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IMPLEMENTING THE IP CHAPTER OF THE FTA BETWEEN CHILE AND THE USA: CRITICISMS AND REALITIES FROM A DEVELOPING COUNTRY PERSPECTIVE

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Abstract

There is an intensive discussion about the incorporation of intellectual property (IP) terms in Free Trade Agreements (FTAs). Some legal scholars suggest that IP terms constitute the price that developing countries have to pay in order to obtain FTA commercial benefits. Thus, it is assumed that economic achievement is the principal motivation for developing countries, while the legal impact of new intellectual property standards is sometimes not immediately obvious. It is in this context that developing countries have been recommended to pay attention to the implementation of the FTAs, assuring that IP terms are compatible with domestic interests. The purpose of this work is to check if developing countries have responded to this concern. Thus, this work will check if Chilean national authorities were aware of the critiques that affect the FTA established with the United States of America and it will see if these critiques were addressed and mitigated by their legislative work. This analysis will be based in the following critical terms: (1) The protection of undisclosed information; (2) Limitations on liability for Internet Service Providers (ISPs).

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1. Introduction

Free Trade Agreements (FTAs) are treaties between two or more sovereign nations, the principal purpose of which consists of removing substantial barriers to trade between the nations.[1] Common barriers are constituted by tariffs and regulatory requirements. From the point of view of this work, those barriers are not relevant. This work will analyse another element of FTA that is becoming more important for states: intellectual property rights (IPRs). For some countries, IPRs constitute an important income source. This situation explains the efforts that these countries are expending to expand the protection of this area of the law and also to diminish modern threats that affect their value, such as the piracy developed under information based economies.[2]

The incorporation of IPR to FTA is a situation not exempt of controversy.[3] There are three main objections against this regulation. First, some legal scholars suggest that IP terms constitute the price that developing countries must pay in order to obtain FTA commercial benefits.[4] These terms usually require relevant reforms on national law for the weakest trading partners. These reforms increase the standards of protection in items such as copyright, patents and trademarks.[5] Thus, the economic achievements are the principal motivation for developing countries, while the impact of new intellectual property standards is sometimes not immediately obvious.[6] Second, IP terms are controversial because they normally require standards that go beyond what was agreed in Trade-Related aspects of Intellectual Property Rights (TRIPS).[7] These new standards are known as TRIPS Plus terms. TRIPS was created by the members of the World Trade Organisation (WTO) in 1995, and is considered a reference regarding IP standards.[8] As will be explained below, the FTA signed with Chile is not an exception because it contains TRIPS Plus terms. Third, it is also argued that developing countries are losing their legislative autonomy through the signing of

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[1] CM Arnold, "Protecting Intellectual Property in the Developing World: Next Stop - Thailand" (2006) *Duke Law & Technology Review* 1-13, at 4.

[2] MR Hassanien, "Bilateral WTO Plus Trade Agreements in the Middle East: A Case Study of OFTA in the Post-TRIPS Era" (2007-2008) *Wake Forest Intellectual Property Journal* 161-195, at 172.

[3] JF Hornbeck, "The U.S.-Chile Free Trade Agreement: Economic and Trade Policy Issues*"* (2003) available at fpc.state.gov/documents/organization/23189.pdf (accessed 1 Sept 10), at 1.

[4] P Roffe, "Intellectual Property, Bilateral Agreements and Sustainable Development: The Challenges of Implementation" (2007) available at www.ciel.org/Publications/FTA_ImplementationPub_Jan07.pdf (accessed 14 May 10) 1-17, at 3.

[5] JJ Schott, "Assessing US FTA Policy", in JJ Schott (ed), Free Trade Agreements: US Strategies and Priorities (Washington: United Book Press, 2004) 359-381, at 367.

[6] P Roffe and C Spennemann, "The Impact of FTAs on Public Health Policies and TRIPS Flexibilities" (2006) *International Journal of Intellectual Property Management* 75-93, at 79.

[7] JJ Schott, see note 5 above, at 369. See also, P Roffe and C Spennemann, see note 6 above, at 79; TP Trainer, "Intellectual Property Enforcement: A Reality Gap (Insufficient Assistance, Ineffective Implementation)?" (2008-2009) *The John Marshall Review of Intellectual Property Law* 47-79, at 61.

[8] CM Arnold, see note 1 above, at 2.

these Agreements because the starting point for the negotiations is always a prepared draft text.[9]

> When the United States or European Union tenders a draft PTA to a developing country, it expects the basic template of its proposal to be followed, and in some areas (such as investment rules or strengthening of IPRs protection), the possibilities for effective counterproposal are almost non-existent.[10]

Some legal scholars affirmed that the main effect of this "restriction to autonomy" consists of developing countries committing their legislature to include IP terms in their local regulation without really knowing the consequences of the application of those rules.[11] Thus, there is no clarity about the benefits of the internalisation of these terms.[12] In this context, Frederick Abbott recommends developing countries to pay attention to the implementation of the FTAs, being sure that IP terms are compatible with domestic interests.[13]

Continuing with this critical perspective, it is argued that FTAs not only affect the local reality of developing countries but also diminish multinational instances of discussion.[14] The shift from multilateral to bilateral instances of negotiation is justified mainly by the negotiating obstacles faced by multinational businesses and because it facilitates reaching an agreement.[15] This shift also debilitates the role that NGOs usually play in multilateral discussions, usually against multinational businesses.[16] For others, an FTA does not diminish multinational debate but on the contrary encourages other countries to participate by creating consensus among countries about the importance of ensuring market access.[17]

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[9] P Drahos, "BITs and BIPs—Bilateralism in Intellectual Property" (2001) *The Journal of World Intellectual Property* 791-808, at 794; P Drahos, "Developing Countries and International Intellectual Property Standard-setting" (2002) available at http://www.iprcommission.org/papers/pdfs/study_papers/sp8_drahos_study.pdf (accessed 24 Aug 10), at 17-18.

[10] FM Abbott, "A New Dominant Trade Species Emerges: Is Bilateralism a Threat?" (2007) *Journal of International Economic Law* 571-583, at 578.

[11] R Rajkumar, "The Central American Free Trade Agreement: An End Round about the Doha Declaration on TRIPS and Public Health" (2005) *Albany Law Journal of Science and Technology* 433-475, at 451.

[12] FM Abbott, see note 10 above, at 571.

[13] FM Abbot, "Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law" (2006), available at http://www.unctad.org/Templates/Search.asp?intItemID=2068&lang=1&frmSearchStr=Abbot&frmCategory=all&section=whole (accessed 14 May 10), at 20.

[14] R Rajkumar, see note 11 above, at 448.

[15] FM Abbott, see note 10 above, at 574.

[16] FM Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health" (2005) *The American Journal of International Law* 317-358, at 354.

[17] "Latin America: US and Chile Sign Bilateral Trade Agreement, South American FTA in the Works" (2002) available at http://ictsd.org/i/news/bridgesweekly/6887/ (accessed 18 May 10).

The objective of this work is to analyse if developing countries are concerned about the implementation of FTAs in order to make them compatible with their domestic realities. For this purpose, the Chilean implementation of the FTA signed with the United States of America will be examined. This article will explore if Chilean authorities were conscious about the critiques that affected the FTA's terms and will see if these criticisms were addressed and mitigated by legislation.

This work identifies two critical terms contained in the FTA between Chile and the US according to the international discussions: (1) The protection of undisclosed information, and (2) Limitations on liability for Internet Service Providers (ISPs).

Both terms will orientate this work for analysing the work of Chilean authorities during the implementation of IP FTA terms. If some of these critiques were explored during the legislative activity of Chilean authorities it would be possible to affirm that the Chilean experience shows that developing countries are concerned about the implementation of FTA. It will be clear that there is awareness about the problematic issues involved with IP terms. On the contrary, if criticisms highlighted by this work were never part of the legislative discussion, then it would be possible to affirm that FTA implementation does not represent a space for making IP FTA standards compatible with developing countries domestic interests.[18]

This work will look at the legislative Chilean activity because this entity is the one entitled to implement FTA terms. It is important to have clarity about the role that the legislature exercises during the negotiation and ratification of a treaty. According to the Chilean Constitution, the President of the Republic is the national authority in charge of negotiating and ratifying treaties in concordance with the interests of the country.[19] Thus, the Executive power defines the content of a Treaty (if it is possible to negotiate those terms) and the Parliament has nothing to do during the process. The only legal faculty of the National Congress consists of approving or rejecting the treaty before its ratification.[20] During this procedure the Parliament analyses the treaty as a whole, without having the opportunity to discuss particular terms in order to change its content. Furthermore, the only contribution that the National Congress can make in relation to treaties is suggesting the possibility of reserving some terms or making interpretative declarations.[21] Thus, it is not possible to expect the National Congress to exercise faculties that go beyond its competence. The purpose of the implementation is to incorporate FTA regulation into national law, a process that could consider the adaptation of those terms with the domestic reality without changing its content. This work will analyse all arguments discussed during the implementation of the FTA, which includes general debates in the Senate, the Chamber of Deputies and the participation of civic organisations that took part in special commissions integrated by members of the Parliament.

If there is interest in knowing which role the Chilean Executive played during the negotiation of the FTA signed with the United States, an article by Pedro Roffe titled

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[18] FM Abbot, see note 11 above, at 20.

[19] Art 32 n 15, Political Constitution of the Republic of Chile.

[20] Art 54 n 1, Political Constitution of the Republic of Chile.

[21] *Ibid.*

"Bilateral Agreements and a TRIPS-plus World: the Chile-USA Free Trade Agreement" shows the efforts made by the Ministry of Foreign Affairs during the negotiation of the Agreement in order to defend the incorporation of some ambiguous terms into the FTA. This ambiguity allows Chilean authority to study the incorporation of those terms without having the pressure of accepting a detailed proposition from the US. It should be particularly highlighted that there was the avoidance of an explicit obligation to protect plants under the patent system, creating only the obligation to undertake reasonable efforts to develop and propose legislation for the protection of that material, within a period of four years.[22]

In the case of the US, the negotiation and implementation of FTAs requires the coordination of both the President and the Congress. According to the US Constitution, the Congress has authority over foreign trade but the President is the one entitled to negotiate international treaties.[23] To avoid possible interference between these authorities the Trade Promotion Authority (TPA) was approved. This regulation coordinates the attributions of both authorities in the sense that the President is entitled to present to the Congress a trade implementing legislation that should be accepted without amendment as long as the Congress is consulted during FTA negotiations.[24] This mechanism, also characterised for being more expeditious, was used for the negotiation and implementation of the FTA agreed with Chile.[25]

2. Critical IP Terms Contained in the FTA Signed between Chile and the US

The FTA signed with the US is not the only Chilean treaty of this nature that regulates IP issues. Chile has signed at least fifteen FTAs that regulate IP matters in different ways.[26] However, the treaty signed with the US is notable because not only contains a specific chapter about this topic but this is by far the most comprehensive text on IP issues. The text contains twelve long and complex articles about trademarks, geographical indications, copyright and related rights, patents, enforcement, and others.[27]

In the following pages, two critical terms of the FTA signed between Chile and the US will be examined. These terms are the following: (1) Protection of undisclosed information, and (2) Limitations on liability for Internet Service Providers (ISPs). These terms were selected for different reasons. First, one provision is a TRIPS Plus term which means that it establishes higher standards than TRIPS. However, this term is not the only provision in the treaty that has this characteristic. For instance, article 17.9.6 of the FTA between Chile and the US regulates time compensation in case of

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[22] P Roffe, "Bilateral Agreements and a TRIPS-plus world: The Chile-USA Free Trade Agreement" (2004) available at http://www.quno.org/geneva/pdf/economic/Issues/Bilateral-Agreements-and-TRIPS-plus-English.pdf (accessed 9 Jul 10) 1-56, at 10, 20; Art 17.9, FTA Chile-USA.

[23] JF Hornbeck and WH Cooper, "Trade Promotion Authority (TPA) and the Role of Congress in Trade Policy" (2011) available at www.fas.org/sgp/crs/misc/RL33743.pdf (accessed 25 Apr 12), at 2.

[24] *Ibid*, 1.

[25] *Ibid*, 7.

[26] Art 3.11, FTA Chile-Panama; Art 106, 111 FTA Chile-China; Art 9.6.3 (b) (i), 9.10.5, FTA Chile-Colombia; Art 11.6, 11.10, FTA Chile-Peru; Title VI, FTA Chile-Mercosur; Ch 16, FTA Chile-Korea; Ch 4, FTA Chile-EFTA; Ch 10, FTA Chile- New Zealand, Singapore and Brunei; Ch 13, FTA Chile-Japan; Ch 15, FTA Chile-Mexico; Ch 15 FTA Chile-Centroamerica; Title VI, FTA Chile-EU; Ch 17, FTA Chile-Australia; Art 170, FTA Chile-EU.

[27] Arts 17.2, 17.4, 17.5, 17.6, 17.7, 17.9, 17.11, FTA Chile-USA.

delays in granting a patent, also known as extension of patent term. The extension is considered to go beyond TRIPS content because it can extend patents exceeding the twenty years of protection imposed by TRIPS.[28] Second, these terms were produced the most debate during their implementation so it is extremely interesting to analyse the arguments about them. Third, following the continental tradition, the IP Chilean regulation distinguishes between intellectual and industrial property law. The two selected terms give a sample of each of these laws. The protection of undisclosed information is related to patent regulations, an aspect of industrial property law, while limitations on liability for Internet Service Providers (ISPs) is connected with the author's rights, an area of intellectual property law.

Both terms will be considered under the same structure. First, a summary of the regulation object of the analysis contained in the FTA will be presented. Second, criticisms that affect those terms will be described. Third, the discussion about the implementation of those terms by the Chilean National Congress will be analysed. Fourth, some observations in relation to the implementation and Parliamentary discussion of the critical term will be developed. As explained above, these discussions are relevant when checking if the Chilean implementation of the FTA signed with the US constituted an opportunity to balance the content of the treaty with possible domestic interests.

2.1. Protection of Undisclosed Information

2.1.1. FTA Regulation

Article 17.10.1 of the FTA between Chile and the US regulates the protection of undisclosed information within the following title: "Measures Related to Certain Regulated Products."

The protection consists of a prohibition. The FTA says that,

> [I]f a Party requires the submission of undisclosed information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product which utilizes a new chemical entity, which product has not been previously approved, to grant a marketing approval or sanitary permit for such product, the Party shall not permit third parties not having the consent of the person providing the information to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information.

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[28] Art 33, TRIPS; G Krikorian, "New Trends in IP Protection and Health Issues in FTA Negotiations" in B Coriat, *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access* (Cheltenham: Edward Elgar Publishing, 2008) 52-77, at 56. See also, J Kuanpoth, "Negotiations toward a Free Trade Area: US Demands for Greater IPR Privileges", available at www.grain.org/rights_files/jakkrit_article_01.pdf (accessed 8 Jul 2010), at 6; Oxfam, "Free Trade Agreement Between the USA and Thailand Threatens Access to HIV/AIDS Treatment" (2004) available at http://www.oxfam.org/en/policy/briefingnotes/bn_USThai_FTA__HIVAIDS (accessed 5 Jul 10), at 9.

Protection lasts at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product. Finally, the FTA term includes an exception to this regulation consisting of the necessity of protecting the public.

2.1.2. Criticisms that Affect this Regulation

The protection of undisclosed information normally has the purpose of avoiding problems of unfair competition that could arise regarding the use of secret information that has commercial value as long as it remains undisclosed.[29] In this case, protected data is submitted for the registration of a medicine to be secured by a patent, which generally is the result of substantial research and investment.[30] If patent protection fails, the originator will know that the data of the product will be protected against generic competitors that would like to copy the drug.[31]

This protection is not uncontroversial.

First, this regulation contains conditions that go beyond the minimum standards required by TRIPS, transforming its content in a TRIPS Plus term.[32] TRIPS regulation about this topic is applicable only to cases of unfair commercial use, and it also requires the existence of considerable effort to obtain the data. The FTA does not limit the application of this protection to cases of unfair non-commercial use and there is no requirement of a considerable effort.[33] The real problem is that the FTA creates a prohibition not only over third parties but also regarding public agencies, because prohibits health authorities from using the information that they have available to grant marketing approval or the sanitary permit required by a third party. In other words, a third party cannot rely on the information that sanitary authorities have regarding a pharmaceutical or agricultural chemical product. In contrast, TRIPS regulations only affect third parties and have no impact on the use that public agencies can do with the information. That is why some authors say that FTA protection of undisclosed information creates monopolies that constitute an obstacle for the registration and marketing approval of generic medicines.[34] As a consequence, this protection affects generic competition by increasing the price of medicines.[35] For instance, a study developed by Oxfam explained that the enforcement of data exclusivity terms contained in TRIPS Plus terms implemented by Jordan "has delayed generic competition for 79 per cent of medicines newly launched by 21 multinational

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[29] WTO, available at http://apps.who.int/medicinedocs/en/d/Jh1459e/6.9.html# Jh1459e.6.9 (accessed 27 Apr 12).
[30] P Roffe and M Santa Cruz, "Intellectual Property Rights and Sustainable Development: A Survey of Major Issues" (2007) available at www.eclac.cl/publicaciones/xml/7/32167/W161.pdf (accessed 27 Apr 20), at 29.
[31] *Ibid.*
[32] NP de Carvalho, *The TRIPS Regime of Antitrust and Undisclosed Information* (The Hague: Wolters Kluwer, 2008), at 320, 322. See also S Matilal, "Do Developing Countries Need a Pharmaceutical Data-exclusivity Regime?" (2010) *European Intellectual Property Review* 268-276, at 271.
[33] R Rajkumar, see note 11 above, at 466.
[34] Oxfam, "How TRIPS-plus Intellectual Property Rules in the US-Jordan FTA Affect Access to Medicines" (2007) http://www.oxfam.org/en/policy/bp102_jordan_us_fta (accessed 27 Apr 12), at 8.
[35] *Ibid*.

pharmaceutical companies between 2002 and mid-2006, that otherwise would have been available in an inexpensive, generic form".[36]

Second, this regulation is problematic from the point of view of issuing compulsory licences.[37] Compulsory licence is a sensible subject within the scope of patent law. Developing countries have serious difficulties accessing appropriate medicine because prices are too high and resources are limited. "There is an emerging consensus that drug pricing and patents have at least something, if not everything, to do with health outcome disparities."[38] Some studies have confirmed that almost 40,000 people per day die in developing countries from illnesses that could be treated with medication available on the market.[39] Within this context, TRIPS regulation of patent law has tried to find a balance between the interests of rights holders and consumers. This balance was reflected in the regulation of compulsory licences.[40] Additionally, the Doha Declaration reaffirmed this intention of balancing interests, establishing that TRIPS should be interpreted in a way that protects and promotes access to medicines and public health.[41]

The protection of clinical data affects compulsory licences indirectly because of the extra costs that the development of the test incurs.[42] As explained above, protection of undisclosed information forces any person who applies for marketing approval or sanitary permission to present their own data, which requires the development of expensive research.[43] There is also a problem of time: generic producers would not

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[36] *Ibid.*

[37] P Roffe, "Acuerdos Bilaterales en un Mundo ADPIC – Plus: El Tratado de Libre Comercio entre Chile y Estados Unidos de Norteamérica" available at http://www.quno.org/geneva/pdf/economic/Issues/Bilateral-Agreements-and-TRIPS-plus-Spanish.pdf, (accessed 2 Sept 10), at 28.

[38] R Rajkumar, see note 11 above, at 439.

[39] G Holguin Zamorano, "TLC y Salud: La Verdad, Las Concesiones Hechas a las Multinacionales Farmacéuticas, Su Impacto Sobre el Indice de Precios y el Acceso a los Medicamentos, y Qué Podría Hacer el Congreso Nacional para Mitigarlos" (2007) available at www.comunicacionpositiva.org/documentos/tlcysalud.pdf, (accessed 2 Sept 10), at 11.

[40] Article 31 TRIPS. See also, K Paas, "Compulsory Licensing under the TRIPs Agreement: A Cruel Taunt for Developing Countries?" (2009) *European Intellectual Property Review* 609-613, at 609.

[41] See http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm (accessed 1 Jul 10); G O'Farrell, "One Small Step or One Giant Leap towards Access to Medicines for All?" (2008) *European Intellectual Property Review* 211-215, at 211-212. See also, H Jin, "Reality and Potentiality: Compulsory Patent Licensing in China from a Comparative Perspective" (2009) *European Intellectual Property Review* 93-100, at 95.

[42] Alliance for Responsible Trade (ART), Alianza Chilena por un Comercio Justo y Responsable – ACJR, "Declaración Conjunta sobre el Tratado de Libre Comercio Propuesto entre Estados Unidos y Chile" available at http://www.derechos.org/nizkor/chile/doc/tlc1.html, (accessed 14 May 10). The criteria of distinguishing FTA terms that affects compulsory licences directly or indirectly was defined by B Mercurio, "TRIPS Plus Provisions in FTAs: Recent Trends" in L Bartels and F Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (New York: Oxford University Press, 2006) 215-237.

[43] EM Cowley, "The Right to Health: Guatemala's Conflicting Obligations under the Central American Free Trade Agreement and the International Covenant on Economic, Social, and Cultural Rights" (2008) *Michigan State University Journal of Medicine and Law* 227-249, at 240. See also, P Roffe, see note 22 above, at 25-26.

have enough time to repeat tests to obtain marketing approval during national emergencies.[44]

Other exceptional criticisms affect the protection of undisclosed information, such as the waste of resources and the ethical problems related with risking the life and causing suffering of animals and humans through the exercise of these tests, especially considering that the safety and efficacy of the product was already determined.[45]

2.1.3. Chilean National Congress Discussion about the Protection of Undisclosed Information

The protection of undisclosed information was originally discussed in a Bill that implemented TRIPS terms into the Chilean regulation.[46] The incorporation of this term was not an initiative of the Executive but a proposition of two members of the Parliament.[47] After almost five years of discussion, the original terms were modified in order to include some aspects that made it compatible with US FTA content. Therefore, in order to analyse the Chilean National Congress discussion about the protection of undisclosed information it is necessary to distinguish two periods.

2.1.3.1. Protection of Undisclosed Information under TRIPS Implementation

As explained above, this discussion was originated during the implementation of TRIPS. This situation explains some differences between the original project in comparison with FTA content.[48] For instance, the original Bill did not determine a clear period of time for the application of this protection.

In the following pages the main observations about the approval of the protection of undisclosed information will be discussed.

The first organisation that warned about this protection was a pharmaceutical corporation named Recalcine. Via its representative, Recalcine explained that it had some concerns about this protection because it could increase the prices of medication and limit access to essential pharmaceutical products, thereby producing a negative impact on public health.[49] Recalcine's representative explained that the technical

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[44] See also, Oxfam, see note 29 above, at 7; R Rajkumar, see note 11 above, at 465, 468; G O'Farrell, see note 42 above, at 214; D Matthews, "TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements" (2005) *European Intellectual Property Review* 420-427, at 426.

[45] R Rajkumar, see note 11 above, at 465; NP de Carvalho, see note 32 above, at 262.

[46] This discussion was initiated 20 Oct 1999, with the presentation of the Bill No 2416-03, an initiative of the Executive. The Bill was finally approved by the regulation No 19.996 (11 Mar 2005). Protection of Undisclosed information is regulated in art 89, Law 19.039.

[47] These members of the parliament were Senator Núñez and Mr Tuma. Their proposition was included during the first report of the Commission of Economy, 8 Aug 2001. The text is available at http://www.bcn.cl/histley/periodos?p=2005 (accessed 5 Jul 10), at 160.

[48] House of Representatives , First Report Commission of Economy (8 Aug 2001) Session 18, Legislature 345, at 160.

[49] P Rodríguez, First Report Commission of the Treasury, House of Representatives (9 Nov 2001), Session 18, Legislature 345, at 281.

complexity, professional requirements, highly specialised equipment, and lack of resources created difficulties in determining procedures developed by international providers for the creation of products.[50]

The representative of the Pharmaceutical Industry of Chile (*Cámara de la Industria Farmacéutica de Chile*) presented another point of view. This organisation argued that the omission of the protection of undisclosed information from the national regulation constituted a serious problem, considering that the commercial and economic value of this information has international recognition.[51] The National Association of Manufacturers and Importers of Phytosanitary Agriculturists Products (*Asociación Nacional de Fabricantes e Importadores de Productos Fitosanitarios Agrícolas AG* (AFIPA)) agreed with this observation. They maintained that undisclosed information is the result of long and costly studies, which are essential for the commercialisation of certain products, and from that point of view its protection is justified.[52]

Some of these observations were included in the debate developed between the members of the Parliament. During the analysis of this Bill there was a discussion about a public campaign that was flourishing in the press, which declared that the approval of this term would dramatically increase prices of pharmaceutical products.[53] This declaration was based on a study from the Centre of Applied Research for the Development of Company (*Centro de Investigación Aplicada para el Desarrollo de la Empresa* (CIADE)).[54] The Economy Commission of the members of the Parliament, after analysing a report of the National Department of Industrial Property, clarified that they decided to continue with the discussion of the Bill because there were serious doubts about CIADE study and, according to the National Department, no price increases would affect pharmaceutical products.[55]

2.1.3.2. Protection of Undisclosed Information Complemented by FTA Terms

Some indications modified the Bill during the session of the Economy Commission of the Senate, on 21 January 2004. The Executive presented a modification to the original proposal about protection of undisclosed information, in order to include some aspects of the FTA between Chile and the US, which was already approved.[56] For instance, a time limit was proposed for the protection under the FTA.[57]

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[50] *Ibid,* 282.

[51] J Véliz Pollier, New First Report Commission de Economy, House of Representatives (16 Jan 2002), Session 28, Legislature 345, at 309.

[52] M Soto, First Report Commission of Economy, Senate (27 Aug 2002), Session 26, Legislature 347, at 719.

[53] This intervention was made by the member of Parliament Mr José Miguel Ortiz.

[54] Discussion House of Representatives, Legislature 345 Session 32. General Discussion. It was approved generally, at 502-503.

[55] JM Ortiz, Member of Parliament. Discussion House of Representatives, Legislature 345 Session 32. General Discussion. It is approved generally, at 503.

[56] Second Report Commission of Economy, Senate (29 Jan 2004), Session 07, Legislature 351, at 807.

[57] *Ibid*, 887.

The discussion of this proposition was focused on finding mechanisms that would restrict the application of this protection to make it compatible with the need for having access to medicine. The Executive proposed three mechanisms for guaranteeing this access. First, the protection would be given if undisclosed data was the object of reasonable measures in order to keep it as undisclosed, including making access to the information difficult for people that work in that area.[58] This was considered a necessary objective for national authorities to define the undisclosed nature of the data.[59] Second, a definition was proposed for the notion of a "new chemical entity". One of the requirements for considering if a chemical entity was a new one is that this element was not registered in any sanitary permit given by the Public Health Institute or the Agriculturist and Cattle Service. Also, the entity would be considered new if it had not been commercialised in the national territory.[60] The purpose of this requirement was avoiding the application of the protection to entities that already exist but for which new uses were discovered.[61] Third, the Executive identified particular cases where no legal protection to undisclosed information would be assured. Some of these hypotheses apply when the owner of the test data has developed conducts or practices declared contrary to free competition in direct relation to the utilisation or exploitation of this information; the decision of the competent national authority based on reasons of public health, national security, non-commercial public use, national emergency; the pharmaceutical or chemical-agricultural product is subjected to a compulsory license; and failure to commercialise the product within twelve months from the date of grant of the sanitary registration.[62]

The Executive also proposed as a requirement the existence of a considerable effort to obtain the data in order to get a protection for undisclosed information.[63] According to the Director of the Public Health Institute (*Instituto de Salud Pública*) this requirement satisfied TRIPS standards, allowing that successive applications do not support a new application on efforts done on the first one.[64] There were some critiques about the subjectivity involved in the application of this requirement.[65]

This new requirement was discussed during a session of the Senate, and was discarded because of its subjectivity.[66]

At the end, the Congress approved the regulation of undisclosed information, including the Executive's three suggestions for guaranteeing access to medicine, a

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[58] New Second Report Commission of Economy, Senate (17 Jun 2004), Session 07, Legislature 351, at 1109-1110.

[59] *Ibid.*

[60] *Ibid*, 1111.

[61] *Ibid*.

[62] *Ibid,* 1111-1112.

[63] *Ibid*, 1109.

[64] R Salinas, at New Second Commission of Economy, Senate (17 Jun 2004), Session 07, Legislature 351, at 1109.

[65] Senator JM Orpis, at New Second Report Commission of Economy, Senate (17 Jun 2004), Session 07, Legislature 351, at 1109.

[66] Discussion Senate, Legislature 351. Session 12 (14 Jul 2004). Particular discussion, approved with modifications, at 1209.

definition about that new active chemical entity means, and the hypothesis for no protection identified above.

2.1.4. Observations about the Chilean National Congress Discussion

After analysing the Chilean National Congress discussion about the creation of a term for the protection of undisclosed information, it is possible to highlight four main points.

2.1.4.1. The Problem of Issuing Compulsory Licenses Analysed by the National Authorities

Unfortunately, there was no particular discussion about the critical relation that could be developed between the protection of undisclosed information and compulsory licenses during the parliamentary implementation of the FTA. This does not mean that there was no awareness of this problematic issue. The Executive incorporated a special modification into the Bill in order to guarantee that no protection would be given to undisclosed information if the product is the subject of a compulsory licence.[67] The Parliament accepted this new term without modifying it. Thus, now is part of the national regulation.[68] This regulation shows that at least the Executive recognises some of the fears that affected the implementation of the FTA, assuring the application of obligatory licences.

It is pity that there is no register of the discussion or criteria that the Executive analysed in order to identify this particular exception that benefits compulsory licences. It is possible at least to highlight an argument given by the Department of Industrial Property during the parliamentary discussion in relation to the incorporation of the exception to the protection consisting in the failure to commercialise the product within twelve months from the date of grant of the sanitary registration.[69] According to this Department, which depends on the Ministry of Economy, that exception was relevant because,

> It will avoid that the absence of commercialization of a registered product could block the access of the population to particular medicine agricultural-chemical products, because it is consider that health is a superior hierarchical good in comparison to the economic benefit.[70]

This recognition of the importance of health by national authorities was also probably the motivation for supporting compulsory licences, by the identification of this item as an exception to the protection of undisclosed information.

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[67] New Second Report Commission of Economy (n 58), at 1111-1112.

[68] Art 91(c), Law No 19.039.

[69] Art 91(d), Law No 19.039.

[70] New Second Report Commission of Economy (n 58), at 1111-1112. My translation. The original text is: *evitará que el registro seguido de la no comercialización bloquee el acceso de la población a determinados medicamentos o productos químico-agrícolas, porque se estima que la salud es un bien de jerarquía superior al beneficio económico.*

2.1.4.2. Chilean Implementation of the Protection of Undisclosed Information does not Satisfy US Expectations

After considering the efforts made by Chilean national authorities in order to resolve the problematic relationship between the protection of undisclosed information and compulsory licences, it is important to analyse the reaction of the US.

Since 2005 the US included Chile on the *Watch List, Special 301 Report of the Office of the United States Trade Representative* (USTR), arguing, among other aspects, that "issues of substantial concern include the inadequate protection against unfair commercial use of undisclosed test".[71] This argument has been maintained in subsequent reports including those that from 2007 included Chile in the Priority Watch List.[72] The US report does not specify the reasons for considering that the Chilean protection against undisclosed information is inadequate. Another report of the Pharmaceutical Research and Manufacturers of America (PhRMA), which was used as an important source for the development of the Special 301 Report, manifest and explains the particular concern about this issue. According to PhRMA,

> Chile's data exclusivity norms impose grounds for revocation of the right to exclusive use that are not authorized by TRIPS or Chile's bilateral trade agreements with the EU and the United States…These grounds for revocation significantly weaken the applicability and usefulness of the available exclusivity.[73]

This declaration shows the negative impact that the compulsory licence exception (and also the others) generates on the Pharmaceutical sector. This negative impact is also clearly addressed by the USTR.

It is important to highlight that there are other organisations that value Chile's efforts to find a balance between this exclusive right and exceptions focused on public health concerns. From this perspective, Chilean regulation should be considered as an important model for other countries.[74]

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[71] Special 301 Report (2006) available at http://www.keionline.org/sites/default/files/ustr_special301_2006.pdf (accessed 7 Jul 10), at 34. See also, Special 301 Report (2005) available at http://www.keionline.org/sites/default/files/ustr_special301_2005.pdf (accessed 7 Jul 10), at 38.

[72] Special 301 Report (2010) available at http://www.ustr.gov/webfm_send/1906 (accessed 6 Jul 10) at 25-26. See also, Special 301 Report (2009) available at http://www.keionline.org/sites/default/files/ustr_special301_2009.pdf (accessed 6 Jul 10), at 18; Special 301 Report (2008), available at http://keionline.org/sites/default/files/ustr_special301_2008.pdf (accessed 6 Jul 10), at 35; Special 301 Report (2007), available at http://www.keionline.org/sites/default/files/ustr_special301_2007.pdf (accessed 6 Jul 10), at 25.

[73] Pharmaceutical Research and Manufacturers of America (PhRMA) "Special 301 Submission 2009" available at www.ipophil.gov.ph/ipenforcement/phrma_submission.pdf (accessed 7 Jul 10), at 119; PhRMA "Special 301 Submission 2006", available at http://www.cptech.org/ip/health/trade/2005phrma301.pdf (accessed 7 Jul 10), at 176.

[74] Consumer Project on Technology, "Response to 2006 PhRMA 'Special 301' Submission for Chile", available at http://www.cptech.org/publications/cptech-response-phrma301chile.doc (accessed 7 Jul 10) at 3.

Furthermore, this opposition of the US to the Chilean regulation is not an easy thing to deal with. The Executive has a different vision to the one sustained by the US. The Chilean government thinks that they satisfied FTA standards of protection of undisclosed information. Thus, any disagreement should be resolved through the Dispute Settlement mechanism identified in the treaty.[75]

2.1.4.3. The Impact of the Protection of Undisclosed Information on Prices was the Main Concern Debated in the Parliament

It is interesting to note that Chilean parliamentary discussions show different concerns about the protection of undisclosed information to the ones identified by legal scholars.

From a developing country perspective, most of the analysis of undisclosed information is based on the problematic relationship between that protection and compulsory licences. This discussion could show that developing countries are represented as countries that challenge public health problems providing pharmaceutical products. The experience of AIDS in Brazil and Thailand could support this point of view.[76]

The discussion developed in the Chilean National Congress shows another perspective on the way that a developing country deals with public health. The interventions of some senators and representatives of local pharmaceutical industries show clear concerns about the effect that the protection of undisclosed information could produce on the prices of pharmaceutical products.[77] The unusual issue in this case is that the impact on prices seems to be considered as a general problem of access to medicine, but the role that the state should play in relation to it was not debated. Thus, there seems to be a non-interventionist position of the state regarding the pharmaceutical market. This position makes sense considering that Chile is a developing country with one of the most open markets in the world and that from the seventies has been promoting structural reforms to the benefit of trade liberalisation.[78] This liberal approach to the market impacted the perspective from which the protection to undisclosed information was analysed. The implementation was

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[75] Report Commission of Economy, House of Representatives (18 Jul 2006), Session 49, Legislature 354, at 27. This discussion was initiated 2 May 2006, with the presentation of Bill No 4180-03 by the Executive. The Bill was finally approved by regulation No 20.169, 26 Jan 2007.

[76] See D Matthews, "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?" (2004) 7-1 *Journal of International Economic Law* 73-107, at 81. See also, SK Sell, "TRIPS-PLUS Free Trade Agreements and Access to Medicine" (2007) 28 *Liverpool Law Review* 41-75, at 72; R Rajkumar, see note 11 above, at 443.

[77] First Report, Commission of the Treasury, House of Representatives (9 Nov 2001), Session 18, Legislature 345, at 281. Also, Discussion House of Representatives, Legislature 345 Session 32, General Discussion. It is approved generally, at 502-503.

[78] C Furche, "Red Hot Chile Peppers the Globe with FTAs" available at http://www.austrade.gov.au/Red-Hot-Chile-peppers-the-globe-with-FTAs/default.aspx (accessed 7 Jul 10). See also, O Facusse, *Chile and the U.S.: Why a FTA?,* available at www.pecc.org/resources/doc_view/6-chile-and-the-united-states-why-a-fta (accessed 7 Jul 10), at 11.

controversial, not necessarily because of the problem of compulsory licences, but because of its existence in itself and its impact on the pharmaceutical market.[79]

2.1.4.4. Executive Intention of Including the Requirement of Considerable Effort for the Protection of Undisclosed Information Creates Doubts about Limits for Implementing FTA Terms

The discussion developed in relation to the requirement of considerable effort for the protection of undisclosed information highlights an interesting aspect of the implementation process.

As explained above, the FTA regulation about undisclosed information was qualified as a TRIPS Plus term because there was no requirement for a considerable effort in order to grant protection to this particular data.[80] The Chilean Executive presented a modification to the Bill incorporating this notion of considerable effort. The Minister of Economy, Promotion and Reconstruction argued that it was convenient to incorporate this new notion to patent regulation because it represented an assimilation of TRIPS industrial property standards.[81] Indeed, considerable effort is a notion that satisfies TRIPS standards. The interesting aspect of this proposition is that its incorporation could divert national regulations away from the FTA standards which were negotiated and approved by Chilean authorities. The question that then arises is about what limits countries should respect to implement FTA terms when considering domestic interests. In this particular case there was no further conflict because the National Congress did not approve this modification but the question remains.

2.2. Limitations on Liability for ISPs

According to Pedro Roffe, limitations on liability for ISPs were extensively discussed during the FTA negotiations; in particular because it was not a common regulation for an FTA at that time. This issue was supposed to be part of the FTA as a side letter but in the end it was included in the IP chapter.[82]

2.2.1. FTA Regulation

The FTA's regulation about enforcement of intellectual property rights includes a detailed term in relation to limitations on liability for ISPs. In the following paragraphs, the four main aspects of this regulation will be explained.

First, the FTA establishes that liabilities limitations will be apply only if ISP develops the following functions (i) transmit, rout, or provide connections for material without

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[79] It is interesting to notice that 49% of the pharmaceutical products that are consumed in Chile are products from outside the country. See http://www.mer.cl/modulos/catalogo/Paginas/2010/07/07/MERSTNA005CC0707.htm (accessed 7 Jul 10).

[80] NP de Carvalho, see note 32 above, at 320, 322. See also, S Matilal, see note 32 above, at 271; R Rajkumar, see note 11 above, at 466.

[81] Discussion, Senate, Legislature 351. Session 12 (14 Jul 2004), Particular Discussion, approved with modifications, at 1209-1210.

[82] P Roffe, see note 22 above, at 45.

modification of its content; (ii) cache carried out through an automatic process; (iii) storage at the direction of a user of material residing on a system or network controlled or operated by or for the provider, including e-mails and its attachments stored in the provider's server, and web pages residing on the provider's server; and (iv) refer or link users to an online location by using information location tools, including hyperlinks and directories. These limitations shall apply only where the provider does not initiate the transmission, or select the material or its recipients including other particular requirements per function.[83]

Second, it determines the obligation of each party to establish a notice and takedown procedure for effective notifications of claimed infringement, and effective counter-notifications by those whose material is removed or disabled through mistakes or misidentification. The regulation includes certain minimum aspects that should be part of the procedure, such as written communication, sign by an authorised representative of the rights holder, and containing information that is reasonably sufficient to enable the service provider to identify and locate material that the complaining party claims in good faith to be infringing and to contact that complaining party.[84]

Third, the treaty exempts from liability any ISP that removes or disables access to material in good faith based on claimed or apparent infringement. To obtain this benefit, the ISP must take reasonable steps to notify the supplier that it has removed or disabled material promptly. If the supplier makes an effective counter-notification and is subject to jurisdiction in an infringement suit, the ISP should restore the material online unless the original notifying party seeks judicial relief within a reasonable time.[85]

Fourth, it prescribes that each party should determine an administrative of judicial procedure for obtaining expeditiously information to identify the alleged infringer from an ISP. This action benefits the copyright owner that gave effective notification of claimed infringement.[86]

2.2.2. Criticisms that Affect this Regulation

The creation of limitation on liability for ISPs assures immunity for providers. They play an important role in the overall infrastructure of the Internet and the impracticalities that affect expectations to monitor or regulate the content that they host on their servers.[87] This restriction on liability could also be considered as a tool for encouraging the expansion of the Internet and the facilitation of access to knowledge and culture because it avoids a monitoring function for ISPs.[88] This

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[83] Art 17.11.23(b) i, ii, iii, and iv, FTA Chile-USA.

[84] Art 17.11.23(f), FTA Chile-USA.

[85] Art 17.11.23(g), FTA Chile-USA.

[86] Art 17.11.23(h), FTA Chile-USA.

[87] C Lim Saw and WH Koh, "Does P2P have a Future?: Perspectives from Singapore" (2005) *International Journal of Law and Information Technology* 413-436, at 418.

[88] Electronic Frontier Foundation, "Internet Service Provider Safe Harbors and Expedited Subpoena Process in the US Digital Millennium Copyright Act and Recent Bilateral Free Trade Agreements", available at www.eff.org/files/filenode/FTAA/ISP_june05.pdf (accessed 20 Jul 10), at 1; L Edwards, "The Fall and Rise of Intermediary Liability Online" in L Edwards and C Waelde (eds) *Law and the*

regulation allows ISPs to assist copyright owners in the enforcement of their digital rights.[89]

The US already has a limitation on liability for ISP systems in its domestic regulation, which is almost identical to the one incorporated in the FTA. There are three principal critiques of this regulation.

First, there are criticisms about the system of notice and takedown. The procedure of this system is considered to be inadequate because it allows people to use it not only for copyright protection but also as a censorship tool that can silence legitimate criticisms expressed on the web.[90] Thus, these provisions could be used to suppress content on the Internet arbitrarily. It is argued that this is a procedural problem because it does not conduct proper due diligence or provide reasonable evidence of infringement.[91] In comparison to other countries, the US regulation seems to give more protection to freedom of expression because it at least requires that the takedown notice must be given to content providers, providing them an opportunity to protest. Also, it contains strict rules that must satisfy this process of notice and the takedown. Rights holders or their representatives must produce the notice, and both must identify themselves using signatures.[92]

In the second place, ISP liability restriction is criticised because it is considered to affect the privacy rights of Internet users.[93] This effect is produced by the possibility for right holders to request ISPs to provide identification of an alleged infringer through an administrative procedure.[94] Subpoenas are issued to ISPs which are asked to match the IP address with a particular named individual so that lawsuits may be filed.[95] Is in this context that there are worries about potential influence that the US regulation can have on an international sphere through FTAs. US privacy standards are lower than other countries so it is relevant that its regulation satisfies some privacy concerns if it is to be used as an international standard.[96]

It is important to clarify that the FTA between Chile and the US allows the parties to establish administrative or judicial procedures for obtaining an infringer's information. This entitles Chile to decide which procedure is better in accordance with its domestic interests.[97]

Internet (Oregon: Hart Publishing, 2009) 47-88, at 61.

[89] GL Middleton, "Copyright Conundrum: Liability of ISPs for Online Copyright Infringement" (2005) available at www.acs.org.au/documents/public/crpit/CRPITV44Middleton.pdf (accessed 19 Jul 10).

[90] Electronic Frontier Foundation, see note 88 above, at 2, 4.

[91] GL Middleton, see note 89 above.

[92] L Edwards, see note 88 above, at 76.

[93] Australian Digital Alliance, "Australia-United States Free Trade Agreement" (2003) available at www.aph.gov.au/senate_freetrade/submissions/sub299.pdf (accessed 19 Jul 10), at 9. See also, GL Middleton, see note 89 above.

[94] P Roffe, see note 22 above, at 45.

[95] GL Middleton, see note 89 above. See also, MA Geist et al, "Copyright and Privacy: Through the Technology Lens" (2004) *The John Marshall Review of Intellectual Property Law* 242-265, at 246.

[96] MA Geist et al, see note 98 above, at 255.

[97] Art 17.11.23 (h). See P Roffe, see note 22 above, at 45. See also, Electronic Frontier Foundation, see note 88 above, at 8.

In the third place, ISP regulation in relation to copyright infringement produces doubt because it is considered a solution that does not solve the dilemma between technology and IP protection.[98] There is a particular concern because technology changes in response to efforts to regulate it and its global nature requires a global solution.[99]

2.2.3. Chilean National Congress Discussion about Limitations on Liability for ISPs

The limitation on liability for ISPs was discussed in a Bill presented by the Executive that had the purpose of changing IP Chilean regulation according to modern standards, including the implementation of FTA terms.[100] The discussion lasted three years and included the participation of a massive and interesting variety of organisations related to this topic. This was a very controversial regulation. Exceptional legislative instances were used by the Executive to try to incorporate certain FTA terms that were discarded by the Parliament even though they were part of the FTA. This was the regulation that benefits ISPs and that removes or disables access to material in good faith.

The parliamentary discussion was so extensive that this work will only present its main aspects in relation to the critiques that were identified above.

2.2.3.1. Information for the Identification of Alleged Copyright Infringers

During the sessions held in the National Congress, there was almost no discussion about the procedure for obtaining the identity of the alleged infringer. The Bill established that the faculty to obtain this information should be exercised through a judicial procedure.[101] This procedure is the same as the one created for denouncing the infringement of copyright material on the Internet. The Bill also declared that the availability of this information must respect the national regulation that protects personal data. This last requirement was finally changed for the protection of private life.[102]

The Director of the Law and Computer Science Association of Chile (*Asociación de Derecho e Informática de Chile*) and the Manager of Governmental and Political Subject for Latin America of Google highlighted the importance of requiring a judicial resolution for obtaining information that allows the right holder to identify the copyright infringer.[103] The adoption of this requirement makes the Chilean regulation comply with contemporary international standards.[104]

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[98] MA Geist et al, see note 98 above, at 248.

[99] *Ibid,* 247, 249.

[100] This discussion was initiated on 2 May 2007, with the presentation of Bill No 5012-03, an initiative of the Executive. The Bill was finally approved by the regulation No 20.435 (4 May 2010).

[101] Art 85T, Message of the President of the Republic (2 May 2007), Session 19, Legislature 355, at 40.

[102] Art 85S, Communication of Law to the Senate (10 Oct 2007), Session 58, Legislature 355. Senate.

[103] C Magliona, First Report Commission of Education, Senate (5 Dec 2007), Session 84, Legislature 355, at 319; P Less, First Report Commission of Education, Senate (5 Dec 2007), Session 84, Legislature 355, at 328.

[104] *Ibid.*

2.2.3.2. The Judicial System for the Notice and Takedown Regime

This topic was the most controversial issue of the parliamentary discussion. The original Bill established a judicial procedure for the notice and takedown regime. According to its text, the rights holder can present a prejudicial or judicial action if there is an infraction on the Internet that affects his or her rights.[105] These actions allow rights holders to ask for the application of specific measures against content providers, such as terminating specified accounts, taking reasonable steps to block access to a specific, online location, removing or disabling access to the infringing material, and other measures that a court may find necessary provided that such remedies are the least burdensome to the ISP and users or subscribers among comparably effective forms of relief.[106] It is important to note that this last measure was discarded during the parliamentary discussions and therefore not included in the final regulation.[107]

The Bill also determined that the court should decree these measures within forty-eight hours once the request was entered into the court.[108] This time limit was discarded during the parliamentary discussion so the final regulation says that the court will decree the requested measures without delay.[109]

In the following pages, the main points of controversy that were discussed about this regulation will be presented.

There were a lot of opinions against having a judicial procedure for the application of the notice and takedown regime. The following arguments were presented by representatives of a variety of organisations and parliamentarians: these manifest the problems of this system. (1) Judicial procedures would take too long and any infraction made in the virtual space requires quick measures if they are to be stopped;[110] (2) There is no equivalent of this judicial procedure on the international

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[105] Art 85R, Message of the President of the Republic (2 May 2007), Session 19, Legislature 355, at 38.

[106] Art 85S, Message of the President of the Republic (2 May 2007), Session 19, Legislature 355, at 39.

[107] See art 85R, Law No17.336.

[108] Art 85R, (n 105), at 38.

[109] Art 85P, Law No 17.336.

[110] A Marinovic, Representative of Association of Distributors of Video AG, and the Camera of Cinematographic Distributors AG (*Asociación de Distribuidores de Videogramas AG, y Cámara de Distribuidores Cinematográficos (CADIC*). First Report Commission of Economy, House of Representatives (4 Oct 2007), Session 83, Legislature, at 153,154; F Chahuán, Member of the Parliament, Discussion House of Representatives. Legislature 355. Session 87 (10 Oct 2007), General Discussion. It is approved generally y en particular, at 223; F Silva, Representative of the Trade Union Association of Phonographic Producers (*Asociación Gremial de Productores Fonográficos de Chile)*, First Report Commission of Education, Senate (5 Dec 2007), Session 84, Legislature 355, at 317-318; K Ruiz, General Manager of the Trade Union Association for the Protection of the Intellectual Rights on Musical Phonograms and Video (*Gerente General de la Asociación Gremial para la Protección de los Derechos Intelectuales sobre Fonogramas y Videogramas Musicales (APDIF AG*.), First Report Commission of Education, Senate (5 Dec 2007), Session 84, Legislature 355, at 323-324; M Pérez, Vice-president of the Chilean Association of Companies of Technologies of Information *(Vicepresidente de la Asociación Chilena de Empresas de Tecnologías de Información AG.*), First Report Commission of Education, Senate (5 Dec 2007), Session 84, Legislature 355, at 331; O Gutierrez, Representative of Association of Distributors of Video AG (*abogado de la Asociación de Distribuidores de Videogramas AG),* First Report Commission of Education, Senate, 5 Dec 2007. Session 84, Legislature 355, at 336; R Velasco, Trade Union Association of Musical Publishers of

sphere;[111] (3) This system is incompatible with the commitment of the FTA signed with US;[112] (4) This system restricts the collaboration that ISPs are supposed to bring for the protection of copyright. There would be no incentive for them to develop a real collaboration with right holders because in order to take any measures they would wait for a judicial notification;[113] (5) There would be relevant monetary costs for rights holders in order to try to obtain any measure for the protection of their rights;[114] (6) This initiative would give extra work to the courts, which will not have the capacity for resolving the disputes. Thus, they would not be properly attendant;[115] (7) The procedure would establish more requirements than those that have been historically required by the Supreme Court. ISPs are currently responsible for copyright infringement if they do not remove or disable access to the infringing material when they know or could know about the existence of the illicit material;[116] and (8) From the point of view of the principle of legal security, there is no difference between a private and a legal notification for the application of a prejudicial measure. In both cases there is no legal certainty for the protection of copyright. Thus, it is not clear why there is an option favouring legal notification.[117]

Two alternatives were suggested in order to resolve the problems mentioned above. The first was the creation of an administrative procedure.[118] The second consisted of allowing an ISP to receive notifications directly from right holders while recognising legal effects to that notification.[119]

Arguments in favour of the judicial procedure were the following: (1) This judicial procedure is coherent with the national legal tradition;[120] (2) Constitutional limitations made it impossible to apply the regime established in the US in Chile. This is because it is not possible to restrict property, or to restrict other rights guaranteed by the Constitution in favour of an imputed person, unless there is a previous judicial

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Chile, (*Asociación Gremial de Editores Musicales de Chile*), First Report Commission of Education, Senate (5 Dec 2007), Session 84, Legislature 355, at 357.

[111] F Chahuán, see note 110 above, at 223-224; F Silva, see note 110 above, at 317-318.

[112] F Chahuán, see note 110 above, at 223-224; F Silva, see note 110 above, at 317-318; M Pérez, see note 110 above, at 331.

[113] F Chahuán, see note 110 above, at 223-224; F Silva, see note 110 above, at 317-318; R Velasco, see note 110 above, at 357.

[114] A Marinovic, see note 110 above, at 154; F Chahuán, see note 110 above, at 223-224; F Silva, see note 110 above, at 317-318

[115] F Silva, see note 110 above, at 317-318.

[116] R Velasco see note 110 above, at 357.

[117] A Chadwick, Senator, Second Report Commission of Economy, Senate (1 Sept 2009), Session 45, Legislature, 357, at 661.

[118] A Marinovic, see note 113 above, at 154; E Jaramillo, Member of the Parliament, Discussion House of Representatives, Legislature 357, Session 82 (29 Sept 2009), Discussion only. Amendments were rejected. E Jaramillo, Member of the Parliament, Discussion House of Representatives, Legislature 357, Session 82 (29 Sept 2009), Discussion only. Amendments were rejected, at 822.

[119] K Ruiz, see note 110 above, at 323-324; O Gutierrez, see note 113 above, at 336; A Chadwick, see note 117, at 656.

[120] C Magliona, see note 103 above, at 327.

resolution;[121] (3) The requirement of a legal notification to an ISP satisfies the principle of legal security, because the determination of the illicit nature of certain objects must be reserved to Courts.[122] Thus, the possible abuse that right holders could do to the system whenever they ask an ISP to takedown licit material is limited;[123] and (4) Recognising legal effects to private notifications could affect the user's right to have access to information because an ISP would be obliged to takedown the material, which is not necessarily illicit.[124]

2.2.3.3. ISP Removes or Disables Access to Material in Good Faith

The original Bill incorporated a term that had the purpose of giving protection to an ISP that removes or disables access to material in good faith. This term was almost identical to the one regulated in the FTA.[125] During the parliamentary discussion this proposition was modified in order to establish a term of ten days for the ISP to counter-notify content providers and only after that term, those entities would be entitled to remove or disable access to material.[126] This term was also the focus of intensive debate and was finally discarded by the Parliament. The following pages show the main arguments discussed during the parliamentary sessions.

Negative comments about this regulation were the following: (1) This faculty allows ISP to act as a censor of work in order to avoid a legal notification;[127] (2) An ISP should be able to cooperate with copyright right holders only if there is a previous legal notification;[128] (3) This regulation makes sense in a country like the US, were

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[121] The argument about property was sustained in art19, nn 24- 25 of the Chilean Constitution Also see. Claudio Magliona, see note 103 above, at 319; Rodrigo Tabja, President of the Association of Internet Providers (*Presidente de la Asociación de Proveedores de Internet*), First Report Commission of Education, Senate (5 Dec 2007), Session 84, Legislature 355, at 354. The argument about an imputed person was sustained in art 83 of the Chilean Constitution.

[122] P Less, see note 103 above, at 327; Daniel Álvarez, Advisor of the Council of the Culture and the Arts, Second Report Commission of Economy, Senate (1 Sept 2009), Session 45, Legislature 357, at 661.

[123] R Tabja, see note 121 above, at 354-355.

[124] R Nuñez and G Vásquez, Senators, Second Report Commission of Economy, Senate (1 Sept 2009), Session 45, Legislature 357, at 655.

[125] Art U, Message of the President of the Republic (2 May 2007), Session 19, Legislature 355, at 40.

[126] Communication with observations of the Executive (10 Dec 2009), Session 109, Legislature 357, at 934.

[127] F Harboe, Member of the Parliament, Discussion House of Representatives. Legislature 357, Session 82 (29 Sept 2009), Discussion only, Modifications rejected, at 819-820; R Sepúlveda, Member of the Parliament, Discussion House of Representatives. Legislature 357, Session 82 (29 Sept 2009), Discussion only, Modifications rejected, at 825; G Arenas, Member of the Parliament, Discussion House of Representatives. Legislature 357, Session 82 (29 Sept 2009), Discussion only, Modifications rejected, at 816, 854; K Rubilar, Member of the Parliament, Discussion House of Representatives, Legislature 357, Session 112 (21 Dec 2009); K Rubilar, Member of the Parliament, Discussion House of Representatives, Legislature 357, Session 112 (21 Dec 2009), Discussing Presidential Veto, Executive's observations approved, at 960.

[128] R Farías and Gonzalo Arenas, Members of the Parliament, House of Representatives. Legislature 357, Session 82 (29 Sept 2009), Discussion only, Modifications rejected, at 854; D Paya, Member of the Parliament, Discussion House of Representatives, Legislature 357, Session 112 (21 Dec 2009), Discussing Presidential Veto, Executive's observations approved, at 952; K Rubilar, see note 127 above, at 960.

there is a diverse market and there is an important amount of creation related to copyright. In the US there are around 1,200 ISPs, while only four ISPs control 96% of the Chilean market;[129] (4) In the case of Chile, the possibility of creating a private notification is unconstitutional because it affects the right to get information and to share it and;[130] (5) There are serious problem related to the application of this term because of the difficulty that exists in knowing if the person that requires its application is acting in good or bad faith.[131]

Positive comments about this regulation were: (1) The term should be approved because it is part of the agreement contained in the FTA signed with the US;[132] (2) This regulation reflects the principle of collaboration that inspires ISP regulation in relation to copyright;[133] (3) Its existence diminishes and prevents major damages for rights holders;[134] and (4) This is just a provisional, temporal and facultative term. A Court will take the final decision.[135]

At the end, the parliament approved the judicial procedure for notice and takedown, discarded the protection when ISP acts in good faith, and established that the availability of the information for the identification of alleged authors' rights infringers must protect their private lives.

2.2.4. Observations about the Chilean National Congress Discussion

There are different elements that should be highlighted about this parliamentary discussion.

2.2.4.1. Controversial Issues Analysed by the Parliament

The regulation analysed in this section is different to the ones presented above, because limitation on liability for ISP is not a term that forms part of the TRIPS Plus content of the FTA. This is because TRIPS says nothing about this type of measure. However, there was much controversy about its content. The number of organisations that participated in the discussion was enormous, arguments were intense and diverse, and the parliamentary debate shows the conflicted relationship that exists between the necessity of protecting copyright and balancing this interest with the function that Internet has in society.

From the point of view of the purpose of this article, this discussion shows, again, that developing countries' work on the implementation of FTA terms is not passive. The implementation of the FTA signed between Chile and the US constitutes an instance

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[129] F Harboe, see note 127 above, at 819-820.

[130] F Harboe, see note 127 above, at 819-820; G Arenas, see note 127 above, at 893.

[131] C Cantero, Member of the Parliament, Discussion House of Representatives, Legislature 357, Session 82 (29 Sept 2009), Discussion only. Modifications rejected, at 857.

[132] C Sepúlveda, Representative of the Ministry of Foreign Affairs, Discussion, House of Representatives, Legislature 357, Session 82 (29 Sept 2009), Discussion only, Modifications rejected, at 855.

[133] *Ibid*.

[134] *Ibid.*

[135] C Sepúlveda, see note 132 above, at 855.

where crucial criticisms developed on the international sphere were analysed and debated by the parliament.

The Special 301 Report of 2011 commented on the Chilean regulation of limitation on liability for ISPs. After confirming that Chile will remain in its the Priority Watch List, the US government declared that Chile should "amend its Internet service provider liability regime to permit effective action against any act of infringement of copyright and related rights".[136] Unsurprisingly, without giving any further explanation about the possible problems that the Chilean regulation has, the US considered that it was inadequate.

It is important to remember mind that this is the first regulation in Latin America that establishes the role that an ISP plays in relation to the infringement of copyright material on the Internet.[137]

2.2.4.2. Comments about the Particular Arguments that Supported the Final Version of the Regulation

As explained above, the debate for the implementation of limitation on liability for an ISP was interesting because all the critical issues identified in the international sphere were part of the local analysis and considered by the parliamentarians. It is necessary to finish the observation by refuting some of the arguments that were generally supported and justified the regulation approved by the Chilean National Congress. These observations are relevant because the system approved by the parliamentarians seems to be rigid, costly, and unbalanced in relation to the different interests that are affected by the use of material protected by copyright on the Internet.

First, there were a lot of opinions presented by parliamentarians arguing that the legal effects of private notifications are not suitable because an ISP could be obliged to takedown material that is not illicit.[138] This argument is usually presented as a problem of freedom of expression. According to the Chilean constitutional norms, freedom of expression is the right that guarantees the possibility of having access to information.[139] It is interesting to raise the point that these critiques affect a FTA term that is practically identical to the US regulation. The US is a country for which one of its primary characteristics is the constitutional recognition and strong protection of the right to freedom of expression.[140] Thus, the creation of this system was not developed without giving any value to this constitutional right, but was a mechanism that balanced it with the protection of copyright. According to a study by Jennifer Urban and Laura Quilter, 31% of the notifications based on copyright claims are subject to matters that are not protected by copyright.[141] Thus, the majority of claims (more than

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[136] Special 301 Report (2011), available at http://www.ustr.gov/about-us/press-office/reports-and-publications/2011/2011-special-301-report (accessed 29 Apr 11), at 28.

[137] R Lavados, "Chile Breaks New Ground in Regulating IP Liability" (2010) available at http://www.wipo.int/wipo_magazine/en/2010/03/article_0009.html (accessed 19 Jul 10).

[138] Senators Nuñez and Vásquez, see note 124, at 655.

[139] Art 19 n 12, Political Constitution of the Chilean Republic.

[140] First Amendment of the Constitution of the United States.

[141] J M Urban and L Quilter, "Efficient Process or "Chilling Effects"?: Takedown Notices under Section 512 of the Digital Millennium Copyright Act" (2006), *Santa Clara Computer & High Technology Law Journal* 621-693, at 631, 667.

two thirds) are justified and motivated by the protection of legitimate interests. Of course, the other third of the notifications can raise a problem. The same study suggests a mechanism for improving the system which does not consist of the legalisation of the notifications through courts. The suggested mechanism consists of delaying the takedown until *after* an opportunity for counter-notice has been offered, allowing the process to be simple, inexpensive, and relatively quick.[142] Furthermore, according to legal scholars, the US regulation represents a model for other countries, as a system that discourages abuses in relation to the notice and takedown regime. According to Lillian Edwards, the US system is better than the United Kingdom regulation because it allows ISP to "put back" the material that was removed, in case the content provider protests about the takedown measure.[143] At the end of the day, this mechanism diminishes private censorship by an ISP.[144]

Interestingly, the Chilean Executive presented a similar mechanism to the one proposed by Jennifer Urban and Laura Quilter in the context of protecting an ISP that removes or disables access to material in good faith. The parliamentarians finally discarded this mechanism.[145]

Second, during the parliamentary discussion it was argued that informal notifications were problematic for the Chilean legal system because according to the Political Constitution of the Republic, it was impossible to restrict a property right without a previous judicial resolution, or a previous judicial approval was required to develop actions that impede the exercise of rights guaranteed by the Constitution in favour of a person imputed of committing a crime.[146] Both objections are questionable. The notice and takedown regime does not restrict a property right but on the contrary creates a system which guarantees protection to a property right, constituted by copyright: the Chilean Constitution recognises the property right nature of copyright.[147] Also, the objection about the necessity of a previous judicial approval to develop actions that impede the exercise of rights guaranteed by the Constitution in favour of a person imputed of committing a crime is absolutely inappropriate. This constitutional requirement affects the Public Ministry, the entity responsible for directing the investigation of the constituent facts of crime.[148] An informal or administrative mechanism of notification does not have any criminal nature so it is impossible to argue that its existence affects a constitutional regulation related with the Public Ministry.

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[142] *Ibid*, 689.

[143] L Edwards, see note 88 above, at 76.

[144] *Ibid*, 74.

[145] Communication with observations of the Executive, 10 Dec 2009, Session 109, Legislature 357, at 934.

[146] Art 19, nn 24-25, and art 83 of the Chilean Constitution were used as a reference to maintain this argument. C Magliona, see note 103 above, at 327; R Tabja, see note 121 above, at 354-355.

[147] Art 19 n 25, Political Constitution of the Chilean Republic.

[148] Art 83, Political Constitution of the Chilean Republic.

3. Conclusion

After analysing the implementation of two controversial IP terms contained in the FTA signed between Chile and the US, it is possible to present the following conclusion.

Discussions and work developed by the Chilean Parliament shows that FTA implementation does not constitute a passive activity for developing countries. On the contrary, in the Chilean case, authorities were concerned about its implementation and how to make it compatible with local needs.

Clarifying this first issue, it is important to make the point that the Chilean implementation also shows other controversial issues involved with the process. What are the limits that parties should respect in order to implement the FTA, adapting it to the national reality, and avoiding distortion of the original content? In the implementation of both terms, the US manifested a negative opinion through the Special 301 Report in which they complained about the final regulation.

It would have been interesting to see if these disagreements could have ended up being the object of a dispute settlement. The treaty entered into force on 1 January 2004. Since then, any disagreements about the following three issues between Chile and the US should be resolved through cooperation, consultations, or even the through participation of an arbitral panel: (1) avoidance or settlement of all disputes between the parties regarding the interpretation or application of the FTA; (2) if a party considers that a measure of the other party is inconsistent with the obligations contained in the FTA or that a party has failed to carry out its obligations under the treaty; and (3) if a party considers that a measure of the other party causes nullification or impairment of certain areas of regulation which includes IP issues.[149] Is the legal implementation of the agreement a matter that could be disputed through the process contained in the FTA or can this procedure only be used regarding matters that arise after the implementation? If it could be the object of a dispute settlement, legal implementation could be clearly used as a threat, and therefore the scope for adapting the treaty to the domestic legal system could be negligible. As a consequence, this situation could put at risk one of the basic and standard principles about implementation of treaties: that implementation should be developed in accordance to the practice of the legal system of each country.[150]

Finally, the implementation of limitations on liability for ISPs shows a new factor. To adapt FTA terms to domestic reality, developing countries can create new norms that are completely inefficient, such as the creation of a judicial system for the notice and takedown regime.

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[149] Art 22.2, FTA Chile-USA.
[150] This principle is recognised not only in the FTA but also in art 1.1 of TRIPS.