

## Chapter 5

### Chile: The Case of IP Opposition from Predominantly Private Interests

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In this chapter, I describe the political field on which the tensions between intellectual property laws and access to medicine play out in Chile. This description includes the political opportunities that have arisen during the period of the study (roughly, 1990–2011) and the positions of the actors that participated in those opportunity structures. The most important feature of this field is that its contours are largely determined by the legal norms imposed by international trade agreements. Because these have changed over time, the implementation game is a dynamic one. However, the field is highly circumscribed. The intellectual property laws propounded in international trade agreements are inescapable starting points. Thus, the conflicts and tensions occur within a narrowly delineated area of action. And given that these agreements allow for the realization of international economic policies defined by a political elite promoting private interests, and that these state policies are largely unquestioned by the population at large, the conflicts involve the government and private economic agents; they rarely include actors from civil society.

Nonetheless, the introduction of the global framework of intellectual property norms followed the adoption of a liberal economic policy and it opened an implementation game where the starting points could be—if not superseded—then relativized in their later administrative and legal application. Subsequent political efforts effectively limited the impact of the international norms on the Chilean population. But here too, private interests dominated. The political processes did not lead to the formulation of public-regarding policies favoring access to medicine. Rather, they involved “back-door opposition” on the part of representatives of the national pharmaceutical industry and government employees who were interested, for private reasons, in opposing barriers to entry into the pharmaceutical market. As a result, questions of distributive justice have remained underrepresented in the implementation game and also in the legal cases addressing access issues.

So far, the cost of medicines has remained low. Accordingly, this strategy, which limits intellectual property rights without considering the public interest, has not led to any significant conflict. However, as the United States increases pressure to

raise Chile's compliance levels with international obligations, tensions are growing. Additionally, problems related to the quality of the generic medicines that dominate the domestic market remain unresolved.

This chapter focuses on patent rights and the protection of non-disseminated information concerning the safety and efficacy of pharmaceutical products. It is structured as follows: section I presents the conceptual framework for the globalization of intellectual property and its local opposition. Section II describes the Chilean pharmaceutical market, showing how it is that it gave rise to a dispute involving largely private interests. Section III provides a chronological and systematic examination of the political opportunities Chile experienced in developing and implementing its international obligations. Section IV concludes. The appendix looks at confrontation in the judicial arena and summarizes the most important legal cases on the issues of debate in Chile. For the purposes of this study, I have reviewed public documents elaborating the policies of governmental agencies, reports from private institutions, press releases, and legal documents (laws and regulations and legal and administrative decisions). I also undertook a series of interviews with diverse actors involved in the relevant political processes.

### I. The Conceptual Framework: The Globalization of the Rules of Intellectual Property and Back Door Opposition

The field of medicine is subject to the rules of international trade within the normative framework of the World Trade Organization (WTO) and is governed, in particular, by the TRIPS Agreement, which binds all WTO members. Within these rules, all innovative technology is subject to protection through patent rights. As regards medicines, WTO member states must provide patent protection for pharmaceutical inventions. Additionally, they must protect trade secrets, including information generated for the authorities responsible for clearing pharmaceutical products as effective and safe for marketing. The rights to patents and trade secrets must be enforceable in court and they are subject to a formal multilateral monitoring system through the TRIPS Council (Zangl and Zürn 2004). In addition, they are the target of a permanent system of both formal and informal unilateral monitoring and reporting, including through the public-private operations of the Office of the United States Trade Representative (USTR), acting under its Special 301 procedure (Sell 2003).<sup>1</sup>

The TRIPS rules constitute a minimum global framework, but TRIPS has been merely one step in the upward trajectory of intellectual property rights. Within the last few decades, protection has increased with respect to aims, time limits, methods of protection, and the efficiency of enforcement. For example, the Chile-US Free Trade Agreement imposes more detailed ("TRIPS-plus") standards; similar free

<sup>1</sup> See the description of Special 301 actions in Chapter 1 and Sean Flynn's comment in Chapter 8 in this volume.

trade agreements (FTAs) have been signed with many other nations. Together, TRIPS and these FTAs create a true international legal regime and form one of the most recognizable structures of global governance institutions. This regime has, however, mainly responded to the interests of large global technology companies, among which the pharmaceutical consortium holds a prominent position. Thus, the intellectual property rights imposed tend to reduce public access to medicines and make the provision of healthcare more difficult. For Tansey,

Health is but one of the areas affected by the struggles regarding who will control and benefit from scientific and technological changes that are occurring. They could bring larger changes in the distribution of wealth and power in the world, and the big players that now have power know it, and want to determine the rules in such a way that lets them maintain their positions. And for this to occur, as some key industries recognized 30 years ago, they need global patent, copyright, trademark and other laws that have been called "intellectual property rights". (Tansey 2006: 2)

TRIPS is a public-private normative regime, in that through the agreement, public actors (governments) protect the interests of the large multinational companies that develop and make intensive use of technology. The pharmaceutical sector is a prime example. The regime builds both through the incorporation of the multinational companies' interests into the normative framework, as well as through the monitoring of compliance with these norms, especially in those countries that are not knowledge producers but rather recipients. Because of the indeterminate reach of exclusive rights and the technical complexity involved in determining compliance, public agents depend heavily on private actors that possess the infrastructure to undertake the monitoring task; these actors are then well positioned to strengthen their interests (Brousseau and Bessy 2006). As Susan Sell states, "in general, TRIPS reflects and promotes the interests of global corporations that seek to increase their control over their intellectual property. These companies, acting through the government of the United States (and with the support of Europe and Japan), dominate the WTO processes and managed to create international public rules in accordance with their particular needs" (Sell 2004: 372).

Chile, by joining the WTO, entered into the TRIPS system and assumed international obligations that demand compliance. But the decision to join does not mean that compliance was free from controversy. The implementation process does not necessarily flow directly from the political process that led to the adoption of TRIPS. Rather, the obligation to implement creates new conflicts and opens new political opportunities. The opportunity structures developed in these domestic spaces can be very different from the structures that surrounded the adoption of the international agreement. The concept of "back door opposition" pertains to this context. "Back door opposition" describes the attitudes of the actors in the political process as they attempt to compensate for, or limit the reach of, the previously adopted obligations. Examining its operation exposes the differences in the options facing policymakers and implementers and shows the conditions under which the goals of the implementers can be fulfilled (Thomson 2010).

The concept of back door opposition was originated in studies of the European Union (EU) (Falkner et al. 2004). There, it was shown that the transposition of EU laws into practice was affected by the preferences and opportunities of political actors in the implementation sphere. That is, in the two spheres (national and international), the capacity of states to propose norms differ, as do the structures of political opportunities that arise in the internal political process of implementation. Because global political processes do not predetermine domestic political opportunities, the results in the implementation process can be partially or completely contradictory to the global processes of rule formation (Meyer 2004). This occurs both because of the separation of opportunity structures at the policymaking and implementation stage (Mazmanian and Sabatier 1983; McLaughlin 1987; Hill and Hupe 2006) and because of differences in the characteristics of global policy arenas when compared with domestic policy arenas (Grande 2001). Following Meyer and Minkoff (2004), it is also important to consider the effect of differences between the general aspects of the global expansion of intellectual property laws and the specifics of developing policy and law related to drugs.

In the final analysis, the structure of the pharmaceutical market, the actors, the lack of important civil society intervention, and the role of governmental intermediation can have immense explanatory power with respect to outcomes. This is certainly true in the case of Chile. Chile adopted a strong intellectual property regime, without limitations or flexibility in the health sphere.<sup>2</sup> However, when it confronted the implementation process, back door opposition found variations in the permissible rules and chose laws that improved the position of the domestic pharmaceutical industry without openly breaking with the policies that had led to the adoption of the strict regime. These variations have not resulted in serious public litigation concerning the right of access to health or even in private litigation over patents rights. Rather, there is relatively light enforcement activity, both by the administrative branch and the legislating power.

## II. The Pharmaceutical Sector in Chile: Concentration and Low Prices

To comprehend the political processes that we describe, it is necessary to understand the structure of the national drug market in Chile. It is here where the hegemonic actors predominating at the implementation phase appear.

In Chile, the pharmaceutical market operates under imperfect conditions. On the side of suppliers, there are two subsectors: domestic and international laboratories. The demand side is highly concentrated among pharmaceutical chains and institutional acquisitions. As a result, laboratories tend to lose negotiating power to the pharmaceutical chains (Latinpharma 2006: 12). The domestic pharmaceutical

<sup>2</sup> Indeed, its law may soon be strengthened by the Trans-Pacific Partnership (TPP) Agreement which was under negotiation at the time of this writing. For more information, see <<http://www.ustr.gov/tpp>>.

industry is composed of more than 159 companies, domestic and international, that together produce and/or import finished product (Vassallo 2010: 13).

In the last decade the structure of the Chilean pharmaceutical market has changed, mainly through mergers among pharmacy chains and between chains and department stores. A critical point in these mergers was the union between the Salco and Brand pharmacy chains, which formed S and B Pharmaceutical (S y B Farmaceutica) in 2000, thus gaining 32.1 percent of the distribution market. According to Vassallo, this situation developed from a price war among chains that, together with the strong presence of generic drugs, led to a large reduction in the price of pharmaceuticals. Thus, drug prices in Chile were the lowest in Latin America, with an average of USD 3.33 (Vassallo 2010: 6).

Four types of drugs coexist in the Chilean pharmaceutical market. In the first category are "originator" or "brand name" drugs, usually produced by international laboratories. Developing the products in this category requires a great deal of effort, including between twelve and fifteen years of research. Normally, these drugs are protected by pharmaceutical patents. Their average price is estimated to be around USD 8.50 per box. The market percentage of brand name sales is slightly more than 20 percent.<sup>3</sup>

"Brand name generics" form the second category, and account for 44 percent of the market. They have an average price of USD 4.8 per box. They are copies of the original product and are brought to market after the patent has expired. The laboratories distributing these drugs will usually invest in marketing and product improvement, such as making coated tablets or developing slow-release formulations. These do not fit the definition of generics used by the US Food and Drug Administration (FDA) or the World Health Organization (WHO). For example, the FDA provides that "a generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use."<sup>4</sup> Because these drugs differ from the original formulation, they cannot obtain a certification of bioequivalence. Therefore, the only guarantee of quality, safety, and effectiveness of the "brand name generic" drug in Chile is trust in the laboratory that produces it. To identify themselves, brand name generics frequently adopt trade names for their commercialization.

The third category of drugs is referred to as "Chilean generics" or simple "similar." These are commercialized under the name of the medical ingredient. They represent around 40 percent of drug sales in Chile, with average prices of USD 1.10 per box. They are generally manufactured by domestic laboratories and do not include a certification of bioequivalence. The only difference between these and brand name generics is that the brand name generics add unique names to their marketing materials, while the Chilean generics rely only on generic names.

<sup>3</sup> Valeria Ibarra, "Pharmaceutical Market in Chile" (in Spanish, "Mercado farmacéutico en Chile facturó más de US\$1,300 millones"), June 11, 2011. Retrieved January 15, 2011 at: <<http://chile-hoy.blogspot.com/2011/06/mercado-farmacéutico-en-chile-facturo.html>>.

<sup>4</sup> US Food and Drug Administration, Glossary of Terms, <<http://www.fda.gov/drugs/informationondrugs/ucm079436.htm>>.



The designation of “generics” in Chile is thus very confusing from an international perspective and is not even well understood by experts. Chileans use the designation “generic,” but the designation corresponds to the concept of “International Common Denomination (ICD)” or “International Nonproprietary Name (INN).” These describe terms granted by an international committee in order to enhance communication among medical, pharmaceutical, and regulatory personnel. The terms precisely identify a medicine (or an active ingredient) and they do so more conveniently than the chemical name. They are not protectable as trademarks. In sum, for Chileans, a “generic” is simply a drug sold under a common international denomination. These medicines are authorized for public sale without scientific tests or technical evidence of safety and effectiveness, although in some cases, the brand name generics rely on scientific information generated by the originators (Saavedra 2010: 13).

The fourth category of medicines is “WHO generics.” These are authentic generic drugs and correspond to international definitions of generic products. They are copies of brand name (originator) drugs and appear in the market once the inventor’s patent has expired. They are registered under an ICD generic name, and are approved and registered by drug authorities on the basis of therapeutic bioequivalence studies. These may be *in vivo* or *in vitro* bioequivalence, or clinical studies, undertaken in laboratories approved and certified by the drug authority (Saavedra 2010: 13). The studies are intended to show that the drugs have the same active ingredients, pharmaceutical form, kinetic, dynamic, and technical characteristics as a medicine used as a technical legal reference (Saavedra, Saldaña, and Ruminot 2006: 206). These drugs thus have a certification of bioequivalence in accordance with international standards.

There are, however, very few WHO generics available on the Chilean market (Saavedra, Saldaña, and Ruminot 2006: 207). Decisions to undertake bioequivalence studies are purely voluntary and are made for marketing reasons—fundamentally, because the drugs are to be commercialized internationally.<sup>5</sup> Until 2010, in Chile there was only one laboratory that could undertake bioequivalence studies, the Pharmacokinetics and Bioavailability Laboratory Program of Molecular and Clinical Pharmacology, Faculty of Medicine, University of Chile. In 2011, two more labs opened: the Bioequivalence Laboratory of the University of Development and the Bioequivalence Unit of the Clinical Research Center of the Catholic University. Furthermore, laboratories enjoy a higher profit margin on similar drugs than on true bioequivalent generics. Accordingly, the labs tend to increase the supply of these. Vertical integration of chains has also had an effect on the composition of the market. One conglomeration can be the owner of a chain of pharmacies, the business that distributes the drugs, and a laboratory (León and Martínez 2011: 12). Since the process of integration began with the labs, their products tend to dominate the market. Chains also have considerable marketing power because they interact directly with patients.

<sup>5</sup> Interview with Ivan Saavedra.

Table 5.1 Map of Chilean pharmaceutical market suppliers

Map of Supplier Players	DESCRIPTION
Laboratories	Domestic (control 50% of pharmacy sales) and foreign.
Pharmaceutical Wholesalers	Undertake the commercialization and distribution as wholesale operators. There are currently two important private wholesalers: Socofar (controls 20% of the market) and Droguería Nuñoa. The Ahumada and Salcobrand pharmacy chains have pharmaceutical wholesalers but do not sell to independent pharmacies.
Pharmacy chains	Farmacias Ahumada, Salco- Brand, and Cruz Verde Pharmacies are the 3 most important. Farmalíder is smaller, but boasts important growth and is tied to the most important supermarket chain in the country.
Pharmacies	1,800 private pharmacies, of which 1,300 belong to chains and 500 are small pharmacies located in sparsely populated areas.

Source: Vassallo 2010: 16.

The structure of the industry demonstrates that the pharmacies form the main distribution network (Vassallo 2010: 12). The landscape of drug suppliers in Chile is shown in Table 5.1.

With respect to demand, there is a public institution with considerable buying power. This player is CENABAST, or the National Drug Supply Center, created in 1920 and whose legal mandate is to centralize public purchases of drugs for Ministry of Health programs, hospitals, municipal offices, and other public health programs. CENABAST purchases amounted to \$210,654,000 pesos (around USD 460,000,000) in 2010. The CENABAST model is one of economies of scale, through large volume purchases, mostly of generics without certifications of bioequivalence, from emerging economies, such as India, China, Malaysia, and the Ukraine. To make these purchases, the Chilean health system has incurred a heavy debt. By April 30, 2011, the public sector owed drug providers, in particular foreign labs, \$79,069 million, pesos (around USD 173,000,000) (CENABAST 2011). This debt poses a difficult political problem because it reinforces the influence of foreign laboratories over the Chilean state.

Despite spending by the public sector, private expenditures also remain high. Figures from 2007 suggest that 47 percent of all spending is private and of this, 55 percent is out-of-pocket spending. More than half of this is spent on originators or brand-name drugs. (Cid and Prieto 2010). These expenditures are not the result of high prices—drugs in Chile are lower than in the rest of Latin America. However, that is not because the country has articulated a policy protecting access to medicines (see Table 5.2).<sup>6</sup>

<sup>6</sup> Interview with Marianela Castillo (health economist).

Table 5.2 Average price of medicines in Latin America

Average prices of medicines in Latin America 2006-2008 (in USD and percentages) Country	Average Price in USD			Percent of Annual Variation	
	2006	2007	2008	Al 07/06	Al 08/07
Argentina	5.93	6.36	7.30	7.4	14.7
Bolivia	4.73	4.90	5.98	3.6	22.0
Brazil	6.86	8.03	8.97	17.1	11.7
Chile	4.15	4.12	4.73	-0.6	14.8
Colombia	4.40	5.41	5.93	23.1	9.5
Ecuador	4.35	4.57	4.77	5.2	4.3
Paraguay	3.65	4.17	4.73	14.2	13.4
Peru	5.81	6.34	7.22	9.0	14.0
Uruguay	3.30	3.47	4.05	5.0	16.8
Venezuela	6.14	7.40	9.42	20.5	27.4

Source: Vassallo 2010: 40, Cuadro 2.3.

Rather, in the Chilean case, the containment of drug prices is due to a combination of factors: a domestic industry dominated by generics; "de facto" substitution of more expensive medications for similar, less expensive, medications by pharmacies; prescription of generics by doctors, and an efficient system of aggregate purchases by CENABAST for the public sector (Godoy 2001). Nonetheless, the market remains relatively small. In 2008, sales amounted to around USD 1,060,000, which makes up 2.6 percent of the total Latin American market, according to figures from IMS Health Chile (Vassallo 2010: 5). According to that institution, between March 2010 and March 2011 the sales volume of the pharmaceutical industry reached USD 1,344,000.

Geographically, the pharmaceutical market is composed of international businesses, small drug importers, and local businesses (Escobar 2006: 50). More than 80 percent of medicines consumed in Chile are produced by domestic labs. Among these, various laboratories stand out. For example, the conglomerate RECALCINE boasts increased growth and presence within the Latin American market. Among foreign labs, Laboratorio Chile (TEVA) is dominant, followed by North American labs such as Abbott, Pfizer, Bristol Myers Squibb, and Merck Sharp & Dhome (MSD) and European labs, in particular German firms, such as Grunenthal, Bayer, Merck, and Swiss firms, including Roche and Novartis. With the exception of Grunenthal, these labs rely on production facilities outside the country, and final products are imported into Chile.

Structurally, laboratories in Chile are organized into large associations. These include the Pharmaceutical Industry Association (CIF) and the Industrial Association of Pharmaceutical Laboratories (ASILFA), which represent foreign and domestic labs, respectively. Along with these, there are various smaller associations of laboratories (see Table 5.3).

Table 5.3 Main pharmaceutical lab associations in Chile

Main Pharmaceutical Lab Associations	Associated Businesses	Characteristics
Pharmaceutical Industry Association (CIF)	20	Multinational Laboratories
Industrial Association of Pharmaceutical Laboratories (ASILFA)	10	Domestic: Bago, Biosano, Labomed, Chile, Pharma Invest, Saval, Sanderson, Sanitas, Tecnofarma, Royal Pharma.
National Association of Laboratories (1999) CANALAB	14	Pasteur, Prater, Knop, Ximena Polanco, Garden House, and others
Association of Over the Counter Medications (CAVEMED)	—	Laboratories that produce over the counter medications

Source: Vassallo 2010: 19.

As suggested earlier, these characteristics of the pharmaceutical market are key to understanding the fundamental players and political processes that are involved in determining the balance between intellectual property protection and access to medications in Chile. The history of domestic implementation of intellectual property rights related to medicine is marked by the confrontation of private interests among local and foreign pharmaceutical companies. As we shall see in section III, in this confrontation, the government has acted mainly as an intermediary between local and global pressures. At the same time, Chilean civil society actors have not consistently articulated the public interests at stake nor have they raised questions of distributive justice. Accordingly, the effect of intellectual property laws on access to medications has largely gone unexamined. This state of affairs, can be attributed, at least in part, to the lack of robust constitutional support for the right to health (Zúñiga 2011; Jordán 2013) in Chile and to its pro-market policies. Moreover, until at least until 2011, there was little debate over access to medicines, relative to other South American countries.

### III. Political Opportunities: Developing and Implementing Intellectual Property Policy

In this section we shall analyze, in chronological order, four sets of controversies, describing the actors and the political opportunities they faced.

#### A. The Patentability of Medications

The first set of controversies that appeared in Chile regarding the relationship between intellectual property and medications revolved around the patentability of medications. Until the middle of the twentieth century, medications were not considered patentable in Chile. Decree No. 958 of the Ministry of Economy, July

27, 1931 regulated patents and inventions. Under Article 5(a), "all types of medications, medicinal pharmaceutical preparations, and chemical, reaction and mixed preparations" were excluded from patentability. This followed the 1844 French model of patent law and did not violate the international norms that existed at the time.

The patentability of medications and pharmaceutical products was first considered in 1984, during the dictatorship of Augusto Pinochet. The military government wanted to accede to the demands of the international pharmaceutical sector to make medications patentable as a way to improve foreign relations, in particular relations with the United States. Thus, in 1989, during his last year as dictator, Pinochet instituted Law No. 18.935, published in the Official Journal on February 24, 1990, which modified Decree No. 958 in various aspects. It not only provided for patents on the excluded subject matter, it also made the protection retroactive to inventions in the so-called "pipeline." Article 10 of the new law allowed for the patenting of medications whenever a request for a patent had been filed in the country of origin prior to December 31, 1984. Article 12 granted legal protection for a period of fifteen years.

At that time, the new patent law, and in particular its application to medications, led to strong criticism from the domestic laboratory industry and society in general. Deliberation on the matter continued until the end of the dictatorship (National Library of Congress 1991: 174–5). Later, the first democratically elected government withdrew the executive regulation of the law, effectively preventing it from entering into force. The same government later presented a new proposal and that measure, Law No. 19.037, became law in 1991. It too covered medications and granted protection for fifteen-year periods. However, this law specified that inventions would be patentable only if they were new—produced and distributed after the law's publication (and, of course possessed an innovative aspect and an industrial application). Thus, this law was not retroactive: it did not allow for the patenting of medications in Chile on the basis of prior-filed applications. The law also excluded surgical, therapeutic, and diagnostic methods for humans and animals, with the exception of products designed to put those methods into practice (art. 37). Finally, the new law contemplated the possibility of compulsory licensing, but only in the case of monopoly abuse (art. 59) and declared all patents to be of "public utility," thereby permitting their expropriation. During the congressional debate, an idea to mitigate the effect of pharmaceutical patents on medication prices was also contemplated. However, that approach was not included in the final text (National Library of Congress 1991: 88).

Even with these limitations, the introduction of Law No. 19.039 provoked resistance and criticism from domestic laboratories. They did not consider that patents were needed as an incentive for pharmaceutical research, arguing that pharmaceutical innovation largely occurred outside Chile and thus incentives to innovation were already guaranteed by patents granted in the companies' home countries (Huenchufir and Escudero 2002). On the other hand, the CIF, acting on behalf of foreign firms, insisted that the pharmaceutical patents law would stimulate local marketing of foreign products and improve quality. Further, CIF

maintained that patenting would not necessarily increase the cost of medications (National Library of Congress 1991: 160). Various political sectors supported the local industry and intimated that the legislation responded primarily to pressure from the United States Department of Commerce (National Library of Congress 1991: 172). Nonetheless, as reflected in the report of the Senate Economic Commission, members of Congress were convinced that the introduction of drug patentability was a global trend, from which Chile had little possibility of escaping (National Library of Congress 1991: 260–2).

Congress's position on patenting was consistent with another larger trend. At the beginning of the transition to democracy, one of the underlying ideas of the political elite was that the power to legislate was escaping the sphere of national sovereignty and that the country had to focus instead on adapting to the challenges of global systems. Former methods for regulating strictly domestic issues were, in short, no longer options. This view did not, however, eliminate disputes among private interests involved in pharmaceutical patents. As a result, political institutions and the government became reactive. Laws were geared toward the execution of global policies, with the government assuming the role of mediator rather than regulator.

## B. Adapting to TRIPS

From its return to democracy at the beginning of the 1990s, the Chilean government made international political integration a main objective of its foreign policy. Towards the end of the 1990s, the specific goal was economic integration at the regional and international level. This objective set the context for the negotiation of free trade and other commercial agreements. Thus, even after a democracy was established, foreign policy was continuous with that of the Pinochet dictatorship. Like Pinochet, the new government pursued an economic policy of trade liberalization; it treated foreign trade relations as untouchable in relation to other policies. The practice of keeping these objectives distinct from other spheres of government was not modified by later democratic governments and remained in the organizational culture of the actors that molded Chilean foreign policy (Giacaman and Faundez 2003: 7). This strategy was based on a viewpoint shared by the elites concerning the relevance of medicines for health in Chile. Because the health system is predominantly private and based on the concept of freedom of choice, the right to health is not guaranteed to the entire population (Goyenechea and Sinclair 2013). Thus, medicines have been considered goods of private consumption rather than goods of common necessity (Goyenechea 2013).

Because Chile's international strategy moved toward incorporation into global markets, entry in the WTO became a priority. In order for a country to join the WTO, it is required to accept a series of multilateral agreements that impose robust legal obligations related to tariffs, intellectual property rights, and a variety of other matters (Kottrow 2009: 2). In 1995, Chile accepted these conditions when it ratified the WTO Agreements, including TRIPS, and published its accession in the Official Journal on May 17. The government's behavior with respect to TRIPS



set a pattern that was repeated subsequently. Its actions marked the starting point for a tendency to adopt rules and accept participation in global trading frameworks as something inevitable, while later assuming a pragmatic role of mediator when addressing controversies between private actors during the implementation phase. In effect, the government commits to rules of trade without regard to questions of distributive justice and then attempts to ameliorate friction between private interests during the implementation process.

In a way, the situation was inevitable. The adoption of TRIPS (as well as the later chapter regarding intellectual property included in the FTA with the United States) was seen as necessary for the success of Chile's economic policy. As a result, the negotiations were characterized by asymmetric power positions, as one of the parties, Chile, was willing to accept any and all conditions in order to obtain access to other parties' markets. In addition, there was a very obvious asymmetry of knowledge regarding the effects of intellectual property rules. Thus, in the words of the ex-director of the Department of Industrial Property (DPI), Chile was willing to exchange gold for trinkets.<sup>7</sup>

But there was a saving grace. The TRIPS Agreement contains the obligation to grant patents in all areas of technology and to give patent owners a minimum of twenty years of exclusive rights. It also requires states to protect clinical studies and other undisclosed information from dissemination and unfair competition. Nonetheless, it also includes flexibilities that allow states to adopt necessary measures for the protection of public health or the life of individuals. Article 39.3, on undisclosed information, does not establish a right of exclusivity and it does not explicitly determine the scope of its applicability. The Agreement does not impose obligations regarding parallel importation: It permits compulsory licensing, subject to a series of conditions. And it includes both general and specific exceptions to patentability. On the whole, TRIPS (along with the later FTAs) reduces legislative competence, but as subsequent events have demonstrated, it left an important sphere for government action.

To implement the TRIPS Agreement, Law No. 19.039 was replaced by a new law, Law 19.996, which modified its predecessor in various ways. The new measure was proposed in 1999, reevaluated in 2001, and a revised version was presented in August 2001. It was finally published as a law six years after its initial proposal, on March 11, 2005, significantly later than the January 2000 deadline that TRIPS established for the adaptation of internal legislation.

The new law established a non-renewable period of patent protection of twenty years (art. 39). Second-use patents in all technological fields are permitted only if the new use resolves a previously unsolvable technical problem, possesses an inventive aspect, and is adaptable to industrial application (art. 37.e). In legal proceedings regarding patent infringement, the law allows the judge to place the burden of proof on the defendant, forcing it to prove that its procedure is novel and different from that described in the patent. Undisclosed information that concerns

<sup>7</sup> Interview with José Pablo Monsalve, Director of the DPI at the time that the FTA with the US was negotiated.

new chemical formulas for pharmaceutical products is protected for five years from the first health registry. Such information refers to test data or other undisclosed information related to the safety and effectiveness of a pharmaceutical product that uses a new chemical makeup not previously approved by the relevant authority (art. 89). The new law also includes a clause that permits third parties to market the protected product if they obtained access to it after it was introduced into the market, and such access was granted by the right-holder or with his consent (art. 49).

The debates surrounding the adoption of Law No. 19.996 provide an excellent opportunity to view and analyze the aforementioned back door opposition, as key players drew out the legal implementation of the Agreement. They presented competing views on various topics, rival interpretations regarding the content of the instrument, and debated the best strategy for fashioning intellectual property law protective of access to medications.

### *1. Domestic Laboratories Lobby to Limit Implementation of Intellectual Property Rights*

When the reform proposal for Law No. 19.039 was first debated, the majority of the domestic pharmaceutical industry, grouped under ASILFA, strongly criticized the original proposal that was sent to the Executive, considering it an obstacle to the growth of the domestic industry.<sup>8</sup> ASILFA's fundamental strategy was to defend the domestic pharmaceutical industry, which was oriented mainly toward the production of generics, and to refute the position of foreign labs and representatives of the United States government. To that end, ASILFA engaged in systematic lobbying with governmental authorities and members of Congress and appealed to the media to attract public attention. In addition, it gathered facts, commissioned expert economic reports, and offered its own experts and attorneys. ASILFA benefited from uncertainty in various sectors, including successive governments and their opposition, regarding the effect of the new order and how the rules would affect or inhibit the government's ability to provide public goods and protect access to health. Although ASILFA consistently advocated for the need to balance the intellectual property norms that Chile had assumed with public interest concerns, in particular public health, its discourse was clearly characterized by the promotion of the particular interests of the domestic industry.

Even before the proposal was put to debate in the National Congress, national laboratories denounced the pressure foreign labs were exerting on the government to interpret existing international laws in ways that provided for strong protection and to accept new international intellectual property obligations. In some cases, these forces were successful. For example, ASILFA opposed second-use patents, arguing that they were not required by TRIPS and were an underhanded method of prolonging patents that were about to expire. While Congress would have

<sup>8</sup> Interview with María Angélica Sánchez.

effectively adopted ASILFA's position, second-use patents were nonetheless incorporated into the final text of the law on the theory that their recognition was an obligation of the WTO framework, and therefore could not be rejected.

But in some instances, the generic industry won. ASILFA also opposed laws on protecting clinical data and linking premarket approval to the protection of patent rights. María Angélica Sánchez of ASILFA argued that "if our already robust present legislation is expanded to establish so-called linkage, and is modified to include the protection of clinical trial data, we must be prepared as a country for prices of medications to increase considerably. In accordance with the last study undertaken by the School of Economics at the University of Chile, prices will increase by 75 percent, which will have a considerable influence on the treatment of illnesses under the AUGE [Chile's Universal Access Plan] and other common illnesses in the country."<sup>9</sup> This view was strengthened by the disparity in price between domestic and foreign manufactured drugs. In 2001, the average price of medications in Chile was calculated to be USD 3.30, while foreign medications cost an average of USD 6.30, in the context of a pharmaceutical market valued around USD 552,000,000. Additionally, ASILFA referenced a study by the Center for Applied Studies for Business of the University of Chile (CIADE), which in 1991 indicated a possible increase in costs if intellectual property rights were strengthened. This study was commissioned by ASILFA and appeared during the initial debates regarding the adaptation of Chilean law to TRIPS.

The then-director of CIADE, David Geller, supported the need for strong intellectual property laws, but indicated that public access to medications also needed to be ensured.<sup>10</sup> He was supported by the North American economist Stephen Schondelmeyer—a pharmacology professor at University of Minnesota—who also maintained that if patent protection in Chile was extended or reinforced, the price of medications would increase. While the then-president of CIF, Jorge Véliz, countered that the price of medications would not increase more than 3.5 percent, considering that very few (37) medications in Chile had patent protection, in comparison to the 4,000 that did not, CIADE's study had an impressive impact on public opinion and members of Congress. They trusted in the credibility of the University of Chile's economists and kept the study in mind during the debate over adapting Chilean intellectual property law to the requirements of TRIPS. As a result, Congress failed to accede to all the demands presented by multinational pharmaceutical companies.

RECALCINE was another player critical of elevating intellectual property norms. Its position was especially interesting. RECALCINE is a network composed of various national laboratories that produce generics. But unlike other generic labs, its partners also put significant resources into research and development. In the debate, RECALCINE was particularly aggressive in questioning the strategies of foreign labs, proposing and defending a process for adapting to international

frameworks to promote national public health. Thus, the director of RECALCINE argued that one of the major objections of national laboratories was the extension of the period of patent protection from fifteen to twenty years, given that the lifetime of a medication is not greater than approximately five years. RECALCINE also accused foreign labs of inflating the amount of money invested in new medications, claiming that they actually invest a mere one-fifth of their stated numbers.<sup>11</sup> But despite these arguments, the discursive strategy of RECALCINE was not entirely public regarding. In fact, it was driven by the private interests of its partners, which it saw as impaired by the actions of foreign laboratories. This positioning can also be seen in a case, described in the Appendix, that RECALCINE filed against Novartis in the Free Competition Court for actions designed to impede its partners' access to markets.

## 2. *Chilean-American Chamber of Commerce and CIF Support for Strengthening Intellectual Property Laws*

The group holding views closest to the position of the United States was represented by the Chilean-North American Chamber of Commerce, AmCham. AmCham attacked the government's initial proposals on the ground that the legislation would not sufficiently safeguard the three non-discrimination principles included in the TRIPS patent provisions: non-discrimination based on the country of origin of the invention, its field of technology, and whether the products embodying the invention were imported or produced domestically.<sup>12</sup> AmCham also claimed that the proposals did not fully protect undisclosed information and offered too little in the way of enforcement. In particular, the proposed laws did not provide for appropriate civil legal proceedings in respect to the presentation of evidence; nor did it provide for adequate provisional measures. Finally, AmCham argued that the legislation failed to provide for extensions in the time of patent protection to compensate for delays in patent prosecution.<sup>13</sup>

In addition to AmCham, the most active supporters of intellectual property laws and multinational pharmaceutical interests were the national subsidiaries of such multinationals, grouped under the CIF. CIF mainly employed discourses used by international public policy networks to support the formation of a robust and strict intellectual property regime. Principally, it sought to reward innovation and support businesses that invent medications and bring them to Chile. It held itself out as an intermediary between the market and the forces favoring trade liberalization. It unreservedly supported the proposal sent by the Ministry of the Economy to Congress, arguing that it strictly followed WTO norms and that streamlining the law was necessary. As evidence, it pointed to the fact that in the absence of linkage between the organization authorizing the commercialization of a medication (the Institute of Public Health (ISP)) and the patent office (then the DPI), 6 of 57

<sup>9</sup> *El Mercurio*, February 19, 2010, Section A, page 2, Letters.

<sup>10</sup> *El Mercurio*, November 20, 2001. Retrieved February 20, 2011 at: <<http://diario.elmercurio.com/detalle/index.asp?id=%7B426ca169-e9d8-4688-9a0d-23f12cbd5542%7D>>.

<sup>11</sup> *El Metropolitano*, September 10, 2001, p. 13.

<sup>13</sup> *El Diario*, June 29, 2001, p. 29.

<sup>12</sup> TRIPS, art. 27.1.



patented medications had been copied. Furthermore, CIF offered evidence that enhancing patent protection would not lead to an increase in the price of medications. It compared countries where pharmaceutical patents were and were not available, showing that in countries where pharmaceuticals were protected, the cost of medications was reduced by 50 percent after patent expiration and generic entry into the market. In contrast, in countries without patent protection, generics had prices close to those of patented medications, and these prices did not decrease once the patents expired.<sup>14</sup>

Throughout the extended period of debate regarding the law, CIF also argued that limitations on patent protection should be as narrow as possible and that the availability of compulsory licenses should be highly restricted. It demanded that undisclosed information shared with health authorities should not be used for a reasonable amount of time when the health authorities are considering marketing requests for similar products (National Library of Congress 2005: 717). ASILFA responded to this position, arguing that the protection of undisclosed information should be limited to cases of pharmaceutical products that used new chemical combinations, because only novelty justified protection; information on other products was not of a confidential nature (National Library of Congress 2005: 723).

### 3. *Chilean Government and its Internal Disagreements*

Within governmental sectors, high-level officials were also in disagreement regarding the proposed law. The ex-director of the ISP, Gonzalo Navarrete, directly criticized the proposal and argued that it was written from a purely economic point of view, failing to consider the interests and opinions of the health sector, even those views coming from within the government. This criticism may have been warranted, given that the project had been mainly developed by specialists from the Ministry of the Economy, without considering the opinion of the ISP.<sup>15</sup>

A former legal advisor of the ISP suggested that the position of the Coalition of Parties for Democracy, then in power, was fundamentally ambiguous.<sup>16</sup> On the one hand, it wanted to keep foreign economic policies intact by agreeing to elevate normative standards of intellectual property. On the other hand, it wished to limit the reach of these provisions by imposing obstacles to their implementation. Again, the criticism was warranted. There were various sectors of the government ideologically opposed to increasing patent rights and to providing further protection for information, as well as groups within the government that supported these changes. In short, two contradictory discursive governmental strategies could be identified: First, the supporters of following Chile's trade agreements (TRIPS—and later on, the FTAs), who thought the state could conform to higher standards and address possible price increases by subsidizing the cost of medication. Second, those who believed that despite international obligations and demands, the effect on price was

<sup>14</sup> *El Mercurio*, October 16, 2001, Section B, p. 9.

<sup>15</sup> *La Nación*, November 22, 2001, p. 9.

<sup>16</sup> Max Fuenzalida, in an interview with the author.

so problematic, Chile should refuse to extend further protection to pharmaceuticals. These divergent viewpoints within governmental policies allowed interested players, in particular ASILFA, RECALCINE, and CIF, to intervene through lobbying. The government's susceptibility to different arguments partly explains the delay in adaptation to international norms. But the cause can also be attributed to the lack of an integral medications policy on the part of the four governments of the Coalition, as well as to the government's lack of necessary experience.

Ambivalence within the government did more than cause delay. Alliances between factions of the government and various industrial sectors, and disagreements among government coalitions on the advisability of implementing international intellectual obligations, once again put the emphasis on private interests. No one articulated a coherent public health policy. Indeed, no player was capable of establishing definitions or developing discursive tools to use in the debate that went beyond a discussion of private interests. This situation was only worsened by the fact that civil society failed to mobilize around a right to health in Chile.

### 4. *The Absence of Civil Society*

In the majority of discussions regarding medications in Chile, civil society actors have failed to intervene to address questions of distributive justice. As a result, the government has largely played the role of intermediary among private interests. While professional associations and consumer organizations have made pronouncements on topics such as the advisability of selling drugs in supermarkets and whether doctors should be required to prescribe drugs by generic name, they have not intervened on questions related to intellectual property protection.

General characteristics of civil society in Chile help to explain this weakness. Social research has shown that Chilean society has long experienced great difficulties in undertaking collective action (PNUD 2000). The privatization of social services and the deterioration of trust in social ties affect the possibility of cooperation and social mobilization. In Chile, there is a clear trend toward individualism, accompanied by privatization. People obtain more autonomy by retracting from social ties, thus creating an impasse with respect to the possibilities for collective action (Rojas 2012). Although the advent of the student movement may have weakened the trend in recent years, Chilean civil society still lacks more durable actors.

The centralist, hierarchical, and non-participative tendencies of the Chilean political system also contribute to the problem. Only since 2000 have there been discussions regarding participation in governmental activities. In that year, via Presidential Instruction, President Ricardo Lagos established a series of ministerial duties for civic participation and the Ministry of Foreign Relations committed to undertake an annual consultative conference with civil society representatives in which the government's foreign policy would be discussed. But even this initiative is weak. It reflects a conception of participation in the formulation of public policy that is, first, unilateral and, second, subordinate to state power. It is of a merely consultative, informative, and sporadic nature. Essentially, such participation is a

post-facto validation of decisions that have already been made. This hierarchical concept of social participation means that NGOs and other civil society organizations still have negligible influence.

The price of drugs constitutes another factor. Although the pharmaceutical market in Chile is partly based on the proliferation of generic drugs that lack bioequivalence certification, prices through 2012 were low and that has led to certain complacency. Despite the volume of private spending on medications, medicines are available. Since the public has not felt the effect of intellectual property laws, it has had little reason to debate the effect of these laws on access. Groups that traditionally represent the public interest in health in Chile, such as health professionals and pharmaceutical unions, could have focused the public's attention and made it see the connection between price and intellectual property protection, but they have been marginal players in the debates. To be sure, this does not mean that the market solved the problem of access to medication in Chile: there is a significant difference in the quantities spent on medication between different socio-economic groups. For example, a study in 2007 established that the quintile with the smallest income spent around 57.2 percent of their total income on medication, while the quintile with largest income only spent around 39 percent (MINSAL 2007). Politically, however, the issue has not achieved any degree of salience.

In addition, civil society actors that have attempted to defend public interests in health have not been capable of establishing lasting coalitions, as we will see later with respect to the debate on FTAs. Instead, the arguments, posturing, and framing of those who support contradictory positions have crystallized the debate as about private business. With one exception, the result is that there has been little effort to develop information and evidence that would support public-regarding arguments. The one exception has been the School of Public Health of the University of Chile, through its Medical-Social Journals. The rest of the debate has been dominated by private lawyers, with economists as ad-hoc allies to support particular positions.

### 5. *The Courts Evolve a Jurisprudence on the Right to Health in Chile and Push the Government into Action*

Perhaps because of the lack of activism with respect to medications, judicial recognition of the right to health as a fundamental right was initially quite weak. The 1980 Constitution incorporates the right to health protection in article 19.9, but it is based on an economic market approach. This constitutional text has thus been understood not as a judicially enforceable right, but rather as a pragmatic norm to guide state action (Diego Portales University 2008: 208; Zúñiga 2011; Jordán 2013). Since 1980, more than 100 modifications have been made in the constitutional text. But article 19.9 has remained untouched and the right to health has not been otherwise addressed (Couso and Reyes 2009).

Two subsystems, one public and the other private, address the provision of health-care. The most important in terms of coverage, is the public system, as two-thirds

of the population depends upon it. The system is administered by the National Health Fund (FONASA), a service within the Ministry of Health, which coordinates the health needs of its affiliates and is responsible for funding healthcare providers. FONASA collects contributions from its affiliates as well as fiscal support from the state. The second subsystem is composed of private health companies (ISAPRES). These institutions offer private health insurance to more than 2.7 million beneficiaries. The system was constituted principally during Pinochet's regime through a series of reforms to the universal system of healthcare that has existed since 1951. Because these changes were attempts to create a new private market for health services, it is not surprising that the only justiciable constitutional guarantee with respect to the right to health is the constitutional right to choose one's health system: public or private. Otherwise, the constitutional guarantee has no direct effect.

Nonetheless, there is an important jurisprudence that has conferred a justiciable right to health based on the protection of the right to life included in article 10.1 of the Constitution. On September 24, 2001, the Court of Appeals of Santiago resolved an appeal for legal protection filed by the Chilean Association for the Defense of People with Catastrophic and Terminal Illnesses. Although the case was brought as a class action and the court rejected that procedure, the decision established that the state has the obligation to grant free, preferential, and integral medical and pharmaceutical attention to individuals affected by certain illnesses, as a derivation of their right to life (Diego Portales University 2008).

In later cases, courts have considered the reach of the decision. For example, in a 2006 case, *Segura et al v. Isapre Consalud S.A.*, the Court of Appeals of Concepción affirmed ISAPRE's refusal to cover ENBREL medication and specialist visits for a patient suffering from systemic juvenile idiopathic arthritis on the theory that the claim was based not on the right to life, but rather the right to health, which was not protected.<sup>17</sup> The Supreme Court confirmed the decision. On the other hand, in the case of *Carlos Fuentes v. Isapre Consalud*, the Supreme Court held that Isapre Consalud had to cover the home treatment of a patient suffering from various illnesses and epilepsy.<sup>18</sup> The decision held that the suspension of coverage was illegal because it breached a contract and threatened the constitutional right to life and integrity of the patient (Henríquez 2010).

HIV/AIDS patients have not been so successful, at least not in court. Between 2000 and 2001, claims were made for triple drug therapy on behalf of patients who could not afford them. On one occasion, the Court of Appeals of Santiago admitted an appeal, indicating that the state allegations of lack of resources for the provision of triple drug therapy were unacceptable because the right to life was absolute, and the combination of drugs in the three-drug therapy was necessary to prolong the lives of the patients.<sup>19</sup> The Supreme Court, however, overturned the decision. But

<sup>17</sup> Court of Appeals of Concepción, Case of Maritza Lilian Segura Figueroa; *Helen Nicole Lagos Segura v. Isapre Consalud Sociedad Anónima*, Ruling of July 19, 2006.

<sup>18</sup> Supreme Court, Case of *Carlos Fuentes Rivas v. Isapre Consalud S.A.*, Ruling of July 18, 2007.

<sup>19</sup> Court of Appeals of Santiago, Ruling of August 26, 2001, Rol No. 3.025.

despite failing to obtain definitively favorable results, these cases have had an impact on public policy. Toward the end of 2001, they led the government to approve a law regarding HIV/AIDS (Contesse and Lovera 2005). This law, Law No. 19.779, establishes Norms Relative to the Human Immunodeficiency Virus and creates a Fiscal Supplement for Catastrophic Illnesses. It also imposes the duty to safeguard medical care for people with HIV/AIDS and to develop adequate public policies (art. 6). Later, HIV/AIDS treatment was incorporated into the AUGE plan (described below), and thus it became financed by the state. The provision of medications for fulfillment of this state duty was possible thanks to an agreement between the government of Chile and foreign labs that held patents on such drugs. The agreement led to a large price reduction in the necessary drugs, allowing the state to cover the needs of HIV/AIDS patients in the public health system.<sup>20</sup>

Starting in 2005, a constitutional reform led to further judicial recognition of the right to health. The Constitutional Tribunal began to hear new claims of unconstitutional deprivation of healthcare. Thus, the Tribunal upheld an action against ISAPRE for gender discrimination in their health plans. In that decision, the Constitutional Tribunal began to treat the right to health as something more than a programmatic right (Couso and Reyes 2009). Rather, it declared that health was a social right, not a simple declaration or mere expectation “whose effective materialization remains suspended until budgetary availabilities of the State can put it into practice.”<sup>21</sup>

As noted with regard to AIDS, judicial activism had an effect on the government. During the Ricardo Lagos administration (2000–6), a large health reform known as Plan AUGE was undertaken. With respect to medications, Plan AUGE required the development of a National Policy of Medications (Exempt Resolution No. 515 of April 2, 2004). The reform was codified by Law No. 19.966 of March 11, 2005. The objective of this legislation was to guarantee the population access to essential medications. It created specific guarantees for the actions of promotion, protection, and maintenance of health, with respect to sixty-nine pathologies. The specific guarantees include guarantees of access, attention, quality, and financial protection. Each pathology covered by the AUGE, which is the basic healthcare plan, covers different treatments, and in some cases coverage includes medications. In Supreme Decree No. 44 of 2007, the Health and Housing Ministries began to clarify the scope of this coverage.

In spite of the strengthening of the right to health through its (rather precarious) recognition in the Constitution, judicial activism for catastrophic illnesses, and attempts to protect the right to health via its close relationship to the right to life, much remains to be accomplished. Because of the extensive private interests at play and the lack of knowledge regarding technological products among civil society, the operative contents of this right are not clearly defined with respect to medications. Furthermore, the Exempt Resolution failed to address intellectual property issues:

it does not include references to limitations on the patentability of medications, the possible use of compulsory licenses, or the issue of parallel importations.

### C. Negotiating and Implementing FTAs

Another political opportunity arose in connection with the negotiation and implementation of free trade agreements (FTAs) between Chile and other countries. Establishing these agreements has been a priority for Chile's international economic relations. However, these agreements contain clauses related to intellectual property and medications that are very demanding.

The Chile–US Free Trade Agreement provides an example. In June 2003, after twelve years of negotiations, the United States and Chile signed a free trade agreement between the two countries. The Chilean government hoped that signing the FTA would bring more economic growth; more and better jobs; investment; and clear, transparent, and effective commercial conflict resolution. During the negotiations, Chile accepted almost all the United States' demands with respect to intellectual property in exchange for advantages in access to US markets (Escobar 2006: 55). Several modifications of local law were made to adapt to TRIPS, several other changes were made to address the new demands of the United States. Thus, the FTA established greater protection for pharmaceutical products, beyond the level established in TRIPS. These TRIPS-plus obligations included an increase in the period of pharmaceutical patent protection, leading to an effective exclusion of generics during the lifetime of the patent: first, the United States succeeded in obtaining several years of compensatory extension for patents when their approval is delayed; second, it negotiated for five years of protection for undisclosed information regarding the effectiveness and safety of new chemical combinations in medicines. Both provisions have a direct effect on the production and marketing of generic products.

On January 1, 2006 the two-year period established for internal implementation of the FTA obligations expired. After a delay, on January 26, 2007, Law No. 20.160 was published, modifying Law No. 19.039, and adapting it to both the FTA with the EU and the agreement with the United States. The goal of the law, with respect to medications, was compliance with Chilean obligations. There were, however, several disputed aspects. Some did not provoke major controversies. For example, the US FTA did not expressly determine a specific period for patent protection because the understanding was that the standard twenty years established by TRIPS would apply. As noted, however, the period can be extended and Law No. 19.996 provided for a three-year extension. But the FTA envisioned other and longer extensions, including extensions for both delays in granting patents and in authorizing products for marketing. Nevertheless, Law No. 20.160 recognized only the possibility of a discretionary extension as compensation for an unjustified reduction of the period of effective patent protection due to the marketing authorization process. Similarly, while the FTA limited the causes for revoking patents, the United States attempted to include another TRIPS-plus provision, which would have limited the use of compulsory licenses (Díaz 2006: 104).

<sup>20</sup> Interview with José Manuel Cousiño.

<sup>21</sup> Ruling Rol 976-07, of June 26, 2008.



The United States also wanted these licenses determined in a judicial, rather than an administrative, proceeding. However, the text of the FTA and Law No. 20.160 did not speak to either issue. The text of the FTA section regarding patents and medical products omitted several other topics of interest to the United States, such as procedural issues, the question of parallel importation, and the availability of second-use patents.

Other open issues led to considerable discussion. One decisive point regarding the adaptation of Chilean law to the FTA related to undisclosed information. The FTA established periods of protection for undisclosed information with respect to a "new chemical entity," but did not provide a definition for the term. This left both countries with considerable flexibility. Foreign companies as well as the United States attempted to increase information protection during the adaptation of Law No. 19.039 to TRIPS, while domestic groups, such as ASILFA and CIF, argued about whether to limit or expand such protection.

ASILFA rejected the opinion that FTA laws regarding undisclosed information were self-executing (National Library of Congress 2007: 82). It approved the government's efforts to avoid monopolies over molecules that were not patented or patentable by transnational companies in Chile, and thus to prevent the unjustified invocation of undisclosed information protection as a way to impede health and safety authorization (National Library of Congress 2007: 82). ASILFA also argued that the concepts of business secrets and undisclosed information should not be confused, as they have very different bases for protection. At the same time, however, CIF attempted to strengthen the protection of undisclosed information, including analytical methodologies, clinical studies, and stability studies, claiming that such information should be protected as business secrets.

Law No. 20.160 sided with ASILFA on certain aspects. For example, it provided that the party seeking information protection must file an application in Chile within twelve months of having obtained its first authorization to sell anywhere in the world. However, as required by the FTA, the law mandated five years' protection for undisclosed information relating to clinical trials on new chemical entities that were undertaken to demonstrate effectiveness and safety. Thus, even after a patent has expired, it is possible that generic medication businesses will be required to present their own studies to clear their products for the market.

To make the law fully operative, on November 28, 2005, the Ministry of Health published Supreme Decree No. 152, which specified concepts, clarified procedural mechanisms for the granting of protection, modified the ISP's role in the process, and established a system of opposition to the granting of health and safety authorization. It also imposed the obligation to safeguard undisclosed information presented when requesting health and safety authorization. This protection covers studies designed to guarantee effectiveness and security of the product (art. 4). The Decree's text did not, however, provide much clarity regarding whether protection of undisclosed information is only granted when expressly requested. Some laboratories were later disappointed by that ambiguity, as they believed they could receive protection by merely requesting health and safety authorization.

In 2008, the Decree was sent to the Comptroller General of the Republic in the Ministry of the Health, as it was thought that the aspects that restricted, clarified, or expanded legal concepts might exceed the regulatory powers of the executive. However, on December 1, 2010, Supreme Decree No. 107, a new Regulation to protect undisclosed information was approved. This emphatically established that in order for a firm to enjoy such protection, it must explicitly request it and submit a separate copy of the clinical trial data or other undisclosed information for which it seeks protection. The Decree allowed the person benefiting from such protection to divulge the information contained in the protected data, in part or in full, once the health and safety authorization has been granted (art. 9). The Decree also provided that protection would end in cases of compulsory licensing or to meet certain public needs related to public health, national emergency, or other circumstances of extreme urgency; for national security reasons; to permit non-commercial public use; or because the protection was requested more than twelve months after the first authorization to sell was granted abroad (art. 10). Decree No. 107 also exempted the ISP from determining whether the information had been divulged, instead putting that duty on those seeking protection. Currently there are around thirty pharmaceutical products that benefit from undisclosed information protection.

On the whole, the relevant players appear content with the level of protection granted to undisclosed information. Nonetheless, there is still a debate regarding when such protection begins. The United States supports an interpretation that starts the time period when the new chemical entity is registered in the country where protection is sought, regardless of whether the medication has already been registered elsewhere. Under this view, generic entry into domestic markets would be delayed, even when the information had been publicly disclosed in publications and to other public agencies. Because Chile regards the protection to be based on the undisclosed nature of the information, it contends that protection should be triggered by the first registration anywhere in the world. In any event, the United States and Chile continue to disagree about the solution offered under current law.

The other continuing bone of contention is the question of linking patent enforcement to health and safety authorization. The linkage mechanism is designed to prevent health authorities from granting authorization to generic drugs without first confirming that the active ingredient is not protected by a patent. Under this approach, so long as the patent is valid, authorization will be denied even if other requirements for marketing approval are met (Holguín 2008).

The new law is silent on the matter of linkage. However, from the middle of the 1990s, multinational companies have been seeking ways to enforce linkage within Chile and to require the ISP to consider patents in the approval process. Thus, these companies sought legal protection through constitutional challenges (art. 21 of the Constitution), arguing that health authorization for a generic pharmaceutical product while the original had patent protection constitutes a threat to their right to industrial property (Egaña 2010: 37). The ISP responded that the only action it could take was to advise that the generic drug's request is inappropriate, but that it could not resolve the dispute by denying authorization (Ordinario June 5, 1998,

cited by Egaña 2010: 37). Later the ISP posted Circular No. 14 of Accreditation of Patents in Pharmaceutical Registries, which appeared to go further. However, the Circular was very difficult to apply as it did not specify what information was needed in order for an application to be denied. Nor did it say whether it would deny registration on account of patent applications (Egaña 2010: 37).

The situation for multinational pharmaceutical companies improved somewhat with the signing of the FTA with the United States. Chapter 17.10.2(c) of the Chile-US FTA provides that the parties shall “not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner.” However, it does not include a specific procedure akin to that found in US law (Roffe and Santa Cruz 2006).<sup>22</sup> Furthermore, according to the Comptroller General of the Republic, it is not a self-executing obligation.

In order to address the ambiguity produced by the FTA, on July 29, 2004, a few months after the FTA entered into force, the Ministry of Health published Decree No. 245-03, modifying Supreme Decree No. 1.876. This Decree eliminated references to the concept of “marketing” associated with the effects of a health and safety authorization, thus clarifying that the ISP would not, as the multinational pharmaceutical companies hoped, undertake a regulatory role regarding patent infringement. Thus, Juan Pablo Egaña has classified the government of Chile’s attitude as “at least elusive” of its international obligations (Egaña 2010: 39). For Egaña,

[t]he evident intention of this modification was to leave without support the application of norm 17.10 2. c) of the FTA that requires Chile to deny the marketing authorization of a pharmaceutical product. If no authority grants marketing permits of pharmaceutical products, in effect the law has no one to apply the FTA provision, and it will simply fall into disuse. In spite of the absurdity of this situation, given that it is undeniable that the health and safety authorization is required for a pharmaceutical product to be marketed in Chile, the discussions on this issue between the government and producers of brand-name and generic drugs has dragged on for years. (Egaña 2010: 39)

Even though the CIF and lawyers like Juan Pablo Egaña<sup>23</sup> view this modification as a trick or legal strategy to avoid compliance with international obligations, ASILFA and the government of Chile have defended this modification as a mere clarification derived from the Chilean constitutional regimen. In accordance with article 19.21

<sup>22</sup> In the United States, 21 U.S.C. § 355(j)(2)(B) establishes that the applicant requesting health and safety authorization may present a certificate affirming that the patents declared in the request are null or will not be infringed by the generic product. The applicant is required to give notice to the patent owner in question within twenty days. In this notification, the applicant must indicate that he intends to manufacture, use, and commercialize the generic before the relevant patents expire, as well as indicate what arguments support patent nullity or non-infringement. The FDA can approve the abbreviated request unless the notified party presents a suit before the district court for patent infringement within forty-five days of notification. If the patent holder does present such a suit, approval is suspended for thirty months from notification (Cárdenas 2011: 11).

<sup>23</sup> Both Juan Pablo Egaña and José Manuel Cousiffo (Director of the CIF) agreed on this in their interviews with the author.

of the Constitution, Chile guarantees the freedom to undertake all types of economic activities in the country, including the production and commercialization of pharmaceutical products. Thus, in Chile, a specific commercial authorization is not required for the sale of pharmaceutical products. Rather, only health authorization from the ISP is necessary, as established in the Regulations for the Management of Pharmaceutical Products of Supreme Decree No. 1876, published in 1995. The ISP grants health authorization to new medications. To do so it reviews studies and tests that support the application, but the authorization is for public health and not commercial purposes. Indeed, Supreme Decree No. 1.876 was modified to eliminate the requirement to cite information regarding previous patents, further emphasizing that health authorization and patents are completely distinct topics, and that the respective granting authorities must remain separate. Patents that claim a relationship between innovation and development are considered outside the competence of the ISP, as the law that establishes its functions indicates (National Library of Congress 2007: 91).

Based on this interpretation, the Directorate of International Economic Relations (Direcon) has insisted that Chile is complying with international standards of intellectual property rights, and has duly honored its international obligations. But the result may be unstable. The new, right-leaning government of Sebastián Piñera has a slightly different view on linkage and CIF has criticized the law for undermining patenting (National Library of Congress 2007: 50) and failing to comply with the FTA. On the other hand, ASILFA praised the definitive exclusion of linkage, a mechanism it considered equivalent to an “administrative patent” (National Library of Congress 2007: 82).

For its part, the USTR has been using the Special 301 procedure to pressure Chile to modify its legislation and appease transnational companies with respect to linkage. The Chilean government has resisted. As a result, in 2006, Chile was on the Watch List for its failure to address linkage issues. In 2007, it was included in the Priority Watch List. In 2008, Chile continued on the Priority Watch List for both linkage issues and insufficient protection of undisclosed information (USTR 2008: 35). The 2008 Report suggested that “further amendments to Chile’s IPR legislation are needed to bring Chile’s IPR regime into line with its multilateral and bilateral commitments” and in 2009 Chile made some changes. It created a specialized unit within the Chilean police to investigate intellectual property rights crimes. Additionally, it opened a National Institute of Industrial Property to control administrative actions related to industrial property, including patents and copyrights. Chile also accepted the Patent Cooperation Treaty, thus fulfilling an obligation in the US-Chile Free Trade Agreement framework. Some of these efforts were mentioned in the 2009 report (USTR 2009: 15, 22). Nonetheless, Chile remained on the Priority Watch List for “fall[ing] well below expectations of a U.S. free trade agreement partner” (USTR 2009: 22). Chile remained on the Priority Watch List of the USTR in 2010 and 2011, due to reports from multinational companies that Chile failed to adequately protect undisclosed information and for lack of linkage (USTR 2010: 25–6; USTR 2011: 34).



Each time Chile has appeared on the USTR Priority Watch List due to linkage or undisclosed information, it has caused controversy in the national press and debate among CIF, RECALCINE, and ASILFA. For ASILFA, the main reason that Chile continues to appear on the United States' "red list" of countries that do not offer sufficient intellectual property protection is because the USTR succumbed to pressure from the US pharmaceutical sector.<sup>24</sup> Regarding Chile's inclusion in the Watch List, the vice-president of ASILFA affirmed, "[i]t is time for the accusatory international pharmaceutical industry to present a complete list of the products and patents that they claim are infringed. It is unacceptable and reproachable that American pharmaceutical companies, with their powerful lobbies and unfounded public accusations, dirty the image of our companies, and, more importantly, our country."<sup>25</sup> With respect to this demand, neither the CIF nor the American embassy has presented a list of ongoing patent infringements, nor has it used the civil or criminal processes authorized by Law No. 19.039 for patent holders.

### 1. *The Role of Civil Society*

Negotiations of free trade agreements proceeded on a different path from the negotiation of TRIPS. This time, consultations offered an avenue for participation.

Concerning the FTA Chile–US, the presence and activities of the NGO Alliance for Just and Responsible Trade (ACJR) was especially important. Between December 1998 and 2002, this organization participated in public consultations and undertook other events and conferences related to the FTA. It was the only member of civil society that based public critiques of the adaptation of intellectual property norms in Chile on distributive justice arguments and on concerns about access to health.

ACJR began in the 1990s, with a small group of supporters of fair trade. As the movement for fair trade within Latin America expanded, eight other actors concerned with cultural and consumer rights in Chile joined. According to Smith and Korzeniewicz, "The Chilean Alliance for Just and Responsible Trade (ACJR in Spanish) was formed in post-Pinochet Chile by a variety of groups critical of their country's status as a 'model' for showcasing neoliberal economic restructuring. The ACJR's priority focus is on the negative social, economic, and environmental consequences of globalization via trade liberalization . . . Recently, the ACJR has taken the lead in lobbying the Chilean Foreign Ministry for a broader consultative role for Chilean civil society" (Korzeniewicz and Smith 2001: 35). It also began to connect fair trade topics to the problem of accessing medicines (Andrade 2009; Agloni and Arizta 2012).

<sup>24</sup> Vice-president of ASILFA: "In the US the pharmaceutical lobby is brutal" (in Spanish, "En los Estados Unidos el lobby farmacéutico es brutal"), *El Diario Financiero*, April 26, 2010.

<sup>25</sup> María Angélica Sánchez, Letter to *La Tercera*, May 26, 2010, p. 2.

The organizational form of the ACJR corresponds more to that of a horizontal space where different organizations can converge.<sup>26</sup> Fair Trade, the Center for National Studies for Alternative Development, the Institute of Political Ecology, the National Council of Consumers and Users, the Inter-American Platform for Human Rights, the Group of Agricultural Studies, and Digital Rights, among others, participated in the common space ACJR created. There were, however, no longstanding, consolidated human rights organizations within the group. Human rights organizations remained focused on civil and political human rights; they did not concern themselves with the relationship between human rights and technological issues.

Despite ACJR's efforts (and its success in deliberations concerning the Free Trade Area of the Americas (FTAA)), civic participation was not very influential in the negotiation of the FTA. NGOs and other organizations were only periodically informed about the progress of the bilateral negotiations. According to Coral Pey, the delay in invitations, the mixed nature of the participants, and a unilateral structure where the negotiators informed the development NGO, and trade networks, prohibited any possibility for dialogue (Pey 2001).

With consultative participation, however, the ACJR had the opportunity to forge new alliances, including in a transnational context. It attempted to create a platform of alternative globalization, with the aims of resisting pressure from the United States and multinational pharmaceutical companies and elevating commitments to distributive justice above other interests with respect to the relationship between intellectual property and health. That objective was evident in a recommendation it made at the conclusion of the conferences of civil society regarding the FTAA: "[e]xclude the health issue from the international trade negotiations and, if applicable, grant it specific regulatory status other than the general services regime of the current agreement, which provides for the observance of international human rights law as regards the right to health" (FTAA.soc/civ/121 2004).

ACJR formed alliances with other civil society organizations, and together they disseminated information and held public debates regarding the right to health and access to medications. During these activities, ACJR advocated for a constitutional right to health, but neither public opinion nor the Chilean Congress paid much attention. Nonetheless, the capacity of ACJR to mobilize legal and economic experts who disagreed with the dominant opinion in global networks and public opinion was notable. It made strong arguments based on the continuous increase in the price of medications, which was more than double the overall increase in the cost of healthcare, and triple the increase of the Index of Consumer Prices (IPC) in the period between 1998 and 2005 (Silva 2004). With respect to the FTA with the United States, the ACJR targeted TRIPS-plus obligations, in particular the five-year exclusivity period, linkage, and the possibility of extending the period of protection for another four years. It was also concerned with the written aspects

<sup>26</sup> Pey, Coral, interview with Astiel Larrúa, "Today trade negotiations are a State Secret" (in Spanish, "Las negociaciones comerciales hoy en día son un Secreto de Estado"). Retrieved June 10, 2011 at: <<http://www.nodo50.org/pretextos/Coral%20Pey.htm>>.



of the treaty, principally the notable silence regarding parallel importations and the use of compulsory licenses (Silva 2004).

Unfortunately, the ACJR dissolved after five years and, during the period of study, was not replaced by other civil society organizations. It was thus the only actor that undertook consistent and relevant activity related to questioning the formation and implementation of intellectual property laws regarding medication from a public interest perspective. The lack of functional equivalents in other organizations and the reduction of the government to the role of mediator of the private interests of laboratory associations have meant that for this period, there was no one to articulate and defend the public interest.<sup>27</sup>

#### D. The Piñera Government and Continued Opposition in Implementation

When the cycle of central-leftist governments of the Coalition of Parties for the Democracy ended in 2010, the new government, ideologically center-right, needed to confront the same international and domestic pressures with which former governments had grappled. The unresolved topics—linkage, undisclosed information, and the like—were the same. Thus, there was a clear continuity between the opportunity structures of the current period and the prior ones. The commitment to an intellectual property system endured, as did the identity of actors who oppose the implementation of international obligations. The government of Sebastián Piñera, which has attempted to end the controversies, began with two policies in the health sector: the linkage law and the policy of bioequivalence of generics.<sup>28</sup>

<sup>27</sup> The debate over the TPP is, however, occurring in the midst of the mobilization of new social movements and cycles of protests. The protests have been largely aimed at promoting the environment, demanding public education, changing the structure of the economy, and enhancing democratic governance (Villalobos-Ruminotti 2012; Garcés 2012; Garretón 2013). However, the changes in contention politics are also reflected in the health arena, where a movement called “Health, a Right” (Salud, un Derecho 2012) has formed. In addition, Chilean activists have coalesced with groups in Mexico and Peru to form TPPabierto.net to coordinate opposition to the TPP and with other conglomerates interested in medicine to form LAC-Global Alliance for the Access to Medicines to demand greater transparency in negotiations and to highlight the threats that the TPP poses to access. Significantly, in August 2013, the Senare accepted an agreement (Document No. 647/SEN/13) which asks the President to open a broader debate on the TPP.

<sup>28</sup> Since 2006, Chile has been involved in negotiations with Australia, Brunei Darussalam, Malaysia, New Zealand, Peru, Singapore, Vietnam, and the United States over the TPP. The details of the initiative have been confidential. However since this study was completed, information about the chapter on intellectual property has emerged. It has become clear that, if adopted, the TPP will impose many obligations with significant impact on the health arena, including rights to patent new uses of known products as well as diagnostic, therapeutic, and surgical methods; adjustments to the patent term to compensate for delays in awarding patents or marketing approval; extension of data exclusivity; and new measures protective of biological products. As noted in n. 27, the threat of the TPP has created new coalitions among international actors, including the formation of LAC-Global Alliance for Access to Medicine, which has highlighted the cost that Chile will incur if it joins the agreement (Public Citizen 2012).

#### 1. Linkage: Proyecto de Ley del Linkage Judicial

As noted, Chile has been skeptical of the linkage mechanism on the ground that patent registration and health authorization are distinct issues, not only because their functions are different, but also because the information that needs to be considered in decision making is different. Patent registration is directed at determining whether molecules are new and have pharmaceutical potential, while health authorities consider studies that prove the safety and effectiveness of these medications. ASILFA also opposed linkage on different grounds. Thus, María Angélica Sánchez, Vice President of ASILFA, argues, “it is inappropriate to apply measures that will directly affect the poorest sectors of society, affecting the health of Chileans.”<sup>29</sup>

Nonetheless, the CIF and the United States have continued to insist that linkage is necessary, that it must be administered by the ISP, and that without linkage, Chile has not fulfilled its FTA obligations. Various interests groups agree. In debate with Sánchez, Gabriel Saliaznik, attorney for RECALCINE, describes administrative linkage as a “good strategy of ‘administrative patenting’ that consists in placing barriers to administrative and legal entry in order to frustrate or restrict the possibility that domestic laboratories commercialize low cost medications that lack a patent in Chile.”<sup>30</sup> Groups in Chile that are close to the United States view non-compliance as an obstacle to the country’s development and well-being. Thus, the president of AmCham has indicated that “without a doubt, Chile hopes to become a developed country, with opportunity, and without the poverty levels that currently plague us. Thus it is important, in particular in this specific case, that Chile respect the international agreements that it signs. We must always honor our obligations, and, in this case it is important to accept that in order to make our hopes reality, it is in our interest and benefit to support those who research, invent, and execute.”<sup>31</sup>

To deal with the difference in views, the Piñera government proposed a type of linkage that did not affect the traditional obligations of the ISP. Thus, the government has proposed fulfilling the FTA obligation with so-called “judicial linkage.” In this system, when the ISP receives the application for health authorization from a producer of generics, it would publish a detailed report of the information online. The ISP could grant the health authorization, but that would not automatically trigger the right to commercialize. Instead, the company that holds the patent would be notified about the application, given an opportunity to bring a legal action to defend its rights, and allowed to petition for provisional measures which would suspend (up to a year) the grant of any marketing

<sup>29</sup> Pharmaceutical Patents (in Spanish, “Patentes Farmacéuticas”), *Letter to La Tercera*, January 26, 2011, p. 30.

<sup>30</sup> Gabriel Saliaznik, “Patents and Access to Medicines” (in Spanish, “Patentes y acceso a las medicinas”), *El Diario Financiero*, October 8, 2010, p.2.

<sup>31</sup> Oped by Javier Irarrázaval, President of AmCham, *La Tercera*, January 29, 2011. Retrieved on February 24, 2011 at: <[http://blog.latercera.com/blog/murodenegocios/entry/chile\\_no\\_esta\\_cumpliendo](http://blog.latercera.com/blog/murodenegocios/entry/chile_no_esta_cumpliendo)>.

registration that would threaten patent rights covering the active ingredients in the relevant medicines.

On January 20, 2012, this proposal was sent to Congress in the form of Bulletin 8183-3. It would create a public book, administrated by the ISP, in which all patent holders of active ingredients could include their patents. Only patents included in the book could be the subject of precautionary measures to suspend health authorization pending the determination of infringement.

Generic producers would be protected in several ways. Actions to suspend the ISP's grant of health registration would not suspend the Bolar exception included in the final section of article 49 of Law No. 19.039. Thus, the generic companies would be permitted to continue to utilize the patented invention in order to obtain information needed to acquire health authorization. To avoid abusive use of precautionary measures, the bill proposes fines for malicious use of the system. Finally, it limits the application of the system to active ingredients, leaving all other patents subject to the current regime.

Unfortunately, this proposal has not managed to reconcile the diverse interests involved. Some legislators opposed to the strict application of intellectual property rules requested that the Congressional process be withdrawn, and that the Constitutional Tribunal review the bill. The Constitutional Tribunal, in its decision of March 22, 2013, rejected the claim and upheld the constitutionality of the bill.

Nor has the United States government accepted the solution proposed by the bill. Thus, even if the proposal were to become law, the Piñera government may continue to see Chile on the USTR's Priority Watch List.<sup>32</sup> Despite the attempt at compromise, market rivals continue to assert non-negotiable positions in the implementation of international obligations in the pharmaceutical sphere.

## 2. *Bioequivalence: Consensus on the Need to Improve the Quality of Generic Drugs*

One issue that has become quite visible in recent years is the quality of generic medications. Although requiring bioequivalence is not a matter of international law, the difficulty in ensuring quality demonstrates how a clash among private interests can impede the adoption of socially important legislation even when the government takes a pro-active role and becomes more than a mediator of private interests.

In May 2011, the current Minister of Health, Jaime Mañalich, announced a proposal to create a new institution, the National Agency of Medicines (ANAMED) to oversee and control the quality, safety, and effectiveness of generic medications (approximately 340 drugs). The proposal, Bulletin 7805-11, would require the certification of the bioequivalence of generics. At the same time, the bill proposes a requirement that doctors prescribe medications with generic alternatives. This bill was later merged with a pending bill that authorizes direct sales of certain medicines in supermarkets (Bulletin 8133-03). Given the extremely low

<sup>32</sup> Furthermore, the bill would likely require revision if Chile accedes to the TPP in its current form, which purportedly includes a provision on linkage.

safety level with respect to the quality of generic medications, these are long-awaited measures. Despite polarization on other initiatives, these have the support of the principal players involved in the policy debates in the medicines arena.

Still, this approach faces significant obstacles. The quantity of active ingredients that must obtain certification is very large and aside from laboratories at the University of Chile, the Catholic University, and the University of Development, there are very few laboratories capable of undertaking bioequivalence studies. Even these labs are problematic, for many in the generics industry perceive them as taking a long time to make the demanding determinations of bioequivalence. Creating ANAMED is therefore an important first step to improving quality. The principal strategic areas ANAMED will focus on include the development of Good Manufacturing Practices, respecting bioequivalence requirements, increasing and reinforcing drug oversight, establishing a framework for clinical studies of medication, reinforcing relationships with other Latin American medical agencies, and reinforcing relationships with other public and private actors at the local and international level. For the current year, the objectives include accrediting good manufacturing standards for at least 50 percent of laboratories, achieving an average health authorization time of 152 days, founding three new centers for bioequivalence determination, and introducing bioequivalence as a requirement in national policies proposed by CENABAST.

The proposed legislation would affect the various sectors of the generic industry differently. As noted at the outset, the acceptability of generics has been largely based on relationships of trust. There are only a few certified generics on the market. These were voluntarily submitted to lab procedures at the University of Chile and the majority of the bioequivalence certificates obtained in the past (around 70) were requested in order to comply with health or commercialization authorization requirements in foreign—not local—markets. Domestically, legislation has been permissive. In accordance with Decree No. 1876, medication quality is the responsibility of the manufacturer, importer and distributor, but not the state. And while the ISP modified Supreme Decree No. 435 via Supreme Decree 1876/1995, Regulations of the National System of Control of Pharmaceutical Products, Foods for Medical Use, and Cosmetics to incorporate bioavailability as a requirement for authorization (article 4), the regulation was never followed (although the WTO has norms regarding Good Manufacturing Processes, they are not mandatory). According to the Ministry of Health, 9 of 34 laboratories in Chile have quality certification in their productive processes.<sup>33</sup>

Similarly, other attempts to ensure quality have affected only parts of the industry. In the National Policy of Medications in the Health Reform, established by Exempt Resolution No. 515 on April 2, 2004, the Ministry of Health indicated which existing generics were bioequivalent of brand-name drugs. On November 14, 2005, the ISP established a list of 43 active ingredients contained in pharmaceutical

<sup>33</sup> Arnaldo Guerra, "Generic Medicines Don't Work" (in Spanish, "Medicamentos genéricos no mejoran enfermos"), *Punto Final*, No. 714, July 23, 2010. Retrieved on April 20, 2011 at: <<http://www.puntofinal.cl/714/genericos.php>>.

products that must establish therapeutic equivalency through *in vivo* and *in vitro* studies via its Exempt Resolution No. 762. The Ministry of Health's Exempt Resolution No. 727 of 2005 established criteria to demonstrate therapeutic equivalency in pharmaceutical products in the country. However, it did not provide norms to accredit laboratories that undertake bioequivalence and bioavailability studies in the country. Later, it passed Exempt Resolution No. 4886 of 2008, which establishes technical guides for the realization of bioequivalence studies of pharmaceutical products and monodrugs on conditional release. Further, it has created forms for the presentation of required background information in order to undertake such studies. Also in 2008, Exempt Resolution No. 934 modified Exempt Resolution No. 726 to incorporate 36 additional molecules that must establish therapeutic equivalency through *in vivo* and *in vitro* studies.

The remaining similar generics, brand-name or not, that lack bioequivalence and bioavailability certification are in a limbo of uncertainty with respect to their quality, safety, and medical effectiveness. Laboratories continue to manufacture drugs without complying with minimum standards. One batch may not be manufactured the same as the following, and no one guarantees that any of the output is bioequivalent to a known pharmaceutical. Additionally, according to figures from ISP, 49 percent of medications sold in the country come from abroad. In many cases, the conditions under which they were manufactured cannot be known, nor can it be determined whether they have the therapeutic effect that their packages claim.

This situation is clearly creating serious problems. However the laboratories that produce generic drugs maintain that a drastic shift in policy in favor of bioequivalence could have a strong negative effect on the domestic pharmaceutical industry. Between 2004 and 2008, the Best Pharma Laboratory was sanctioned for irregularities 30 times. Laboratorio Chile received 8 fines, Sanderson had 7 sanctions, RECALCINE had 6, and Andrómaco, Biosan and Mintlab each had 4. Until its closing in 2008, Best Pharma had become the principal provider to the state, but a series of scandals closed the laboratory. In 2005, a 3.5 centimeter piece of glass was found in a vial. In 2006, an insect was found in an antibiotics strip. In 2007, a sewing thread appeared in a bottle of ampicillin. In 2008, a hair was found in a sealed bottle. Finally, in 2008, the ISP revoked Best Pharma's license, after a scandal in which the sale of a generic version of Tamoxifeno, a drug advertised to treat breast cancer, was found to produce no curative effect. Another medication, Midazolam, used as a sleep aid, was also found ineffective. The Cancer Institute undertook tests on the drug, and found that in more than 60 percent of patients it did not reach optimal effect. In total, Best Pharma accumulated 56 fines and investigations before it was closed.

Currently, there is no guarantee with respect to the quality of medications imported from foreign producers. This situation has been exacerbated by an explosive growth in Chinese and Indian imports. In 2008, in accordance with ISP estimates, 40 percent of medications imported to Chile are made in China. With respect to such drugs, the ISP does not strictly control their quality: it does not make visits to the laboratories in which they are produced to exercise control

over their manufacturing conditions. Such conditions are only known to Chilean authorities via the reports provided by the companies themselves.

In 2011, the Ministry of Health changed the Regulation of Control of Medications, publishing Supreme Decree No. 3 on June 25, 2011. This Decree approves the Regulation of the National System of Control of Pharmaceutical Products for Human Use, which makes effective the bioequivalence requirement. Nonetheless, it still does not contemplate rules for Good Manufacturing Processes or accreditation for the standards of laboratories that produce generics. Through various resolutions (3225/08, 728/09, 2920/09, 244/11), around 400 generic drugs must certify their bioequivalence by the beginning of 2012, which will mean the end of similar drugs that do not manage to certify their bioequivalence before then.

As demonstrated by the data of ISP, laboratories have complied with deadlines for only 36 generic drugs.<sup>34</sup> Together with those, laboratories have voluntarily submitted to certification for an additional 18 bioequivalent generic medications. Only 54 drugs are WHO certified generics, out of a total of 12,564 registered medications—0.42 percent of all medications. To address this situation, the ISP has imposed more than 90 fines on non-compliant laboratories, but these labs have appealed these decisions to the Comptroller, which halted the bioequivalence process by determining that the ISP overstepped its role in imposing such sanctions.

In the meantime, laboratories that produce generic drugs have removed more than 100 products from the market and a study by consumer groups has raised fears that the strengthening of the process will likely raise the cost of generic drugs that obtain the bioequivalence certificate (SERNAC 2013). The bottom line is that despite the unusual consensus on improving drug quality, there is still considerable conflict between domestic and foreign laboratories. Chile is thus far from developing an effective, consensual policy of medications that resolves the problem of back door opposition. Neither the generics bioequivalence certification nor the judicial linkage policies undertaken by the current administration have managed to reduce tensions between the players of the pharmaceutical market with respect to implementation of intellectual property laws. Additionally, as noted in the margins, a confluence of social movements and Chile's participation in negotiations of the Transpacific Partnership Agreement has led to, a rejection of the private health model currently functioning in Chile, and within it, the policies that affect medicines.<sup>35</sup>

#### IV. Conclusions

In Chile, the collision between intellectual property rights—particularly patents and the protection of undisclosed information—can be characterized by two

<sup>34</sup> "Bioequivalence in Chile: Far from a Success" (in Spanish "Cumplimiento de bioequivalencia en Chile: muy lejos del éxito"), May 1, 2012. Retrieved June 20, 2012 at: <<http://www.saludunderecho.cl/2012/03/cumplimiento-de-bioequivalencia-en-chile-muy-lejos-del-exito>> and <<http://www.politicafarmacuticas.cl/2012/03/01/cumplimiento-de-bioequivalencia-en-chile-muy-lejos-del-exito/>>.

<sup>35</sup> See nn. 27–8.



phenomena. First, the basic tenets of Chilean foreign policy are oriented toward trade liberalization and voluntary subordination of national interests to the demands of private multinational companies. Second, public health policy related to medications is largely forged through debate among private interests—foreign and national laboratories. The government acts mainly as mediator between these interests. As a result, there is inadequate attention to the public interest.

On the whole, the result is a triumph for intellectual property rights, with gradual concessions to almost all of the demands of the United States and foreign pharmaceutical companies and an absence of public-regarding policies and laws safeguarding access interests. Nonetheless, one can find evidence of back door opposition. True, civil society was weak—the major exception was the Chilean Alliance for Just and Responsible Trade (ACJR), which is no longer active. Thus, civil society did not manage to furnish the expertise necessary to further local and public interests. Nor did NGOs prove capable of mobilizing resources to protect public goods. However, alliances between government officials and the domestic pharmaceutical industry, which were based on the desire to maintain a strong domestic pharmaceutical industry in the face of international competition, had an effect. Law concerning second-use patents, linkages between patents and safety and health registration, and rights over undisclosed information are marked by deliberate ambiguities in legal terminology and deliberate delays in implementation.

While not everyone is completely satisfied with what has been achieved, Chile has managed to address health problems with its current medications policy. Because it has maintained strong competition in the pharmaceutical market, it enjoys the lowest prices in the region. But this positive result may be one of the reasons that civil society activism has been lacking.

If the situation does not change and expert critics, a stronger civil society, and networking with social movements outside Chile do not emerge, then public interest problems regarding the effects of intellectual property laws on medications will continue to be inadequately unaddressed. But there is reason to be hopeful. Thanks to a cycle of social mobilizations in Chile that began in 2010, a social movement for the right to health is on the rise. Since this study was completed, there has been a growing opposition to policies that limit access to medicines, major knowledge resources are being mobilized, and there is increasing coordination and among national and international activists.

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## APPENDIX

## Relevant Legal Decisions in Disputes Regarding Intellectual Property Rights over Medications

The majority of the debate surrounding the relationship between intellectual property and access to medications has taken place during the legislative process of adapting Chilean law to the norms imposed by international agreements. The judiciary has entertained few pharmaceutical patent cases. However, some litigation has taken place in the Comptroller General of the Republic, the courts, the Free Competition Court, and, recently, the Transparency Council. Decisions from these bodies have had a palpable impact on current controversies. Accordingly, the courts could be considered an additional locus of confrontation. But the cases show it to be a weak one. First, the confrontations are—once again—between the private interests of the large market players, foreign and domestic laboratories. As a result, judicial involvement has not produced judicial activism in the form of firmly establishing a right to health or articulating doctrine that promotes access medication. Second, as described above, the courts have mostly thrown the debate back into the legislative arena.

## A. Pronouncements of the Comptroller General of the Republic

The internal body of administrative accounting and court of auditors of Chile, the Comptroller General of the Republic, entertained two important cases pitting several of the “usual suspects” against one another in arguments about the relationship between patent rights and health authorization. In the first case, Decision 51760 of December 17, 2002, CIF questioned ISP practices and ASILFA intervened. In the second, Decision No. 61817 of December 26, 2006, Bristol Myers Squibb Chile brought the challenge and the Department of International Economic Relations (DIRECON) participated. Both cases raised the familiar linkage question, on whether the ISP could register generic medications for marketing when some ingredients were protected by patents. The first challenge was based on rights under the patent statutes and the second also included claims based on the linkage requirement in Chile’s FTA with the United States.

Rehearsing many of the same arguments made in the legislative debates, the Comptroller General decided the ISP could authorize sale of these products, and could even entertain successive requests for authorization from multiple generic companies. In the first case, the Comptroller reasoned that the ISP did not have the legal power to deny authorization. In the second, it stressed the conceptual distinction between determining safety and determining patentability. The second case also involved an argument that that authorization could not be granted because it required the ISP to rely on undisclosed information regarding quality, but the Comptroller rejected that as well. As to both the linkage and the data issue, it held that the FTA was not self-executing. Indeed, the Comptroller reasoned, that was why the legislature understood that it had to pass Law No. 19996 to implement the FTA.

## B. The Courts

Chilean courts have shown themselves somewhat sympathetic to patent rights. For example, in a celebrated case on patent infringement, Criminal Decision RIT 185-2007, *Sanofi-Aventis v. Royal Pharma*, the third chamber of the criminal court held a Royal Pharma manager guilty of criminal patent infringement for producing and distributing a medication whose active ingredient, Copidrogel, had been patented by the French laboratory Sanofi-Aventis. The case was an unusual one in that it involved two different crystalline forms of the same compound, both used to treat the same infirmity (arthritis); one argument in the case drew on work by noted lawyer and economist Carlos Correa, who argued that a patent on a new form of a known compound is invalid (Correa 2009). However, the court rejected the argument and fined the manager 100 UTM (approximately USD 4,000). Furthermore, the Constitutional Tribunal upheld the judgment against a constitutional challenge that the criminal law was being applied retroactively.

*Sanofi-Aventis* appears, however, to be exceptional. There have not been other significant cases finding patent violations, and certainly no criminal ones. Moreover, on issues related to implementing TRIPS and the US FTA, the courts have taken positions similar to the Comptroller General. In one 2003 case, Pfizer SA sued the ISP and RECALCINE, arguing that approval of a RECALCINE drug violated Pfizer’s constitutional right to property because it permitted RECALCINE to engage in patent infringement.<sup>36</sup> The Supreme Court affirmed the decision of the Fifth Chamber of the Court of Appeals of Santiago, which rejected Pfizer’s argument. A similar result was reached in the 2009 decision of Invalidity of Public Law, Rol No. 6313-2003, between Pfizer and RECALCINE. Here, the Court of Appeals of Santiago echoed a point the Comptroller made, holding that the ISP is not competent to consider patents when granting health authorization, and must only consider elements related to quality, safety, and effectiveness.

In another case, Appeal for Protection, Rol 2891-03, Eli Lilly tried a somewhat different argument, claiming that actions granting generic firms health authorization for patented inventions was illegal and arbitrary because the background information the ISP used included the patent. Lilly also asserted that the ISP threatened Lilly’s legitimate exercise of the right to property, protected in article 19.24 of the Constitution. But once again, the ISP practice was upheld. The Court of Appeals of Santiago reasoned that the ISP’s competence is limited to activities related to the quality control of medications, and thus it is barred from involving itself in the resolution of conflicts related to intellectual property. The Supreme Court’s ratification of the decision helped convince foreign laboratories of the need to pressure the United States to continue to demand that Chile enact a strong linkage requirement.<sup>37</sup>

## C. Cases of Free Competition (the Free Competition Court)

A review of actions of the Free Competition Court underscores the degree to which the judiciary in Chile has left confrontation to other spheres. In these cases, the generic industry tends to be the aggressor and to bring suits against foreign pharmaceutical firms for abusing patent law by pursuing invalid claims. RECALCINE/Novartis Case, Decision No. 46, November 28, 2006 stemmed from a set of legal actions initiated by Novartis against the generic laboratory to enforce its patent on Glivac, which is used to combat myeloid

<sup>36</sup> Case *Laboratorios Recalcine SA v. Pfizer Chile SA* in Santiago Chile, March 26, 2003. Retrieved at: <http://www.gala-markedaw.com/membersonly/pdfs/Amsterdam2003.pdf>.

<sup>37</sup> Ruling Rol No. 839-2007-INA.