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Viviane Yumy Mitsuuchi Kunisawa

The TRIPS Agreement Implementation in Brazil

Patents in the Pharmaceutical Area

Nomos

MIPLC Munich Intellectual Property Law Center
Augsburg München Washington DC

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Volume 25

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Acronyms and Abbreviations

ABAPI	Associação Brasileira dos Agentes da Propriedade Industrial (Brazilian Association of Industrial Property Agents)
ABPI	Associação Brasileira de Propriedade Intelectual (Brazilian Intellectual Property Association)
AIDS	acquired immunodeficiency syndrome
AIPPI	Association Internationale pour la Protection de la Propriété Intellectuelle
ALANAC	Associação dos Laboratórios Farmacêuticos Nacionais (Association of the National Pharmaceutical Laboratories)
ANVISA	Agência Nacional de Vigilância Sanitária (National Agency of Sanitary Surveillance)
CADE	Conselho Administrativo de Defesa Econômica (Administrative Counsel for the Economic Defense)
CAMEX	Câmara de Comércio Exterior (Brazilian Chamber of Foreign Trade)
CIA	Central Intelligence Agency
DSB	Dispute Settlement Body
et al.	*et alii*
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GDP	gross domestic product
HDI	Human Development Index
HIV	human immunodeficiency virus
IBGE	Instituto Brasileiro de Geografia e Estatística (Brazilian Institute for Geography and Statistics)
IBRD	International Bank for Reconstruction and Development
Id.	identical
i.e.	*id est*
IMF	International Monetary Fund
INMETRO	Instituto Nacional de Metrologia, Normalização e Qualidade Industrial (National Institute of Metrology, Normalization and Industrial Quality)

INPI	Instituto Nacional da Propriedade Industrial (Brazilian Patent and Trademark Office)
IP	intellectual property
IPR	intellectual property rights
LAFEPE	Laboratório Farmacêutico do Estado de Pernambuco (Pharmaceutical Laboratory of the State of Pernambuco)
LPI	industrial property law
MoH	Brazilian Ministry of Health
OECD	Organisation for Economic Cooperation and Development
PAHO	Pan American Health Organization
PMA	Pharmaceutical Manufacturers Association
PhRMA	Pharmaceutical Research and Manufacturers of America
rDNA	recombinant deoxyribonucleic acid
R&D	research and development
SUS	Sistema Único de Saúde (Unified Health System)
TRIMS	Trade-Related Investment Measures Agreement
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNICEF	United Nations Children's Fund
US	United States
USA	United States of America
USD	United States Dollar
USTR	Office of the United States Trade Representative
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Zusammenfassung

Das Übereinkommen über handelsbezogene Aspekte der Rechte am geistigen Eigentum (TRIPS), welches Anhang 1C des Marrakesch-Abkommens zur Errichtung der Welthandelsorganisation (WTO) darstellt, beinhaltet einen umfassenden Katalog internationaler Bestimmungen zum Schutz und zur Durchsetzung geistiger Eigentumsrechte. Da es ein wichtiger Bestandteil des WTO-Systems ist, sollten seine Vorschriften im Kontext der Förderung des internationalen Handels betrachtet werden. Streitigkeiten, die zwischen den Mitgliedsstaaten bezüglich der Einhaltung der im TRIPS-Abkommen verankerten Pflichten auftreten könnten, sind im Wege eines Schlichtungsverfahrens der WTO beizulegen. Das TRIPS-Abkommen gibt bestimmte Mindestanforderungen für den Schutz geistiger Eigentumsrechte vor, die von den Mitgliedsstaaten zu gewährleisten sind. Darüber hinaus legt es allgemeine Grundregeln fest, die hinsichtlich der Durchsetzung geistiger Eigentumsrechte auf die entsprechenden Verfahren und Maßnahmen anzuwenden sind.

Diejenigen TRIPS-Vorschriften, die zu den intensivsten und ausgiebigsten Debatten unter den Mitgliedsstaaten Anlass gaben, bezogen sich auf die Patentrechte. Im Zuge der TRIPS-Verhandlungen setzten sich die meisten hochentwickelten Staaten für Bestimmungen ein, die ein strengeres und harmonischeres internationales Patentsystem sicherstellen würden, in welchem Zusammenhang sie insbesondere das Argument ins Feld führten, dass ein solcher gesetzlicher Rahmen wichtige Grundlage für den technologischen Fortschritt sei. Die Entwicklungsländer hingegen standen diesem Ansinnen skeptisch, wenn nicht gar ablehnend gegenüber: Nach ihrer Auffassung würden nämlich strengere Regelungen zum geistigen Eigentum – und insbesondere zum Patentrecht – vor allem dazu führen, ihnen den Zugang zu innovativen Errungenschaften zu erschweren, die der Befriedigung elementarer menschlicher Bedürfnisse dienten; auf diese Weise würde die wirtschaftliche Dominanz der hochentwickelten Nationen noch weiter zementiert werden. Vor allem in den Bereichen Gesundheit, Pharmazeutik, Ernährung und Landwirtschaft dauern die Diskussionen rund um das TRIPS-Abkommen immer noch an.

Die Exportgüter Brasiliens umfassen ein Spektrum, das von Zucker, Kaffee und Soja über Textilien und Fußbekleidung bis hin zu Stahl und

Luftfahrzeugen reicht. Im Außenhandel war zuletzt sowohl beim Import als auch beim Export ein kräftiger Anstieg zu beobachten, was zu einer Zunahme des Handelsüberschusses führte. Indem Brasilien der WTO beitrat, profitierte das Land zwar von niedrigeren Handelsschranken, im Gegenzug musste es aber die TRIPS-Standards zum Schutz des geistigen Eigentums akzeptieren.

Das derzeit in Brasilien gültige Gesetz zum Schutz des geistigen Eigentums ist das Gesetz Nr. 9.279 vom 14. Mai 1996 (auch Patentordnung genannt). Es wurde verabschiedet, um den Pflichten gerecht zu werden, die sich aus der Zeichnung des TRIPS-Abkommens ergaben. Das Gesetz fügt sich in den allgemeinen Kontext der wirtschaftlichen Modernisierung Brasiliens ein: Es beseitigte Restriktionen hinsichtlich des Spektrums patentierbarer Erfindungen, so dass heute nur noch wenige Gegenstände von der Patentfähigkeit ausgenommen sind, und sah effizientere Verfahren für den Schutz des geistigen Eigentums vor; des Weiteren zielte es darauf ab, das brasilianische Patentsystem an die neuen internationalen Rahmenbedingungen anzupassen und speziell Patente auf pharmazeutischem Gebiet zuzulassen.

Die Erteilung von Zwangslizenzen als eine der Maßnahmen, die das TRIPS-Abkommen für die Flexibilität mit Patentrechten vorsieht, spielt eine wichtige Rolle für das brasilianische Regierungsprogramm einer freien Verteilung von Arzneimitteln für die Behandlung von AIDS. Gerade an diesem Beispiel zeigt sich in aller Deutlichkeit das komplexe Verhältnis zwischen privaten und öffentlichen Interessen.

Die vorliegende Studie befasst sich mit der Dynamik der globalen und speziell der brasilianischen wirtschaftlichen Entwicklung sowie mit der Notwendigkeit, diese mit politischen Entscheidungen im öffentlichen Gesundheitswesen in Einklang zu bringen. Sie gliedert sich in drei Hauptteile, entsprechend den Kapiteln II, III und IV, und wurde mit bibliographischen Methoden durchgeführt, um auf diese Weise eine Analyse der brasilianischen Patentordnung innerhalb des durch das TRIPS-Abkommen vorgegebenen Rahmens vorlegen zu können und diese im Kontext des Welthandels zu untersuchen. Als wesentliche Kriterien der Analyse wurden hierbei diejenigen Bestimmungen herausgegriffen, die zum einen für pharmazeutische Patente und zum anderen für Zwangslizenzen gelten.

Der erste Teil (Kapitel II) liefert einen umfassenden Überblick über die TRIPS-Bestimmungen und die ihnen zugrunde liegenden Prinzipien sowie über die Debatten, die letztlich zur Doha-Erklärung führten, wobei ein allgemeiner Eindruck des internationalen Szenariums vermittelt werden soll;

des Weiteren wird der geschichtliche Hintergrund des brasilianischen Patentrechts vor der Zeichnung des TRIPS-Abkommens erläutert; im Anschluss daran werden diejenigen Grundsätze beleuchtet, die für das internationale Patentrecht maßgeblich sind, wobei insbesondere auf die Regelungen einzugehen sein wird, die der Harmonisierung der nationalen Rechtssysteme der einzelnen Mitgliedsstaaten durch die Festlegung von Standards für den Erwerb und die Durchsetzung von Patentrechten auf internationaler Ebene dienen. Da diese Standards lediglich als Minimalanforderungen mit dem Ziel einer Vereinheitlichung der Schutzbestimmungen aufzufassen sind, um so zu verhindern, dass die nationalen Gesetzgebungen zu Handelsschranken werden, belässt das TRIPS-Abkommen den einzelnen Mitgliedsstaaten einen gewissen Spielraum bei der Anpassung ihres Patentrechts an die im jeweiligen Land betriebene Politik, anstatt sie zur Einführung überall gleicher Schutzstandards zu zwingen. Folglich sieht das TRIPS-Abkommen ein gewisses Maß an Flexibilität vor, was insbesondere die Ausschlüsse von der Patentfähigkeit, die Regelungen über die Erschöpfung und den Parallelimport, allgemeine Ausnahmen von den Rechten aus einem Patent oder Zwangslizenzen betrifft. Auch die Doha-Erklärung und die Entscheidung zur Umsetzung von Absatz 6 der Doha-Erklärung sind Gegenstand dieses Kapitels II, welches mit Anmerkungen zur Anwendbarkeit der TRIPS-Bestimmungen in Brasilien schließt.

Im zweiten Teil (Kapitel III) wird die brasilianische Patentordnung beschrieben, wobei das besondere Augenmerk den Bestimmungen über Zwangslizenzen gilt, die im Lichte des TRIPS-Abkommens betrachtet werden. Es soll ein allgemeiner Überblick über die Vorschriften geliefert werden, die für das brasilianische Patentsystem maßgeblich sind, und zwar speziell in Bezug auf pharmazeutische Patente sowie auf Zwangslizenzen. Zunächst werden die Bestimmungen über die Patentfähigkeit erläutert, um anschließend auf die Regelungen zur Schutzdauer, die durch ein Patent in Brasilien verliehenen Rechte sowie auf die bestehenden Ausnahmen und Beschränkungen einzugehen. In Brasilien besteht eine Vorschrift, wonach die Nutzung von Patenten auf pharmazeutische Produkte und Verfahren der vorherigen Genehmigung durch die ANVISA bedarf, einer nationalen Behörde, die in erster Linie für die Zulassung des Handels mit Arzneimitteln zuständig ist. Dieses Kapitel geht folglich auf die Rolle der ANVISA im Patenterteilungsverfahren und bei der Prüfung von Ansprüchen auf eine zweite medizinische Verwendung ein und endet mit einer Analyse der Bestimmungen über Zwangslizenzen.

Im dritten Teil (Kapitel IV) werden anhand konkreter Beispiele – sie betreffen die Arzneimittel Kaletra von Abbott, Efavirenz von Merck und Tenofovir von Gilead – spezifische Problemfälle erörtert, die sich aus dem Kontext des brasilianischen Anti-Aids-Programms ergeben. Dabei werden die Auswirkungen des multilateralen Handelssystems der WTO auf die brasilianische Wirtschaft, die Diskussionen über die Vergeltungsmaßnahmen, die im Rahmen von Streitschlichtungsverfahren der WTO seitens der brasilianischen Regierung verhängt wurden, sowie insbesondere die Auswirkungen der Implementierung des TRIPS-Abkommens auf die Pharmabranche berücksichtigt. Im Anschluss an einige Zahlen zum öffentlichen Gesundheitswesen und zur Situation von Aids in Brasilien folgt eine Beschreibung des dort initiierten Anti-Aids-Programms. Bei Kaletra, Efavirenz und Tenofovir handelt es sich um Arzneimittel, die häufig in den "Cocktails" Verwendung finden, welche an HIV-Patienten verabreicht werden. Sie spielen eine erhebliche Rolle für die Strategie der brasilianischen Regierung, Patentrechte als Werkzeuge in den Verhandlungen mit der Industrie zu nutzen. Dieses Kapitel möchte Fälle aufzeigen, die veranschaulichen, welche Rolle Patentvorschriften und geistige Eigentumsrechte im Allgemeinen heute, nach der Implementierung des TRIPS-Abkommens, tatsächlich in der brasilianischen Wirklichkeit spielen; folgerichtig endet es mit einer Analyse des Baumwollstreits, der vom Streitbeilegungsgremium der WTO (Dispute Settlement Body) geschlichtet wurde, sowie mit Anmerkungen zu den Vergeltungsmaßnamen bei geistigen Eigentumsrechten.

Das Ziel der vorliegenden Arbeit besteht darin, die Implementierung der TRIPS-Bestimmungen in der brasilianischen Rechtsordnung näher zu untersuchen. Die Förderung des freien Handels und der Zugang brasilianischer Waren zu ausländischen Märkten sind von höchster Bedeutung für die Entwicklung der brasilianischen Wirtschaft, und gerade vor diesem Hintergrund sollten die Patentrechte analysiert werden, wobei hier die Pharmaindustrie im Mittelpunkt steht.

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-

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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-

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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.

II. CHAPTER. THE FRAMEWORK OF TRIPS

A. Brazilian context prior to TRIPS

Patents were first introduced into the Brazilian legal system through the Charter of April 28, 1809, enacted by the Portuguese Regent Prince D. João VI, which granted temporary privileges for exclusive exploitation of new machines and inventions useful in industry to their creators.[14] Far from being a totally new field of law, Patent Law is one of the oldest in the Brazilian legal system. The first Constitution of 1824 already safeguarded the property of inventions to their inventors, and the Law of August 28, 1830 was enacted to regulate this right.[15] From the end of the nineteenth century until the Second World War, it is possible to argue that Brazil maintained a level of patent protection (and other intellectual property rights) that was compatible with which was established in international agreements.[16] Brazil was a founding Contracting State of the Paris Union for the protection of industrial property, which entered in force on March 20, 1883.[17]

During the period following the Second World War until the beginning of the 1990s, the Brazilian government adopted economic policies that protected national industry against competition from imports. These policies discredited the country's patent system and led to the erosion of legal work, scarce scholarly production and few judicial decisions regarding patents.[18] The country sought to profit from technology created in developed countries (in the public domain or not), to the benefit of national industry, which drew hostility against the idea of patents as an important component of industrial development.[19]

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14 See *Cerqueira*, Industrial Property Treaty, p. 1-48.
15 *Id.*
16 *Id.*
17 See *WIPO*, Contracting Parties, table 2.
18 See *Licks*, Patent Law, p. 9-10.
19 *Id.*

The exclusions from patentable subject matter, such as chemical and pharmaceutical products[20], were introduced into the Brazilian legislation in 1945[21] and remained in succeeding statutes.[22] Law 5772/1971, the Brazilian statute that was in force prior to the enactment of TRIPS, stated in Article 9 (a) and (b) that products obtained by chemical processes or means, as well as foodstuff, chemical-pharmaceutical products, medicines and the processes for obtaining or modifying them were not patentable. It excluded peremptorily pharmaceutical products and processes from patentable subject matter.

The Pharmaceutical Manufacturers Association or the PMA (currently the Pharmaceutical Research and Manufacturers of America – PhRMA) filed a complaint on June 11, 1987, at the Office of the United States Trade Representative (USTR), regarding the lack of patent protection for inventions in the pharmaceutical field, either for products or processes.[23] The industry association considered Brazilian policies and activities unreasonable as they would harm the American pharmaceutical industry in around US$160 million during the period between 1979 and 1986.[24] Brazilian manufacturers were accused of copying American inventions without paying licensing fees.[25] The USTR started investigating immediately.[26]

The PMA pointed out that there were several other countries that did not adequately protect pharmaceutical products. However, Brazil was a unique case since neither products nor processes for pharmaceuticals were protected and trade sanctions would serve as an example to others.[27] The complaint against the Brazilian law took into account that the country was considered to be the seventh biggest market for the pharmaceutical industry.[28]

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20 Pharmaceutical products and processes were excluded from patentable subject matter under the Law 5772/1971.
21 DL 7903/1945, Article 8.
22 DL 254/1967, DL 1005/1969 and Law 5772/1971.
23 Article 9, item c of Law 5772/1971 prohibited the granting of patents for pharmaceutical products and processes.
24 See *PMA*, Petition for Relief, p. 53.
25 *Id.*
26 See *Cepaluni*, Patent Regime: Brazil x USA, p. 54.
27 See *PMA*, Petition for Relief.
28 See *Tachinardi*, The Patent War: The Conflict Brazil x USA, p. 112.

In the same year, the Uruguay Round of Negotiations began. Brazil, along with India, strongly opposed the American proposal for introducing new topics in the GATT Agenda, such as intellectual property rights, believing that they should remain under the structure of the World Intellectual Property Organization (WIPO).[29] Brazil explicitly opposed granting patent protections for pharmaceutical products because the country considered them to be harmful to economic development.[30]

In June 1988, the Brazilian government announced that it would be prepared to protect pharmaceutical processes, but postponed the granting of product patents.[31] This decision was deemed insufficient by the US because Brazilian manufacturers would be able to easily circumvent patents by using alternative production processes. The Reagan administration accused Brazilian policies of being unreasonable and implemented trade sanctions of 100% *ad valorem* import tax on certain products, including paper, chemicals and electronic devices.[32] As a response, Brazil filed a claim to hold a panel before the GATT against the trade sanctions imposed by the US.[33]

The American punitive measures came to an end, however, only with the election of the Brazilian President Fernando Collor de Mello in November 1989. The newly elected president's political platform centered around Brazil becoming an open market and inserting itself into the globalized economy.[34] On June 26, 1990, after six months in the government, in order to keep his campaign promises, the new president announced intentions to provide protection for pharmaceutical products and their manufacturing processes.[35] The USTR, then, immediately suspended the trade sanctions and the Brazilian government withdrew the claim to hold a panel before the GATT.[36] Bill of Law 824/1991 was sent to Congress in the following year, on May 8, 1991, with the aim of modifying the Brazilian industrial property regime and providing patents for pharmaceutical processes and products.[37]

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29 See *Arslanian, Lyrio*, The Patent Statute Reform in Brazil, p. 4.
30 *Id.*
31 See *Tachinardi*, The Patent War: The Conflict Brazil x USA, p. 110.
32 *Id.*, p. 111.
33 See *Heringer*, Pharmaceutical Patents: International Context, p. 41.
34 See *Tachinardi*, The Patent War: The Conflict Brazil x USA, p. 111.
35 *Id.*
36 *Id,* p. 117-119.
37 See *Curzel*, Access to Medicines: the Brazilian Case, p. 29.

In the international sphere, the Uruguay Round was coming to a conclusion. Brazil changed its initial position towards the exclusion of intellectual property rights from international trade law and no longer opposed the patentability of pharmaceutical inventions.[38] The country opted to accede to the WTO and, consequently, to accept TRIPS in order to benefit from international trade in other sectors such as agriculture and textiles.[39] On December 15, 1993, the negotiations on market access for goods and services came to a conclusion.[40] The Final Act with the agreement was signed by ministers from most of the 123 participating governments at a meeting in Marrakesh, Morocco on April 15, 1994.[41]

The Brazilian Congress ratified the Agreements of the Final Act of the Uruguay Round on December 15, 1994, when it approved DLG 30/1994, and the TRIPS Agreement was incorporated into Brazilian law on December 31, 1995, when the Presidential Decree 1355/1995 was published in the Official Gazette. Law 9279/1996, which was published soon after on May 15, 1996, regulated industrial property rights and revoked the previous statute (Law 5772/1971). The new law did not exclude pharmaceutical inventions from patent protection and sought to harmonize with provisions in TRIPS.[42]

The following is an assessment of TRIPS provisions on patents that will allow for an analysis of their implementation within the Brazilian law.

B. TRIPS Agreement

1. General Principles

As Annex 1C of the Marrakesh Agreement, TRIPS is the result of recognition by the WTO Member States that different standards of protection and enforcement of IP rights were leading to problems in the international economy, resulting in non-tariff barriers to international trade.[43] The Agreement seeks to harmonize – rather than make uniform – protection

38 See *Arslanian, Lyrio*, The Patent Statute Reform in Brazil, p. 4.
39 *Id.*
40 See *WTO*, The Uruguay Round, para. 9.
41 *Id.*
42 See *Cepaluni*, Patent Regime: Brazil x USA, p. 61-62.
43 Preambles of TRIPS.

and enforcement of IP in Member States by establishing minimum international standards. The Preambles establish the need to promote effective and adequate protection of IP rights and to ensure enforcement as the driving goals of the Agreement,[44] taking into account the areas of IP that Member States perceived as leading to trade distortions.[45]

TRIPS determines that the basic principles of GATT 1994 and other international IP agreements are applicable, in addition to providing for multilateral prevention and settlement of disputes between parties.[46] Member States acknowledge the need for an international framework to regulate international trade in counterfeit goods and recognize that IP rights are private rights and that public policies, including those relating to development and technology, lie at the foundation of the IP system.[47] TRIPS also establishes that the needs of least-developed countries must be taken into account when implementing national legislation so as to maintain a maximum level of flexibility.[48]

The TRIPS Preamble already makes explicit reference to the bond between the protection of IP rights and the GATT rules on international trade. TRIPS provisions are not to be interpreted in isolation, but rather as an integral part of the WTO system as found in the case of *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*.[49]

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44 Preambles of TRIPS.

45 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 30.

46 Preambles of TRIPS.

47 Preambles of TRIPS.

48 Preambles of TRIPS.

49 See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products.* Complaint filed by the United States. Report of the Panel, September 5, 1997 (WT/DS50/R). Para. 5.19. In this case, the US alleged that India's patent law violated Articles 27, 65 and 70 of TRIPS. The DSB found that India was not complying with Article 70.8(a) and Article 63(1) and (2) of the TRIPS Agreement by failing to establish a mechanism that adequately preserved novelty and priority in respect of applications for product patents covering pharmaceutical and agricultural chemical inventions. India was also not in compliance with Article 70.9 of the TRIPS Agreement by failing to establish a system for granting exclusive marketing rights. See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Summary of key findings, February 24, 2010 (WT/DS50). The European Communities filed a similar complaint against India in which they alleged that the Indian legal regime – India's "mailbox rule" – according to which patent application for pharmaceutical and agricultural chemical products could be filed was insufficient, and the lack of a mechanism for granting exclusive marketing rights to such products. In this case, the DSB also decided that the Indian leg-