I. CHAPTER. INTRODUCTION

International relations among countries and their citizens have become increasingly significant as a result of globalization. In this context, rules regarding international trade are of paramount necessity, leading to the creation of the World Trade Organization (WTO). The WTO, successor to the General Agreement on Tariffs and Trade (GATT), was established in January 1, 1995, as a result of the Uruguay Round of Multilateral Trade Negotiations (1986-1994), aiming at promoting the reduction of trade barriers among Member States.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is in Annex 1C of the Agreement establishing the WTO – the Marrakesh Agreement – and provides for a comprehensive international set of rules regarding intellectual property protection and enforcement. As part of the WTO system, its provisions should be interpreted in the context of promotion of international trade. Disputes between member states regarding the compliance with the TRIPS obligations are subject to the WTO's dispute settlement procedures. TRIPS sets out minimum standards of protection that should be provided for by the member states for intellectual property rights. In addition, it establishes general principles to be applied to procedures and remedies concerning the enforcement of intellectual property rights.

The TRIPS provisions that have generated the greatest debate among Member States are those related to patent rights, which have been the subject of many studies from both legal and economic perspectives. As Machlup summarizes, justifications for the patent system can be classified into four categories: natural-law, reward-by-monopoly, the monopoly-profit-incentive, and exchange-for-secrets theories.[1] Some scholars justify the existence of intellectual property rights, taking John Locke's theory of natural-law, which states that man has a natural right to property when he employs his own labor to cultivate land, and applying this theory to ideas.[2] Under the reward-by-monopoly theory, inventions are useful to society and, thus, justice requires that inventors be rewarded for their services to

1 See *Machlup*, Economic Review, p. 51-61.
2 See *Locke*, Second Treatise on Government, p. 1-5.

society. Patent rights for inventions represent such a reward through exercising temporary monopolies.[3]

The theory of monopoly-profit-incentive argues that industrial progress and technological development is a very risky task that would only be undertaken by private persons and companies if they could receive profits and returns on their investments. This model establishes that property rights promote saving and investing, as well as the internalization of externalities.[4] It provides incentives for innovators to invest their money and energy into the creation of inventions under the circumstances of the appropriability problem associated with intangible assets.[5] Effort that goes into inventing and developing products is time-consuming and costly, which would not be performed without the possibility of a return on such investment.

The exchange-for-secrets theory assumes that patent rights stimulate innovation and industrial development by promoting the dissemination of technical knowledge that would otherwise be kept secret. It presumes a bargain between the inventor and society in which the former reveals knowledge and information in exchange for a temporary monopoly to be secured by the latter. This monopoly aims to protect inventors against information leaks concerning their invention, after being disclosed, preventing competitors from entering the market. In some cases, when a product can reach markets without information being revealed (i.e. without the possibility of reverse-engineering the technology), this theory plays an important role.[6]

Within the context of TRIPS, most developed countries support provisions that would create a stronger and more harmonious international patent system, stating that such a legal framework would serve as a basis for technological development. On the other hand, developing countries have been skeptical, defending that strong IP systems, especially patents, would limit access to innovations that are critical for the basic needs of their populations and would increase economic dominance of developed countries. The debate surrounding TRIPS continues, especially in the areas of health, pharmaceuticals, food, and agriculture. Developed countries argue that strong patent systems are essential to provide incentives for in-

3 See *Machlup*, Economic Review, p. 51-61.
4 See *Demsetz*, Theory of Property Rights, p. 6-12.
5 See *Levin et al.*, Appropriating Returns from R&D, p. 61-68.
6 See *Machlup*, Economic Review, p. 51-61.

novation in an industry where developing new products is highly time consuming and costly, such as the pharmaceutical industry. However, developing countries affirm that the standards imposed by TRIPS could harm the rights of Member States to protect public health and, in particular, to promote access to essential medicines.

As a result of the conflicts between developed and developing countries, the Doha Declaration on the TRIPS Agreement and Public Health of November 14, 2001, was adopted by the Fourth WTO Ministerial Conference, recognizing that intellectual property protection is important for the development of new medicine. The Declaration states that TRIPS should neither prevent Member States from taking measures to protect public health nor prevent them from making use of the flexibilities regarding patent rights provided in the Agreement – especially the granting of compulsory licenses.[7] For least developed countries, with insufficient or no manufacturing capacity in the pharmaceutical sector making it impossible to effectively utilize traditional compulsory licensing mechanisms, the Doha Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health allows them to import compulsorily licensed essential medicines.[8]

Brazil exports commodities that range from sugar, coffee and soybeans to aircraft, steel, textiles and footwear. The country's entrance in the WTO system has stimulated fast economic growth.[9] With diversified export partners, global trade has propitiated an increase of exports and imports, leading to an expansion of the Brazil's trade surplus.[10] In addition to benefiting from lower trade barriers, by acceding to the WTO, Brazil has accepted the TRIPS standards of intellectual property rights as a part of the international bargaining game.

The current industrial property law in Brazil, Law No. 9,279, of May 14, 1996 (hereinafter Law 9279/1996 or patent statute) was enacted to comply with promises made by the Brazilian government during trade negotiations with the United States, as well as with the obligations stemming from TRIPS.[11] The patent statute was inserted into the general context of economic modernization in Brazil, trying to attract foreign investments af-

7 See *WTO*, Doha Declaration (WT/MIN(01)/DEC/2).
8 See *WTO*, Doha Decision (WT/GC/M/82).
9 See *Workman*, Brazil's Trade Partners, para. 1-2.
10 *Id*.
11 See *Cepaluni*, Patent Regime: Brazil x USA, p. 49-63.

ter decades of import substitution policies. It suppressed restrictions to patentable subject matter, leaving out only a few areas, and adopted more effective procedures for the protection of rights. The statute's aim has been to adjust the Brazilian patent system to the new international context and, above all, allow for patents in the pharmaceutical field.

Despite theories affirming that a strong patent system may lead to internal development of technology, many Brazilian scholars and politicians still believe that patents are measures to designate a large share of the Brazilian market to foreign companies without creating benefits for the national economy.[12] The Brazilian government has sought to play the role of leader among the community of developing countries at the international level, stating that pharmaceutical patents go against public health policies and are detrimental to populations' ability to access medicine.[13]

Compulsory licenses, whose granting is considered one type of flexibility to patent rights within TRIPS, play an important role in the Brazilian government's program that distributes free drugs to treat AIDS. In this context, the complex relationship between private and public interests becomes clear. Under the argument that patents on these drugs result in increased prices, which is harmful to the long term maintenance of the free distribution program for budget constraints, the granting of compulsory license or the absolute denial of patents for such drugs are raised as a flag by the government. On the other hand, policies that threaten patent rights may have an impact on investments by foreign and national private companies due to the insecurity concerning adequate protections for inventions in the pharmaceutical field. This is an issue that should be analyzed in the particular context of each country and each respective public healthcare system.

This study is divided into three main parts – consisting of Chapters II, III and IV, respectively – that discuss the dynamics of global and Brazilian economic development that need to be reconciled with political decisions relating to public health. Through the use of bibliographical research method, this study seeks to analyze the Brazilian patent law within the framework provided by TRIPS and the context of international trade. The provisions ruling patents on the pharmaceutical area and those on compul-

12 See for example *Arruda, Cerdeira*, Patents on Medicines and Public Health, p. 117-132; *Assumpção*, Chemistry Patent in Brazil: A Troubled History, p. 1; *Basso*, The Brazilian Practice of the Prior Consent, p. 54-74.

13 See *Basso*, The Brazilian Patent Statute and the WTO Rules, p. 37-40.

sory license have been chosen to serve as the main driver for such analysis.

The first part (Chapter II) offers a broad picture of TRIPS provisions, its principles, as well as of the discussions leading to the Doha Declaration and Decision. The aim of this chapter is not to discuss these topics in depth, but rather provide a general sense of the international setting. The chapter includes historical background on Brazilian patent law prior to TRIPS, as well as principles governing the international patent system and the rules that seek to harmonize national legislations in Member States by establishing standards for acquisition and enforcement of patent rights. These should be regarded as minimum standards that are in tune with protection patterns in order to prevent national laws from becoming trade barriers. Rather than imposing protection standards to be equally implemented by different Member States, TRIPS creates room for each country to mold their respective patent laws in accordance with national policies. Consequently, some flexibilities are provided, namely, exclusions from patentable subject matter, exhaustion and parallel importation rules, general exceptions to patent rights, and compulsory licensing. Chapter II also discusses the Doha Declaration, the Decision Implementing Paragraph 6 of the Doha Declaration and concludes with remarks on the applicability of TRIPS in Brazil.

The second part (Chapter III) describes the Brazilian patent law, including compulsory licensing provisions, and provides assessment within the context of TRIPS. The goal of chapter three is to provide a general overview of the provisions ruling the country's patent system, specifically in the pharmaceutical area, as well as those regarding compulsory licensing. Provisions on patentability, rules on terms of protection, rights conferred and exceptions and limitations are all described in detail. There is a provision that requires patent applications related to pharmaceutical products and processes be subject to prior consent by the ANVISA, the regulatory agency primarily responsible for granting approval to market drugs. Chapter III discusses the role of the ANVISA in the Brazilian patent granting procedure, the agency's impact on the examination of applications that claim second medical uses, and ends with an analysis of provisions concerning compulsory licenses.

The third part (Chapter IV) analyzes the context of the Brazilian anti-AIDS program, addressing the cases of Abbott's Kaletra drug, Merck's Efavirenz drug and Gilead's Tenofovir drug. The impact of the WTO trading system on the Brazilian economy is taken into account, as well as dis-

cussions on cross-retaliation by the Brazilian government within the WTO dispute settlement proceedings and the effects of the implementation of TRIPS on the pharmaceutical sector. Data on the public health care system and a panorama of AIDS in Brazil are presented. The drugs used in the cocktail administered to treat AIDS, Kaletra, Efavirenz and Tenofovir, play an important role in government policies towards the use of patent rights as a tool to negotiate with industry. The goal of this chapter is to identify cases that illustrate how patent provisions, and intellectual property rights in general, are present in the Brazilian scenario after the implementation of the WTO system and TRIPS. Hence, Chapter IV ends with an analysis of the cotton case, which was judged by the WTO Dispute Settlement Body, and a discussion of the cross-retaliation in regards intellectual property rights in this case.

This work aims to analyze the implementation of TRIPS in the Brazilian legal framework and presupposes that the promotion of free trade and the access of Brazilian goods to foreign markets are of paramount importance to the development of the Brazilian economy. It is within this context that patent rights will be analyzed with a focus on the pharmaceutical industry.