go on sale, the product price falls between 22% and 80%, depending on the number of producers. [33] That explains why in Colombia generics cost only a quarter of the worth of branded drugs. Hence, the efforts of the authorities should be oriented towards more generic production of good quality. TLC, however, pressures in the opposite direction.[34]

Other studies show that the introduction of these measures on intellectual property would generate a total price increase of about 30% in 2010 and 40% by 2020. To maintain the same level of consumption would have to increase spending by $ 500 million annually in 2010 and U.S. $1 billion annually by 2020. If there are no resources - and it seems that it will given that the government has offered a subsidy as in agriculture-, drug consumption could decrease by 40% by 2020, which would result in a loss access to medicines for more than five million Colombians.[35]

However aspirations had major drug companies have grown hand in hand with a sense of ambition.[36] Pharmaceutical corporations have not only tried to go beyond the prohibition of the production and reproduction of generic products, but they also have opted for a strategy of protection falls on drug patents. (Although even have expired and that in countries like Colombia and should be able to freely exploit).[37]

32 Tribunal de Justicia de la Comunidad Andina, sentencia de diciembre 8 de 2005. Proceso 114-AI-2004. Énfasis fuera del texto.

33 Misión Salud TLC *y Salud: La Verdad- Las concesiones hechas a las multinacionales farmacéuticas, su impacto sobre el índice de precios y el acceso a los medicamentos, y qué podría hacer el Congreso Nacional para mitigarlos.* (2007). Pp. 14.

34 Cesar Rodriguez Gabarito y Diana Rodriguez Franco, *"Es el TLC consticional?",* en: Boletín de Observatorio de los Derechos Sociales y Políticas Publicas, Editorial no.1, 2007.

35 IFARMA-misión Salud, *Op. cit.*

36 J.E Robledo, TLC, medicamentos y "expropiación indirecta", on-line at http://www.bilaterals.org/article.php3?id_article=5955. 2007

37 Ibid.

North American strategy for negotiation in pharmaceuticals areas with Colombia

Before 1993, generic equivalents had a market share being 10% and 15%. However, after it went into effect as discussed reform of the health of that same year, market activity increased about 15% to 37%. [38]Despite this, the branded drugs were those directly affected, since through the law of generic production and sales declined 70% to only 41% in a period of 15 years since the law went into effect.[39] In 2004, the difference was even greater: 33% of the market for patented drugs and 67% for generics. Also, in the same year, the average price of generic drugs was just 25% of patent equivalents.[40]

This situation reflects the real background of interest in American country had the place to Colombia on a priority list report watching "301 Special", embodied in a summary was made through five U.S. congressmen. They concluded that under intellectual property rights as follows:

"Due to the support of the farming community of Intellectual Property Rights (IPR in English) in the U.S. is essential to pass the FTA. The delegation believes that the FTA should have a strong chapter of IPR (Intellectual Property Rights) with the rules that go beyond TRIPS (Trade-related aspects of intellectual property rights in English), and the Andean countries and supporters.".[41]

Also through the document that emanated directly from congressional Republicans announced "Colombia is the only Andean country that grants five years of data protection for pharmaceutical products from the date of the date of marketing approval".[42]

Almost immediately to the Colombian government learned of this news, very obediently accepted and adopted the terms related to North American legislation because of the test data exclusivity, which was stipulated in Decree 2085 of 2002.[43]

Likewise, namely for all people, under the force of Decree 2085 the percentage of applications for marketing approval for data protection drugs increased from 9% in 2002 to 63% in 2004.[44] Likewise, the cost of the adoption of data protection guaranteed by the same decree has

38 G. Holguín-Zamorano, *La bolsa y la vida. Impacto de la agenda norteamericana para el TLC sobre el acceso a medicamentos y la salud pública*. Bogotá, Misión Salud, 2004.

39 *Ibid.*

40 *Ibid.*

41 Informe de congresistas de EEUU sobre TLC Andino. Septiembre 2005. On-line at: www.bilaterals.org/IMG/doc/Resumen_del_Informe_de_congresistas_de_EEUU_Sept_05.doc+informe+"Especial+del+301

42 Homedes N., Ugalde A. *Multisource Drug Policies in Latin America: survey of 10 countries.* WHO Bulletin, 2005: 83:64-70.

43 Ibid.

44 ME. Cortes, Zerda, D., Sarmiento, A., De la Hoz, GA. 2004. Modelo prospectivo *del impacto de la protección a la propiedad intelectual sobre el acceso a medicamentos en Colombia*, Organización Panamericana de la Salud. Fundación Instituto para la Investigación del Medicamento en los Sistemas de Salud, Bogotá: Noviembre, 2004.

been estimated at about two hundred million dollars a year in 2010,[45] which means that four hundred thousand Colombian citizens did not have access to medicines. All studies that have estimated the impact of NAFTA[46] on health show that the treaty would aggravate the already worrying problem of access to medicines Colombian population.[47]

Other studies and critical systems as the Pan American Health Organization (PAHO), the end of 2005, show similar results. Under the assumption that Colombia signed a treaty as CAFTA, PAHO concluded that a higher level of intellectual property protection would cause prices to rise to 41% in 2010. This would imply an increase in drug spending $ 940 million to maintain the same level of consumption. In case you cannot make such spending seven million people could lose access to medicines.[48]

In addition, studies show that there will be a decrease in the number of people with access to medicines, and therefore a serious violation of the right to health.[49]

The explanation is as follows: intellectual property rules of NAFTA entail an increase in drug prices, which in turn implies higher spending and hence less ability of the State to ensure access to medicines and citizens to acquire on their own.[50]

When the U.S. entered into early negotiations regarding the Free Trade Agreement with Latin American countries such as Ecuador, Peru and Colombia, was a dominant trend visible from the North American country. This position is characterized by intransigence in this country, and in the opposite way and anti submissive position held the position of countries like Colombia. It was evident then a monopoly abuse in the United States on drug derived from FTA.

Colombian society, with the help of the media, based on those rounds of negotiations, were able to reflect almost immediately. The former consisted mainly that the real intention of the U.S. government, given through the first statements regarding the Free Trade Agreement, stated that he had no interest in accepting laws different from those by which it absolutely shield of monopoly of patents that were big business.

45 Ibid.

46 ME. Cortes, Zerda, D., Sarmiento, A., De la Hoz, GA. Op.Cit

47 OPISFARMA, Determinación del impacto de fortalecer las medidas de propiedad intelectual como consecuencia de las negociaciones de un Tratado de Libre Comercio con Estados Unidos. OPS y Fundación IFARMA Bogotá; OPS-IFARMA (2005). Determinación del impacto de fortalecer las medidas de propiedad intelectual como consecuencia de las negociaciones de un Tratado de Libre Comercio con Estados Unidos", OPS y Fundación IFARMA, Bogotá.; IFARMA-misión Salud (2006) La propiedad Intelectual en el TLC: impactos sobre el gasto farmacéutico y el acceso a medicamentos en Colombia, Publicaciones misión Salud, Bogotá; e IFARMA-misión Salud (2007) Impacto del TLC sobre la esperanza de vida de los pacientes viviendo con VIH-Sida en Colombia Publicaciones misión Salud, Bogotá, 2004.

48 ME. Cortes, Zerda, D., Sarmiento, A., De la Hoz, GA. *Op.cit.*

49 OPS-IFARMA Op. Cit (2005)

50 Cesar Rodriguez Gabarito y Diana Rodriguez Franco, *Op. cit.*

Namely during this process USA vetoed the participation of Carlos Correa, one of the negotiators of Colombia, who is a respected expert in public health and a well-known critic of the TRIPS measures. (Aspects of Intellectual Property Rights on Trade).[51] Similarly, another Colombian negotiator, Luis Guillermo Restrepo, resigned after Colombia agreed provisions of intellectual property rights that were initially deemed unacceptable.[52]

The final text of the agreement with Colombia reflects each of the conditions imposed by the United States, including for this greater restriction on the marketing of generics. (Even higher than those negotiated in CAFTA, Central America Free Trade Agreement-). Also in the official agreement are absent all commercial proposals, which initially led the Colombian country.[53]

Analysis to the negotiation in the TLC: benefits for the U.U.S.S pharmaceutical companies.

Then there will be a detailed and critical analysis on chapter sixteen, intellectual[54] property refers explicitly to pharmaceutical medical products based on the final text of the Free Trade Agreement between Colombia and the United States. This study will be addressed through an exhibition of items I consider most relevant and most closely matched to what was discussed at the epicenter of this publication. It should be noted that the official document is a publicly broadcast in the government website of the Ministry of Industry and Tourism.[55]

Article 16.9.1:
Article 16.9.1 states: "Each party will obtain patents for any invention, product or process, in all fields of technology, provided it is new, involves an inventive step and is industrially applicable." The 9/16/11 article expresses itself as follows: "Each Party shall provide that a claimed invention is industrially applicable if you have a specific utility, substantial and credible" If you read both articles with harmony and agreement, it is understood that starting from them, patents can be pharmaceutical drug products that have been patented before, only when through them to allow a new use.

However, it is important to note that the above thesis, based on Article 16.9.1 of the FTA, adds an element you must be very careful. This is that innovation must include a need to have an "inventive step". This term conveys again a limitation of generic drugs; it is evident

51 Homedes, N., Ugalde, A. Las reformas de salud neoliberales en América Latina: una visión crítica a través de dos estudios de caso. Rev Panam Salud Publica/Pan Am J Public Health. 2005.

52 Restrepo, L.G. 2006. La protección de los datos de prueba: un caso típico de la "negociación" con Estados Unidos. Deslinde No 39.

53 Bernardo Useche, Op. cit., p. 59.

54 The Trade Promotion Agreement between the United States and Colombia also called TLC. Approved on October 10, 2011 by the Congress of the United States and in force since May 15, 2012.

55 Ministry of Commerce, Industry and Tourism. Trade Promotion Agreement between the Republic of Colombia and the United States of America. TLC. On-line at: http://www.tlc.gov.co/publicaciones.php?id=727

that an equivalent product does not allow an "inventive step" in building issues. "A generic drug is one sold under the name of the active ingredient incorporated, being equivalent to the original brand, with the same composition and dosage form. This means that a generic drug is made with the same active ingredients and has the same strength and dosage form as the equivalent brand, because both contain the identical active ingredients. However, a generic medication compared to a brand name drug costs less considering that in the first, does not incur high manufacturing costs. (Research, promotion and development) "Quoted from the World Health Organization (WHO).

Article 16.9.2

On the other hand in Article 16.9.2 thereof, to find a topic that gets a lot of attention. This explicitly refers to "A party that does not provide patent protection for plants wing entry into force of this agreement, to undertake all reasonable efforts to make such patent protection" Through the concept mentioned above, confirms that Colombia accepts a patent protection for plants, trying to print ideals of pharmaceutical companies patenting on plants that are considered to have medicinal attributes or effects. The innovative concept had not been used before, reason for which this element may boost scientific development on plants, which can become under typography and Colombian geography, at a point in its favor.

Article 16.9.3

16.9.3 Using the text of the Free Trade if evidence yet few direct implications for the world of pharmaceutical drug markets. The former is the "Bolar forecast", also established in article number thirty agreements on Trade Related Intellectual Property Rights Trade-Related, commonly known as TRIPS. A reason for this is as follows: "Each Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice unjustified the legitimate interests of the patent owner, taking into account the legitimate interests of third parties".[56]

Articles 16.9.5 and 16.10.3.

Within these restricted parameters, a company that produces generic can prepare its generic version of a patented drug and obtain the information required for marketing approval before the end of the patent, but the generic can enter the market only after the patent has expired. However, block artículos16.9.5 and 16.10.3 previous forecast, making the "Bolar forecast"[57] is completely useless and prevent the establishment of compulsory licensing or parallel imports.

56 Bernardo Useche, Op. cit., p. 60.

57 Ibid.

It should be noted, that pointing to all the research that has been done throughout this article, the restrictions granted by Article 16.9.5, the chapter concerning intellectual property rights in the Trade Promotion Agreement between the Republic of Colombia and the United States of America, commonly called as Free Trade, "Coincidentally" completely agree and identical with the internal laws of patents established within the North American nation.[58]

Literal Article 16.9.6 (a) and (b).
It also found that in the same official text of the Free Trade under Article 16.9.6 literal, and in turn, the literal 16.9.6 b, we find that the patents in respect of pharmaceutical products extend indirectly twenty years by the mechanism to compensate the patent holder for the time it takes the process of marketing approval in Colombia. Saying implicitly as the official text is not exact precision of the term of the patent and is supposed to apply the term of twenty years on the contrary if it is specified in the agreement Aspects of Intellectual Property Rights Property Rights (TRIPS).

This view is reflected in subparagraphs a) and b) as: Literal to "Each Party shall provide the means and shall, on request of the patentee, compensate for unreasonable delays in the issuance of the patent, restoring the term of the patent or rights of patent. Any restoration shall confer all the exclusive rights of a patent subject to the limitations and exceptions applicable to the original patent. For the purposes of this subparagraph, an unreasonable delay shall at least include a delay in the issuance of the patent more than five years from the date of filing of the application in the territory of the party, or three years from the date who made the request of the examination of the patent, whichever is later provided that the period attribute to patent applicants Actions not included in the determination of such delays "and the literal b in the same article" With respect to any pharmaceutical product that is covered by a patent, each party shall make available a restoration of the term of the patent or patent rights, to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process , related to the first marketing of the produce that part. Any restoration shall confer all the exclusive rights of a party subject to the same limitations and exceptions applicable to the original patent."[59]

Article 16.10.1 subparagraph (A), (B) and (C)
For its part, Article 16.10.1 (a) states that "If a party requires or permits, as a condition of marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of information on safety or efficacy product, the shall not, without the consent of the person who previously presented such safety or efficacy information to obtain marketing approval from the ... For a period of at least five years for pharmaceutical products".[60]

58 Ibid.
59 Ibi*d.*
60 Ibid.

Under this article shows a standard that exceeds legislation TRIPS agreement and likewise Act 2085 which came into force in the year 2002, since both set limits to a maximum of five years, and Article 16.10.1 in its literal reference to "a period of at least five years" stipulating for it himself as minima.

Also, a criticism to be made is that which arises when accepting exclusivity for all "the safety or efficacy information" and not only for the information "not disclosed" because by including this element is denoted a restriction much more acute towards the generic or equivalent to that which was stipulated by the CAFTA. (Central America Free Trade Agreement for its acronym in English). The above shows that the treaty only accepts data exclusivity marketing patented drugs for a period of "at least five years".

Following the analysis of the clauses or articles of the treaty, we find that in accordance to the term "at least five years" 16.10.1 clearly stipulated in paragraph b, is to specify that data exclusivity is granted equally the data sent for marketing approval in "other territory". This means that it is banning the generic companies that use the data or "evidence prior to marketing approval in another territory" when applying for marketing approval in Colombia, even if the patent equivalent drug brand has already expired.[61]

This legally argued in clause 16.10.1 section b, and saying "If a party requires or permits, as a condition of marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of safety information or efficacy of the product that was previously approved in another territory, such as evidence of prior marketing approval in the other territory, the party shall not, without the consent of the person who previously presented such safety or efficacy to obtain approval marketing in another territory, authorize another to market a same or a similar product based on:

(I) The safety or efficacy information submitted in support of marketing approval in the other territory, or
(II) Evidence of the marketing approval in another territory. "

Similarly paragraph c Article 16.10.1 states the following regarding pharmaceutical drugs "new pharmaceutical product is one that does not contain a chemical entity that has been previously approved in the territory of the party to be used in a pharmaceutical.. "Under the previous clause, we try to ensure market exclusivity in Colombia to the branded drug patents expired because defining a" new product "as one that contains a chemical entity that has not been previously approved in the country. This definition of "new product" is different and does not interfere with the concept of "new use" contained in the articles mentioned above.[62]

61 Ibid.

62 Ibid., p. 61.

It should be noted, that the North American country has slowly been monopolized medical industry and in turn the pharmaceuticals market. A reason for this is that it has obtained special character prerogatives and thus achieves their goal of obtaining patents trilogy with great protection. These three categories of patents are divided in story to its very core. The first is that which develops on the axis of the product, which is called patent product. Second, we find those who are governed in their use, which namely are called utility patents. In the third category, it is related to the process patent.[63]

However, these categories of patents are not limited to, the act because of the same drug, a pharmaceutical company; you can give the three natures mentioned above. This means that a company can have a patent for each of the chemical elements that make up the product itself, in turn countless patents for using this medicine and simultaneously have multiple patents granted for different processes to reason that the product is occur in different modalities. [64]Anyway, the three categories described above were discussed in the negotiations of the free trade agreement between Colombia and the United States, where they were finally included in the text of the official agreement.

Currently Colombia, by Decree 2085/02, has a high standard of intellectual property protection, even exceeding the Andean Community of Nations (CAN). The FTA further strengthens it by introducing four obstacles to generics. The first and most controversial is the protection of test data exclusivity[65] in a more restrictive than the 2085 Act (section 16.10.1 TLC).[66] Second, the patent-registration link health that aims to delay generic entry to the market (Art. 16.10.3 TLC). Third, the extension of the patent by undo delays in the registrar's office or the patent office (Art. 16.9.6 b TLC), with the same purpose as the patent-registration link. Fourth, restricting the use of the word "generic" and the obligation to retain only brand names (section 16.2.3 TLC), making it impossible for doctors and users know what other products-cheap-have the same principle as the brand name drug.

63 Ibid.

64 Ibid.

65 The test data protection is the mechanism created to protect undisclosed information that presents a laboratory to the health authority (INVIMA in Colombia) to show that the active ingredient in a drug is effective and nontoxic, and obtain permission marketing (veterinary). With exclusivity means that the person who submitted the information on the active ingredient has an exclusive marketing rights for some time (at least five years according to TLC). The practical consequence of the exclusivity protection, unlike non-exclusive protection is devised by the WTO and the CAN host, is that the health authority cannot grant registration based generic security proof and effectively pre-sented by the innovator. So if a generic manufacturer wants to market the drug for as long as the information submitted by the innovator is protected, must submit their own proof of safety and efficacy of the active ingredient, which is very expensive for the complex procedures. See, Health IFARMA-mission (2007) pp. 3-5.

66 This link between the patent office and health office is known internationally as "linkage." Means that when a person applies for permission to market a competing drug to the health office, it is required to inform the alleged owner of the respective patent the identity of that person, to have the opportunity to act against it and the obligation to implement measures to prevent the product is marketed competitor during the term of the patent. While it is a mechanism to prevent proprietary products are marketed in practice to delay market entry of national brand name and generic name for as long as the competent authority decides that the alleged oppositions patentee did against the competitor. See, Health IFARMA-mission (2007). op. Cit. Pp 44-45.

Literal Article 16.10.3 (a) & (b)
Where a Party permits, as a condition of marketing approval of a pharmaceutical product, persons, other than that originally submitted the safety or efficacy information, to rely on evidence of safety or efficacy information for a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory that party shall:

> *a. Implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent, claiming the product its approved method of use during the term of that patent, unless it is with the feeling or acquiescence of the owner of the patent.*
> *b. To establish that the patent owner will be informed about the identity of any person seeking marketing approval to enter the market during the term of the patent identified by the approving authority as it protects the product.*

In subparagraphs (a) and (b) of this Article is evident that connectedness or intimate relationship between patent protection and marketing approval for the same. This means that for a generic drug order can be established in the market, you must wait until the patent period expires main brand, and thus seek approval for marketing, since in such case, is required before of that term, he was not favorably granted marketing.

However, critiquing to the date of this article, we find that the TRIPS agreement (Aspects of Intellectual Property Rights Trade-Related) develops in a manner contrary. Under this agreement, opens the possibility that relevant government agencies will grant marketing approval, allowing equivalent or generic drugs to enter the market of pharmaceuticals immediately, upon expiration of the period Product patent brand. It should be noted however, that the marketing approval is granted only when referring to terms of safety and efficacy. "Simultaneously, the link provides additional protection to patents irregular through the government agency responsible for approving the registration and marketing mechanism can also be used as a barrier to enforce compulsory licensing".[67]

67 Ibid.

Conclusions

Studies conducted by PAHO, Pan American Health Organization, identified a trend estimate given by 2020.[68] To do this it is concluded that in this year, about six million Colombian citizens, under the super-price orbiting nine hundred forty million dollars a year, tax multinational pharmaceutical companies will not have access to medicines. Indeed, it is understood that by 2030 there will be increased four hundred sixty million dollars a year, whose expenses reach about 1400 million for that year roughly of an inequitable access to vulnerable populations.

Undoubtedly this policy will affect the profits of the Colombian companies engaged in the production of generic drugs, since it is estimated that there will be a market decline of 41%, taking into account the use you have the product Colombian population.[69]

The above thesis is intended to imply that after studying the legislative background can have the Free Trade agreement between Colombia and the United States, in the field of pharmaceuticals, it can be concluded that the drug market will be monopolized absolutely by large companies. And in turn, the generic drug market represents only a tiny minority poor.

In this vein, the Colombian state is obliged to increase its resources for the purchase of medicines for people, undoubtedly critical situation to Colombia, because they know the high prices of the products will be a limiting apparent to the population to access to pharmaceutical drugs.[70]

But specifically on the subject of Chapter 16 of NAFTA dealing with intellectual property can make the following conclusions:

First, using the tool of "evergreening" by which larger multinational pharmaceutical drug market, may request the competent authority to grant them patents for new uses of products, even when patents are about to overcome or worse when they have expired. Mechanism to maintain a monopoly on the millionaire market.

Second, when you enable extensions or renewal of patents for a twenty year period in addition to those that had been granted previously, this incurring a clear violation of the prerogatives of the TRIPS agreement. (Aspects of Intellectual Property Rights on Trade).

Third, That by virtue of the laws agreed by the FTA, that after all is not as free or as trade, at least for the Colombian people, accepting the data exclusivity to test with large companies and likewise protection is given to the marketing of the products to them.

68 Bernardo Useche, Op. cit.

69 Ibid.

70 Ibid.

Fourth, at the time of signing the Treaty as mentioned, is allowed as compensation due to delays in the approval of the commercialization of patents, and in turn, for the delay of the whole process for granted before.

Finally we can say that the official document that Colombia and the U.S. signed the Free Trade Agreement, positioned in a very high degree of benefit to multinational drug companies, protecting interests to do the same. This takes into account that has operated under the strategy to phase out the threat posed by drugs or generic equivalents. Where therefore be absolute shielding protection through legislation such as the "Free Trade" which will allow you to open a new way for pharmaceutical companies to set prices of drugs under its discretion, marginalizing the average population to have access to essential products to maintain minimum living.

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