INTELLECTUAL PROPERTY IN THE FTA: IMPACTS ON PHARMACEUTICAL SPENDING AND ACCESS TO MEDICINES IN COLOMBIA

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MISION SALUD	**FUNDACION IFARMA**

The impacts discussed in this paper were calculated on the basis of the "Guide to estimate the impact on access to medicines of changes in intellectual property rights (IPR)", by the World Health Organization – Pan American Health Organization (WHO/PAHO).

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GLOSSARY

TRIPS-plus
Higher levels of protection for intellectual property than what was established in the WTO's TRIPS Agreement.

Doha Declaration
A declaration on the TRIPS Agreement and public health that was approved on November 14th, 2001 during the World Trade Organization's Ministerial Conference that took place in Doha with the participation of 142 member countries.

International Nonproprietary Name (INN) or generic name
Common and generic names selected by experts to identify new pharmaceutical substances. The selection process is based upon a procedure and some guiding principles that were established by the World Health Assembly. Its use is recommended worldwide as a unique and public (unregistered) identification.[2]

Compulsory License
The permission to produce a patented or otherwise protected good without authorization from the owner of the patent or of the other legal protection.

Generic medicine
A medicine that is produced and marketed by someone other than its inventor, innovator, or patent owner. Generics may be marketed under their own brand name or the generic name followed by the manufacturing lab's name.

Innovator medicine
A medicine that provides a new therapeutic use[3] (e.g., new chemical entity or new association).

Essential medicines
Those that meet the health care needs of the majority of the population and, as a consequence, must be made available at all times, in sufficient quantities, and in the appropriate dosage.[4]

Commercial name
The name for a medicine created by the laboratory that produces it.

Patents for minor modifications to existing products
When a patent right is applied for or issued to a product resulting from a small or insignificant modification to an already existing product.

Patent for uses
When a patent is applied for or granted to a new use discovered for an already existing product.

Registration of medicines (marketing approval)
A regulatory procedure to authorize the marketing of a medicine after its evaluation by the competent drug regulatory authority.[5]

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[2] Velasquez, German and Boulet, Pascale. Globalization and Access to Drugs: Perspectives on the WHO TRIPS Agreement. 2nd edition. World Health Organization, 2000.
[3] Giarcovich, Silvia. Genéricos, Similares y el problema de la intercambiabilidad. En: Revista SAFYBI. Vol. 40. No. 101 – 2001. P.3
[4] Velásquez, G. Op Cit.

Generic substitution
The practice of substituting one product, regardless of its having been marketed under a commercial or generic name, with an equivalent product, usually cheaper and containing the same active principles.[6]

Effective marketing period
Real period of economic exploitation of a patent. In the pharmaceutical field, even though the nominal patent term is twenty years, it is common to see an effective marketing period of between eight and twelve years due to the health and safety requirements for the product that delay its entry onto the market.

Abbreviations and Acronyms

TRIPS	Trade-Related Aspects of Intellectual Property Rights
FTAA	Free Trade Area of the Americas
CAN	Community of Andean Nations
INN	International Nonproprietary Name
GATT	General Agreement on Tariffs and Trade
WTO	World Trade Organization
WIPO	World Intellectual Property Organization
WHO	World Health Organization
NGOs	Non-governmental Organizations
PAHO	Pan American Health Organization
PCT	Patent Cooperation Treaty
IP	Intellectual property
ACJ	Andean Court of Justice
FTA	Free Trade Agreement
SIT	Superintendence of Industry and Trade [Colombia's patent authority office]

[5] The International Federation of Pharmaceutical Manufacturers Associations (IFPMA), IFPMA Doc 75, cited by Benett, et al, Op cit
[6] 73rd Executive Council Meeting, Geneva. January 11 – 20, 1984, (EB73/1984/REC/1), Appendix 7, P. 60. Cited by Benett, et al. Op. cit

Summary

In 1994, the member countries of the World Trade Organization (WTO) signed the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This agreement establishes the minimum requirements these countries must respect, yet it also allows them to increase the requirements through regional or bilateral agreements and other domestic measures. Recently, the United States of America has been signing trade agreements with a number of countries. The U.S. requires that these agreements contain a chapter on intellectual property. This paper addresses the issue of intellectual property from the point of view of health in Colombia in order to provide elements to interpret the final text and its possible consequences. The paper will provide detailed analyses of those issues from chapter 16 on intellectual property that can have an impact on pharmaceutical spending and access to medicines in Colombia.

The impacts discussed in this paper were calculated on the basis of the "Guide to estimate the impact on access to medicines of change in intellectual property rights (IPR)", developed by the World Health Organization – Pan American Health Organization (WHO/PAHO).[7] The guide determines the impact by means of the "scenario method." The impact is the result of the difference between a basic scenario, which describes the current situation and its possible evolution if no changes happen to IPR, and different alternative scenarios that describe possible evolutions according to different changes to IPR.

In this study, TRIPS is considered the basic scenario, and the alternative ones were constructed by taking into account the changes that Articles 16.2 (Trademarks), 16.9 (Patents), and 16.10 (Measures related to certain regulated products) of the FTA introduce to the current intellectual property legislative regime.

The overall conclusion is that the adoption of the FTA text as published will generate negative impacts on pharmaceutical spending and on access to medicines in Colombia, increasing the former and consequently erecting a barrier for the latter. Some provisions could be regulated so as to mitigate their impact, while others will generate direct impacts that would be difficult to ease through legislation. The measures and their options are discussed throughout the paper.

Each article is analyzed in three parts. The first presents some necessary contextual information for understanding each issue. The second gives a detailed analysis of what is contained in the FTA text focusing on the changes in IPR that will be required with regard to TRIPS. Lastly, the third part evaluates the impacts and presents the respective results.

Trademarks:

"A trademark is a distinctive sign which identifies certain goods or services as those produced or provided by a specific person or enterprise. It follows then that trademarks contribute to differentiating products and services from those of the competition,"[8] thereby avoiding the manufacture of copies of varying quality.

The case of medicines is special, however. There is no relationship between quality and the trademark since all medicines in Colombia must comply with the same standards of quality and have an International Nonproprietary Name (INN) or generic name in order to be able to be marketed. The marketing company decides whether to market the medicine under this

[7] Rovira, Joan, et. al. "Guide to estimate the impact on access to medicines of changes in intellectual property rights (IPR)". WHO / PAHO, 2005.
[8] www.wipo.org

common name or under the trademark name. Yet the use of the INN in the formulation and marketing of medicines has shown widespread advantages, both in economic terms like reducing costs, as well as in technical and clinical terms, such as improving information and making it more transparent to all stakeholders.

The FTA limits and puts at risk the possibility of using the INN. The impact of this measure is unclear and directly depends on the interpretation as to which uses of the common name could impair the use or effectiveness of the trademark. Generally speaking, the FTA text carries with it two risks:

- Restricting the use of the INN as a means of information for consumers
- Limiting the future adoption and implementation of other internationally recognized and effective provisions that encourage the use of the INN.

The restriction of INN use caused by the implementation of the Trademark article, with the assumptions adopted in this study, can generate an impact of 168 million dollars for the total pharmaceuticals market in 2020, equivalent to health-care expenditures for 950,000 people who are enrolled as contributors in the social security system, caused by an average price increase of 7%.

Patents

A patent is an exclusive right that is granted for an invention, that is, a product or a process that offers a new way of doing something or a new and innovative solution to a problem.

The FTA text contains two types of provisions involving patents: those related to the object of protection and those related to the period of protection.

The provisions involving the product that is protected focus on relaxing the patentability requirements: novelty, inventive step, and industrial application. This will mean that more products can be protected. Thus, there is a possibility of granting patents for minor modifications to already existing products or for different uses of medicines, the latter currently prohibited in Colombia's legislation. The first of these measures could imply an increase of 11% in medicine prices in Colombia in 2020. This would mean an impact of more than 240 million dollars for that year, equivalent to health-care expenditures for approximately 1.4 million people who are enrolled as contributors in the social security system. If expenditures are not increased, then this could imply an 11% reduction in consumption. Due to expanded marketing exclusivity, the national industry could lose up to 17% of its market share. Issuing patents for uses could generate for the same year an increase of about 8% in medicine prices, an economic impact of more than 180 million dollars, equivalent to health-care expenditures that year for more than 1 million people who are enrolled as contributors in the social security system. If expenditures are not increased, then this could mean an 8% reduction in consumption, and the national industry could lose up to 13% of its market share.

Measures related to the period of protection basically have to do with compensation for delays by the country's patent and drug regulatory authority offices. The impact of these measures depends in large part on the domestic regulations set forth and on the strengthening of the corresponding offices so they can respond to the applications in the time periods established.

The entire article on patents could cause a more than 18% increase in medicine prices for the year 2020, which could generate an impact of more than 401 million dollars. If there is no

increase in spending, then consumption of medicines would have to be reduced by as much as 18%. The needed spending increase is equivalent to expenditures for more than 2.3 million people enrolled as contributors in the social security system, and the national industry could stand to lose up to 28% of its market share. To a large degree, these results are the product of the flexibility in patentability criteria, especially the possibility of issuing patents for uses and for minor modifications to existing products.

Measures related to certain regulated products

Regulated products, as referred to in the FTA text, are agricultural chemicals and pharmaceutical products. In order to obtain marketing approval for these products in the country, the data proving safety and efficacy, commonly called "test data", must be submitted to the drug regulatory authority.

TRIPS Article 39 states: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use." In 2002, the Colombian government passed Decree 2085, which states the following: "When a new chemical entity has been approved for marketing, the undisclosed data may not be directly or indirectly used as support for the approval of another application for the same chemical entity."[9]

The FTA intellectual property chapter contains three types of measures that reinforce protection in this regard:

1. Those related to the object of protection: The types of products and information that are considered able to be protected are discussed.

2. Those related to the type of protection: Whether the protection generates exclusivity for a product's use and, if so, for how long, is discussed.

3. Other measures not included in TRIPS: Linkage between the patent and drug regulatory authority offices, limitations to the Bolar provision, and restrictions to using the compulsory licenses.

The impact of this article on the total pharmaceuticals market is estimated at approximately 710 million dollars, of which 674 million, or 95%, corresponds to "test data" protection measures. These measures involving test data would be responsible for increasing the average medicine price by up to 30%, equivalent to health-care expenditures for 3.8 million people enrolled as contributors in the social security system. If expenditures are not increased, then this would imply reduction in consumption of up to 30%. Likewise, due to expanded marketing exclusivity, the national industry could lose up to 47% of its market share.

Total impact

For the total pharmaceuticals market, adopting the FTA text with its intellectual property chapter without measures to mitigate its impacts, as described throughout this study and in the conclusions and recommendations, could mean the following by 2020:

1. Reaching a level of market monopoly of approximately 63% due to the combined effect of patent and test data protection. This would mean a huge limitation on

[9] Ministry of Health, Republic of Colombia. Decree 2085, year 2002. Article 2.

generic competition, monopoly prices for a large part of the national pharmaceuticals market, and serious limitations for the national industry, which could lose up to 57% of the value of its current market share (about 37%).

2. An approximate 40% increase in the price index for medicines.
3. By 2020, a 919 million dollar increase in spending on medicines, which is equivalent to health-care expenditures for 5.2 million people enrolled as contributors in the social security system that year. If expenditures are not increased, there could be a 40% reduction in consumption with consequences for access to medicines, particularly for low income people and families that cannot afford the higher costs.

INTRODUCTION

In 1994, the member countries of the World Trade Organization (WTO) signed the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This agreement establishes the minimum requirements these countries must respect, yet it also allows them to deepen the requirements through regional or bilateral treaties and other domestic measures. In the recent trade agreements that have been negotiated between the United States and several countries, the U.S. insisted on including a chapter on intellectual property.

In May 2004, Colombia began a negotiation process for a free trade agreement (FTA) with the United States of America. The issue of intellectual property was a key element of the discussion. At the start of the negotiations, both countries set forth their goals for each chapter of the agreement overall, and for each intellectual property issue in particular.

The initial Colombian position was to respect and maintain the current intellectual property standards that are contained in TRIPS and the Andean Community Decision 486 of 2000, which brings into agreement Andean law and the TRIPS regime (which was adopted by the countries of the CAN). The United States, for its part, expressed its intention to strengthen those standards in response to proposals from its pharmaceutical industry,[10] just as had been done in the agreements signed with Chile and with Central American countries and the Dominican Republic (DR-CAFTA).[11]

The negotiation stage between the governments ended in February 2006 when an "agreement" on the text was reached, subject to legal review.[12] In May, the Colombian government made public the chapter on intellectual property.

This paper will address the issue of intellectual property from the point of view of health in Colombia in order to provide elements to interpret the agreed-upon text and its possible consequences. Using the text made public by the Colombian government as the foundation (Appendix 1 of this document), this paper will provide a detailed analysis of those issues identified in the intellectual property chapter (16) that can generate impacts on pharmaceutical spending both by families as well as by the health-care system.

This paper is divided into five parts. The first one describes the methodology used, the markets evaluated, and the way in which the results are presented. The next three parts describe the analysis and impacts of the pertinent articles from the intellectual property chapter: Trademarks (Article 16.2), Patents (Article 16.9), and Measures related to certain regulated products (Article 16.10). The fifth part evaluates the total impact of the three articles. Lastly, there is a chapter with conclusions and recommendations.

[10] See www.PhRMA.org
[11] You can find information on these agreements at www.sice.oas.org
[12] Even though in reality the final text on agriculture had to go through five more months of renegotiation

1. Estimation of the Impact: Methodology and Markets

The impacts discussed in this paper were calculated on the basis of the "Guide to estimate the impact on access to medicines of changes in intellectual property rights (IPR),"[13] developed by the World Health Organization – Pan American Health Organization (WHO/PAHO). The complete version of the guide is provided in Appendix 2 of this paper.

The guide determines the impacts by means of the "scenario method". The impact is the result of the difference between a basic scenario, which describes the current situation and its possible evolution if there are no changes in IPR, and different alternative scenarios that describe possible evolutions according to different changes in IPR.

In this study, TRIPS is considered the basic scenario, and the alternative ones were constructed by taking into account the changes that Articles 16.2 (Trademarks), 16.9 (Patents), and 16.10 (Measures related to certain regulated products) introduce in the current IP regime.

The described method can be applied to an overall market (e.g., a country's total market, or its total institutional market, etc.) or to specific markets (a particular institution or a specific therapeutic group). This paper describes the impacts on Colombia's total pharmaceuticals market and the sub-markets that make it up: private/retail and institutional. The model with its assumptions and results is provided in Appendix 3 of this paper. Table #1 lists the values for the markets evaluated.

Table #1: Pharmaceutical market segmentation by buyer type (2000 – 2004) *

	2000	2001	2002	2003	2004
Total Market	1302	1303	1292	1135	1302
Retail sales (Private) **	784	808	828	758	891
Institutional sales	518	495	464	377	410
Institutional sector participation	39.8%	38.0%	35.9%	33.2%	31.5%
Private sector participation	60%	62%	64%	67%	68%

Source: Interdata – IMS, Calculos Econometria S.A.
* – Values in millions of constant dollars from December 2004
** – The IMS sales were deflated by 15% to place them at the price of the wholesale distributor.

In order to assess the model's sensitivity, the basic variables were modified, and different results were calculated. In this way, three cases were calculated for the basic scenario and each one of the alternative scenarios: a pessimistic, an optimistic, and an average case. The results shown in this study are those that correspond to the average of each case. The sensitivity analysis is provided in Appendix 4.

The results are presented in tables using the following data:

% of active principles protected: This shows the total percentage of the market that these protected products would hold, whether they be patented or protected by test data.[14] The

[13] Rovira, Joan, et. al. . "Guía para estimar el impacto sobre el acceso a los medicamentos de cambios en los derechos de propiedad intelectual (DPI)". WHO / PAHO, 2005
[14] This concept involves the article on "certain regulated products". Its meaning and implications are described further ahead.

total market result is the weighted average of its segments (institutional and private pharmaceuticals markets).

Price index: This shows the impact different changes to IPR would have on pharmaceutical prices in the country. A value of "1" would indicate no impact exists, and higher values would indicate directly related increases. For example, a value of "1.3" indicates a 30% increase in price. The total market result is the weighted average of its segments.

Variation in expenditure: This shows the budget change that has to be made in the entire market evaluated in order to keep acquiring the same basket of medicines at the new prices. The total market result is the sum of its segments.

Variation in consumption: This shows the change in consumption that would occur if the same budget is maintained in the market evaluated. The total market result is the weighted average of its segments.

Variation in the national industry's market share: This shows the change in percentage of the national industry's current market share based on the value of the medicines.

Overall, if prices rise, the budget must increase by a determined amount. If there is no budget increase, then the basket of medicines acquired must decrease and, as a consequence, so will consumption of medicines in the country.

The next section presents the three issues evaluated. Each chapter is subdivided into three parts. The first presents some necessary contextual information for understanding each issue. The second gives a detailed analysis of what is contained in the text of the FTA, focused on looking at the changes to IPR this text implies with regard to TRIPS. Lastly, the third part evaluates the impacts and presents the respective results.

2. Article 16.2: Trademarks

2.1 Contextual Information

"A trademark is a distinctive sign which identifies certain goods or services as those produced or provided by a specific person or enterprise. It follows then that trademarks contribute to differentiating products and services from those of the competition."[15]

The trademark owner enjoys the right to exclusivity, preventing its use by third parties and thus avoiding inferior quality copies. Furthermore, a trademark creates a differentiating mechanism through which consumers can choose the brand that most satisfies them out of several similar products.

In the case of medicines, there are special connotations:

- There is no relationship between quality and the trademark.
  - All medicines have an International Nonproprietary Name (INN), or generic name. The marketer decides whether to put the medicine on the market under this common name or under the trade name. It is common to find the same laboratory marketing the same product under two product lines, one with the common name and the other with the trade name, depending on the segment of the market it wishes to address.

[15] www.wipo.org

- To obtain marketing approval in Colombia for any medicine, it must comply with quality, safety, and efficacy requirements found in Decree 677 of 1995 and in other pertinent regulations,[16] which are the same for all products. The regulations on trademarks are defined by the Superintendence of Industry and Trade (SIT).

- From the above, it is possible to state that marketing with or without the common name is purely an economic decision and has no relation to a medicine's quality.

❖ The use of the INN is critical for providing information to consumers and has been shown to be an efficient cost containment tool:

- So that consumers (doctors, institutions, or patients) can choose from different trade names of the same product, it is necessary that a product be identified through its International Nonproprietary Name (INN). If only the trade names were used, then consumers would not have the full information to know with which other products they could compare an option; hence, they would not be able to make a free choice in the market.

- The market price is directly related to whether the drug has been marketed under the trade name or its INN. Trade names, because of the rights they confer, the investment made in them, and their placement on the market, generally establish higher prices than medicines marketed under their common name. One recent study from the Pan American Health Organization states that medicines marketed in Colombia with the INN, on average, are 48% cheaper than those marketed under the trade name.[17]

❖ The country's current regulation encourages the use of the INN.[18]

- Colombia's Law 100 of 1993, Article 156 c) establishes that "all people enrolled in the General Social Security System for Health Care will receive a Comprehensive Health Protection Plan, including preventive care, surgery, and essential medicines; it will be called the Obligatory Health Plan." Article 162 of the same law states that "for the contributing members, according to the rules of their program in the social security system, the contents of the Obligatory Health Plan, which are to be defined by the National Council of the Social Security System for Health Care, will be those set out by Decree-Law 1650 of 1977 and its regulations, including the *supply of essential medicines in their generic forms*…"

- Article 5 of Agreement 228 of 2002, which defined the Obligatory Health Plan, states that "**the use of International Nonproprietary Names (generic names)** on prescriptions for medicines will be obligatory. Medicines to be dispensed must correspond to the active principle, pharmaceutical form and concentration prescribed, regardless of their marketed form (generic or trade name), as long as the criteria of quality, safety, efficacy, and patient comfort are maintained."

❖ In conclusion, on the matter of medicines in Colombia, it is understood that the use of the trade name as a commercial right of its owner has no relationship to a medicine's quality or other technical characteristics. On the other hand, the use of the INN in the

[16] Ministry of Health, Republic of Colombia, Decree 677 of 1995. "Partially regulates the Registration and Licensing Regime, Quality Control, and the Health Monitoring Regimen for Drugs, Cosmetics, Pharmaceutical Preparations based on Natural Resources, Personal Cleanliness, Hygiene, Cleaning Supply, and other domestic use products and provides other provisions on the matter."
[17] WHO/PAHO. "Estudio prospectivo del impacto de la propiedad intelectual sobre el acceso a medicamentos en Colombia. 2005".
[18] Taken from: "El uso de la denominación común internacional y la calidad de los medicamentos: dos temas distintos" Communiqué from the National School of Pharmaceutical Chemists. June 2006.

formulation and marketing of medicines has shown widespread advantages in terms of cost reduction, as well as in technical and clinical terms, by improving information and making it more transparent to all stakeholders. In this context, the health-care system has set several regulations that encourage INN use throughout the entire pharmaceuticals chain.

2.2 Text analysis

Article 16.2 of the FTA addresses the issue of trademarks, and its sub-article 3 directly refers to the use of common names.

EXISTING REGULATION
Encourage INN use for medicines through various regulations mentioned above. **TRIPS, Article 20. Other Requirements:** The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings. This will not preclude a requirement prescribing the use of the trademark identifying the undertaking producing the goods or services along with, but without linking it to, the trademark distinguishing the specific goods or services in question of that undertaking.
FTA TEXT
Article 16.2.3: "In view of the obligations of Article 20 of the TRIPS Agreement, each Party shall ensure that its measures mandating the use of the term customary in common language as the common name for a good or service ("common name") including, inter alia, requirements concerning the size, placement, or style of use of the trademark in relation to the common name, do not impair the use or effectiveness of trademarks used in relation to such good or service." *Footnote in the FTA text:* "For greater certainty, the existence of such measures does not, per se, amount to impairment."

The FTA text specifically introduces the notion of "the common name." This was not contained in TRIPS Article 20.

Even though emphasis is placed on the "requirements concerning the size, placement, or style of use of the trademark in relation to the common name," the text makes reference to all those provisions that force the use of the common name.

There are two consequences resulting from the this FTA text:

- Use of the INN as a consumer information mechanism is restricted. In order for the INN to fulfill this function, it must have special characteristics. According to Decree 677 of 1995:[19] "On the labels and packaging of all medicines that are marketed under the trade name, the respective generic name must also appear. For essential medicines, the **size** of the generic name will be the same as that of the trade name (Article 72, Paragraph 5)." Along the same lines, it clarifies that "…the bibliography upon which the information is based will always be cited, and the active principle must always be identified by its generic name, which, in the case of essential medicines, **will use the exact same letter size as the trade name** (Article 79, Paragraph 2)."

[19] Ministry of Health. Republic of Colombia. Decree 677 of 1995.

To continue implementing these measures could be considered a factor amounting to "impairment" of the use or effectiveness of the trade name. Repealing or modifying them could mean that the generic name would appear in a less visible place and size in order to promote the use of trade name medicines. This would be to the detriment of information transparency in the pharmaceuticals market.

- Adoption and implementation in the future of other internationally recognized, effective provisions that stimulate the use of the INN would be partially or totally limited. Some examples of these measures are described by Tobar:[20]

  Regarding doctors: Prescription control, verifying the medical formularies prescribed under the International Nonproprietary Name.

  Regarding pharmacists (who dispense medicines):

  - **Control of marketing margins**: "The falling percentages, that is, those that decrease as the product price increases, provide incentives for selling lower priced products. Such a system is used by France and Germany. Some countries also use special incentives to promote dispensing determined products, particularly generic medicines. Such is the case in Holland, where there is a bonus for dispensing generics or parallel import products that are priced lower than trade name medicines in the country. The HMOs[21] in the U.S. set premiums or bonuses for dispensing generics or medicines included on a list, in addition to the bonuses given to pharmacies that dispense the most of these types of medicines."[22]

  - **Product substitution**: In the United States and some European countries, pharmacists are allowed to substitute the prescribed medicine when the active principle is identical and the dosage equivalent.[23]

  Regarding patients:

  Establish selective co-payments, stimulating the use of medicines by their common name.

  Information campaigns so the consumer can substitute the product for another when the latter has the same active principle, pharmaceutical form and concentration as the former.

  Some measures are already contained in our laws through the National Pharmaceutical Policy, NPP.[24]

  "Disseminating the concept of essential medicines and the use of the International Nonproprietary Name as a means of improving the understanding of therapeutics."[25]

  "Promoting prescriptions using the International Nonproprietary Name, complemented by strategies for education of users and prescribing doctors."

[20] Tobar, Federico, Estrategias de financiamiento del medicamento. Taken from Bermudez, Jorge, et al. "Acceso a medicamentos: Derecho fundamental, papel del Estado. Rio de Janeiro, 2004, Pg. 103-136. Tobar classifies the strategies for controlling pharmaceutical spending as those directed at the industry, at doctors, at pharmacists, and at patients.
[21] Health Maintenance Organization
[22] Ibid, p. 118
[23] Ibid.
[24] Ministry of Social Protection. Republic of Colombia, National Pharmaceutical Policy.
[25] Ibid. p, 21

The FTA, by addressing all those provisions that include the obligatory use of the INN, permits law suits to be brought against any of the above-mentioned measures, charging that they impair the use or effectiveness of the trademark. Their modification, repeal, or the impossibility of adopting them runs counter to the promotion of understanding of therapeutics and expenditure containment in the area of medicines.

2.3 Estimated impacts

The FTA limits and jeopardizes the possibility of using the INN as a mechanism for cost containment and understanding of therapeutics. The impact of this measure is uncertain and directly depends on the interpretation as to which uses of the common name could impair the use or effectiveness of the trademark.

The following are the results for scenarios that would allow its restriction:

2.3.1 Private Market

Trademarks Scenario				
Year	Price Index	Expenditure Increase (in millions of $)	Equivalents in Per Capita Payment Units (CPU) of the Contributive Program (in millions)	Reduction in consumption if no increase in expenditure
2010	1.05	47.64	0.29	-5%
2020	1.04	63.72	0.36	-4%
2030	1.04	93.42	0.50	-4%

For the year 2020, INN use restrictions would require the private market either to increase its expenditure by 63 million dollars or to reduce its consumption by approximately 4%. The necessary expenditure to cover the impact would be equivalent to the total health expenditure for approximately 360,000 people enrolled in the contributive program of the social security system[26] for that year.

2.3.2 Institutional Market

Trademarks Scenario				
Year	Price Index	Expenditure Increase (in millions of $)	Equivalents in Per Capita Payment Units (CPU) of the Contributive Program (in millions)	Reduction in consumption if no increase in expenditure
2010	1.07	36.05	0.22	-7%
2020	1.14	103.98	0.59	-14%
2030	1.14	152.45	0.81	-14%

The results of this scenario are obtained under the assumption that the INN use restrictions would equally affect this segment of the market. Nevertheless, these effects can be significantly reduced if institutional purchases and the professionals in charge use the INN as a market mechanism to improve their negotiating power.

Using the above assumption, in 2020 the INN use restriction would force an institutional budget increase, or a more than 103 million dollar increase in the percentage of CPU allocated for medicines. If this does not occur, it would be necessary to reduce the health system's benefits by 14%. The spending increase is equivalent to health-care expenditures

[26] In Colombia, the health care system is made up of a contributive regime for those people who are able to pay and a subsidized system for those who cannot. In each case, a Per Capita Payment Unit, or CPU, is set whose value must cover the cost of health care for all members.

for approximately 600,000 people who would be enrolled in the contributive program of the social security system.

2.3.3 Total market

Trademarks Scenario				
Year	Price Index	Expenditure Increase (in millions of US$)	Equivalents in Per Capita Payment Units (CPU) of the Contributive Program (in millions)	Reduction in consumption if no increase in expenditure
2010	1.05	83.68	0.51	-5%
2020	1.07	167.70	0.95	-7%
2030	1.07	245.87	1.30	-7%

In sum, the INN use restriction caused by the implementation of the article on Trademarks with the described assumptions could generate an impact of more than 167 million dollars in 2020, equivalent to health-care expenditures for nearly 950,000 people enrolled in the contributive program of the social security system for health care, and resulting from a 7% increase in average prices.

3. Chapter 16.9: Patents

3.1 Contextual Information

A patent is an exclusive right that is granted for an invention, that is, for a product or a process that offers a new way of doing something or a new and innovative solution to a problem.

In exchange for protection by a patent, the patent holder has the obligation to disclose all the information about the invention. This growing body of public knowledge is thereby promoting greater creativity and innovation by researchers and innovators.

The patent grants a monopoly on the production, use, marketing, and the import or sale of the invention, in territories that have granted this protection for a determined period of time according to their current legislation. The TRIPS Agreement set that period of protection at 20 years for all fields of technology. The Superintendence of Industry and Trade (SIT) is the entity in Colombia responsible for evaluating and issuing patents.

This monopoly is granted under the assumption that the "costs to consumers or other producers are less than the benefits that patents provide by promoting the development of inventions and investment."[27] In other words, the cost of administering the patent system and the higher cost to consumers that may result will be compensated by the investment and research and development of products that benefit society.

In the case of pharmaceuticals, the process of obtaining a patent begins when the "inventor" believes that, as a result of several trials and a "pre-clinical" phase, the invention could be therapeutically or commercially successful. In this event, the inventor applies for a patent with the appropriate [national] entity.

The explicit description of the technical contribution of the inventor and, thus, the scope of the protection, is defined by the so-called "patent claims." For pharmaceuticals, these claims usually cover several compounds in one single patent.

[27] National Planning Department (NPD). Republic of Colombia. Impact of the Patent System.

The evaluation of the application can last an average of five years, after which the applicant is informed whether the patent has been issued or rejected. Once the patent is issued, the inventor must obtain marketing approval from the corresponding drug regulatory authority. The patent's effective term, that is, the period during which the "invention" is actually sold on the market, will depend on the efficiency of both the patent and drug regulatory authorities, the applicant's fulfillment of the requirements for obtaining the patent and for gaining marketing approval for the medicine.[28] Thus, the effective term could be within a wide range, somewhere between 5 and 15 years, depending on the product or procedure in question.

3.2 Text Analysis

There are two types of provisions in the FTA text that refer to patents, those related to the object of protection and those related to the period of protection:

3.2.1 Related to object of protection

EXISTING LAW
TRIPS, Article 27, Patentable Material "…patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application[29]. …patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
According to the Superintendence of Industry and Trade of Colombia, current requirements for something to be patented are: **Novelty**: This means the invention must be new or must feature a new characteristic that is unknown in the world. **Inventive step**: An invention is considered to have an inventive step if it is neither an obvious result of prior art nor is it obvious to an expert on the subject. It is not obvious when it produces a surprising or unexpected effect. In other words, it behaves in a way different from what is already known through prior art. **Industrial Application**: This means the invention may be manufactured or used in any type of industry, with the understanding that industry refers to any productive activity, including services.
FTA TEXT
Article 16.9.1: "Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. For the purposes of this Article, a Party may treat the terms "inventive step" and "capable of industrial application" as being synonymous with the terms "non-obvious" and "useful," respectively."
Article 16.9.7: "Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure (a) was made or authorized by, or derived from, the patent applicant, **and** (b) occurred within 12 months prior to the date of filing of the application in the territory of the Party."
16.9.11: "Each Party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility." Footnote for this last article: "For greater certainty, this paragraph is without prejudice to paragraphs 1 and 2."

[28] When the patent is for a new chemical entity, studies that show its safety and efficacy are required (this will be discussed in detail in the following chapter), which are the product of several clinical trials that could delay its entry onto the market.
[29] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

The TRIPS agreement does not define either how to interpret clearly each of the patentability requirements or to what degree the claims must be acceptable. Therefore, countries are given the freedom to define the scope of patentability in their domestic legislation. In Colombia, the SIT has defined those requirements. Although the TRIPS Agreement states in a footnote that "the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful', respectively," in a similar way to the FTA text, Colombia's domestic legislation has opted to use the former terms and not their synonyms.

The language of the FTA is adjusted to that contained in U.S. legislation, which uses the expressions "non obvious" and "useful." The FTAs recently signed by the United States show a clear tendency towards harmonization of terms with those used in that country. For Colombia, this implies an important change in the criteria for patentability that could broaden the scope of currently patentable subject matter.

Novelty: The novelty of an invention is evaluated by deeming that it is not known in the world, that it is not contained in the prior art. This criterion is applied before evaluating the requirement for inventive step. If the former is not met, then it will not be necessary to evaluate the latter.

Generally speaking, novelty is destroyed by any form of public communication about the invention, including written disclosure or prior use.[30] Article 16.9.7 in the FTA enables novelty to be conserved when "public disclosure (a) was made or authorized by, or derived from, the patent applicant, **and** (b) occurred within 12 months prior to the date of filing of the application in the territory of the Party."

The FTA text links the two conditions by writing the conjunction "and". This interpretation makes it possible to keep the current standard used in Colombia. Nevertheless, if the interpretation or translation of the texts were to convey a sense of applying **one or the other** of the conditions established in parts a) and b) of the cited article, then it could be said that the current concept of novelty in Colombia is contradicted. Inventions or their characteristics that are already known worldwide (by one or both concepts established in Article 16.9.7) and therefore would not currently comply with the criterion of novelty, could do so under the FTA text. In the United States, for example, novelty is only wiped out if the information is written and if it is found in just one publication.

In this second interpretation, the concept of "novelty" is relaxed and enables the patenting of more products or processes. One characteristic example is the strategy commonly used with pharmaceuticals whereby a patent holder attempts to artificially extend the patent period by patenting other similar products based on the information developed for the first patent. Currently, in Colombia this information is considered as already known and therefore not able to comply with the novelty criterion; hence, the product is not patentable. If the FTA is interpreted so that disclosure with the patent holder's authorization is not enough to wipe out novelty, then the product would be patentable regardless of when that information becomes part of the public domain.[31]

Inventive Step: Article 16.9.1 ratifies what is contained in the TRIPS Agreement when stating that each party "may" deem this expression as synonymous with "non-obvious". Thus, at first glance, there is no change implied to the current standards. However, harmonizing the terms to the U.S. standard makes the adoption of the term "non-obvious" foreseeable in Colombian legislation and, with that, the adoption of a similar interpretation to

[30] Correa, Carlos, "Integrando la salud publica en la legislación sobre patentes de los países en desarrollo" South Centre, Buenos Aires, 2001. Pg. 47, 48

[31] Concrete examples are described in the work by Correa, Carlos, "tendencias en el patentamiento farmacéutico, estudios de casos". Ediciones corregidor, Buenos Aires 2001.

that contained in U.S. legislation, where requirements are more relaxed. The following are some examples of this.

- In Colombia, according to the SIT, inventive step is that which "produces a surprising or unexpected effect, that is, it behaves in a way not yet known in the prior art." The U.S. considers that patentable inventions can be the result of laborious research, a slow study, or a chance discovery.[32] The interpretation and the scope are clearly different: research can be laborious but lead to a result that is foreseeable to an expert on the subject and that therefore does not contribute anything to the prior art.

- Colombia evaluates inventive step by taking into account several sources of information: documents that specifically indicate the claim, information that can be derived from other related documents, information on other patents and other components of the prior art. The United States, however, asserts that "a claim is not obvious by virtue of the prior art unless some suggestion or specific lesson in the prior art points to it."[33] In other words, inventive step is only evaluated using the first source of information cited by Colombia. Thus, information derived from the study of other related documents and applications and, hence, that is found in the prior art is not taken into account in the U.S. when determining the "non-obvious" criterion.

- In the pharmaceutical sector, it is common to apply for patents for compounds with structures similar to other already existing ones. Such is the case with different salts of one acid, optical isomers,[34] and polymorphs,[35] among other examples. The claim is applied for when some advantage from the new compound is "discovered". In many cases, the purpose of this type of application is to "artificially" prolong the protection of a soon-to-expire patent for a product that would continue to be protected through a newly-issued patent, thus restricting the entrance of competing medicines. In Colombia, the discovered advantage is considered obvious when it involves a similar structure or composition and therefore would not be patentable. Contrary to this, in the United States, "the presence of a foreseeable advantage is not considered sufficient for excluding patentability.[36]

The relaxing of this requirement takes on particular importance when taking into account that the development of new chemical entities shows a declining evolution since the 1990's and only represents a tiny fraction of the thousands of patents issued for pharmaceuticals.[37] Thus, the trend is to patent changes in already known products and even those found in the public domain, such as new formulations, combinations, optical isomers, active metabolites, salts, manufacturing process variations, and polymorphs. Many of these do not fulfill the inventive step requirements under Colombia's current standards. Yet with the FTA provisions adjusting the requirements to those in U.S. legislation, these applications would be considered as "non-obvious" and therefore patentable, expanding the level of monopoly in the pharmaceutical market.

The following describes some of the impacts that would result from the FTA if patents could be issued for minor changes to already known products. The demonstrated results are for the total pharmaceuticals market in Colombia.

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[32] Dratler, Op Cit. Taken from Correa, Carlos, "Integrando la salud publica en la legislación sobre patentes de los países en desarrollo" South Centre, Buenos Aires, 2001.
[33] Ibid.
[34] One compound is the exact mirror image of the other.
[35] Some chemical entities can crystallize into different forms, modifying their properties and in some cases their therapeutic activity.
[36] Grubb, 1999. Taken from Correa, Carlos. "Integrando la salud publica en la legislación sobre patentes de los países en desarrollo", Op cit.
[37] See Commission on Intellectual Property Rights, Innovation, and Public Health (CIPIH) (2006), available at www.who.int. Taken from Correa, Carlos, Protección de productos farmacéuticos y agroquímicos en DR CAFTA. 2006

Minor Modifications Scenario						
Year	**Active principle with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	0.10	1.02	24.66	0.15	-2%	2%
2020	0.28	1.11	241.01	1.37	-11%	17%
2030	0.28	1.11	353.35	1.87	-11%	17%

According to these results, issuing patents for minor modifications to products could imply an almost 11% increase in medicine prices in Colombia. This would result in an impact of over 240 million dollars in 2020, equivalent to health-care expenditures for approximately 1.4 million people enrolled in the contributive program of the social security system. If the expenditure is not increased, this could mean an 11% reduction in consumption. The national industry could stand to lose up to 17% of its market share.

Industrial application: This term is dealt with in a contradictory fashion in the FTA text. Article 16.9.1 establishes that the parties "may" consider the expression "capable of industrial application" as being synonymous with the term "useful". Yet Article 16.9.11 states that "each party shall provide that a claimed invention is industrially applicable if it has a specific, substantial, and credible utility." The former gives autonomy to a country for interpretation in its domestic legislation, while the latter sets out an obligation in the matter.

The change in terms relaxes the requirement. The term "industrial application" focuses on concretely providing a solution to a problem and not to abstract knowledge. In Colombia, industry is understood to be "any productive activity, including services." Thus, the inclusion of services would not be a justification for changing the terms, contrary to the explanations given during working meetings by Colombia's Director of negotiations on intellectual property. Under U.S. legislation, it is possible to patent innovations that do not result in an industrial product; rather, it is sufficient that the innovation be executable and capable of satisfying some beneficial function for humanity, thus fulfilling the criteria of being "useful, substantial, and credible." Thus, purely experimental inventions can be patented in the U.S. without needing to have any industrial application. For example, it would be possible to patent "in-vitro tests on a model of animal tumors for products destined for human use," which are useful but still have no industrial application.[38]

According to Correa,[39] the change in the criterion might lead to patenting the uses of products since "the uses of inventions related to health can be considered as treatment methods for the human body, though lacking industrial application and therefore not patentable," but certainly "useful, specific, and credible."

By establishing the obligation to change the interpretation of the terms, the relaxing of the industrial application requirement becomes the most obvious reason for increasing the scope of patentable subject matter.

The likelihood that the agreed-upon text opens the possibility of issuing patents for uses of the same chemical entity deserves particular attention because of the impact it might have. This is further discussed here.[40]

[38] Correa, Carlos. "Integrando la salud publica en la legislación sobre patentes de los países en desarrollo" South Centre, Buenos Aires, 2001. Op Cit, Pg. 56
[39] Ibid
[40] Comments based on: Holguin, German. "TLC Y Medicamentos: contenido e impactos de la cláusulas negociadas", Mision Salud paper for the Congress of Colombia. September 2006.

The FTA text does not establish a specific obligation for issuing patents for uses of the same chemical entity. However, in light of the reference made about the relaxing of the industrial application criterion and the expression used in Article 16.10.3 (a) "or its method of use,"[41] one could interpret that the commitment to issue them does exist.[42]

To be clear in this regard, one memo from a meeting held between the President of Colombia and the USTR[43] stated: "The Intellectual Property Director of the USTR made the following clarifications and commitments in relation to the intellectual property chapter of the Peru-U.S. FTA:…2) Within the agreement's framework, it was clearly stated that Colombia would not be obligated to patent methods of use or second uses." Unfortunately, the United States did not allow this agreement to be incorporated in either the FTA text or side letters. This leaves serious doubts about its evidentiary value.

Along the same lines, the Colombian Trade Minister made it clear that "just because a Party has abandoned one specific negotiation proposal does not necessarily mean that it has abandoned its aspiration…It is important to keep in mind that the United States maintains in the multilateral arena that methods of use cannot be excluded per se from patentability." In support of this argument, a document sent by PhRMA, an association of multinational pharmaceutical companies based in the U.S., to the USTR in 2006 recommended leaving Colombia on the Priority Watch List (list of countries that the USTR has under observation for supposed intellectual property violations) and justified this recommendation stating, among other things, "the inflexibility of the Colombian patent office in approving second-use patents, which is a violation of Article 27.1 of the TRIPS Agreement." Thus, it is expected that the U.S. will continue pressuring Colombia to grant patents for uses through a variety of means, including any ambiguity in interpreting the FTA text.

The following describes some impacts that could occur if the FTA is interpreted to require issuing patents for uses. The results shown are for the total pharmaceuticals market in Colombia.

Patents for Uses Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	0.10	1.02	24.66	0.15	-2%	2%
2020	0.25	1.08	180.76	1.03	-8%	13%
2030	0.25	1.08	265.01	1.40	-8%	13%

According to these results, issuing patents for uses could imply an almost 8% increase in medicine prices in Colombia. This would result in an impact of more than 180 million dollars in 2020, equivalent to health-care expenditures for more than 1 million people enrolled in the contributive program of the social security system. If the expenditure is not increased, this could mean an 8% reduction in consumption. The national industry could stand to lose up to 13% of its market share.

In conclusion, the FTA text relaxes the currently existing criteria for patentability, thereby allowing more products to receive patent protection than is possible today and resulting in a

[41] Article 16.10.3 (a): "…to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent…"
[42] See reference to this in: Ministry of Social Protection, "Comparativo textos CAFTA y Perú en Propiedad Intelectual", Internal document, 2006
[43] USTR = Office of the United States Trade Representative

greater level of monopoly in the pharmaceuticals market, higher prices, and thus greater barriers for access to medicines.

3.2.2 Related to the period of protection

EXISTING LAW
TRIPS Article 33, Term of protection: The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.
FTA TEXT:
Article 16.9.6 (a): Each Party shall provide the means to and shall, at the request of the patent owner, compensate for unreasonable delays in the issuance of the patent by restoring patent term or patent rights… For purposes of this subparagraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods attributable to actions of the patent applicant need not be included in the determination of such delays. **Annex 16.1.2**: Permits a two year postponement in applying this measure.
Article 16.9.6 (b): With respect to any pharmaceutical product that is covered by a patent, each Party shall make available a restoration of the patent term or patent rights to compensate the patent owner for any unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party…

The FTA text includes additional provisions to those contained in TRIPS. While the total patent term is 20 years from the filing date in TRIPS and it is understood that the patent and marketing approval processes are included within this period, the FTA establishes compensations for "unreasonable delays" in those processes. This is described below.

Compensation for unreasonable delays in the patent office: Article 16.9.6 seeks to compensate the patent holder for "unreasonable" delays, defined as more than five years from the filing date in the territory of the Party or three years counting from the date a request for examination of the application has been made.

Table 2 shows the "review period for pharmaceutical and biotech applications related to pharmaceutical processes and/ or products received from January 1st, 1994, when protection for pharmaceutical products was first granted."[44]

Table 2: Calculation for the compensation for unreasonable delays in the patent approval process

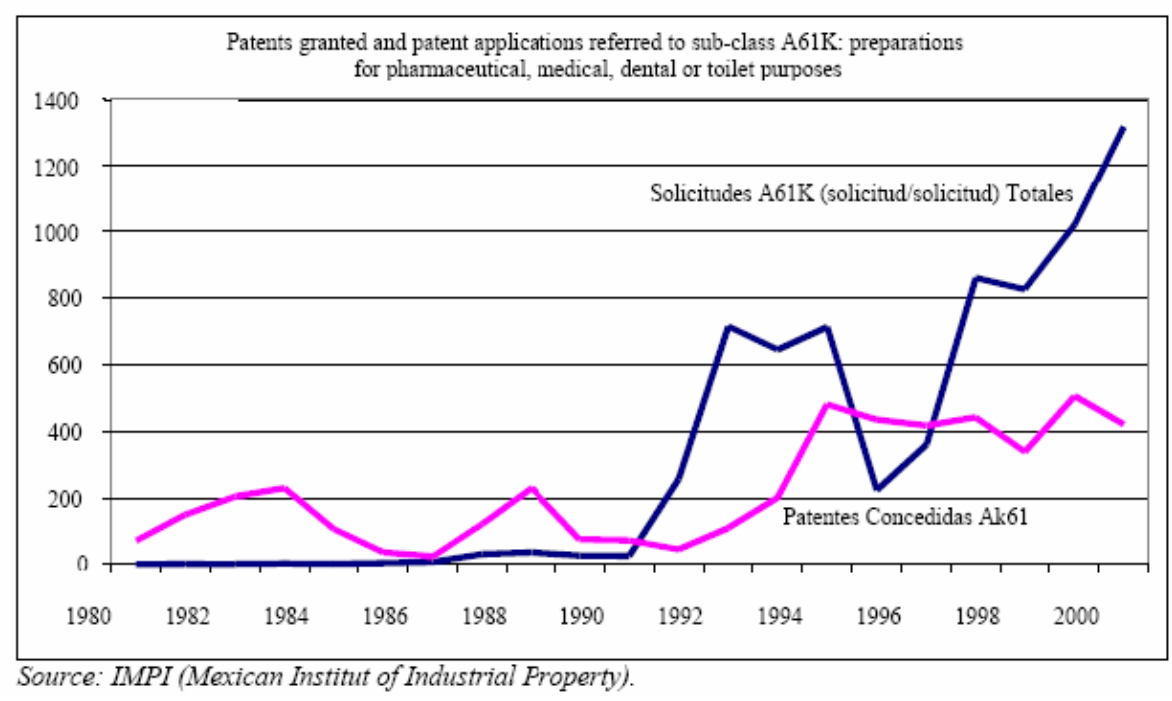
Delays	Number of patents granted until 2000	%	Years of Compensation	% * Years of Compensation	Number of patents delayed more than 5 years	%	% * Years of Compensation
0 to 5 years	1030	80%	0	0.00	0		
5 to 7 years	242	19%	2	0.38	242	97%	1.94
7 to 10 years	8	1%	5	0.03	8	3%	0.16
Total	1280	100 %	N/A	0.41	250		2.10

Source: SIT, August 2006

[44] Source: SIT, August 2006. Response letter to a request made by German Holguin Zamorano, Director of Mision Salud, to the SIT.

The data in the table indicates that, with the current amount of applications and the patent office's infrastructure, compensation for all patents would be 0.4 years, or the equivalent of having 20% of the patents extended by 2.1 years.

Nevertheless, taking into account, as described above, that the FTA increases the scope of patentable subject matter thus creating more applications and issuances, it is possible to expect compensations to increase in time and percentage. In this regard, what happened in Mexico after NAFTA (North America Free Trade Agreement) was signed with the U.S. and Canada could be a good indicator. Graph #1 shows how the number of applications and issuances has permanently increased since 1992, when the Agreement was signed.



Source: IMPI (Mexican Institut of Industrial Property).

Article 2 of Appendix 16.1 allows the implementation of this article to be delayed for two years. It is assumed that this time will be used to strengthen the patent office in such a way as to reduce the time needed for analysis of applications and hence avoid having to grant compensations. However, with an increasing number of applications, it is likely that even an improved SIT will be overwhelmed and, therefore, a large number of products will continue to receive extended patent periods.

Compensations for delays in the process of marketing approval: Article 16.9.6 (b) demands "compensation to the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process."

In contrast to part (a), which refers to patent approval, this article neither establishes what is considered "unreasonable delays" nor establishes whether terms attributable to the applicant's action will be included in determining the delays.

Approval for marketing by INVIMA (National Institute for Food and Drug Regulation) is determined by the testing done on the product: pharmacological evaluation, pharmaceutical evaluation, and legal evaluation. While the relevant aspects of these evaluations will be presented in the following chapter, for the purposes of this section it should be clarified that the pharmacological evaluation takes the longest amount of time. The defined interval for this procedure by the INVIMA is 180 working days, according to what is stipulated in Decree

677 of 1995.[45] Yet this same decree clarifies that in cases where additional information is required, "the indicated term in the present article will be suspended until the time in which the interested party provides the data requested," permitting the total period to be extended until the applicant delivers that data. If this period were to be "unreasonable," then the percentage and time of the patent extension compensation would increase indefinitely.

Compensation for delays in the marketing approval of medicines in the United States cannot surpass five years and in no case can the exclusivity period exceed fourteen years from the date of marketing approval by the Food and Drug Administration. In the FTA text, nowhere is any maximum term established for either of the compensations that would extend the patent term.

3.3 Estimated Impacts

The following indicates the full impact of the article on patents. However, it is important to clarify that to a large degree, the results are due to the flexibility of patentability criteria, especially in terms of the possibility of issuing patents for uses and minor adjustments, whose impacts were described earlier in this paper.

3.3.1 Private Market

Patents Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	11%	1.02	19.56	0.12	-2%	3%
2020	44%	1.21	318.28	1.81	-21%	33%
2030	48%	1.23	521.27	2.76	-23%	37%

By 2020, the article on patents would cause an impact of more than 318 million dollars. If the expenditure is not increased, then consumption would have to be reduced by 21%. The required spending increase would be equivalent to health-care expenditures for approximately 1.8 million people enrolled in the contributive program of the social security system. The national industry could stand to lose up to 33% of its market share.

3.3.2 Institutional Market

Patents Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	9%	1.01	5.10	0.03	-1%	1%
2020	23%	1.11	83.01	0.47	-11%	16%
2030	25%	1.12	135.95	0.72	-12%	18%

The article on patents would mean an increase in institutional expenditures of more than 83 million dollars in 2020, equivalent to health-care expenditures for approximately 470,000 people enrolled in the contributive program of the social security system for that year.

[45] Decree 677 of 1995, Article 28

3.3.3 Total Market

Patents Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	0.10	1.02	24.66	0.15	-2%	2%
2020	0.38	1.18	401.29	2.28	-18%	28%
2030	0.40	1.20	657.22	3.48	-20%	31%

The article on patents could mean an impact of more than 400 million dollars in 2020 for the total pharmaceuticals market in Colombia, equivalent to health-care expenditures for approximately 2.3 million people enrolled in the contributive program of the social security system. If the expenditure is not increased, this could mean an 18% reduction in consumption. Market share losses for the national industry could reach 28% due to expanded market exclusivity.

4 Chapter 16.10 Measures related to certain regulated products

4.1 Contextual Information

The products regulated by this chapter are agricultural chemicals and pharmaceuticals. To grant marketing approval for these products in a country requires that data be submitted to the drug regulatory authority in order to prove the product's safety and efficacy, commonly called "test data".

In Colombia, the conditions for granting marketing or regulatory approval for a medicine are established in Decree 677 of 1995. Some relevant aspects for analyzing this chapter are described below.

Article 19: on drug regulation. All medicines require registration or marketing approval for health and safety purposes to be granted by the competent drug regulatory authority according to the established guidelines of this decree, for their production, import, export, processing, packaging, packing, dispensing and marketing. The process of issuing marketing approval differentiates between two classes of medicines:

a) Those included in the officially accepted pharmacological standards, and

b) New medicines defined as those "whose active principle has not been included in the Manual of Pharmacological Standards..."[46]

Article 20. …The necessary requirements for granting marketing approval contained in the pharmacological standards are:

a) Pharmaceutical evaluation
b) Legal evaluation

Article 21…The purpose of the pharmaceutical evaluation is to judge the manufacturer's technical capacity, manufacturing process, and product quality.

[46] Decree 677 of 1995, Article 2.

Article 26….In order to issue marketing approval for a new medicine, the following are required:

a) Pharmacological evaluation
b) Pharmaceutical evaluation
c) Legal evaluation

Article 27: on pharmacological evaluation. This involves the procedure used by the drug regulatory authority to form an opinion on the medicine's usefulness, convenience, and safety. The evaluation is carried out taking into account the product's safety and efficacy, as well as other characteristics.[47]

1st Paragraph: When the product applying for marketing approval is registered in at least two (2) countries of reference and has not been rejected in any other country of reference, then the pharmacological evaluation will simply require a summary of the clinical data, including the corresponding bibliography, presented in a format set by INVIMA. The Pharmaceutical Products Review Commission will ask for additional information on the product whenever there are doubts about it.

2nd paragraph: For purposes of this article, the countries of reference are: the United States of America, Canada, Germany, Switzerland, France, England, Denmark, Holland, Sweden, Japan, and Norway.

Article 28: on the procedures for pharmacological evaluation of new medicines. The interested party must submit an application to INVIMA along with documents that enable an evaluation of the variables listed in the previous article. The Pharmaceutical Products Review Commission will provide a term of one hundred eighty (180) working days for issuing the corresponding technical report, during which time it could request, in writing, that the applicant provide additional information or studies in order to judge the usefulness, safety or convenience of the new medicine. If the period expires without a response to the application for marketing approval, the Commission shall make a decision on the application in its next meeting.

The period indicated in this article will be suspended until the time in which the interested party submits the data that was requested.

Note that for those medicines already included in the manual of pharmacological standards, the pharmacological evaluation requirement is waived since, in order to be included in the manual, such requirements, including safety and efficacy, had to have been met previously for the medicine's first commercial marketing.

However, since the issuance of Decree 2085 of 2002, "When the marketing of a new chemical entity has been approved, non-disclosed data shall not be directly or indirectly used as supporting data for the approval of separate application for the same chemical entity."[48] In other words, if safety and efficacy data submitted for the first commercial marketing has been protected as "non-disclosed", then another manufacturer of the same medicine will not be able to use that data as a basis for its medicine in order to obtain marketing approval and, therefore, must go through the its own pharmacological evaluation.

Colombia's adoption of this Decree generated a wave of controversy with respect to whether Decision 486 of the CAN, which is consistent with TRIPS provisions, allows periods of

[47] Other unnecessary characteristics were omitted for this analysis. The complete list of characteristics is in Article 27 of Decree 677 of 1995.
[48] Ministry of Health, Republic of Colombia. Decree 2085 of 2002. Article 2.

marketing exclusivity. A suit was brought against the decree before the Andean Court of Justice, which ruled in November 2005 that the aforementioned provision of the decree was inapplicable and contrary to Andean law. Since this would have made it impossible to include a similar provision in the FTA with the U.S., Ecuador, Colombia, and Peru concluded in a meeting of the CAN Commission on April 7th, 2006 (in the absence of dissenting votes because Venezuela and Bolivia were not present) that Decision 486 could be interpreted at each individual country's discretion so that if a country so decided, it could establish periods of marketing exclusivity.

Overall, data protection does not generate exclusive rights like a patent does. However, it is a barrier to the entrance of competing medicines onto the market because, as long as the protection exists, there can be no marketing approval unless the competing company develops all the necessary test data, which would end up being costly and require lots of time, while raising serious ethical and economic concerns. "Duplicating existing tests is not only a social waste but is also ethically questionable since it implies inflicting unnecessary pain and suffering to animals and is a risk to people."[49] Repeating tests implies re-doing clinical trials that were already carried out by the company who first marketed the medicine.

4.2 Text Analysis

EXISTING LAW
TRIPS, Article 39.3: Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.[50] **Colombian Decree 2085 of 2002**. **Article 1**: For purposes of this decree, a new chemical entity will be understood to be an active principle that has not been included in Colombia's Pharmacological Standards. New or second uses will not be considered to be new chemical entities. Likewise, novelties or changes to the following aspects will not be considered new chemical entities: pharmaceutical forms, indications or second indications, new combinations of known chemical entities, formulations, dosage forms, ways of administering, modifications implying pharmacokinetic changes, marketing and packing conditions and, in general, changes that imply new presentations. **Article 2**: When the marketing of a new chemical entity is approved, the related undisclosed information may not be used directly or indirectly as support for the approval of a separate application relating to the same new chemical entity. The generation of undisclosed information whose use is protected must have required considerable effort for the one submitting it to the competent drug regulatory authority.

[49] Correa, Carlos, "Integrando la salud publica en la legislación sobre patentes de los países en desarrollo" Op Cit.
[50] World Trade Organization. Annex 1C. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Article 3: The protection of the use of undisclosed information regulated herein shall be as follows:

Three (03) years counted from the date of marketing approval in Colombia for those applications filed during the first year this decree comes into force.

Four (04) years counted from the date of marketing approval in Colombia for those applications filed during the second year this decree comes into force.

Five (05) years counted from the date of marketing approval in Colombia for those applications filed during the third year this decree comes into force.

Article 4: The protection referred to in this decree does not apply in the following cases:

a) When the holder of the marketing approval of a new chemical entity has authorized the use of undisclosed information to support another subsequent application.

b) When the new chemical entity applying for marketing approval is similar to another that has been approved and marketed in Colombia and the term of protection in Article 3 has expired.

c) When it is necessary to protect the public, as assessed by the Ministry of Health.

d) When the new chemical entity applying for marketing approval has not been marketed in the country one year after the issuance of said marketing approval.

FTA TEXT

Article 16.10.1 (a): If a Party requires or permits, as a condition of granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of information concerning safety or efficacy of the product, the Party shall not, without the consent of a person that previously submitted such safety or efficacy information to obtain marketing approval in the Party, authorize another to market a same or a similar product based on:

(i) the safety or efficacy information submitted in support of the marketing approval; or

(ii) evidence of the marketing approval, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval in the territory of the Party.

Article 16.10.1 (b): If a Party requires or permits, in connection with granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of evidence concerning the safety or efficacy of a 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 a person that previously submitted the safety or efficacy information to obtain marketing approval 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 the prior marketing approval in the other territory; or

(ii) evidence of prior marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval of the new product in the territory of the Party. In order to receive protection under

this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory.
Article 16.10.1 (c): For purposes of this Article, a new pharmaceutical product is one that does not contain a chemical entity that has been previously approved in the territory of the Party for use in a pharmaceutical product and a new agricultural chemical product is one that contains a chemical entity that has not been previously approved in the territory of the Party for use in an agricultural chemical product.
Article 16.10.2: When a product is subject to a system of marketing approval in the territory of a Party pursuant to paragraph 1 and is also covered by a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1 in the event that the term of patent protection terminates on a date earlier than the end of the term of protection specified in paragraph 1.
Article 16.10.3: Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence of safety or efficacy information of 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 or its approved method of use during the term of that patent, unless by consent or acquiescence of the patent owner[17]; and (b) provide that the patent owner shall be informed of the identity of any such other person who requests marketing approval to enter the market during the term of a patent identified to the approving authority as covering that product. **Footnote**: [17] For greater certainty, the Parties recognize that this provision does not imply that the marketing approval authority should make patent validity or infringement determinations.

A comparison of the texts of the TRIPS Agreement, Decree 2085 of 2002 and the FTA indicates that the article on test data is clearly the one that most strengthens the current IP standards. The following provides an analysis of the different areas where the FTA extends protection: 1) object of protection, 2) type of protection, and 3) others not contained in TRIPS.

1. Object of Protection

a. In TRIPS
   i. Test data or other undisclosed data.
   ii. Pharmaceutical products using new chemical entities.

b. In Decree 2085 of 2002
   i. Undisclosed information.
   ii. Information must have represented a considerable effort.
   iii. New chemical entity (one not contained in the pharmacological standards).
   iv. Establishes exceptions to what is considered a new chemical entity.

c. In the FTA

i. Information on the product's safety and efficacy.
ii. New pharmaceutical product, defined as one that does not contain a chemical entity previously approved in the territory of the Party for use in a pharmaceutical product.

The FTA introduces several changes to the current legislation.

Change #1: The FTA substantially modifies the spirit of the TRIPS Agreement. In the latter, the object of protection is the undisclosed information, which is protected in order to avoid its unfair commercial use and to reward the considerable amount of effort it took the innovator to obtain it. This logic is maintained in Decree 2085, although there is no reference made to being framed in the context of protecting against unfair competition, it maintains the characteristics of non-disclosure and considerable effort. To the contrary, the FTA completely eliminates any reference to undisclosed information and refers to ALL safety and efficacy information so that the Parties are obliged to protect test data whether it is confidential or not. This certainly broadens the possibility of getting the protection and particularly increases the type of information that is protected, hence creating barriers to competition.

Change #2: Modification of the definition of what is protected. Decree 2085 refers to a new chemical entity, whereas TRIPS and the FTA refer to a pharmaceutical product. But the FTA defines this as "one that does not contain a chemical entity previously approved in the territory of the Party for use in a pharmaceutical product." This change has several implications:

1. It limits the possibility of protecting associations. This is the only positive implication in terms of public health interests. Within the framework of the contents of Colombia's Decree 2085, it is possible to protect a chemical entity that is unapproved in the country and later include it as part of an association with other known and marketed chemical entities, limiting the marketing approval of competing products that use the same association. A similar interpretation can be given to TRIPS, in which it would be understood that if a pharmaceutical product includes at least one new chemical entity, it would be an object of protection. The FTA excludes this possibility because if a pharmaceutical product includes a previously approved chemical entity, it is no longer "new" and, therefore, cannot be protected.

2. It does not establish exclusions for chemical entities that could be part of a new pharmaceutical product. By establishing the condition of "not approved in the territory of the Party", it leaves open the possibility of protecting products with "different" chemical entities but which do not represent a considerable amount of effort in obtaining the test data.[51]

3. In contrast to TRIPS and Decree 2085, the FTA specifies that the nature of "novelty" is only lost when the product contains a chemical entity that has already been approved "for use in a pharmaceutical product." Thus, the product is considered new even when the chemical entity already exists, its information was disclosed, and even if it has been marketed in the country of the Party. It is common to discover a therapeutic use for already known molecules that before had no application in the pharmaceutical sector, and, therefore, to consider giving the characteristic of novelty to a pharmaceutical product that contains them.

[51] An example of this is the case in which INVIMA ruled on levocetirizine: Record #13, May 19th, 2004. "Taking into account that cetirizine is a racemate with equal proportions of the levo and dextro forms, and since both are active forms, the fact of isolating and separating one of these forms (in this case, levo) does not confer on it the nature of a new molecule. It is obvious that since cetirizine is in the pharmacological standards as a racemate, the levo form is included in it." This case could be subject to protection under the FTA.

4. Protection of information regarding safety and efficacy of the "product" can broaden the field of application to pharmaceutical areas, that is, those related to the product's technical specification and manufacturing methods.[52]

2. Type of protection

In TRIPS, undisclosed information is protected against all unfair commercial use.

a. Decree 2085 of 2002
   i. Prevents the use of undisclosed information to support marketing approval for another medicine with the same chemical entity.
   ii. Grants a period of protection beginning with three and up to five years.
   iii. Restricts applying protection in some specific cases, for example, where it would be necessary to protect the public or because the medicine has not been marketed.

c. The FTA:
   i. Prevents the use of safety and efficacy information as well as evidence of prior marketing approval to obtain marketing approval for the same or similar product by a different manufacturer.
   ii. Grants at least five years of exclusivity for pharmaceutical products.
   iii. Allows a Party to require that the one providing the information for marketing approval in the other territory request marketing approval in the Party within five years of having obtained marketing approval in the other territory.
   iv. Prohibits a Party from altering the period of protection in the event that the patent term expires prior to the expiration of the protection of information on safety and efficacy.

As in the case of the object of protection, this would cause several changes to the current situation.

Change #1: Protection changes substantially in terms of the concept and consequences. Test data protection against unfair commercial use contained in TRIPS, which refers to dishonest practices such as industrial espionage or theft of trade secrets, becomes an express ban on authorizing competitors in the market based on the protected information. As a result, the possible competitor would have to submit all the required safety and efficacy information to get the corresponding pharmacological evaluation, a lengthy and costly process, resulting in the exclusion of competition.

Decree 2085, in contrast to TRIPS and just like the FTA, establishes a ban on using protected information to obtain approval "for the same chemical entity." But the FTA broadens the measure to all "similar" products. It does not define "similar", which leaves open the possibility of excluding a wide range of products that might make reference to the protected product's information.

Change #2: The FTA establishes a period of exclusivity and increases its length. TRIPS does not include a period of exclusivity for using information, but Decree 2085 does include such a provision and sets increasing periods of three to five years. The FTA further extends the requirement, establishing that five years is no longer the maximum period of protection provided, as Decree 2085 establishes, but rather the minimum by setting a period of "at least five years." This enables the period of exclusivity to be prolonged indefinitely. Experiences

[52] Ministry of Social Protection, "Comparativo textos CAFTA y Perú en Propiedad Intelectual", Internal document, 2006

that could indicate a trend are the ten years of protection granted by some European countries[53] or even the fifteen years Guatemala once agreed to in its Industrial Property Law.[54]

Moreover, the FTA fails to clarify whether a competitor can begin the process of obtaining marketing approval during the period of protection. If not, the effective period of exclusivity will be greater than five years, since the total time it would take for a competitor's products to be approved would have to be added on once the period of exclusivity ends.

Change #3: The FTA limits protection through a period of exclusivity to information regarding relatively recent molecules. Nevertheless, it permits an effective term of protection that could be for "at least ten years."

Decree 2085 enables the protection of information for molecules that have been marketed for many years in other countries but that, because they are not listed in the manual of pharmacological standards, are considered new in the country. The FTA restricts this protection to information for those products that have been marketed for a maximum of five years in another country by allowing the country to "require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory." This is known as exhaustion of the right of data protection.

But article 16.10.1 (b) establishes that "the Party shall not, without the consent of a person that previously submitted the safety or efficacy information to obtain marketing approval 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 the prior marketing approval in the other territory; or (ii) evidence of prior marketing approval in the other territory." This clearly establishes a period of protection that could be longer than ten years: five years of marketing in the other territory and "at least five years" of protection in ours.

The same article, 16.10.1 (b), limits the application of what article 27 of Decree 677 of 1995 established in its paragraphs 1 and 2 that state:

1st paragraph: "When the product applying for marketing approval is registered in at least two (2) countries of reference and has not been rejected in any other country of reference, then the pharmacological evaluation will simply require a summary of the clinical data, including the corresponding bibliography, presented in a format set by INVIMA."

2nd Paragraph: "For purposes of this article, the countries of reference are: the United States of America, Canada, Germany, Switzerland, France, England, Denmark, Holland, Sweden, Japan, and Norway."

The application for marketing approval may not be based on the marketing approval in another country if the safety and efficacy information is protected in that country.

Along the same lines, the text discussing the exhaustion of rights, which benefits the country, leaves room for doubt about its application since, as was explained earlier, it is directed at those products approved by reference. Those products that go through a normal approval process, that is, that directly submitted to the pharmacological evaluation, will not benefit as a result. Therefore, it would still be possible to continue protecting substances that have been on the market for many years in the other country and, therefore, contribute no

[53] Belgium, France, Italy, Germany, Holland, Sweden, and the UK
[54] Correa, Carlos. Protección de productos farmacéuticos y agroquímicos en DR CAFTA. May 2006. The Guatemalan law was modified later and currently grants five years of protection.

knowledge on the matter. This issue was clarified in the meeting held between the President of the Republic of Colombia and the USTR in Washington on February 16th, 2006. Yet the agreement has only been captured in a "memo" from that meeting that was neither signed by the USTR nor forms part of the FTA's appendices. This leaves room for doubt about its legal validity.

In conclusion, these provisions restrict competition in the pharmaceuticals market and prevent the country from benefiting from therapeutic solutions that already exist in other countries.

Change #4: FTA Article 16.10.2 increases the effective period of protection for some products by establishing that the exclusivity granted by a patent and that generated from the protection of safety and efficacy information are periods that can be added together [if they do not overlap].

3. Other provisions not contained in TRIPS

a. Linking the marketing approval process and review of safety and efficacy information to the existence of a patent.

b. Restrictions on possible compulsory licenses.

Linking marketing approval and patent status (Linkage)

FTA Article 16.10.3 creates a new exclusive right: to prevent marketing approval of a medicine if it is presumed to be protected by a patent. This right does not exist in TRIPS or in the current national legislation and would delay the entry of competitor products in the market in various ways.

The FTA text establishes the obligation that the State must prevent marketing approval of a product protected by a patent and forces it to report to the patent holder the identity of any person or entity applying for marketing approval.

Intellectual property rights are private rights. Thus, if the patent holder deems that a product being sold on the market is infringing her rights, she may sue the presumably violating company and receive compensation for loss of benefits due to the violation. But the FTA inverts this commercial logic, since the measures are not taken after marketing and, thus, after a presumed violation has taken place. Instead, it prevents a product from being marketed because a patent exists, thus giving the State the responsibility and risks derived from the defense of this private right. If marketing approval is granted for a product covered by a patent, the State will be sued under the FTA. And if the State unreasonably prevents a competitor's marketing approval, it will be sued by the company whose economic interests were damaged and will have to cover the costs for the damages.

The FTA does not establish terms for resolving the controversy or provisions for avoiding unreasonable complaints. In the United States, according to research done by the Federal Trade Commission (1996-2001),[55] delays in the introduction of generic competition were often due to suspension of the marketing approval process as a result of patent violation claims. Approximately three years after filing suits, the verdicts favored the competitors in 70% of the cases. This is an example of how the linkage of marketing approval to patent status becomes a tool for delaying the market entry of a large number of competitors for several years.

[55] www.ftc.com Cited by Holguin, German, "La Bolsa y la Vida" Pg. 68, Bogotá, 2004.

A number of products can suffer delays in marketing for this reason. The FTA article establishes the obligation to prevent marketing of "a product covered by a patent claiming the product or its method of use." As explained earlier, claims on a patent usually cover a wide number of products and on occasion, particularly with the relaxing of patentability requirements, may even cover pharmaceutical forms, composition, dosage forms, and so on. The linkage contained in this article refers generally to any patent and includes "its method of use." Thus, competing company products that contain an active principle in the public domain whose patent has expired cannot be granted marketing approval because the active principle is covered by a patent for another form of the product.

Bolar Exception

The Bolar Amendment allows the technological and marketing approval processes to move forward during the patent term in order to be able to market the competing product immediately upon patent expiry. The objective is to respect the rights of the patent holder by preventing the marketing of a competitor's product while still allowing this competing company to go through the approval process for the product. Even though this provision is included in the FTA text, it can be limited by applying article 16.10.3 along with the side letter on linkage,[56] which orders the Parties "to prevent **approval** of a pharmaceutical product to enter the market during the term of a patent." The reference to "approval" and not to "marketing" can stop the practical application of the Bolar Exception. This issue was also clarified in the abovementioned meeting between the Colombian President and the USTR. Yet, the agreements from that meeting are only written as a "memo" and are not signed by the USTR.

Restriction on compulsory licenses

A compulsory license is a mechanism to try to avoid abuse by the patent holder of his dominant market position. It enables a country to decide to allow generic production of a product protected by a patent when it deems so necessary under conditions established in TRIPS Article 31 ("other use without authorization of the right holder").

Data exclusivity may limit the issuance of compulsory licenses. The licensee, by arguing one of the grounds established in the legislation, may manufacture the product without authorization of the patent holder. However, if the product's safety and efficacy data is protected because of the FTA provisions, the licensee may not obtain marketing approval for the medicine, thus preventing the use of one of the fundamental public health safeguards included in TRIPS.

4.3 Estimated Impacts

As described, the article on "certain regulated products" has several components. The following will show the impacts of two of those considered most relevant: the protection of data on safety and efficacy or "test data" and "linkage".

[56] See side letter Concerning Patents and Certain Regulated Products.

4.3.1 Private Market

Test Data Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	48%	1.30	309.02	1.88	-30%	43%
2020	63%	1.35	535.25	3.04	-35%	56%
2030	63%	1.35	784.71	4.16	-35%	56%

Linkage Scenario						
Year	**Active principle with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	9%	1.00	0.00	0	0%	0%
2020	19%	1.02	28.67	0.16	-2%	3%
2030	19%	1.02	42.04	0.22	-2%	3%

Provisions in the article on "certain regulated products" could cause an impact of more than 560 million dollars by the year 2020. Of this amount, 95% or 535 million dollars is attributable to "test data" protection. This is equivalent to health-care expenditures for more than 3 million Colombians enrolled in the contributive program of the social security system. If the expenditure is not increased, then consumption will be reduced by 35%. The national industry could stand to lose up to 56% of its market share as a result of the expanded marketing exclusivity.

4.3.2 Institutional Market

Test Data Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	33%	1.20	101.58	0.62	-20%	28%
2020	33%	1.18	139.60	0.79	-18%	27%
2030	33%	1.18	204.66	1.08	-18%	27%

Linkage Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	7%	1.00	0.00	0	0%	0%
2020	10%	1.01	7.48	0.04	-1%	1%
2030	10%	1.01	10.96	0.06	-1%	1%

The institutional sector would need to increase its budget by approximately 147 million dollars by the year 2020 as a result of provisions in the article on "certain regulated products". Of this increase, 139 million dollars result from the "test data" provision,

equivalent to health-care expenditures for approximately 800,000 people enrolled in the contributive program of the Colombian social security system for health.

4.3.3 Total Market

Test Data Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	0.43	1.26	410.60	2.50	-26%	38%
2020	0.54	1.30	674.84	3.84	-30%	47%
2030	0.54	1.30	989.37	5.24	-30%	47%

Linkage Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	0.08	1.00	0.00	0.00	0%	0%
2020	0.16	1.02	36.15	0.21	-2%	3%
2030	0.16	1.02	53.00	0.28	-2%	3%

The total pharmaceuticals market could require a budget increase of approximately 710 million dollars due to provisions in the article on "certain regulated products," of which 674 million or 95% corresponds to "test data" protection. This provision alone would be responsible for increasing average medicine prices by up to 30%, equivalent to health-care expenditures for 3.8 million people that were enrolled in the contributive program of the social security system. If the expenditure is not increased, there would be a 30% reduction in consumption. Expanded marketing exclusivity would cause the national industry to lose up to 47% of its market share.

5. Estimated impact of all provisions in the text

5.1 Private Market

Complete Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	51%	1.34	353.70	2.16	-34%	46%
2020	74%	1.44	677.91	3.85	-44%	69%
2030	81%	1.49	1,099.81	5.83	-49%	77%

The intellectual property chapter of the signed FTA could mean a more than 677 million dollar increase of expenditures in the private market. If the expenditure is not increased, then it will be necessary to reduce consumption of medicines by up to 44%. The increase in expenditure would be equivalent to health-care expenditures for more than 3.8 million people.

5.2 Institutional Market

Entire Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	29%	1.22	113.02	0.69	-22%	24%
2020	39%	1.32	241.29	1.37	-32%	33%
2030	42%	1.34	377.43	2.00	-34%	37%

Implementing the intellectual property chapter of the FTA could mean an increase in expenditure in the institutional market of nearly 241 million dollars, equivalent to health-care expenditures for more than 1.3 million people enrolled in the contributive program of the social security system by 2020, or a reduction in consumption of approximately 32%.

5.3 Total Market

Entire Scenario						
Year	**Active principles with protection**	**Price Index**	**Expenditure Increase (millions of US$)**	**Equivalents in Per Capita Payment Units of the Contributive Program (in millions)**	**Reduction in consumption if no increase in expenditure**	**National industry's loss of market share**
2010	0.44	1.30	466.72	2.84	-30%	39%
2020	0.63	1.40	919.20	5.22	-40%	57%
2030	0.69	1.44	1,477.23	7.83	-44%	64%

For the total pharmaceuticals market, implementing the FTA with its intellectual property provisions without adopting any measures to mitigate its impacts described in this study, could mean the following by 2020:

1. Approximately 63% of the market would receive monopoly protection as a result of the combined effect of patent and test data protection. This would significantly limit generic competition, lead to monopoly pricing for a large part of the national market, and would cause serious limitations for the national industry, which could lose up to 57% of the value of its current market share (about 37%).
2. The price index for medicines would increase by approximately 40%.
3. There would be an increase of 919 million dollars in spending on medicines by 2020, which is equivalent to health-care expenditures for 5.2 million people enrolled in contributive program of the social security system for that year. If this expenditure is not increased, consumption of medicines could be reduced by up to 40%, with significant consequences for access to medicines, particularly for low-income people and families who cannot afford the higher cost.

One example of the impact of the recommendations made in this study is shown by estimating the impact on the total market excluding provisions enabling patents for uses. The increase in medicine prices by 2020 could drop from 40% in the "total" scenario to 32% by excluding patents for uses. There would be a similar change in the reduction of consumption. The impact on expenditures would decrease by almost 180 million dollars, equivalent to health-care expenditures for more than 1 million people enrolled in the contributive program of the social security system for that year,[57] and the loss of the national industry's market share would drop from 57% to 44%.

[57] This calculation was done by deducting the impact of patents for uses from the impact of the entire text. However, it is likely that those products that cannot obtain patent protection for new uses will be the object of "test data" protection, which would again increase the impact on expenditures and on access to medicines.

6. Conclusions and recommendations

6.1 Overall

The FTA signed by the governments of Colombia and the United States strengthens currently existing intellectual property standards.

Implementing the provisions as signed will generate negative impacts on pharmaceutical spending and access to medicines in Colombia, increasing the former and consequently erecting a barrier to the latter.

The scenario that generates the most impact on pharmaceutical spending and access to medicines is that involving "measures related to certain regulated products," due in particular to the "test data" protection with higher standards than those in Decree 2085 of 2002.

It is generally advisable to establish, within the framework of the country's pricing policy, that all products entering the market with either patent or data protection be included in a direct price control regime that prevents abuses by those who dominate the market.

Some provisions contained in the FTA could be implemented in a manner so as to mitigate their impact. This is the case for provisions involving: use of the INN, the patent criterion of "inventive step," compensation for "unreasonable" delays in the patent and drug regulatory authority offices, the period of protection for safety and efficacy data and exceptions to this protection. However, other provisions would generate a direct impact that it would be difficult to mitigate through implementing legislation. Such is the case with provisions involving: relaxing the patent criteria of "novelty" and "industrial application," the provision protecting all safety and efficacy information regardless of whether it is disclosed or not, and linkage between the patent and drug regulatory authority offices. Each case is explained below.

6.2 Trademarks

The FTA limits and jeopardizes the possibility of using the INN as a means of containing costs and improving the understanding of therapeutics. The impact of this measure is uncertain and depends directly on the interpretation that is given as to which uses of the common name can impair the use or effectiveness of the trademark.

The possibility of using the INN throughout the entire chain of prescription, distribution, marketing, and use of medicines is an important tool for containing costs and for the proper flow of information. The optimal solution, therefore, would be to not mention the issue of the common name in the article so that its use would not be compromised.

Nevertheless, since the article is written especially for that purpose, adopting this solution seems to be very unlikely. As a result, a reasonable modification of the text could include restricting the application of Article 16.2.3 to the concepts of size, location, or style of use of the trademark in relation to the common name. This could be done by eliminating the expression "including, inter alia", which broadens without limit the field of action of this provision. The language would then be: "Each Party shall ensure that its measures mandating requirements concerning the relative size, placement, or style of use of the trademark in relation to the common name, do not impair the use or effectiveness of trademarks used in relation to such good or service."

Lastly, the side letter "Understandings Regarding Certain Public Health Measures" to the FTA makes it possible to determine during the process of implementing the trade agreement that if a government policy, such as the national pharmaceutical policy, sets forth among its

strategies to attain universal access to medicines the promotion of the use of the INN, such a provision will not be considered a violation of Article 16.2.

It is therefore necessary for the government, when implementing the FTA, to: 1) limit the application of Article 16.2.3 to the concepts of size, placement, and style of the trademark in relation to the common name; 2) reaffirm the promotion of the use of the INN as part of its strategy to attain universal access to medicines,.

If these necessary measures for mitigating the impact are not taken, restrictions to the use of the INN could cause spending increases of up to 167 million dollars in 2020, equivalent to health-care expenditures for nearly 950,000 people enrolled in the contributive program of the social security system for that year as a result of a 7% increase in the average price of medicines.

6.3 Patents

In general, a developing country must decide whether to adopt strict patentability standards that will grant a high value to a patent, limit the level of monopoly and allow local industry to learn from foreign technology and improve their products and processes with new ones that do not generate exclusive rights, or whether instead to relax those criteria and permit a large scope of patentability, which will enable, among other things, national researchers to patent products that would not be patentable under stricter criteria and in this way stimulate the use of this mechanism as support to local research. To date, according to the National Planning Department (NPD), "When talking about patents in Colombia, reference is made to patent holdings of foreigners and, thus, the patents obtained by foreigners reflect the fact that inventive activity is not at the national level. Yet when analyzing the models of usefulness…85% are owned by Colombians. Hence, it can be concluded that Colombia is not a country that innovates but, rather, improves [upon innovation]."[58] Consequently, it would be to Colombia's benefit to maintain strict levels of patentability.

To the contrary, the FTA relaxes the patentability requirements in order to harmonize them with U.S. legislation. This increases the scope of patentable subject matter with foreseeable negative consequences for access to medicines in Colombia.

The current version of the FTA text allows the actual standards that are used to evaluate the "novelty" criterion to be maintained. It is important to verify in the final version that the obligation to fulfill both letters (a) and (b) in Article 16.9.7, and not just one of them, is expressly indicated. Otherwise it is foreseeable that the U.S. standards in interpreting this criterion will be adopted, which would relax it. To avoid this, it could be established in domestic legislation that "novelty will be considered to no longer exist after any written or verbal disclosure, including that derived from use anywhere in the world."[59]

The FTA text provides the possibility of using the term "inventive step" or exchanging it for the term "non-obvious". It is beneficial to ratify the use of the former since the latter will promote the adoption of the U.S. interpretation and thus relax the requirement existing in current legislation. To this end, the current SIT definition must be maintained, which states that "an invention has an inventive step if the latter is neither an obvious result of the prior art nor is it obvious to an expert on the subject. It is not obvious when it produces a surprising or unexpected effect. In other words, it behaves in a way different from what is already known in the prior art."

[58] NPD, Patent System Impact, Colombia
[59] Correa, Carlos, "Integrando la salud publica en la legislación sobre patentes de los países en desarrollo" South Centre, Buenos Aires, 2001. Pg. 49

The FTA text determines that “capable of industrial application” will be equated with the concept of “useful, substantial, and credible,” thus preventing domestic legislation from defining it. Yet, it is possible to legislate the definition of this new concept. It would be fitting to maintain the current definition and to apply it to the new term, emphasizing that in order for a patent application to fulfill this requirement, it must solve some concrete problem and not solely be abstract knowledge.

Regarding patents for uses, it is important that the Colombian government avoid ambiguity and the legal debate on the issue. To this end, it will be necessary to propose to the USTR that it sign the memorandum of their meeting with President Uribe in Washington, D.C. on February 16th, 2006 and annex it to the FTA. Otherwise, the Colombian government would have to annex it unilaterally and incorporate it into the documentation provided to Colombia’s Congress for study of the Agreement’s implementing legislation, as well as to the Constitutional Court for a constitutionality ruling on the Agreement.

The FTA allows the effective patent term to be extended through compensations for delays in the patent and drug regulatory authority offices.

Possible inefficiencies in these offices that may cause unreasonable delays should not be compensated with a longer term of exclusivity, since this will make the consumer the one who pays for these inefficiencies. Yet the FTA text is explicit in this regard. Some recommendations can be made for implementing this, as follows.

Compensations should have a maximum time limit. This maximum should be established in two ways: limiting the maximum compensation time and limiting the effective patent term. In the United States, compensation for delays in granting marketing approval for a medicine cannot exceed five years and in no case can the exclusivity exceed fourteen years from the date of approval by the Food and Drug Administration. Similar criteria could be adopted in Colombia.

Compensations for delays in the drug regulatory authority office should clearly establish what constitutes an “unreasonable delay” and clearly state that the compensation will not apply if the delay is caused by the applicant.

Issuing patents for minor modifications to an already existing product could imply a nearly 11% increase in medicine prices in Colombia. This is an impact of more than 240 million dollars for 2020, equivalent to health-care expenditures for approximately 1.4 million people enrolled in the contributive program of the social security system. If the expenditure is not increased, then it could imply an 11% reduction in consumption. The national industry could stand to lose up to 17% of its market share.

Issuing patents for uses could generate an increase of nearly 8% in the price of medicines in Colombia. This would cause an impact of more than 180 million dollars in 2020, equivalent to health-care expenditures for more than 1 million people enrolled in the contributive program of the social security. If expenditures are not increased, this will mean an 8% reduction in consumption, and the national industry could lose up to 13% of its market share.

The article on patents could mean an impact of more than 400 million dollars for the entire Colombian pharmaceuticals market for the year 2020, equivalent to health-care expenditures for more than 2.3 million people enrolled in the contributive program of the social security system. If this increase does not occur, there would be an 18% reduction in consumption, and the national industry could stand to lose up to 28% of its market share as a result of the expanded marketing exclusivity.

6.4 Measures related to certain regulated products

Comparing the text of TRIPS, Decree 2085 of 2002, and the FTA leads to the conclusion that the FTA measures in this Article are those that most strengthen the intellectual property (IP) standards.

The FTA broadens the number of products granted marketing exclusivity by moving from a framework of protecting against unfair competition to expressly denying marketing approval for competing medicines and granting protection to all types of information, whether disclosed or not. The following discusses some recommendations that are likely to mitigate the negative impacts of these measures.

It is necessary to define exceptions for those chemical entities that will give "novelty" to a pharmaceutical product. One possible suggestion for modification could keep what exists in Decree 2085: "a chemical entity not approved in the territory of the Party" will not be deemed a new pharmaceutical product if it involves "new uses or second uses, or novelties or changes to the following aspects of a product: pharmaceutical form, indications or second indications, new combinations of known chemical entities, formulations, dosage forms, forms of administration, modifications implying pharmacokinetic changes, marketing conditions, packaging, and in general new forms of presentation of the pharmaceutical product."[60]

The uncertainty of what is considered a "similar" product in the framework of protecting safety and efficacy information could become one more barrier for marketing competitor products. It is therefore important to define a similar product as that which contains the same chemical entity, the same pharmaceutical form, and the same concentration as the original product.

To establish "at least five years" as the term of protection for a product's safety and efficacy information creates a risky uncertainty for the country. Instead, the term of protection should be established as five years.

The implementing language should include provisions that allow a competing medicine to begin the marketing approval process during the term of protection so it can enter the market immediately after the protection expires. So to avoid ambiguities, the side letter on linkage ["Side Letter Concerning Patents and Certain Regulated Products"], which states that the "approval" of a competitor product is to be prevented, should be modified in order to make clear that only the marketing of the product is to be prevented.

The concept of exhaustion of the right of data protection should be applicable to all products, both those that go through the approval process by reference and those that go through the normal approval process.

Decree 2085 of 2002 contains some grounds for "non-applicability of protection" that the FTA text ignores. It is important to keep such exceptions, particular the following:

- "To protect the public, as assessed by the Ministry of Health.
- When the new chemical entity that is the object of the marketing approval has not been marketed in the country one year after the issuance of said marketing approval."[61]

Concerning the provisions that create linkage between the patent and drug regulatory authority offices, the following is recommended:

[60] Ministry of Health, Republic of Colombia, Decree 2085 of 2002.
[61] Ibid

- Limit the linkage to those patents protecting active principles. Thus, for purposes of patent-marketing approval linkage, a "product covered by a patent" can be defined as a patent that protects a specific active principle.[62]

- Establish that the drug regulatory authority can only stop granting marketing approval if so ordered by a judicial order that has deemed the approval is infringing the rights of the patent owner.[63]

- Establish a dissuasive penalty so that if the marketing of a competitor product has been unjustly obstructed, thereby causing damage to the respective company, this company can claim from the plaintiff compensation to pay for the losses. Likewise, this penalty should include a method of compensation that benefits society for being adversely affected by having to pay monopoly prices for products instead of competitive prices.

- Establish a maximum term during which the marketing approval process of a competitor product may be suspended.

- Clarify though explicitly written text that in any case, the SIT [patent office] and not IMVIMA [drug regulatory office] is the competent authority for processing comments by the patent owner and for determining if a product is covered or not by a patent.

- Clarify that any linkage established between the patent and the drug regulatory authority offices makes reference to the patents granted and not to the patents applied for.

- Establish that the patent owner will receive information as to the identity of an applicant for marketing approval via a publication rather than personal notification.

- Set a brief period to exercise the right to submit comments and define an abbreviated procedure for that purpose.

Finally, it is important to clearly establish that issuing a compulsory license or license for government use includes the power to use the medicine's safety and efficacy information or to grant marketing approval by reference to prior marketing approval abroad.

As a result of the article on "certain regulated products," the total pharmaceuticals market could require a budget increase of approximately 710 million dollars, of which 674 million, or 95% results from "test data" protection. These test data provisions would be responsible for increasing the average price of medicines by up to 30%, or the equivalent of health-care expenditures for 3.8 million people enrolled in the contributive program of the social security system. If expenditures are not increased, this would imply a 30% reduction in consumption. Likewise, expanded marketing exclusivity could cause the national industry to lose up to 47% of its market share.

For the total pharmaceuticals market, adopting the FTA text with its intellectual property chapter without measures to mitigate its impacts, as described throughout this study and in the conclusions and recommendations, could mean the following by 2020:

1. Reaching a level of market monopoly of approximately 63% due to the combined effect of patent and test data protection. This would mean a huge limitation on generic competition, monopoly prices for a large part of the national pharmaceuticals

[62] See, for example, Mexico's Decree of September 19th, 2003 that limits the linkage to patents for the "active substance or active ingredient", thus reducing the restriction on competition created by the linkage. Cited by Correa, Carlos, "Integrando la salud publica en la legislación sobre patentes de los países en desarrollo" South Centre, Buenos Aires, 2001.
[63] Correa, Carlos, "Integrando la salud publica en la legislación sobre patentes de los países en desarrollo", Op cit.

market, and serious limitations for the national industry, which could lose up to 57% of the value of its current market share (about 37%).

2. An approximate 40% increase in the price index for medicines.

3. By 2020, a 919 million dollar increase in spending on medicines, which is equivalent to health-care expenditures for 5.2 million people enrolled as contributors in the social security system that year. If expenditures are not increased, there could be a 40% reduction in consumption with consequences for access to medicines, particularly for low income people and families that cannot afford the higher costs.

By clearly excluding patents for uses, as explained in this study, the combined impact of all the FTA provisions on the total market would be reduced as follows. The increase in medicine prices by 2020 could fall from 40% in the "total" scenario to 32%, with a similar drop in the reduction of consumption. The impact on expenditures would decrease by almost 180 million dollars, equivalent to health-care expenditures for more than 1 million people enrolled in the contributive program of the social security system for that year,[64] and the loss of market share by the national industry would drop from 57% to 44%.

[64] This calculation was done deducting the impact of patents for uses from the impact of all the FTA provisions. However, it is likely that those products that cannot attain a patent for uses will be subject to "test data" protection, which would again increase the impact on expenditures and access to medicines.

Appendices

Appendix 1: IP chapter of the FTA on which this study is based.

Appendix 2: “Guía para estimar el impacto sobre el acceso a los medicamentos de cambios en los derechos de propiedad intelectual (DPI)”

Appendix 3: Model and results

Appendix 4: Sensitivity analysis (p. 45)

Appendices 1 – 3 are available in the archives of Ifarma and Mision Salud:

Ifarma: ifarma@etb.net.co

Mision Salud: misionsalud@yahoo.com

Annex 4: Sensitivity analysis

Abbreviations:

PA: number of active principles that enter from year to year
PAT: percentage of new active principles that enter the market covered by a patent
DATOS: percentage of new active principles that enter the market with data protection
TIEMPO DATOS: number of years of data protection
DCI: percentage of the market, in value terms, of active principles marketed under the international nonproprietary name (INN)
DIF I-C: price differential between innovator medicines and competitor medicines, with 100% being the innovator's price
IDF M-G: price differential between medicines marketed under the trade name and medicines marketed under the common name, with 100% being the price of those marketed under the trade name
COMP: percentage of active principles that would be subject to compensation for delays in the patent office
TIEMPO COMP: number of years of compensation that would have to be given to the percentage of active principles in the previous column
VINC: percentage of active principles that would suffer delays due to the effect of linkage between the patent and drug regulatory authority offices
A.V.: number of years of compensation that would have to be given to the percentage of active principles in the previous column

Private Market

TRIPS SCENARIO (BASIC)											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		10%	0	0	60%	67%	40%	0%	0	0%	0
AVERAGE	25	20%	0	0	40%	75%	50%	0%	0	0%	0
PESSIMISTIC		30%	0	0	20%	80%	60%	0%	0	0%	0

TRADEMARK SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		10%	0%	0	40%	67%	40%	0%	0	0%	0
AVERAGE	25	20%	0%	0	30%	75%	50%	0%	0	0%	0
PESSIMISTIC		30%	0%	0	20%	80%	60%	0%	0	0%	0

PATENTS SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		30%	0	0	60%	67%	40%	0%	0	30%	1
AVERAGE	25	55%	0	0	40%	75%	50%	20%	2	50%	3
PESSIMISTIC		70%	0	0	20%	80%	60%	40%	4	70%	5

TEST DATA SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		10%	63%	5	60%	67%	40%	0%	0	0%	0
AVERAGE	25	20%	90%	7	40%	75%	50%	0%	0	0%	0
PESSIMISTIC		30%	100%	10	20%	80%	60%	0%	0	0%	0

TOTAL SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		30%	63%	5	40%	67%	40%	0%	0	30%	1
AVERAGE	25	55%	90%	7	30%	75%	50%	20%	2	50%	3
PESSIMISTIC		70%	100%	10	20%	80%	60%	40%	4	70%	5

PATENTS FOR USES SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		30%	0	0	60%	67%	40%	0%	0	0%	0
AVERAGE	25	35%	0	0	40%	75%	50%	0%	0	0%	0
PESSIMISTIC		45%	0	0	20%	80%	60%	0%	0	0%	0

MINOR MODIFICATIONS SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		30%	0	0	60%	67%	40%	0%	0	0%	0
AVERAGE	25	40%	0	0	40%	75%	50%	0%	0	0%	0
PESSIMISTIC		55%	0	0	20%	80%	60%	0%	0	0%	0

EVERYTHING EXCEPT PATENTS FOR USES SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		30%	63%	5	40%	67%	40%	0%	0	30%	1
AVERAGE	25	40%	90%	7	30%	75%	50%	20%	2	50%	3
PESSIMISTIC		65%	100%	10	20%	80%	60%	40%	4	70%	5

LINKAGE SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		10%	0	0	60%	67%	40%	0%	0	30%	1
AVERAGE	25	20%	0	0	40%	75%	50%	0%	0	50%	3
PESSIMISTIC		30%	0	0	20%	80%	60%	0%	0	70%	5

Institutional Market

TRIPS SCENARIO (BASIC)											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC	5	10%	0	0	90%	67%	40%	0%	0	0%	0
AVERAGE	7	20%	0	0	70%	75%	50%	0%	0	0%	0
PESSIMISTIC	9	30%	0	0	20%	80%	60%	0%	0	0%	0
TRADEMARK SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC	5	10%	0%	0	50%	67%	40%	0%	0	0%	0
AVERAGE	7	20%	0%	0	40%	75%	50%	0%	0	0%	0
PESSIMISTIC	9	30%	0%	0	30%	80%	60%	0%	0	0%	0

PATENT SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC	5	30%	0	0	90%	67%	40%	0%	0	30%	1
AVERAGE	7	55%	0	0	70%	75%	50%	20%	2	50%	3
PESSIMISTIC	9	70%	0	0	20%	80%	60%	40%	4	70%	5

TEST DATA SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC	5	10%	63%	5	90%	67%	40%	0%	0	0%	0
AVERAGE	7	20%	90%	7	70%	75%	50%	0%	0	0%	0
PESSIMISTIC	9	30%	100%	10	20%	80%	60%	0%	0	0%	0
TOTAL SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC	5	30%	63%	5	50%	67%	40%	0%	0	30%	1
AVERAGE	7	55%	90%	7	40%	75%	50%	20%	2	50%	3
PESSIMISTIC	9	70%	100%	10	30%	80%	60%	40%	4	70%	5
PATENTS FOR USES SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		30%	0	0	90%	67%	40%	0%	0	0%	0
AVERAGE	25	35%	0	0	70%	75%	50%	0%	0	0%	0
PESSIMISTIC		45%	0	0	20%	80%	60%	0%	0	0%	0
MINOR MODIFICATIONS SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		30%	0	0	90%	67%	40%	0%	0	0%	0
AVERAGE	25	40%	0	0	70%	75%	50%	0%	0	0%	0
PESSIMISTIC		55%	0	0	20%	80%	60%	0%	0	0%	0
EVERYTHING EXCEPT PATENTS FOR USES SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		30%	63%	5	50%	67%	40%	0%	0	30%	1
AVERAGE	25	40%	90%	7	40%	75%	50%	20%	2	50%	3
PESSIMISTIC		65%	100%	10	30%	80%	60%	40%	4	70%	5
LINKAGE SCENARIO											
SCENARIO	AP	PAT	TEST DATA	TEST DATA TERM	INN	DIF I-C	DIF M-G	COMP	COMP TERM	VINC	A.V.
OPTIMISTIC		10%	0	0	60%	67%	40%	0%	0	30%	1
AVERAGE	25	20%	0	0	40%	75%	50%	0%	0	50%	3
PESSIMISTIC		30%	0	0	20%	80%	60%	0%	0	70%	5

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