MIPLC Studies 25

Viviane Yumy Mitsuuchi Kunisawa

The TRIPS Agreement Implementation in Brazil

Patents in the Pharmaceutical Area

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MIPLC Munich Intellectual Property Law Center
Augsburg München Washington DC

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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)

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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

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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

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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;

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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.

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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.

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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.

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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.

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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.

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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.

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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-

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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.

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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.*

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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.

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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.

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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.

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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-

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Although the Preamble should not be used in an attempt to modify and renegotiate the obligations assumed in the agreement, they should be taken into consideration and be interpreted together with articles 7 and 8, which establish the objectives and governing principles of the Agreement. Article 7 of TRIPS defines the objectives of protection and enforcement of IP rights as promoting technological innovation. As a result of a proposal by developing countries in the context of patents,[50] Article 7 evidences the importance of balancing the protection of IP rights with the promotion of social and economic welfare and technological innovation through the due transfer of technology.[51] This provision reflects the equilibrium that IP policies should set, aiming both at rewarding creators for innovation and securing access to science, technology and culture.[52] It provides for a policy foundation within the structure of the Agreement for the protection and enforcement of IP rights.

Article 8 of TRIPS establishes the policy making principles that govern the Agreement,[53] which must be taken into consideration by Member

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islation was inconsistent with articles 70.8 and 70.9 of TRIPS. See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Complaint filed by the European Communities. Summary of key findings, February 24, 2010 (WT/DS79).

50 Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay presented a proposal to the Uruguay Round Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, reflecting their concern on the possibility of using patents for advancing their technological and economic development. See *WTO*, Uruguay Round – Group of Negotiations on Goods – Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods; and *Carvalho*, The TRIPS Regime of Patent Rights, p. 122-123.

51 "Article 7. Objectives. The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

52 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 117.

53 "Article 8. Principles.
1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights

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States in the implementation of any provisions therein.[54] It clearly safeguards the possibility for Member States to adopt the actions and procedures needed to protect public health and nutrition. It also fosters the public interest in areas that are important to socioeconomic and technological development and prevents the abuse of IP rights, as long as they are consistent with TRIPS. This provision was based on the same proposal submitted by developing countries that influenced Article 7.[55]

Under Article 8.1, Member States may have rules on government control of quality and safety of drugs and food, price control systems on pharmaceutical products, as well as financial incentives and tax credits in areas of the national economy that are deemed essential, for example small and medium enterprises, in order to preserve competition.[56] To balance this, the provision allows for measures which may impact patentee rights, such as price control, as long as they are necessary and consistent with the other provisions in the Agreement.[57]

Article 8.2 establishes the conditions under which Member States can issue preventive measures against the misuse of IP rights (such as abuse of patent rights), practices that unreasonably restrain trade (anti-competitive practices) and practices that adversely affect the international transfer of technology.[58] Such measures must be: (i) appropriate, i.e. adequate and proportionate to the seriousness of the practice to be inhibited; (ii) consistent with other TRIPS provisions, specifically articles 3, 4, 27 and 40; and (iii) necessary.[59] According to this provision, Member States are allowed to issue regulations and guidelines forbidding the inclusion of abusive clauses, such as exclusive and non-reciprocal grant-back to the licensor of

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by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology".

54 Article 8 explains the rationale to be taken into consideration when assessing and implementing articles 30, 31 and 40 of TRIPS. See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 121-122.

55 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 137.

56 *Id.*, p. 139-140.

57 *Id.*

58 Acts that adversely affect the international transfer of technology are to be hindered only in case they are considerd abusive or anti-competitive. See *Carvalho*, The TRIPS Regime of Patent Rights, p. 154.

59 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 154.

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improvements introduced by the licensee as well as prohibition of challenging the validity of a licensed IP right.[60]

It is possible to conclude that Articles 7 and 8 make it clear that the freedom of Member States to legislate depends on these policy making guidelines and countries are no longer completely free to pursue their own national interests.[61] On the other hand, these same provisions have served as the foundation for discussions concerning TRIPS and public health, as well as the possibility for both developing and least developed countries to make use of TRIPS flexibilities when legislating.[62]

Apart from Articles 7 and 8, which provide general policy making guidelines, the essential principles of TRIPS that relate to IP rights are territoriality, national treatment (or non-discrimination) and most-favored nation.

TRIPS does not expressly provide for the territoriality principle (according to which intellectual property rights are to be enjoyed within the territory of one country and their effects should not extend beyond its boundaries), but rather recognizes the sovereignty of each Member State to choose the adequate method of implementing the provisions of the Agreement (see Article 1.1 of TRIPS). Accordingly, intellectual property rights are subject to the laws in force within the territory of each Member State. Within the scope of the patent holder's rights, Member States must provide for the right to prevent unauthorized parties to import a patented product or a product obtained by a patented process, as stated in Article 28.1 of TRIPS. Importation shows that patent rights should be comprised within a country's boundaries. The Agreement also indirectly refers to this principle when Article 2 determines that Articles 1 through 12 and 19 of the Paris Convention should be complied with regarding Parts II, III and IV of TRIPS, which include most of the substantive provisions on patents. It is Article 4 *bis* of the Paris Convention that establishes that a patent granted in one country is independent of patents obtained for the same invention in other countries. This independence relates primarily to causes of nullity, forfeiture and duration, but also to the scope of rights, as well as to exhaustion and compulsory licenses – invalidity of a patent in one

60 *Id.,* p. 155.

61 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 161.

62 The discussions on the relationship between TRIPS and public health resulted in the Doha Declaration, which will be dealt on further in this chapter.

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country does not automatically lead to invalidation of a patent covering the same invention in another country.

The TRIPS Agreement seeks to provide minimum standards in the patent field and create a balance between different laws; thus, it restricts the sovereignty of Member States.[63] It still confines, however, the legal effects of a patent to the boundaries of each country. It is important to note that exactly because of the territorial effects of patent rights, different standards on patentability and scope of protection were becoming non-tariff barriers to international trade. Minimum standards provided by TRIPS are aimed at diminishing the adverse effects of IP rights in international commerce without abolishing the territoriality principle – such abolition would, then, indeed imply removing the sovereignty of Member States on the matter.

Article 3 of TRIPS establishes that each Member State must treat the nationals of other Member States in a no less favorable way than its own nationals. Exceptions to the national treatment principle are those already provided for by international treaties and in paragraph 2 concerning the appointment of an attorney in the jurisdiction of a Member State in order to secure enforcement of laws and regulations. TRIPS follows the logic of the Paris Convention, according to which the national treatment principle would apply to persons – as opposed to goods as in the national treatment principle of GATT Article III.4.[64] However, different from the language adopted by the Paris Convention and more similar to GATT, TRIPS suggests that even in case the WTO Member State does not protect the rights of its own nationals, the rights of the nationals of other Member States are to be protected up to the minimum threshold required by the Agreement.[65]

In the case of *Indonesia – Certain Measures Affecting the Automobile Industry*, a panel was established by request of the European Communities, Japan and the US, alleging that the Indonesian National Car Programmes, which established benefits including luxury tax and import duty exemptions on motor vehicles and their components, would violate provisions of the GATT.[66] A subsidiary argument claimed that the provisions

63 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 161-162, footnote 4.

64 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 84-86.

65 *Id.*

66 See *Indonesia — Certain Measures Affecting the Automobile Industry*. Request for Consultations by the European Communities, October 3, 1996 (WT/DS54). Re-

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of the Indonesian programmes discriminate against nationals of other WTO Member States regarding the acquisition and maintenance of trademarks.[67] The panel found that the fact that only certain signs can be used as trademarks for meeting the relevant qualifications under the Indonesian National Car Programmes is not discriminatory treatment towards nationals of other countries.[68] Furthermore, the panel made a special recommendation regarding the interpretation of Article 3 of TRIPS. Taxes and other benefits to which an Indonesian company is entitled to under the program may give it a competitive advantage in relation to foreign companies.[69] However, it would not be reasonable to construe the national treatment principle "in relation to the maintenance of trademark rights as preventing the grant of tariff, subsidy or other measures of support to national companies on the grounds that this would render the maintenance of trademark rights by foreign companies wishing to export to that market relatively more difficult".[70] The scope of the national treatment principle should be cautiously interpreted and not unreasonably enhanced, at the risk of extending it far beyond the objectives of the Agreement.

The relationship between the national treatment principle in TRIPS, GATT and the Paris Convention has been addressed in *United States – Section 211 Appropriations Act*. In this case, the European Communities requested the establishment of a panel against the US, alleging that Section 211 of the US Omnibus Appropriations Act would not conform to Article 3 of TRIPS. Section 211 prohibited the registration or renewal of a trademark in the US concerning business and assets confiscated by the Cuban Government without the original owner's consent.[71] No US court should recognize or enforce any trademark rights either. Pursuant to the Appellate Body's findings, the national treatment principle is a corner-

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quest for Consultations by Japan, October 4, 1996 (WT/DS55). Request for Consultations by Japan, November 29, 1996 (WT/DS64). Request for Consultations by the United States, October 8, 1996 (WT/DS59).

67 *Id*.

68 See *Indonesia — Certain Measures Affecting the Automobile Industry*. Report of the Panel, July 2, 1998 (WT/DS55/R, WT/DS56/R, WT/DS59/R WT/DS64/R), para 14.268.

69 *Id*., para 14.273.

70 *Id*.

71 See *United States — Section 211 Omnibus Appropriations Act of 1998*, Summary of key findings, February 24, 2010 (WT/DS176).

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stone of the Paris Convention and the WTO trading system,[72] and, as Article 3.1 of TRIPS adopts similar language to Article III.4 of the GATT regarding the expression "treatment no less favorable," jurisprudence in the GATT could be helpful in interpreting this principle under TRIPS.[73] In this case, the Appellate Body established non-compliance with the national treatment obligation because Section 211 imposed an extra procedural hurdle on "original owners" of Cuban nationality, but not "original owners" who were US nationals.[74] Accordingly, there would be a violation of the principle if a multiphase procedure were imposed on non-nationals and a single-phase procedure on nationals, putting the nationals of other Member States in an inherently less favorable situation.[75]

The most favored nation treatment foreseen in Article 4 of TRIPS provides that any advantage, favor, privilege or immunity given to the nationals of one country must be immediately and unconditionally granted to nationals of all other Member States. There are four possible exceptions: i) in case this beneficial treatment derives from international agreements on judicial assistance or law enforcement, ii) if they are granted according to the provisions of the Berne Convention or the Rome Convention authorizing that the treatment accorded be a function of the treatment accorded in another country, iii) if they relate to the rights of performers, producers of phonograms or broadcasting organizations not provided for in the agreement, and iv) if they derive from agreements which entered into force prior to the WTO as long as they do not constitute an arbitrary or unjustifiable discrimination against nationals of other Member States.

In *United States – Section 211 Appropriations Act*, the Appellate Body understood not only that there was a violation of the national treatment principle, as stated above, but also of the most favored nation treatment obligation. Cuban nationals residing in an authorized trade territory, such the Member States of the European Communities, would face an additional administrative procedure not applicable to non-Cuban foreign nationals.[76]

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72 See *United States — Section 211 Omnibus Appropriations Act of 1998*. Report of the Appellate Body, January 2, 2002 (WT/DS176/AB/R), para. 241.

73 See *United States — Section 211 Omnibus Appropriations Act of 1998*. Report of the Appellate Body, January 2, 2002 (WT/DS176/AB/R), para. 242.

74 *Id*., para. 256.

75 *Id*., para. 265-269.

76 *Id*., para. 314.

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The TRIPS Preamble and the provisions defining the goals and general principles of the Agreement should drive the implementing legislation of the Member States, especially considering the flexibilities therein provided for. It is most important to remember that TRIPS provisions must be interpreted within the WTO system as part of the framework governing international trade among countries. Globalization made GATT 1994 and TRIPS practically inseparable[77] and any attempts either to enhance or hinder IP standards of protection should be balanced with their respective impacts in the context of international trade.

2. TRIPS Provisions on Patent Law

Provisions pertaining specifically to patents were considered to be the most difficult to negotiate.[78] They comprise Articles 27 through 34 in Section 5 of TRIPS, Articles 65 and 66 concerning transitional provisions, as well as Article 70 concerning the protection of existing subject matter.

2.1. Patentable Subject Matter and Conditions on Patent Applicants

The TRIPS Agreement provides for the enjoyment of patent rights and patent eligibility of product- and process-inventions in all fields of technology, without discrimination as to the place of the invention, importation or local production of the goods (as per Article 27.1). Thus, Member States are obligated to provide for patents covering pharmaceutical products.

Article 27 may be considered one of the core provisions of the Agreement in relationship with patent rights, since it provides for substantive harmonization criteria for the granting of patents – novelty, inventive step and industrial application – and the non-discriminatory treatment towards patentable subject matter. Its importance relies on the fact that many countries had not previously afforded patent protection in the chemical and

77 See *Straus*, The Impact of the New World Order on Economic Development, p. 14-15.

78 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 220. For a brief summary of the draft proposals and negotiations results, see *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 178-179.

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pharmaceutical fields. Article 27.1, however, does not define the concepts of inventions, novelty, inventive step and industrial application capability. A delimitation between invention and discoveries is also not provided in the Agreement.[79] Thus, countries have preserved the ability to determine substantive requirements, such as how novelty, inventive step and industrial application capability requirements are fulfilled under Article 1.1 of TRIPS.[80] It is important to note that the language adopted in Article 27.1 does not allow Member States to adopt other substantive requirements that either reject or invalidate a patent.[81]

In the case of *Canada – Patent Protection of Pharmaceutical Products*, the DSB panel analyzed the scope of the non-discrimination principle of Article 27.1 of TRIPS.[82] The European Communities requested a panel against Canada in 1998, alleging that there would be insufficient protection in the area of pharmaceuticals. Section 55.2(1) of the Canadian Patent Act allowed the so-called regulatory review exception, which would be inconsistent with Article 27.1, as per the arguments by the European Communities. This provision allowed potential competitors of a patent holder to use the patented subject matter for obtaining government marketing approval in order to be able to enter the market on the date the patent expires[83] The DSB ruled that the Canadian legislation providing for such

79 Accordingly, scientific principles, business methods, algorithms, as well as biological material of natural origin could be excluded from patentability. Compliance with TRIPS in this case is determined by the way such exclusions are provided in the implementing legislations. See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 187-188.

80 See *Carvalho*, The TRIPS Regime of Patent Rights, p.63-65, 192-193.

81 *Id.*, p. 193. Under this issue, *Carvalho* refers to a further requirement of "unity of invention" (according to which a patent must concern a single general inventive concept) foreseen in patent statutes of many Member States as a substantive requirement for granting a patent, since it relates to the nature of the claimed invention. Nevertheless, the author points out that the lack of unity of invention may not be a ground for patent invalidity in such Member States.

82 See *Canada – Patent Protection of Pharmaceutical Products*, Summary of key findings, February 24, 2010 (WTO/DS114).

83 In addition to Section 55.2(1) of Canada's Patent Act, this panel also handled with the so-called stockpiling exception, provided for in Section 55.2(2) of Canada's Patent Act. According to the EC challenges, this provision would be inconsistent with Article 28.1 of TRIPS, and not covered by Article 30 of TRIPS. Canada's stockpiling exception, which allowed the manufacturing and stockpiling of patented inventions for a period of 6 months before patents expire, is going to be analyzed in this work together with Articles 28 and 30 of TRIPS.

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early working for regulatory review purposes was consistent with Article 27.1, i.e. not discriminatory towards pharmaceutical patents.[84] It stated that there had not been evidence that the legal scope of Section 55.2(1) of the Canadian Patent Act was limited to pharmaceutical products, finding no discriminatory treatment towards a certain field of technology.[85]

Article 27.1 also refers to non-discrimination towards the local production of goods. Accordingly, this provision does not prohibit Member States to require that patents be worked as already foreseen in Article 5.A. 2 of the Paris Convention, but it prevents the establishment of a *local* working requirement as a condition for enjoying patent rights.[86] If a patent holder imports the patented products or the products manufactured by the patented processes, this case would be in compliance with the obligation of working a patent to avoid compulsory license or forfeiture.[87]

On May 30, 2000, the US requested consultations with Brazil under Article 4 of the Understanding on Rules and Procedures Governing the Settlement Disputes at the WTO and Article 64 of TRIPS, complaining that Article 68 of the Brazilian industrial property law, which establishes the grounds for compulsory licenses, provided a local working requirement that violates the non-discrimination principle of Article 27.1 of TRIPS.[88] In a cross dispute, Brazil filed on January 31, 2001, a request for consulta-

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84 The panel analyzed whether the non-discrimination principle would apply to article 30 of TRIPS that provides for exceptions to patent rights. Accordingly, the regulatory review exception in the Canadian legislation would fall under the scope of article 30 of TRIPS and, as the panel understood, its applicability was not restricted to the pharmaceutical field and, thus, would respect the non-discrimination principle. See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.105.

85 See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.93.

86 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 196-198.

87 This concept of working of a patent differs from the notion established by Bodenhausen. According to this author, "working" a patent means "manufacturing" the patented product or "industrially using" the patented process, and the acts of "importing" or "selling" would not be regarded as "working". See *Bodenhausen*, Guide to the Application of the Paris Convention for the Protection of Industrial Property, p. 71.

88 See *Brazil – Measures Affecting Patent Protection*. Request for Consultations by the United States, June 8, 2000 (WT/DS199/1). This case will be further analyzed in the following chapter of this work.

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tions with the US, alleging that the provisions of the US Patent Code, Sections 204 and 209 of Chapter 18 on "Patent Rights in Inventions Made with Federal Assistance" in special, also violated TRIPS obligations by demanding a local working of patents.[89] According to the US Patent Code, small businesses or non-profit organizations which received title to any invention (i.e. patents) could only grant a person the exclusive right to use or sell the invention in the US if such person manufactures the patented product or uses the patented process substantially in the US.[90] Furthermore, the US statute limited the right to use or sell any federal owned invention in the US to a licensee that agrees to manufacture the patented product or to use the patented process substantially in the US.[91] Both Brazilian and US statutes violated Article 27.1 of TRIPS,[92] and the two States came to a mutual understanding to amicably settle the disputes.[93]

Pursuant to paragraph 2 of Article 27 of TRIPS, Member States are allowed to exclude subject matter from patentability whenever the exploitation of such subject matter is prevented in order to protect *ordre public* or morality, including human, animal or plant life and health, and to avoid serious damage to the environment. Therefore, under article 27.2 of TRIPS, national legislations may exclude from patentability inventions which exploitation put in risk *ordre public* and morality.[94] Justifications for these exclusions revolve around economic reasons related to an unnecessary engagement of resources (concerning the activities of patent offices in prosecuting applications) for the granting of patents which enforcement is unethical or socially undesirable and around the public perception towards some inventions which are deemed repugnant to social beliefs and should not deserve any public appraisal by the State.[95] This provision precludes, however, Member States to exclude inventions from patentability on the basis that exploitation of such patented subject matter is prohibited

89 See *United States – US Patents Code.* Request for Consultations by Brazil, February 7, 2001 (WT/DS224/1).
90 *Id.*
91 *Id.*
92 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 202.
93 See *Brazil – Measures Affecting Patent Protection*. Notification of Mutually Agreed Solution, July 19, 2001 (WT/DS199/4).
94 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 182. Discussions on the prohibition of patents covering transgenic animals and plants when national legislation prohibits exploitation of this technology.
95 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 207.

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by national legislation (but for the public order and morality cases) following article 4 *quater* of Paris Convention. TRIPS and Paris Convention aim to guarantee that patents will not be refused or invalidated because the marketing of an invention is subject to security or quality requirements, or its exploitation may only be carried out by the State.[96]

Moreover, diagnostic, therapeutic and surgical methods for the treatment of humans or animals, plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes may also be excluded from patentability under Article 27.3. The availability of protection to plant varieties is an express obligation, either through patents, adoption of a sui generis system or a combination of both.[97]

96 See *Bodenhausen*, Guide to the Application of the Paris Convention for the Protection of Industrial Property, p. 65-66.

97 This wide range of protection alternatives leaves up to each Member State to choose the one preferred. For instance, the US afford protection to plant varieties by patents or by a specific regimen of breeders rights, whereas the EC countries follow a sui generis system which basis is laid out in the Convention for the Protection of New Varieties of Plants established by the International Union for the Protection of New Varieties of Plants (UPOV). See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 185-186. Nevertheless, it is important to note that TRIPS does not obligate UPOV protection and Member States may develop their own protection system. See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 225.

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Both paragraphs 2 and 3 of Article 27 of TRIPS were inspired by the European Patent Convention of 1973 (Articles 52.4 and 53[98]).[99] The expressions *ordre public* and morality represent a clear and direct influence by the language used in Article 53(a) of the EPC 1973. It is important to note that the text in TRIPS – as well as the EPC – adopts the French term "ordre public" instead of public order.[100] Under the EPC, the Board of Appeals of the European Patent Office has already established that the concept of public order encompasses the protection of public security and the physical integrity of individuals as part of society, in addition to the protection of the environment.[101] TRIPS also refers to the same notion of se-

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98 The European Patent Convention of October 5, 1973 was subject to a revising act of November 29, 2000. The 1973 text is now referred as EPC 1973.
EPC 1973:
"Article 52. Patentable Inventions.
(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods."
"Article 53. Exceptions to patentability.
European patents shall not be granted in respect of:
(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.".

99 The European Communities supported by the developing countries put forward proposals for the exclusion of certain matters from patentability. See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 181-183, referencing the document compiled by the GATT secretariat, "Synoptic Tables Setting Out Existing Standards and Proposed Standards and Principles", of February 2, 1990 (GATT Doc. MTN.GNG/NG11/W/32/Rev. 2) and the Guidelines and Objectives Proposed by the European Community for the Negotiations on Trade Related Aspects of Substantive Standards of Intellectual Property Rights of July 7, 1988 (MTN.GNG/NG11/26/III,3(ii)).

100 "Ordre public" is a concept linked to the notion of public policy and principles which derrogation could endanger the institutions of a society; public order, on the other hand, would be limited to the maintenance of public safety concept. See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 222-223.

101 See *EPO*, Case Law of the Board of Appeal: 2. Breaches of "ordre public" or morality.

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curity, both collective or individually, containing the conception of protection against physical damage and not a general and abstract idea of general or collective interest.[102] Morality, in turn, concerns the beliefs serving as the foundation for a society, representing its cultural perceptions and values.[103] Protection of human, animal or plant life and health as well as the environment are of the concern of *ordre public* and morality.

Both Article 52.4 of the EPC 1973 and Article 27.3(a) of TRIPS refer to therapeutic methods as subject matter that is excluded from patentability (in the case of the former) or possibly excluded (in the latter case). Doctors and surgeons making use of a patented therapeutic method would have their medical activities severely restricted through enforcement of patents on therapeutic methods, which would not be well regarded by society – additionally there is the discussion of whether the success of medical treatment results from a patented method of treatment or from the skills of the doctor or surgeon.[104] Unlike the European provision, TRIPS does not expressly state that products, substances and compositions are not part of the exclusion. Despite this, Article 27.1 of TRIPS that allows for patents in all fields of technology (in addition to the explicit reference made by Article 70.8 of TRIPS) mandates Member States to grant patent protection for pharmaceutical products.[105]

Under Article 27.3 b) of TRIPS, animals and plants as higher life forms may be excluded from patentability, but Member States are obliged to afford patent protection for microorganisms, microbiological processes and non-biological processes for the production of plants and animals. In contrast to the EPC, TRIPS adopts broader options for exceptions from patentability, allowing Members States to exclude plants and animals in general, whereas Article 53(b) of the EPC limits the exception to plant and

102 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 208-209.

103 See *EPO*, Case Law of the Board of Appeal: 2. Breaches of "ordre public" or morality; and *Carvalho*, The TRIPS Regime of Patent Rights, p. 209.

104 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 214-215. This exclusion from patentable subject matter is not fully justifiable because including doctors' and surgeons' activities as a mandatory exemption to infringement could solve any lack of freedom-to-operate.

105 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 182.

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animal races.[106] According to G1/98, the Enlarged Board of Appeal of the EPO established that claims towards plants (or animals) would be permissible when the teaching of the invention is not restricted to a single variety.[107] TRIPS leaves to the national legislators the option to exclude patentability of higher life forms in general, not only to varieties.

In G2/07, the Enlarged Board of Appeals of the EPO found that the exclusion from patentability of essentially biological processes for the production of plants under the EPC seeks to preserve the freedom to operate of traditional breeding processes consisting of sexual crossing of plants (whole genomes) and the selection of those with the desired traits.[108] However, the board also found that addition technical steps, irrespective of their inventiveness, technical character or contribution to the invention, would not change the character of the invention. The steps of sexually crossing the whole genomes of plants and subsequently selecting the plants with the desired characteristics are deemed essentially biological.[109] A step of technical nature, which would assist biological steps, would also be excluded under Article 53(b).[110] In order to be patentable, the claimed process needs to contain, within the steps of sexually crossing and selecting, a further technical step, which by itself introduces a trait into the genome or modifies a trait in the genome.[111] Virtually all breeding processes have become exempted from patentability as a result of this threshold, which is a consequence that was unlikely intended by legislators.

The harmonization of patent standards through TRIPS aimed to favor international trade and minimize distortions deriving from very different laws in Member States regarding patentable inventions and the enjoyment of patent rights. Article 27, in addition to the framework established by

106 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 224-225; *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 184-185.

107 See *EPO*, Transgenic plant/NOVARTIS II, case G1/98, Decision of the Enlarged Boards of Appeal December 20, 1999, para. 3.10, p. 25.

108 See *EPO*, Broccoli/PLANT BIOSCIENCE, case G2/07, Decision of the Enlarged Boards of Appeal consolidating proceedings of cases G2/07 and G1/08, of December 9, 2010, p. 65-66.

109 Pursuant to Rule 26 (5) EPC, declared invalid by the Enlarged Board of Appeals, an essentially biological process would consist entirely of natural phenomena, such as crossing and selection.

110 *Id.*, p. 69-70.

111 *Id.*, p. 70-71.

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Articles 28, 30 and 31, essentially means that immaterial objects should receive the same extraterritorial treatment as other goods in international trade.[112] Patents and IP rights, in general, are now part of the world trade system.

As a condition for the patent granting, Article 29.1 of TRIPS requires disclosure of the invention in a clear and complete way so as to enable persons skilled in the art to reproduce it.[113] This mandatory requirement relates to the role of the patent system in the dissemination of technology.[114] It ensures that a patented invention may serve as basis for further development of technology and that it may be exploited without any cumbersome effort after patent expiration.[115] The text in the Agreement has been left open regarding the issue of microorganisms and biological material, such as cell lines, viruses and plasmids. In such cases, Member States – which are obligated to afford protection to those kinds of inventions under Article 27.3 of TRIPS – should establish that the deposit of such microorganisms and biological material fulfills the disclosure requirement.[116] However, TRIPS does not obligate Member States be party to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, which accredits International Depositary Authorities.

In addition, requiring disclosure of best mode as per Article 29.1 of TRIPS is an option that Member States may adopt. According to this provision, national legislation may require inventors to specify the best manner to carry out the invention known to him/her at the time of the filing or

112 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 180.

113 "Article 29. Conditions on Patent Applicants
1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants".

114 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 254.

115 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 239.

116 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 196.

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priority. This was an initiative by the US with the support of developing countries.[117]

Another option left open to Member States is to require that an applicant provide information on foreign applications and grants corresponding to the same invention pursuant to Article 29.2 of TRIPS. As stated earlier, Article 4 *bis* of the Paris Convention regarding the principle of independence of patents is to be respected by Member States, leading to the conclusion that submitting such information before national patent offices and courts serves to provide subsidies, for instance regarding searches.[118]

2.2. Rights Conferred and Term of Protection

The rights conferred by a patent and its term are of paramount importance, considering that the goal of TRIPS is to minimize the differences among national systems and prevent different standards of patent protection from becoming non-tariff barriers to international trade. Developed and developing countries not only afforded different standards regarding patentable subject matter, but also the scope and duration of patents. Preventing imports and extending protection to products obtained by a patented process were often not included among the patent holder's rights and the term of protection could be of five or seven years.[119]

Article 28.1 of TRIPS lists the rights of patent owners, which essentially consist of the right to exclude others from exploiting an invention (and not the right to use the invention).[120] Making, using, offering for sale, selling or importing for these purposes are the acts of exploitation that may be prevented and according to the DSB they are not subject to any hierarchy;

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117 The US legislation, namely Section 112(1) USC 35, provides for best mode requirement. See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 197; and Section 112 USC 35. As seen in the following chapter of this work, the Brazilian law mandates in article 24 indication of best mode whenever applicable. See Lei N. 9279, of May 14, 1996, on industrial property rights, published in the Official Gazette on May 15, 1996, as amended by Law N. 10196, of February 14, 2001, published in the Official Gazette on February 16, 2001.

118 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 197.

119 *Id*., p. 198.

120 "Article 28. Rights Conferred.

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"making" and "using" are not secondary in relation to "selling."[121] The footnote of Article 28.1 of TRIPS refers to "other distribution of goods" and extends those rights to the prevention of exporting, sampling and stockpiling.

In *Canada – Patent Protection of Pharmaceutical Products*, Section 55.2(2) of the Canadian Patent Act was found be inconsistent with Article 28.1 of TRIPS. This allowed for manufacture and storage of articles covered by a patent intended for sale after the patent expiration date during a six month period before the patent expiration. [122] The act of stockpiling while a patent was still valid was deemed to be in violation of TRIPS. Allowing third parties to make or use the invention without the patent holder's authorization during the patent term must be excused under Article 30 of TRIPS, which addresses limitations to the rights conferred.[123] This pro-

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1. A patent shall confer on its owner the following exclusive rights:
(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing (6) for these purposes that product;
(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts
(6) This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6".
Among the patentee's rights is the right to prevent importation by third parties of the patented product, which relates to the issue of international exhaustion which is dealt later in this chapter.

121 See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.33.

122 *Id.*, para. 7.38.

123 The DSB ruled in *Canada – Patent Protection of Pharmaceutical Products* that violation of article 28.1 of TRIPS would occur in case Section 55.2(2) of the Canada's Patent Act were non-compliant with the conditions of article 30 of TRIPS. See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.18.

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vision, however, does not deal with contributory and indirect infringement issues.[124].

In case of patents covering processes, protection extends to the product obtained by such patented process. This derives from enforcement difficulties raised in case of unauthorized use of a patented process in country with products shipped to and marketed only in a second country.[125]

Article 28.2 of TRIPS, which allows the patentee to assign, transfer by succession and license patents, may be regarded as a means to minimize government interference in the freedom of patent owners regarding their property title. It is important to note that if, on one hand, limitation of maximum limits to royalties is considered to be allowed under Article 8.1, on the other hand, government approval of contracts based on criteria of mere convenience, for example towards the nature of the technology transferred, should be considered an undue limitation of patent rights.[126]

Article 33 of TRIPS establishes that patent terms shall not end before a twenty-year period as of the filing date. During negotiations, proposals considered term from the date of filing and from the date the patent is granted, and there were attempts to extend protection for certain products which marketing is delayed by regulatory approval processes.[127] The patent term was also subject to discussions by the DSB in *Canada – Patent Protection of Pharmaceutical Products*.[128] The panel rejected the Canadian defense alleging that not allowing a third party to manufacture and stockpile patented goods in a short period prior to expiry would result in an additional period of market exclusivity.[129] According to the decision,

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124 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 199.

125 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 236.

126 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 248.

127 For more, see *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 255-256; *Carvalho*, The TRIPS Regime of Patent Rights, p. 378-379.

128 Despite dealing with term of protection, because of its findings of inconsistency of Section 55.2(2) of Canada's Patent Act with article 28.1 of TRIPS, the DSB decided not to examine the EC claims that article 33 would be also violated. See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.38.

129 See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.35.

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such a brief period of exclusivity should be regarded as normal.[130] From this understanding it is possible to conclude that the twenty-year term provided by Article 33 is a minimum period of protection in which the patentee has the exclusive right to extract economic value from the patent and, therefore, a patent may lawfully generate effects which extend beyond its expiration.[131]

In another case filed against Canada, *Canada – Term of Protection*,[132] the DSB ruled that Article 33 of TRIPS provides the forthright obligation that Member States make a term of protection available which should not end before twenty years as of the filing date.[133] In this case, the US requested that a panel be established against Canada on July 15, 1999, in which it alleged that Section 45 of the Canadian Patent Act would be inconsistent with Article 33 of TRIPS.[134] The Canadian provision established that patents granted for applications filed before October 1, 1989, were valid for seventeen years from the date the patent was issued, which could result in a protection period shorter than the twenty-year term as of the filing date set by TRIPS.[135] The DSB found that Section 45 violated TRIPS obligations, refusing the argument that under Canadian regulatory practices and procedures applicants could control and delay the patent-granting procedure, which would give them the chance to have a the twenty-year term set by TRIPS patent term.[136] The term of protection must be

130 *Id.*, para. 7.56.

131 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 381.

132 In this case, the DSB analyzed how the 20-year term of protection would apply to existing patents. The decision clarifies that patents already granted and not yeat expired by the time TRIPS entered in force in Canada are to be considered existing subject matter under article 70.2 of TRIPS and given the term of protection provided in article 33 of TRIPS. This does not represent a retroactive application of TRIPS obligations foreseen in article 70.1 of TRIPS. See *Canada – Term of Patent Protection*. Report of the Appellate Body, September 18, 2000 (WT/DS170/AB/R), para. 79. Article 70 of TRIPS will be discussed further in this chapter.

133 See *Canada – Term of Patent Protection*. Report of the Appellate Body, September 18, 2000 (WT/DS170/AB/R), para. 95.

134 See *Canada – Term of Patent Protection*, Summary of key findings, February 24, 2010 (WTO/DS170).

135 *Id.*

136 See *Canada – Term of Patent Protection*. Report of the Appellate Body, September 18, 2000 (WT/DS170/AB/R), para. 90-92.

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set as a clear right when the application is filed, being "available as a matter of legal right and certainty".[137]

This case also dealt with the relationship between Articles 33 and 62.2 of TRIPS. Accordingly, as Article 33 of TRIPS foresees a minimum date of expiration, Article 62.2 establishes the further obligation that procedures for patent granting are not excessively time consuming and the term of protection is not unreasonably curtailed. Some reduction may be allowed under Article 1.1 of TRIPS (which mandates Member States to implement TRIPS obligations, but allowing them to choose an appropriate method of implementation). However, Article 33 and 62.2 must be implemented into national law without patent applicants being forced to take extra measures in prosecution proceedings to comply with them.[138] This means that applicants should not be obliged to request for abandonment or reinstatement, not to pay fees or avoid replying to office actions to delay prosecution and reach a twenty-year term.[139]

The footnote of Article 33 of TRIPS clarifies that Member States, which simply re-register patents granted in other territories without conducting their own examination, may count the term of protection as of the date of a patent's first filing abroad.[140]

It is important to note that TRIPS does not provide for any provisional protection for patent applications.[141] Member States are not obligated to secure any right until the patent is granted.

2.3. Flexibilities within TRIPS concerning Patents

In order to mitigate the possible negative effects of exclusivity deriving from patents, TRIPS provides flexibilities for patent rights. The main instruments for these flexibilities are a) rules on implementation allowing transition periods for developing and least developed countries as well as

137 *Id.*

138 See *Canada – Term of Patent Protection*. Report of the Panel, May 5, 2000 (WT/DS170/R), para. 6.94.

139 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 381.

140 Footnote 8 of article 33 of TRIPS makes clear that member states are not obligated to carry out their own substantive examination, allowing patents of revalidation. This is the case of the Brazilian pipeline patents addressed in the following chapter of this work.

141 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 381-382.

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transitory arrangements concerning protection of existing subject matter, b) exceptions to patentable subject matter, c) exclusion of the international exhaustion issue from dispute settlement proceedings, d) general exception rules to exclusive rights, and e) compulsory licenses.

2.3.1. Rules on Implementation and Protection of Existing Subject Matter

The rules allowing transition periods for accession to the Agreement grant all Members States one year to apply TRIPS standards on protection of intellectual property pursuant to Article 65.1 of TRIPS. This provision establishes that no Member State is obligated to apply TRIPS provisions for one year as of January 1, 1996, the date the Agreement entered into force. However, TRIPS recognizes that not all Member States are equally prepared to implement TRIPS provisions at the same pace. Developing countries and countries transforming from a centrally-planned economy to a market economy system were entitled to an additional four years to apply TRIPS provisions (see Articles 65.2 and 65.3 of TRIPS), with the exception of Articles 3, 4 and 5 of the Agreement.[142]

A further five-year period was given for countries to provide for product patents in previously unprotected areas of technology (see Article 65.4 of TRIPS). The transition period included in Article 65.4 of TRIPS was important for many Member States that did not provide for patents in the chemical and pharmaceutical fields. These countries were given the possibility to delay the granting of patents in such previously unprotected areas of technology until January 1, 2005. The DSB confirmed this date of applicability in *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, complaint filed by the US.[143]

Nevertheless, not all developing countries have used the full term provided to them. Brazil passed a new law in 1996, which conformed national

142 In *Indonesia – Certain Measures Affecting the Automobile Industry*, the the DSB confirmed that article 3 of TRIPS should be applied as of January 1, 1996, not being subject to the additional four years of article 64.2 of TRIPS. See *Indonesia — Certain Measures Affecting the Automobile Industry.* Report of the Panel, July 2, 1998 (WT/DS55/R, WT/DS56/R, WT/DS59/R WT/DS64/R), para. 14.266.

143 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. 8.27.

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legislation to TRIPS obligations.[144] India, on the other hand, was one of the few developing countries that made use of the ten-year term to fully implement TRIPS.[145] In addition to India, in 2003, there were five other Member States that were still making use of the transition periods including Egypt, Pakistan, Qatar and United Arab Emirates.[146]

Article 65.5 of TRIPS prohibits Member States benefiting of the transition periods from reducing the level of protections in national laws and practices; this is referred to as the "standstill clause." It derives from ethical commitments made during negotiations, since changing protection conditions when trade concessions are in place leads to uncertainty.[147] In the case of *Indonesia – Certain Measures Affecting the Automobile Industry*, the US complained that the Indonesian National Car Programme was introduced during the transition period and lowered the existing IP standards of protection. Nevertheless, the DSB did not find any inconsistency of the Indonesian Programme with the obligations provided in Article 20 of TRIPS (on requirements related to the use of trademarks) and, thus, concluded that there was no violation of Article 65.5[148]

Least developed countries had an eleven-year implementation period according to Article 66.1 of TRIPS, which only required the application of Articles 3, 4 and 5 – regarding national treatment and most-favored-nation treatment principles – as of the entry in force of the Agreement. The TRIPS Council Decision of 2002 following the Doha Declaration on the

144 Lei N. 9279, of May 14, 1996, on industrial property rights, published in the Official Gazette on May 15, 1996.

145 Patent Act as amended by Act No. 15 of April 4, 2005 published in The Gazette of India on April 5, 2005.

146 See *Musungu*, *Oh*, The Use of Flexibilities in TRIPS by Developing Countries, p. 7. Egyptian Law # 82, of June 3, 2002, Law on the Protection of Intellectual Property Rights, published in Egypt Official Gazette of June 2, 2002; Ordinance no. LXI, of December 2, 2000, Patents Ordinance, published in the Gazette of Pakistan of December 2, 2000; Qatari Law-Decree No. 30, of August 6, 2006, To Issue Patents Law, published in the Qatar Official Gazette of December 12, 2006; Federal Law No. 31 for the Year of 2006, of July 24, 2002, Pertaining to the Industrial Regulation and Protection of Patents, Industrial Drawings, and Designs, published in the United Arab Emirates Official Gazette of July 24, 2002.

147 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 426-427.

148 See *Indonesia — Certain Measures Affecting the Automobile Industry*. Report of the Panel, July 2, 1998 (WT/DS55/R, WT/DS56/R, WT/DS59/R WT/DS64/R), para. 14.282.

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TRIPS Agreement and Public Health[149] granted an additional ten-year term, until January 1, 2016, for least developed countries to implement TRIPS provisions on patents and protection of undisclosed information regarding pharmaceutical products.[150] Without prejudice to this extension pertaining to pharmaceutical products, the TRIPS Council decided on November 29, 2005, to extend the transition period until July 1, 2013 or until the date a country ceases to be considered least developed, whichever is earlier.[151] The TRIPS Council granted a second extension of eight years on June 11, 2013, and the least developed countries will have until July 1, 2021, to fully apply the provisions of TRIPS, unless they leave their status of least developed earlier.[152] Those extensions should not alter the least developed countries rights to make full use of the flexibilities in the Agreement and to seek further extension periods.[153] Although the standstill clause was not specifically mentioned in Article 66 of TRIPS, least developed countries are also bound by it and are not allowed to reduce current standards of protection.[154] This is clearly established in the nonrollback clause of the TRIPS Council's Decision of November 29, 2005, which states "any changes in their laws, regulations and practice made during the additional transitional period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement".[155] Accordingly, if a least developed country already complies with some protection of

149 The Doha Declaration on the TRIPS Agreement and Public Health will be further analyzed in this work.

150 See *WTO*, Doha Declaration; and *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members with Respect to Pharmaceutical Products. The Doha Declaration on the TRIPS Agreement and Public Health was passed by the WTO's Ministerial Conference in 2001. It deals with the interpretation of TRIPS provisions in light of public health issues faced by many developing and least developed countries. The document will be further analyzed in this chapter.

151 See *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members of November 29, 2005, item I.1.

152 See *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members of June 11, 2013, item 1.

153 See *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members of June 11, 2013, item 2; and *WTO*, Responding to Least Developed Countries' Special Needs in Intellectual Property, para. 8.

154 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 422-427, 432.

155 See *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members of November 29, 2005, item III.5.

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IP rights, it may not reduce its level of compliance. The TRIPS Council's Decision of June 11, 2013, still reflects this commitment of the least developed Member States "to preserve and continue the progress towards the implementation of the TRIPS Agreement".[156] The longer transition period afforded to least developed countries is not intended to foster the creation of a technological base, but rather to provide more time to craft new legal measures to implement TRIPS obligations.[157]

Article 66.2 of TRIPS establishes that developed countries should create incentives for promoting the transfer of technology to least developed countries. The aim is to assist least developed countries accede to the international market by assisting them in creating a technological base.[158] This would be achieved by encouraging private companies – owners of IP rights – to participate in enterprises with companies based in the least developed countries.[159]

The transitional arrangements in TRIPS are interlinked with the provisions of Article 70. As Member States enjoy extended terms for implementing TRIPS obligations, in counterpart, they are subject to the determinations of Article 70 that address the protection of existing subject matter.

Article 70.1 of TRIPS establishes that the Agreement does not include obligations towards past acts, generally excluding retroactive application of TRIPS. However, pursuant to Article 70.2 of TRIPS, it does include obligations concerning subject matter existing at the date of application of TRIPS for that country. Subject matter which is either protected in that country on that date or meets or comes to meet the criteria for protection under the Agreement, except as otherwise provided in the agreement itself, is included in TRIPS. Under Article 70.2 of TRIPS, obligations refer to all WTO obligations to which Member States are bound, including those in Section 5, Part II of TRIPS.[160] In the context of patents, subject matter means patentable or patented inventions.[161]

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156 See *WTO*, Decision on the Extension of the Transition Period for Least-Developed Members of June 11, 2013, item 2.

157 *Id.*, p. 433.

158 *Id.*, p. 434.

159 *Id.*, p. 435-436.

160 See *Canada – Term of Patent Protection*. Report of the Panel, May 5, 2000 (WT/DS170/R), para. 6.53 and 6.54.

161 See *Canada – Term of Patent Protection*. Report of the Appellate Body, September 18, 2000 (WT/DS170/AB/R), para 65-66.

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In *Canada – Patent Term*, the DSB panel defined that the term 'acts,' as referred to in Article 70.1 of TRIPS, comprises acts of public authorities including examination of patent applications, the granting or rejection of a patent, the revocation or forfeiture of a patent, the granting of a compulsory license, and the confiscation by customs authorities of goods alleged to infringe IP rights. Additionally it comprises the acts of private and third parties including filing of a patent application, infringement or other unauthorized use of a patent, unfair competition or abuse of patent rights.[162] Article 70.1 of TRIPS does not exclude existing rights, such as patent rights, even if such rights derive from acts which occurred before the application of TRIPS in the Member State. As a result, the DSB panel established that Canadian patents that were already granted would be within the scope of the Agreement.[163]

Addressing the relationship between Articles 70.1 and 70.2 of TRIPS, the panel further stated that existing patent rights are not finalized acts; rather, they are existing subject matter.[164] The DSB panel clarified that Article 70.1 excludes obligations only to acts that occurred prior to the date of application of TRIPS, not continuing situations; whereas Article 70.2 applies to existing subject matter that should be deemed a continuing situation and, thus, be excluded from the scope of Article 70.1. In this case, application of Article 33 of TRIPS to inventions protected under the Canadian Patent Act would be justified under Article 70.2 and not 70.1 of TRIPS.[165]

Article 70.3 of TRIPS establishes that Member States are not obligated to restore protection to subject matter that is in the public domain on the date the Agreement is applied. This applies to subject matter previously protected, but whose term of protection has lapsed, has fallen into public domain for failure to pay maintenance fees, or has been revoked. In spite of its reference to subject matter that has already been protected, the rationale of Article 70.3 is also applicable to subject matter contained in a patent application that has been published and is later rejected by the patent office.[166]

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162 *Id*., para. 54.
163 *Id.*, para. 60.
164 *Id.*, para. 58-59.
165 *Id*., para. 69-70.
166 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 441.

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Article 70.4 of TRIPS determines that Member States may limit remedies available to the patentee, excluding the availability of injunctions, but guaranteeing at least equitable remuneration. The Article refers to the continuation of initially non-infringing activities that started prior to the application of TRIPS or in which significant investments were made and that become infringing under the laws implementing the Agreement. Article 70.4 aims to secure that Member States are free to allow the continuance of infringing acts provided that equitable remuneration is paid to the patentee. It is important to note that the equitable remuneration seeking to compensate losses of patent holders has a time restriction, since the activity would not be deemed an infringement until the date that laws implementing TRIPS entered in force.[167]

Article 70.6 of TRIPS is a further limitation to the rights of patent holders, determining that Member States may exclude from Article 31 and paragraph 1 of Article 27 of TRIPS the use of patented subject matter without the patent holder's authorization when such use had been permitted by the government before TRIPS' text became known. The language adopted in this Article assumes that the text of the Agreement was known to all governments at the date of its conclusion on April 15, 1994.[168] This provision protects compulsory licenses granted under existing national laws that were inconsistent with TRIPS because discriminated a certain field of technology, but it is not applicable to compulsory licenses granted based on lack of local working[169] Despite being considered "existing subject matter," Article 70.6 is an exception to Article 70.2 and compulsory licenses may continue under the condition that payment of equitable remuneration is made in accordance with Article 70.4.[170]

Amendments to IP rights that are subject to registration (which clearly include patents) should be allowed in order to enhance protections in accordance with which is provided in the Agreement as long as no new subject matter is included (see Article 70.7 of TRIPS). This provision establishes that Member States may allow applicants in pharmaceutical and chemical areas to claim products in addition to already claimed processes when such products have already been disclosed in the application, but

167 *Id.*, p. 442.
168 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 212.
169 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 442-443.
170 *Id.*

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which have not been claimed due to legislative restrictions in Member States.[171] Nevertheless, Article 70.7 must be reconciled with Article 65.4 of TRIPS and, therefore, developing countries may wait until January 1, 2005, to let the enhancement of the scope of pending applications in order to encompass product patent protection in fields of technology not protected prior to the date of application of TRIPS.[172]

Article 70.8 of TRIPS establishes the mailbox, where Member States that do not provide for patents covering pharmaceutical and agricultural chemical products when TRIPS entered in force were obligated to a) provide a means by which applications for such subject matter may be filed, b) apply TRIPS patentability criteria to such applications, and c) provide for protection according to TRIPS standards for the remainder of the term as of the filing date pursuant to Article 33 of TRIPS. *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, complaint filed by the United States, established that the term "means" referred to a mechanism entitling the filing of mailbox applications and the allocation of filing and priority dates so as "to provide a sound legal basis to preserve novelty and priority as of those dates."[173] However, it was not within the scope of obligations deriving from Article 70.8 to provide legal certainty towards the future granting of the patent in question.[174]

Exclusive marketing rights are provided for in Article 70.9 of TRIPS and must be granted by Member States for a five-year period after marketing approval is granted in that country or until a patent covering the product is either granted or rejected. For the enjoyment of such exclusivity rights, a patent application for such subject matter must have been filed after the Marrakesh Agreement entered in force and another Member State must have granted a patent for that product, as well as marketing approval. Article 70.9 expressly establishes that it will be applicable only in situations where a product patent application is filed under Article 70.8 of TRIPS.

In *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, complaint filed by the United States, the DSB made it

171 *Id.*, p. 443.
172 *Id.*, p. 444.
173 See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*. Complaint filed by the United States. Report of the Appellate Body, December 19, 1997 (WT/DS50/AB/R). para. 54 and 57.
174 *Id.*, para. 58.

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clear that the transition period in Article 65 is not applicable to Article 70.8 of the Agreement. Accordingly, if product patents were not available for pharmaceutical and agricultural chemical products, a means must be in place as of January 1, 1995 allowing the filing of patents for such inventions, in order to secure novelty and priority dates.[175] Exclusive marketing rights in Article 70.9 are also mandatory in case a Member State makes use of the transition periods in Articles 65 and 66.[176] For least developed countries, obligations under Article 70.9 of TRIPS regarding pharmaceutical products were waived until January 1, 2016 by means of the General Council Decision of July 8, 2002.[177]

2.3.2. Exclusions from Patentable Subject Matter

Article 27.1 of TRIPS established that patents must be granted for inventions in all fields of technology, provided that they are new, inventive and applicable to industry. Exceptions to patentable subject matter are only allowed in the cases set forth in Articles 27.2 and 27.3, as discussed previously in this text.[178]

The Agreement does not define novelty, inventive step, industrial application or invention. National legislatures are left to provide such definitions, which may differ from country to country. For instance, the patentability of second medical uses[179] is handled differently among

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175 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. 7.27.

176 *Id.*, para. 7.59.

177 See *WTO*, General Council Decision of July 8, 2002, Obligations Under Article 70.9 of the TRIPS for Least Developed Countries.

178 Member States may consider certain subject matter unpatentable in order to protect public order or morality, which includes protecting human, animal or plant life or health or avoiding serious prejudice to the environment. Diagnostic, therapeutic and surgical methods for the treatment of humans or animals, plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes may also be excluded from patentability.

179 The expression "second medical use inventions" generally refer to a new use, as medication, of a known product with use outside the medical field (which actually corresponds to the first medical use of this product) or to a new medical use of a product already known as medication.

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Member States regarding the concept of novelty. Such inventions are deemed to fulfill the novelty requirement in Europe, while they are not deemed so in India, Chile and Uruguay.[180] Some bilateral or regional free trade agreements have been negotiated as TRIPS-plus, such as the bilateral free trade agreement signed between Chile and the US, obligating their signatories to provide for the patentability of second uses.[181] Whether the requirement of novelty is fulfilled by the new use of a known compound represents a policy making debate. The patentability of new polymorphs also follows the same line of discussion.

2.3.3. Exhaustion and Parallel Importation

The patent holder may decide to produce, market, license or import a patented product into a country and has the right to exclude third parties from exploiting patented subject matter. However, after the product is legally put into the market, the rights of the patentee are deemed exhausted and the products may circulate, independent of the patent holder's authorization. For this to occur, the placement of the product in the market must have been made directly by the patentee or with his/her consent by means of a licensee. The exhaustion rules may be restricted to a country's national market or be international. In the first case, there is national exhaustion, the rights of the patentee are only exhausted within the territory of the country where the product was first marketed. A first sale in another country – from where the patented product was imported – does not lead to exhaustion of patent rights, and the patent holder must authorize such importation into the country. On the other hand, international exhaustion occurs when a patented product is legally put into the market in any coun-

180 European Patent Convention, of October 5, 1973, 14th edition of August, 2010, published by the European Patent Office. Indian Patent Act as amended by Act No. 15 of April 4, 2005 published in The Gazette of India on April 5, 2005. Ley n. 19.039, estableciendo normas aplicables a los privilegios industriales y proteccion de los derechos de propiedad industrial, of January 24, 1991, published in the Chile's Republic Official Diary of January 25, 1991. Ley n. 10.089, of December 12, 1941, published in the Official Gazette of December 23, 1941. For more see *Musungu, Oh*, The Use of Flexibilities in TRIPS by Developing Countries, p. 70-96.

181 See United States – Chile Free Trade Agreement (FTA), of June 6, 2003.

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try in the world. In this case, the first sale abroad will lead to the exhaustion of the patent holder's rights.

Exhaustion has been considered one of the problem topics during the negotiations on TRIPS. The final text of Article 6 of TRIPS reflects the agreement reached, excluding the issue from dispute settlement proceedings.[182] Article 6 establishes that nothing in the Agreement must be used to address exhaustion in dispute settlement cases subject to the national treatment and most-favored nation principles of Articles 3 and 4 of TRIPS. This means that the adoption of international exhaustion by a certain country may not be invoked as a direct violation of the TRIPS Agreement.[183] Considering the wording of the provision, it is not possible to conclude that TRIPS leaves the matter completely open to its Member States.[184] Article 27.1 combined with Article 28.1 of TRIPS establishes that national laws in Member States must afford patent holders the right to prevent sale and importation irrespective of the manufacturing location, which is an impediment to the general adoption of international exhaustion.[185] Despite this, the interpretation that TRIPS does not handle with the question of exhaustion of intellectual property rights and that applicability of international exhaustion is left to each Member State has prevailed, at least in areas pertaining to the protection of public health.[186] In paragraph 5(d) of the Doha Declaration, the WTO Member States affirmed the understanding that exhaustion of IP rights are to be freely determined by each country.[187]

The expression parallel importation refers to importation of a patented product without the patent holder's authorization, usually being sold abroad at lower prices.[188] Whether parallel importation is prohibited or not is a question of the exhaustion rules adopted by each country. In the case

182 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 112-115.
183 *Id.*, p. 112.
184 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 192-193.
185 *Id.* See also *Carvalho*, The TRIPS Regime of Patent Rights, p. 105.
186 See *Correa*, Integrating Public Health Concerns Into Patent Legislation In Developing Countries, p. 76; *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 191; *Carvalho*, The TRIPS Regime of Patent Rights, p. 106.
187 See *WTO*, Doha Declaration (paragraph 5(d)).
188 The price differentiation practice is not only governed by the patentee's own charging policies in the different countries but may be also influenced by factors such as government regulation of price.

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of international exhaustion, the patentee may not prevent third parties from importing patented goods, which have been put into the market abroad directly by the patent holder or when consent is given. On the other hand, according to the national exhaustion principle, the patentee may prohibit such parallel importation. As a consequence of the interpretation of Article 6 of TRIPS in light of paragraph 5(d) of the Doha Declaration, by providing national or international exhaustion rules, allowing parallel importation, at least in the pharmaceutical field, is a faculty given to each national legislator by TRIPS.

The national exhaustion rule over patent rights has been adopted by the United States[189] and Brazil,[190] whereas Argentina[191] and India[192] have adopted international exhaustion.[193] The Japanese Supreme Court decided that a Japanese patent could not be enforced and, consequently, parallel importation should be allowed whenever a patented product is sold outside Japan with the consent of the patent holder. In order to prevent parallel

189 In Quanta v. LGE, the US Supreme Court clearly established that the first sale leads to patent exhaustion; however, the court did not deal with the issue of foreign sales. See *United States Supreme Court,* Quanta Computer Inc. v. LG Electronics Inc., case 06-937, Decision of June 9, 2008, p. 17-9. Following Quanta v. LGE, the US Court of Appeals for the Federal Circuit, confirmed its previous understanding that the first sale must occurr within the US territory to result in patent exhaustion, and parallel importation is not allowed. See *United States Court of Appeals for the Federal Circuit*, Jazz Photo Corporation v. International Trade Comission, case 264 F.3d 1094, Decision of August 21, 2001, p. 16; *United States Court of Appeals for the Federal Circuit,* Fujifilm Corporation v. Benun, Jazz and Polytech, case 605 F.3d 1366, Decision of May 17, 2010, p. 7; *United States Court of Appeals for the Federal Circuit,* Ninestar Technology v. International Trade Commission, case 09-1549, Decision of February 8, 2012, p. 7. See also *Moore*, Parallel Trade, Unparallel Laws, p. 84-86.

190 The Brazilian patent statute, Law 9276/1996, refers to national exhaustion when limiting the patentee's rights in article 43, IV. The provision excludes from the scope of patent rights products which have been placed into the *internal* market directly by the patent holder or with his consent. There is an express reference to the internal market, leading to the interpretation that products placed in the *international* market are not encompassed by the provision. This provision will be also analyzed in the following chapter.

191 Law n. 24.481, of March 30, 1995, on Patents and Utility Models**,** published in the Argentinian Republic Official Bulletin on September 20, 1995.

192 Patent Act as amended by Act No. 15 of April 4, 2005 published in The Gazette of India on April 5, 2005.

193 For an analysis of the legislation of more countries, see *Musungu*, *Oh*, The Use of Flexibilities in TRIPS by Developing Countries, p. 70-96.

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importation into Japan, there should be an agreement between the purchaser and the patent holder establishing that Japan be excluded from the allowed territory of sale or use. Also, resales would be prevented only if it is noted clearly on the product itself that importation into Japan is prohibited (on the label or packaging for example).[194]

In 1974, under the principle of free movement of goods, one of the pillars of the Treaty Establishing the European Communities,[195] the European Court of Justice (ECJ) decided in C-15/74 that the exercise of patent rights should not prohibit the importation into the Netherlands of products that were put into markets in other Member States with the patent holder's consent.[196] The patentee should not be able to partition off the national markets and, thus, jeopardize the free flow of goods within the Common Market.[197] The ECJ adopted the exhaustion rule for importation of patented products from countries belonging to the economic block and referred to it as European exhaustion. The ECJ reiterated its understanding in later cases,[198] having observed in one judgment issued in 1985 case C-19/84 that the patentee may prevent importation to a Member State whenever the product has been marketed in the exporting country under a compulsory license.[199] In this case, the court understood that an essential element for exhaustion was missing, which is the consent of the patentee to the product's marketing.[200] The national exhaustion rule had been applicable in

194 See *Supreme Court of Japan*, BBS Kraftfahrzeug Technik AG, BBS Japan Kabushiki Kaisha, Washimayor Kabushiki Kaisha v. Kabushiki Kaisha Racimex Japan, The Third Petty Bench of the Supreme Court, judgment of July 1, 1997.

195 Article 30 of the Treaty Establishing the European Communities, amended and renumbered to article 28 in the Amsterdam version of the treaty.

196 See *European Court of Justice,* Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc., Case C 15/74, judgment of October 31, 1994, para. 10-15.

197 See *European Court of Justice,* Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc., Case C 15/74, judgment of October 31, 1994, para. 10-15.

198 See *European Court of Justice*, Merck & Co. Inc. v Stephar BV and Petrus Stephanus Exler, Case C 187/80, judgment of July 14, 1981, para. 11-14, *European Court of Justice*, Merck & Co. Inc., Merck Sharp & Dohme Ltd and Merck Sharp & Dohme International Services BV v Primecrown Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd and Beecham Group plc v Europharm of Worthing Ltd, Joined Cases C 267/95 and C 268-95, judgment of December 5, 1996, para. 54.

199 See *European Court of Justice*, Pharmon BV v Hoechst AG., Case C 19/84, judgment of July 9, 1985, para. 27.

200 *Id.*, para. 25-26.

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Germany and the German Supreme Court expressly recognized that only products placed into the market by the patentee (or with his/her consent), in States belonging to the European Communities or to the European Economic Area, could be imported into the country without infringing the German patent or the German part of a European patent.[201] The adoption of European exhaustion conformed to the case law established by the ECJ to avoid partitioning of the Common Market and should not mean that the principle of international exhaustion was adopted.[202]

Regarding medicines, the pharmaceutical industry practices price differentiation among the countries,[203] which may lead to considerable economy through the practice of parallel importation. At the end of the 1990s, South Africa based its anti-AIDS program on parallel importation in order to be able to acquire cheap antiretroviral drugs. The South African government purchased patented anti-AIDS medications in neighboring countries where they were cheaper and a group of pharmaceutical companies supported by the US government sued the South African government in a South African court on February 18, 1998. In the lawsuit, the companies claimed that South African parallel importation rules – as well as compulsory license provisions – were not compliant with TRIPS.[204] Only after worldwide protests did the pharmaceutical companies withdraw the lawsuit in 2001.[205]

Adopting the international exhaustion rule allows for a product that is legally introduced into a market to be imported and sold by a third party for a lower price in a different country. Countries would be free to purchase medications or pharmaceutical ingredients wherever it is sold cheaper. International exhaustion would then stimulate international trade and competition, forcing local distributors to lower their prices according to cheaper prices in other markets. On the other hand, when considering the implementation of international exhaustion, one should also consider that this might serve as a disincentive to establishing local industry. In light of

201 See *German Supreme Court*, "Karate", case X ZR 61/98, of Dec. 14, 1999, p. 686.

202 *Id.*, p. 687-688.

203 It is important to consider that the different prices found may also result from government regulation of price.

204 See *Consumer Project on Technology*, Pharmaceutical Firms against the South African Government, para. 1.

205 *Id.*, para. 3.

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the perspective of competing with cheaper prices through importation, national or transnational corporations would not be encouraged to build local facilities and industrialization policies would be jeopardized. Furthermore, a general and uniform adoption of international exhaustion would hinder the practice of price differentiation by patent holders, which discriminates prices in accordance with the income of each country's population. If price discrimination ceases, international exhaustion would result in the opposite outcome and access to cheaper products would be more difficult.

2.3.4. General Exception Rules

Article 30 of TRIPS allows Member States to provide general exceptions to the exclusive rights conferred by a patent, if they do not unreasonably conflict with normal exploitation and do not unreasonably damage the legitimate interests of patent owners and third parties. This is a general provision that is applicable whenever there is no specific rule, for instance Article 31 of TRIPS governing compulsory licenses.[206] Accordingly, TRIPS allows Members States to limit patent holder's rights and adjust them to the principles and purposes established in Articles 7 and 8 of the Agreement. As in any limitation to rights, the exceptions provided must be interpreted in a restrictive manner. Examples of exceptions to patent rights covered by Article 30 are found in the early drafts of the provision, such as prior user rights, experimental research and compounding pharmacy activities and products.[207]

The exception rules in Article 30 played an important role in *Canada – Patent Protection of Pharmaceutical Products,* the dispute settlement between Canada and the European Communities in 2001 that was discussed earlier. Section 55.2(1) provided for an "early working" exception for regulatory review and Section 55.2(2) allowed the generic company to manufacture the generic drug six months before the end of the patent term and store the production in order to market it without delay as soon as the patent would lapse.[208]

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206 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 241-242.

207 See *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, March 17, 2000 (WT/DS114/R), para. 4.30.

208 *Canada – Patent Protection of Pharmaceutical Products*. Summary of key findings, February 24, 2010 (WTO/DS114).

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Addressing the structure of Article 30, the DSB made it clear that exceptions must fulfill three conditions in order to be compliant with TRIPS: 1) they must be limited, 2) they must not unreasonably conflict with normal exploitation of the patent and 3) they must not unreasonably damage the legitimate interests of the patent owner and take into account the legitimate interests of third parties.[209] If one of these conditions is not present, it constitutes a violation of the Agreement. The limitation of exceptions to exclusive rights conferred to patent holders addresses the extent that these rights are curtailed, rather than the extent of the possible economic impact.[210] However, limitations are unrelated to the number of exclusive rights foreseen in Article 28.1 – to make, use, offer for sale, sell and import – that have been prejudiced by an exception.[211] The extent to which such legal rights have been shortened is what should be limited.[212] It is irrelevant if only one right is ultimately preserved by the exception and not all rights are affected, e.g. the acts of making and using are exempted from infringement while the acts of sale are not).[213]

The expression "normal exploitation" contained in the second condition of Article 30 should be understood as the exclusion of "all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant market exclusivity." Accordingly, Section 55.2(2) of Canada's Patent Act that allows manufacture and storage was inconsistent with Article 30 of TRIPS because the benefits obtained by the patentee, in the period between the legal end of the patent term and the actual end of the patent, refer to the normal exploitation of a patent.[214] The enjoyment of the right to exclude third parties to "make" the patented product during the patent term would naturally result in the prevention of such party from immediately entering the market after expiration.[215] On the other hand, carrying out tests for regulatory review is not considered normal exploitation of a patent; therefore, Section 55.2(1) of the Canadian

209 See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.20-7.21.
210 *Id.,* para. 7.49.
211 *Id*., para. 7.32-7.33.
212 *Id.*, para. 7.31.
213 *Id*., para. 7.32-7.33.
214 *Id.,* para. 7.56-7.57.
215 *Id.*

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Patent Act providing for the "early working" exception was not in violation of TRIPS.[216]

Pursuant to the third condition established by Article 30 of TRIPS, the assessment of Canada's legislation should verify if patent holders would have a "legitimate interest" in the economic benefits deriving from *de facto* market exclusivity and if their "legitimate interest" would be "unreasonably prejudiced" by the regulatory review exception.[217] According to the DSB, "legitimate interests" are not a synonym for "legal interests" pursuant to Article 28.1 of TRIPS.[218] Rather, they should be regarded as interests that are "justifiable" to be supported by public policies and social norms, such as the use of patented subject matter for scientific research, which would take into consideration dissemination of technology, a public policy concern at the foundation of the patent system. (The "legitimate interest" of society to use the information contained in the patent specification for advancing science and technology would be justified).[219] Furthermore, the "legitimate interests" of the patentee, which would have been affected by the Canadian legislation, relate to the effective term of exclusivity enjoyed by the patentee, which is actually shortened due to the extensive trials needed to support the regulatory approval of the innovative product, the patented subject matter.[220] The panel concluded that the concept of "legitimate interest" should not be used to encompass the need of compensation for losses, since this would amount to an area of policy making that is still unresolved among countries.[221] As a result, Section 55.2(1) of Canada's Patent Act would not prejudice the "legitimate interest" of patent holders.

Article 30 of TRIPS does not specify the activities that should be exempt, but rather establishes general conditions to be fulfilled by national legislatures when regulating the matter. According to this rationale, international exhaustion should not be regarded as a general exception under Article 30 because it would conflict with the normal exploitation of a

216 *Id.*, para. 7.58.
217 *Id.*, para. Para. 7.61.
218 *Id.*, para. 7.68.
219 *Id.*, para. 7.69.
220 *Id.*, para. 7.74-7.76.
221 *Id.*, para. 7.77-7.83.

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patent and may impair the legitimate interests of a patent holder.[222] In *Canada – Patent Protection of Pharmaceutical Products* decision, the DSB wisely concluded that Article 30 recognizes that the rights given to a patent owner under Article 28 of the Agreement must be balanced in order to achieve what Articles 7 and 8.1 establish.[223] Nevertheless, the three conditions set in Article 30 make it clear that the exceptions to patent rights, which may be implemented by each Member State, should be narrowly interpreted and are not to be considered a renegotiation of the Agreement.

2.3.5. Compulsory Licenses

Compulsory licensing is the most important flexibility instrument provided in TRIPS (see Article 31 of TRIPS). It is a license granted under certain conditions by a government to a third party in order to allow the production or marketing of a patented product or the use of a patented process, regardless of the consent of the patent owner.

Compulsory licenses have always been the subject of controversial debates relating to effects on a country's economy and especially on investments in research and development (R&D). For a long time, many studies have sought to evaluate and quantify such effects.[224] Though inconclusive, studies have indicated that in the long run, granting of compulsory licenses has minimal effects on investments by companies in developing countries.[225] The discussions are mostly theoretical and revolve around the balance between private interests and social welfare. On the one hand, stronger patent rights would provide better incentives for the international transfer of technology because it depends on high investments in R&D by

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222 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 202.

223 See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), para. 7.26.

224 See *Scherer*, The Economic Effects of Compulsory Patent Licensing; *Jewkes, Sawers, Stillerman*, The Sources of Invention; and *Chien*, Cheap Drugs at What Price to Innovation.

225 See *Rosenberg*, Patents on Medicines and International Trade, p. 172-173; and *Primo Braga, Fink*, The Economic Justification for the Grant of Intellectual Property Rights, p. 108.

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transnational companies in developing and developed countries.[226] On the other hand, flexible rights would introduce competitors in an otherwise monopolized market, leading to a decrease in prices.[227]

Compulsory licenses have arisen as an alternative to prevent voiding of patents as a result of violating restrictions. Until the Paris Convention, the failure to work a patent would have resulted in loss of patent rights, i.e. forfeiture.[228] At that time, compulsory licenses represented a less cumbersome measure than forfeiture for patent owners. According to the 1883 text of the Paris Convention, the patentee was obligated to work a patent according to national laws.[229] The Convention did not define the expression "working," leaving it up to Member States to establish meaning at their own discretion.[230] In some countries, working implied local manufacture of the patented subject matter, whereas in others it would be enough if the patented product were simply being marketed.[231]

The idea of compulsory licenses as a legitimate mechanism to hinder abuses became widespread during the Paris Convention Hague Revision of 1925.[232] This concept was further elaborated in the London Revision of 1934, when Member States agreed that a waiver of patent rights would only be possible in cases where the effects of abusive conduct were still occurring two years after the first compulsory license.[233] The use of compulsory licenses was originally linked to the concept of abuse and, afterward, the mechanism was conceived as a way to restrict the rights of patent holders in the case of public interest even if abusive conduct had not occurred. The granting of compulsory licenses in the case of public interest was not expressly foreseen in the text of the Convention, but it was not prohibited. The Lisbon Revision of 1958 established that compulsory li-

226 See *Tang*, The International Trade Policy for Technology Transfers, p. 193.
227 See *Rosenberg*, Patents on Medicines and International Trade, p. 157.
228 The original text of the Paris Convention of 1883 and the subsequent acts amending it have been received by the candidate from the IP Laws and Treaties Section of the WIPO as files attached in electronic correspondance. See also *Reichman*, *Hasenzahl*, Non-voluntary Licensing of Patented Inventions, p. 10.
229 *Id*., p. 29.
230 See *Ladas*, Patents, Trademarks, and Related Rights, p. 524.
231 See *Ladas*, Patents, Trademarks, and Related Rights, p. 523.
232 See *Reichman*, *Hasenzahl*, Non-voluntary Licensing of Patented Inventions p. 10, 28. See also *Bodenhausen*, Guide to the Application of the Paris Convention for the Protection of Industrial Property, p. 68.
233 *Id.*, p. 11, 28.

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censes could be granted non-exclusively and determined time limits for granting.[234]

The latest Revision of Stockholm of 1967 with an amendment in 1979, establishes that importation of goods would not result in forfeiture when such goods are manufactured in another member country.[235] National legislation may provide for the granting of compulsory licenses seeking to prevent abuses resulting from exclusive rights, such as the failure to work.[236] Only if compulsory licenses have not been able to prevent abuse, forfeiture may occur; in this case, proceedings for forfeiture or revocation may be established only after a two year period following the date of granting of the first compulsory license.[237] In addition, lack of or insufficient working may only trigger a compulsory license after a four year period following the filing date of the patent application or after a three year period following the date the patent is granted – whichever occurs last. The patentee is entitled to present legitimate reasons to prevent the granting of a compulsory license.[238] The compulsory license will be non-exclusive and non-transferable. Sub-licensing is also prohibited, except with that part of the enterprise or goodwill which exploits such license.[239]

It is important to note that the provisions of the Paris Convention on compulsory licenses are still applicable within the context of TRIPS by virtue of Article 2.1 of TRIPS. Accordingly, compulsory licenses should be granted in compliance with article 5A(2) of the Paris Convention and Article 31 of TRIPS. In case their granting was grounded on failure to work or insufficient working of the patent, the requirements of Article 5A(4) of the Paris Convention must also be fulfilled.[240]

During the GATT negotiations, developed countries sought to restrict the Paris Convention's interpretation, which allowed each Member State to adopt its own criteria of abuse, so as to inhibit developing countries from continuing to embrace local production requirements.[241] Evidence of

234 *Id*., p. 27.
235 Article 5A(1) of Paris Convention.
236 Article 5A(2) of Paris Convention.
237 Article 5A(3) of Paris Convention.
238 Article 5A(4) of Paris Convention.
239 Article 5A(4) of Paris Convention.
240 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 205.
241 See *Reichman*, *Hasenzahl*, Non-voluntary Licensing of Patented Inventions, p. 13-14.

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this is present in the wording of Article 27 of TRIPS, which prohibits discrimination based on local production or importation. This discussion resulted in a panel requested by the US against Brazil and will be discussed later on in this text.[242]

Public interest, which includes cases of national emergency, other circumstances of extreme urgency or public non-commercial use, is one of the major grounds for granting compulsory licenses. Patent laws in most countries, if not all, allow the use of patents for public interest. Abusive conduct and cases of dependent patents are also cited expressly in Article 31 of TRIPS, yet the provision does not provide an exhaustive list of all situations where compulsory licenses are granted except for one hypothesis. According to Article 31(c) of TRIPS, in the field of semi-conductor technology, compulsory licenses are only for public non-commercial use or a remedy for practices deemed judicially or administratively anti-competitive.

Under Article 31, TRIPS establishes the conditions upon which compulsory licenses may be granted. Among the necessary requirements are: 1) the request for the license has been analyzed on its individual merits and on a case by case basis,[243] 2) the interested party has previously sought to obtain the patent holder's authorization in reasonable commercial standards and that those efforts have not been successful within a reasonable period of time (this is exempted in case of urgency or national emergency),[244] 3) the scope and duration of the license is proportional, limited to the purpose for which it was granted,[245] 4) the license is non-exclusive and non-assignable except with the part of the enterprise or goodwill which enjoys such license,[246] and 5) the products manufactured under the compulsory license serve predominantly to supply the domestic market.[247]

In cases of anti-competitive practices, prior negotiations with the patentee and the need for supplying the domestic market are not required. It is

242 See *Brazil – Measures Affecting Patent Protection*. Request for Consultations by the United States, June 8, 2000 (WT/DS199/1). Request for Establishment of a Panel by the United States, January 9, 2001 (WT/DS199/3). Notification of Mutually Agreed Solution, July 19, 2001 (WT/DS199/4).

243 Article 31 a) of TRIPS.

244 Article 31 b) of TRIPS.

245 Article 31 c) of TRIPS.

246 Article 31 d) and e) of TRIPS.

247 Article 31 f) of TRIPS.

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important to note that a controversial issue among scholars has been whether compulsory licenses for anti-competitive practices should be granted with the goal of increasing access to medicines by poor populations in developing countries.[248] Even assuming that there is a violation of competition laws, for the majority of developing countries, the compulsory licenses for anti-competitive practices are not actually available either because there is not a system of competition law or their system is not mature enough.[249] Brazil, for instance, provides this tool in Article 68 of Law 9279/1996, but there is no record that it has ever been used.

The provision in Article 31(f) of TRIPS that addresses a *de facto* limitation for the least developed countries was especially disputed. The problem was that generic products manufactured under a compulsory license could not be exported to these poor countries. As a result of this limitation, least developed countries and many developing countries were barred from the benefits of compulsory licenses, since they do not have the capacity to manufacture drugs themselves. This debate resulted in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health of November 14, 2001 (Doha Declaration), and the General Council Decision of August 30, 2003 (Doha Decision), as a compromise to elucidate this issue.[250] The Doha Declaration and Decision in theory would solve the problem of the countries that lack sufficient manufacturing facilities.

Adequate compensation should be paid to the patent owner in exchange for the withdrawal of exclusive production and marketing rights in favor of the general welfare. However, payment is not calculated strictly according to losses. The patent owner must receive reasonable compensation in the concrete case taking into consideration the economic value of the license, as per Article 31(h) of TRIPS. The Agreement does not contain any criteria for determining suitable compensation, but the Guidelines of the World Health Organization (WHO) provide examples in which royalties are between 1% and 6% of the market price.[251] Payment of reasonable

248 See *Godt*, The so-called "Waiver Compromise" of Doha and Hong Kong. *Hoen*, TRIPS, Pharmaceutical Patents and Access to Essential Medicines, p. 52. *Amaral Júnior*, Compulsory Licensing and Access to Medicine in Developing Countries, p. 11-2.

249 *Id*., footnote 67 (until 2002 only 20 developing countries have passed legislation regulating competition law).

250 See *WTO*, Doha Declaration (paragraph 6); *WTO*, Doha Decision. The Doha Declaration and Decision will be dealt further on this chapter.

251 See *Correa*, A Commentary on the TRIPS Agreement, p. 323.

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royalties could serve as a means for reducing the negative effects of granting compulsory licenses for technological development.[252] In the case of anti-competitive practices, Article 31(k) of TRIPS allows Member States to grant compulsory licenses with reduced payment of royalties or even for free.

TRIPS also establishes that judicial review must be available to assess both the legal validity of the granting of the compulsory license and the remuneration to be paid to the patentee as adequate compensation.[253]

In the case of dependent patents, Article 31(l) of TRIPS authorizes compulsory license of the original patent whenever the second patent concerns an important technical advance and it has considerable economic significance, which is to be evaluated in relative terms regardless of its absolute economic value.[254] The owner of the first patent is also entitled to a cross license to be able to use the second patent on reasonable terms. The license issued in this case is only assignable upon assignment of the patent that enjoys such use.

Although the issue of compulsory license has received a lot of attention in discussions regarding access to medicines in developing and least developed countries. Developed countries like the US have long provided for compulsory licenses in their national laws.[255] Several cases of compulsory licenses can be found for correcting anti-competitive practices in the US.[256] In 2001, under the menace of an anthrax epidemic, the US Depart-

252 See *Scherer*, The Economic Effects of Compulsory Patent Licensing, p. 86.

253 Article 31 i) and j) of TRIPS.

254 Patents covering new use of an orphan drugs are cited as an example of patents which would be of small absolute value but of big economic significance. See *Carvalho*, The TRIPS Regime of Patent Rights, p. 370.

255 See in this regard the following provisions of the US legislation foreseeing compulsory licenses cases: US Clean Air Act 1988 (42 USC Sec. 7608) on products that become mandatory technical standards in consequence of environmental legislation; Atomic Energy Act 1988 (42 USC Sec. 2183) on patents of public interest regarding atomic energy; 7 USC Sec. 2402 (1988) on plant varieties; 28 USC Sec. 1498 on governmental use. See also *Love*, Don't interfere with the Thai government's decision, p. 1-2; and *Correa*, IP Rights and the Use of Compulsory Licenses, p. 1.

256 See, for example, Federal Trade Commission, Merger Ciba-Geigy and Sandoz in 1997 (compulsory license of the patent portfolio covering HSV-tk, hemophilia genes and other genetic engineering related products). Federal Trade Commission, Merger Baxtel International/Immuno International AG in 1997 (compulsory license granted for fibrin sealant, of which the merging company would be one of

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ment of Health threatened to grant a compulsory license under 28 USC Section 1498 for Bayer's patent covering the drug Cipro in order to obtain a discount in its price.[257]

TRIPS does not adopt any criteria that limits the notion of public interest or define "circumstances of extreme urgency," "national emergency," "public use," and "anti-competitive practices." Nevertheless, when interpreting and implementing Article 31 of TRIPS, Member States should do it in harmony with other provisions of the Agreement in light of the balance between intellectual property and the welfare of nations, as per Article 8.1 of TRIPS.[258] Furthermore, it is important to keep in mind that the flexible interpretation of TRIPS is not unlimited – neither to raise nor decrease protection levels. In the panel *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, complaint filed by the United States, the DSB decided that TRIPS patent terms should be interpreted following the common meaning deriving from its context and in light of the Agreement's subject matter and purpose (pursuant to Article 31 of the Vienna Convention on the Law of Treaties).[259] The DSB disapproved interpretations that would elevate or diminish the rights and obligations provided in the Agreement.[260]

Although there might be homogeneity among the hypotheses for granting compulsory licenses in different Member States, legislation should vary according to the desired level of patent protection, the importance of promoting R&D, the need to have lower priced medicines and the degree of competition policies – the latter plays an important role in the pharmaceutical sector and the marketing of generic products. Despite these policy making considerations, compulsory licenses are exceptions to the rights

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the few to request the FDA approval). Federal Trade Commission, Merger Upjohn/Pharmacia Aktiebolag in 1995 (compulsory license granted for the patent covering 9-AC on cancer treatment). Federal Trade Commission, Eli Lilly in 1979 (compulsory license of the patents and know-how for the production of insulin).

257 See *Fleischer-Black*, The Cipro Dilemma, para. 14-15.

258 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 204.

259 See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products.* Complaint filed by the United States. Report of the Appellate Body, December 19, 1997 (WT/DS50/AB/R), p. 16.

260 *Id.*

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conferred by a patent and should be treated accordingly as exceptional; that is, measures to be taken only in certain cases that are duly justified.

2.4. Other Provisions

Article 32 of TRIPS determines that any decision revoking or declaring the forfeiture of a patent is subject to judicial review. Within the WTO system it establishes a principle specifically directed at patents based on the general guarantee that exists in most democratic states where judicial power is entitled to review measures that restrict rights. Accordingly, decisions revoking and forfeiting patents may be submitted to independent judicial assessment. In the EPC context, the Boards of Appeal of the EPO issues final decisions regarding the revocation of European patents in opposition proceedings (see Articles 106, 111 and 112 of the EPC). As its members are deemed independent and enjoy stability prerogatives similar to those granted to judges, the Boards of Appeal and the Enlarged Board of Appeal are to be considered quasi-judicial bodies following procedures similar to those of courts.[261] Therefore, review by the Boards of Appeal of decisions issued by the Opposition Division should be considered the judicial review of Article 32 of TRIPS.[262]

One could consider that the grounds on which a patent may be revoked or declared forfeited is left open by this TRIPS provision. Nevertheless, in spite of a lack of an explicit list of grounds, revocation and forfeiture of a patent may not occur based on convenience criteria under the penalty of nullifying the main objective of TRIPS to provide a sound system of protection of intellectual property. Any security deriving from the patent system would be compromised because there would always be the chance of forfeiture or revocation based on generally alleged public interest.[263] Cancellation of a patent is a consequence that is too severe even for cases of public interest; therefore, to balance this, the remedy lies with compulsory licenses.[264]

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261 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 254.
262 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 208-209.
263 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 375-376.
264 *Id.*

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Forfeiture may only occur under Article 5.A.3 of the Paris Convention, which must be complied with by Member States according to Article 2.1 of TRIPS.[265] This provision establishes that forfeiture be conditioned to the cases in which compulsory licenses have not inhibited abuses resulting from exclusivity rights such as failure to work a patent.[266] Failure to pay maintenance fees may also justify the lapse of a patent.[267] Member States may be able to revoke patents on the following grounds: 1) the grounds included in the Paris Convention such as insufficiency of compulsory license as a measure to prevent abuses and failure to pay maintenance fees (Article 5.A.3 of the Paris Convention), 2) failure to meet substantive conditions of patentability or to qualify as an invention pursuant to Article 27.1 of TRIPS, 3) the invention consists of subject matter falling under the admitted patentability exclusions of Article 27.2 of TRIPS, and 4) failure to comply with full disclosure requirement of Article 29 of TRIPS.[268] Limitations on grounds for forfeiture and revocation are necessary in order to make TRIPS effective as an agreement establishing minimum standards for IP rights. Otherwise, any harmonization of patentable subject matter and rights conferred to patent holders would be void if a patent could be invalidated or declared forfeited based on a mere convenience criteria within each country legal system and the result would be different standards of protection that create barriers to international trade.

Article 34 of TRIPS establishes the reversal of the burden of proof in civil proceedings related to the enforcement of patents for processes for obtaining new products. It aims to facilitate patent enforcement in cases where there is no direct evidence of the use of patented processes.[269] Pursuant to this provision, judicial authorities should be authorized to order the defendant to prove that the process used to obtain the product is different than the process which is patented. Member States should provide for such reversal (i) either in the case that the product obtained by the patented process is new, (ii) or there is a high likelihood that the product was

265 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 376.

266 Article 5.A.3 of Paris Convention also determines that forfeiture or revocation proceedings may only start after two years from the granting of the first compulsory license.

267 Article 5*bis*.2 of Paris Convention foresees a loss of rights resulting from the lack of payment of maintenance fees.

268 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 376.

269 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 260.

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obtained by the patented process and this could not be proved by the patentee through reasonable efforts. It is important to note that Member States must provide for reversal of the burden of proof in case of patents covering processes for obtaining a product, but not for other kinds of processes including methods and uses.[270] When alleged offenders submit evidence opposing the infringement allegation, their legitimate interests in protecting manufacturing and business secrets must be taken into account and, thus, the burden rests on the plaintiff as in regular civil lawsuits.[271]

If national laws provide for the reversal of the burden of proof either in one of the cases – (i) or (ii) – discussed above, then they are in compliance with TRIPS. For reversal to occur (as per the second possibility), it is not necessary for the product obtained by the patented process to be new. This is considered helpful for the enforcement of patents covering modern biotechnology processes that use rDNA technology for producing already know proteins.[272]

3. The Pharmaceutical Industry Context

Patent provisions in TRIPS have been the subject of heated debate among Member States, especially concerning the pharmaceutical context. In the past, the exclusion of certain areas of technology from patentable subject matter had been regarded as decisive for a country's development. This was the position adopted in the 1970s towards pharmaceuticals by India and Brazil; Switzerland allowed patents for pharmaceuticals only in 1977; whereas Spain, Italy and Portugal only introduced them in 1992.[273] Before

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270 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 384.

271 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 260.

272 See *Straus*, Implications of the TRIPs Agreement in the Field of Patent Law, p. 210.

273 Brazilian Federal Law 5772, of December 21, 1971, The Industrial Property Code, published in the Official Gazette on December 31, 1971. Indian Patent Act, of September 19, 1970, published in The Gazette of India on April 20, 1972. Swiss Ordinance 232.141, of October 19, 1977, on Patents for Inventions, published in the Official Gazette on October 19, 1977. Portuguese Decree N. 52/91, of August 30, 1991, ratifying the European Patent Convention, published in the Republic Diary on August 30, 1991. Spanish Law N. 11/1986, of March 20, 1986, Patent Law, published in the Official Bulletin of Spain on March 26, 1986. Italian Law N. 349/1991, of October 19, 1991, on provisions for the issue of a

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the Uruguay Round in 1995 there were thirteen GATT Member States that did not provide patents for pharmaceuticals.[274] The WTO system along with TRIPS has been criticized for creating barriers to the access of essential medicines in developing countries. The introduction of patent rights in countries that did not provide this exclusivity rights would lead to a price increase. In many developing countries, the problem is considered to be quite large since medicine is purchased directly by patients without health insurance or governmental aid due to inadequate public health systems or infrastructure.

The pharmaceutical sector is highly dependent on patents to reduce competition in the marketplace. According to an early study in 1986, the pharmaceutical industry depends on the patent system twice as much as the chemical sector.[275] The research based industry defends itself by alleging that the process of developing new drugs is costly and time consuming. According to an estimate made in 2010, only one out of 10,000 potential drugs reaches the market after a fifteen year period of research and trials, costing over US$800 million.[276] Patents are considered necessary in the pharmaceutical industry to be able to recuperate investments and fuel the R&D cycle,[277] since the cost of drug development is high compared to the marginal cost for manufacturing. As settled during TRIPS negotiations and the discussions surrounding the Doha Declaration, the issue is not about protecting incentives to innovate, but how much protection is justified.

Public policies such as price control, reimbursement of expenses for medications, governmental subsides for pharmaceutical R&D activities, acquisition of patents by governments, introduction of policies regarding generic drugs, price differentiation among countries, and the use of flexibilities within TRIPS (especially the granting of compulsory licenses) may be used as tools to minimize market distortions and negative social effects

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certificate of additional protection for medicines or its members, subject to patent, published in the Official Gazette on November 4, 1991.

274 Argentina, Brazil, Cuba, Egypt, India, Kuwait, Morocco, Pakistan, Paraguay, Tunisia, Turkey, United Arab Emirates and Uruguay. See *WTO,* Pharmaceutical patents and the TRIPS Agreement, footnote 2.

275 See *Mansfield*, Patents and innovation, p. 175.

276 See *PhRMA*, Chart Pack, p. 19.

277 PhRMA points out that R&D investments by the research based pharmaceutical industry were of USD 50,7 billion in 2010. See *PhRMA*, *PhRMA*, Chart Pack, p. 21.

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of patents in this field.[278] The proposed combination of compulsory licenses and price control should be carefully considered by policymakers in order to enhance access to medicines through price reduction.[279] Governments would impose a decision on patent holders: either they accept price control on patented products or agree to non-exclusive licenses to national industry.[280] Instead of an aggressive price control system, licensing would be the better option and would not be prevented under Article 31 of TRIPS because in the end there is consent from the patent holder.[281]

TRIPS includes a number of possible grounds for granting compulsory licenses, which are to be adopted by developing countries aiming to promote access to medicines. These include a) the refusal to license the patent under reasonable commercial terms, whenever the non-licensing affects the availability of a product or the development of a new activity; b) declared state of national emergency, resulting for instance from a natural catastrophe, war or epidemic; c) whenever there is a public health crisis, in order to assure the population has access to essential medicine, or in situations of public interest including national security; d) anti-competitive practices; e) the use of government to make medicine available on a non-commercial basis; f) when the lack or insufficient exploitation of the patent subject matter hinders access to health or prevents the development of a sector that is essential to a country's economy; g) facilitating the use of dependent patents; and h) public interest, broadly defined in order to cover other situations in which society's welfare is at stake.[282]

It is important to note that the flexibilities included in TRIPS such as compulsory licenses and parallel importation were barely used during the first years of the WTO system because developing and least developed countries were afraid of trade retaliation. In 1997, South Africa began making use of parallel importation seeking to reduce the price of medications for the treatment of AIDS. The US Congress then threatened to withhold all development aid and the South African government was sued by

278 See *Rosenberg*, Patents on Medicines and International Trade, p. 86-102.
279 See *Weissman*, A Long, Strange TRIPs, p. 1115-1116.
280 The granting of compulsory licenses and price control should take due care so as to not violate article 31 TRIPS, especially considering that compulsory licenses must be granted on an individual basis and not provided by national laws as a general measure.
281 *Id.*
282 See *Correa*, IP Rights and the Use of Compulsory Licenses, p. 10-22.

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39 international pharmaceutical companies.[283] In addition, in 2009, the US government requested a panel against Brazil before the WTO Dispute Settlement Body alleging that the Brazilian industrial property law provided for a local working requirement on its Article 68 compulsory licenses, which would be inconsistent with the non-discrimination principle of Article 27.1 of TRIPS.[284]

Due to the need to clarify issues surrounding the controversy between patent rights and public health concerns, Member States held a Ministerial Conference in Doha in 2001 that resulted in the Doha Declaration on the TRIPS Agreement and Public Health.

3.1. The Doha Declaration on the TRIPS Agreement and Public Health

Prior to the Ministerial Conference held in Doha in 2001, developing countries were afraid to make use of the flexibilities negotiated in TRIPS due to steady resistance by industrialized countries. Developing countries were afraid of economic sanctions for the granting of compulsory licenses. As mentioned earlier in this chapter, the lawsuit relating to parallel importation against the South African government served to enhance these fears.[285] The same was true when WTO panel was established following the complaint by the US government against Brazil.[286] The problematic provision in Article 31(f) that made access to medicines difficult for least developed countries was another clear reason for developing countries to want to reform TRIPS.

The US, which at the beginning of the Doha Round strongly resisted the softening of patent rights, found itself in a weakened position. This was the result of the US government's threats against the Bayer company to grant a compulsory license for the importation of a me-too drug of the

283 See *Consumer Project on Technology*, Pharmaceutical Firms against the South African Government, para. 1-3.

284 See *Brazil – Measures Affecting Patent Protection*. Request for Consultations by the United States, June 8, 2000 (WT/DS199/1). Request for Establishment of a Panel by the United States, January 9, 2001 (WT/DS199/3).

285 See *Consumer Project on Technology*, Pharmaceutical Firms against the South African Government, para. 1-3.

286 See *Brazil – Measures Affecting Patent Protection*. Request for Consultations by the United States, June 8, 2000 (WT/DS199/1). Request for Establishment of a Panel by the United States, January 9, 2001 (WT/DS199/3).

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patented antibiotic Cipro from India. The drug is used for treating anthrax, which became an issue after important US politicians received letters containing the anthrax agent following the terrorist attack of September 11, 2001.[287] The German company has made an offer to the US government and the parties have reached an agreement, but at the end the acquisition of generics has not taken place.[288]

In June 2001, a group of developing countries submitted a document to the Council for TRIPS in order to discuss intellectual property and access to medicines.[289] In November of the same year, the WTO Ministerial Conference passed the Doha Declaration. All WTO Member States expressly recognized that, although the protection of intellectual property is important for the development of new medicines, there are concerns about its effect on prices. Accordingly, TRIPS neither prevents nor should prevent members from taking measures to protect public health and promote access to medicines. The Doha Declaration reaffirms the right of WTO members to make use of the provisions in TRIPS that provide flexibility for this precise purpose.

The flexibilities established by the Doha Declaration comprise the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. Additionally, the Declaration establishes the right for countries to determine what constitutes national emergency or other circumstances of extreme urgency such as a public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics. Regarding Article 6 of TRIPS, the Doha Declaration confirms that the Agreement leaves Member States free to establish their own regimes for exhaustion without challenge, being subject to the most favored nation and national treatment provisions in Articles 3 and 4 of TRIPS.

In paragraph 6, the Doha Declaration instructed the Council for TRIPS to find a solution before 2002 to the problem faced by WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector in order to allow them to make effective use of compulsory licensing.

The final paragraph agrees, with respect to pharmaceutical products, that least developed countries will not be obligated to implement or apply

287 See *Fleischer-Black*, The Cipro Dilemma, para. 14-15; *Moore*, Parallel Trade, Unparallel Laws, p. 91; *Herstemeyer*, Human Rights and the WTO, p. 16.

288 See *Fleischer-Black*, The Cipro Dilemma, para. 14-15.

289 See *Carvalho*, The TRIPS Regime of Patent Rights, p. 144-145.

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Sections 5 and 7 of Part II of TRIPS nor to enforce rights established under these Sections until January 1, 2016. Accordingly, the Council for TRIPS and the General Council issued decisions implementing this waiver on June 22, and July 8, 2002, respectively.[290]

Although the Doha Declaration has not modified TRIPS, it has served as a policy making tool and the granting of compulsory licenses became an undoubtful prerogative of any Member State. Moreover, interpretations of Article 6 of TRIPS, which could lead to an increase of TRIPS protection standards, should be hindered. The possibility that medicines be exported and sold in other countries at cheaper prices was confirmed, as long as laws in such countries allow for parallel importation. Additionally, least developed countries received an additional ten-year term to implement TRIPS into their national legislation.

The position assumed by developing countries towards the Doha Declaration has been criticized for the assumption that compulsory licenses would be a tool to solve the problem of access to essential medicines in poor countries. Compulsory licenses stand as an exception to established rights and should not be used to mold public health policies at the risk of undermining private rights and incentives. Lacking access to essential medicines should not be regarded simply as a problem caused by the research-based pharmaceutical industry when in most countries the solution depends on the general restructuring of social development policies. Generic drugs may be sold at cheaper prices, but, in general, the generic pharmaceutical companies are private and profit-oriented, except some government owned industries, and the supply of essential drugs would still be subject to price negotiation between governments and private industry.

One issue that was left unanswered by the Doha Declaration, with express instructions for the Council for TRIPS to solve, was the importation of products manufactured in other countries within the scope of compulsory licenses. Since those goods have not been manufactured with the consent of the patentee, in principle there would be no exhaustion of rights. Furthermore, pursuant to Article 31(f) of TRIPS, a compulsory license

290 See *WTO*, Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, Decision of the Council for TRIPS of June 22, 2002 (IP/C/25); *WTO*, Least-Developed Country Members — Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, Decision of the General Council of July 8, 2002 (WT/L/478).

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must be granted primarily for supplying the domestic market, which poses a severe problem for developing and least developed countries that do not possess the technical capacity to manufacture drugs in general or the specific drug covered by the compulsorily licensed patent. This problem led to the General Council Decision Implementing Paragraph 6 of the Declaration, which will be discussed below. In its essence, the Doha Declaration is a reaffirmation of concepts that were already established in TRIPS with the goal of settling any misinterpretations that could lead to a distortion of the TRIPS regime.

3.2. The Decision Implementing Paragraph 6 of the Doha Declaration

After difficult negotiations between developing countries and industrialized countries regarding the implementation of paragraph 6 of the Doha Declaration and the possibility of amending TRIPS, a decision was adopted by the General Council on August 30, 2003.[291] Pursuant to the decision, in cases of compulsory licenses of medicines Article 31(f) of TRIPS is not applicable when granted for combating public health problems. This decision was deemed as a waiver of Article 31(f) through a special procedure.

On December 6, 2005, the General Council in Hong Kong approved the waiver as permanent and thereby amended the TRIPS Agreement for health issues. The parties agreed and passed a Protocol establishing that Article 31bis (whose contents reported to the Decision of 2003) be introduced in the Agreement.[292] The transition period before entering into force was until December 1, 2007. This deadline was extended to by the General Council until December 31, 2009 and again until December 31, 2011, since the quorum of two-thirds of WTO Member States had not yet been

291 For more, see *Carvalho*, The TRIPS Regime of Patent Rights, p. 329-339; *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 48-54.

292 *WTO*, Protocol Amending TRIPS.

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achieved.[293] As of today only 44 parties have ratified the Protocol[294] and, until it enters into force, the 2003 Decision is still applicable.

The Protocol does not differ much from the 2003 Decision. In summary, the mechanism foreseen in the Decision and the Protocol provides that Article 31(f) of TRIPS be waived, allowing for the exportation of pharmaceutical products under a compulsory license to an eligible importing Member State with insufficient or no manufacturing capacities. The mechanism must be used only in cases of national emergency or other circumstances of extreme urgency or public non-commercial use. A systematic interpretation of the Doha Declaration and the Decision leads to the conclusion that the waiver of Article 31(f) must be used to protect public health and concerns medicines for treating diseases that afflict many developing and least developed countries such as AIDS, tuberculosis, malaria, and other epidemics.

Both importing and exporting countries must grant a compulsory license. Only the exporting country, and not the country in need of the medicines, should pay adequate remuneration. Importing countries should notify the Council for TRIPS of the medicines they need and in what quantity. As for the exporting country, the following conditions must be fulfilled: a) only the needed quantity may be exported, b) the whole amount that the manufacturing country will produce under the license is to be exported to the importing country, and c) the medicines imported under this procedure should bear a special label.

Within a regional trade area, if half of the members are deemed to be least developed countries, it is allowed that medicines that are imported under compulsory licenses be further exported into all the other countries in the trade area. In practice, this provision most probably only applies to African countries.

Member States must take measures against undue further sales of medicines imported under this procedure so as to ensure that they are used

293 *WTO*, Members accepting amendment of the TRIPS Agreement.

294 The following member have formally accepted the Protocol Amending TRIPS: United States, Switzerland, El Salvador, Republic of Korea, Norway, India, Philippines, Israel, Japan, Australia, Singapore, Hong Kong, China, European Union, Mauritius, Egypt, Mexico, Jordan, Brazil, Morocco, Albania, Macau, Canada, Bahrain, Colombia, Zambia, Nicaragua, Pakistan, Former Yugoslav Republic of Macedonia, Uganda, Mongolia, Croatia, Senegal, Bangladesh. See *WTO*, Members accepting amendment of the TRIPS Agreement.

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only for the public health purposes justifying the compulsory license. An important provision prohibits Member States from bringing cases before the WTO Dispute Settlement Body against measures taken under the Doha Decision (or article 31*bis* once it is formally incorporated into TRIPS) and its annexes.

The mechanism may not be used by every Member State for importing medicines. Industrialized countries (Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States) have consented that they will not import medicine under the provision. Importation is allowed by developing countries through the mechanism only in case of national emergency or other urgent situations.[295]

Until February 28, 2011, few Member States had adapted their national laws to the new mechanism, including Canada, Norway, India, European Union/European Communities, Hong Kong, Switzerland, Philippines, Singapore, Albania, Croatia, China, The Republic of Korea, and Japan.[296] Four years after its creation, the mechanism was used for the first time in the second semester of 2007 between Rwanda and Canada. The African country notified the WTO General Council on July 19, 2007, that it would like to use the mechanism to import 260,000 packages of the antiretroviral drug TriAvir (a pharmaceutical combination of Zidovudine, Lamivudine and Nevirapine).[297] On October 8, 2007, Canada submitted a notification to the Council for TRIPS informing that it exported 15,600,000 generic tablets to Rwanda[298]

It is important to note the WTO General Council Chairperson's Statement on the Implementation of paragraph 6 of the Doha Declaration, according to which good faith directed at protecting public health should instruct the use of the mechanism established in the Doha Decision. The

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295 Hong Kong, Israel, Korea, Kuwait, Macao, Mexico, Qatar, Singapore, Taiwan, Penghu, Kinmen and Matsu, Turkey and the United Arab Emirates. See *WTO*, General Council Meeting adopting Doha Decision, para. 29.

296 See *WTO*, Members' laws implementing Doha Decision.

297 See *WTO,* Notification by Rwanda under paragraph 2(a) of the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, of July 19, 2007 (IP/N/9/RWA/1).

298 See *WTO*, Notification under paragraph 2(c) of the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, of October 8, 2007 (IP/N/10/CAN/1).

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mechanism should not serve as a tool to pursue industrial or commercial objectives and be used parsimoniously in circumstances of national emergency or extreme urgency.[299]

Only after the Doha Ministerial Declaration of 2001 and the Decision of 2003 – in which all Member States agreed that each country is entitled to make use of the flexibilities within TRIPS to combat public health problems – developing countries started to mold their patent systems allowing themselves to implement TRIPS flexibilities. However, due consideration must be given to the fact that problems related to the lack of access to medicines are not to be blamed exclusively on patent rights. These problems are essentially caused by poverty, and entering the WTO system serves as a tool to foster economic growth and, therefore, raise living standards of a country's population. The fact that the mechanism established in the Doha Decision has not been widely put into practice, except possibly in the unique case of Rwanda mentioned above, corroborates the fact that access to medicines is not only a matter of drug prices imposed by the pharmaceutical industry owning patents. The generic drug industry is also profit oriented and cannot simply give away its products for free, or for a minimum price without profit, to poor populations. The mechanism will probably only work in cases where there is a not-for-profit foundation or government sponsoring the manufacturing of a drug under a compulsory license. It does not solve the inherent social and economic problems of least developed and developing countries.

C. Remarks on the Applicability of TRIPS in Brazil

International agreements and treaties[300] must be approved by the Brazilian Congress and ratified by the President, as per Articles 49, I and 84, VIII of the Brazilian Federal Constitution of 1988, and are incorporated into the country's legal system through Presidential Decree.[301] The Brazilian Pres-

299 See *WTO*, General Council Meeting adopting Doha Decision, para. 29.

300 For the purposes of this work, no distinction is made between the international agreements, treaties or acts, being the terms treated as synonims.

301 This is a long established practice in the Brazilian law becoming a customary rule and has no specific provision foreseeing it in the Federal Constitution of 1988 or in the previous ones. Brazilian scholars and the Supreme Court agree that the presidential decree of promulgation is a requirement for an international treaty to be incorporated into the domestic legislation. For more see *Mello*, Public Interna-

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ident is empowered to sign international treaties, conventions and acts through a referendum of Congress. Accordingly, for Brazil to be bound by international agreements that are negotiated by the President, ratification is necessary and may only occur after Congress has voted favorably and issued a legislative decree of approval. This procedure laid out in the Brazilian Constitution is the only way for international treaties to come into effect in the country and there is no way to fast track this process.

After accepting the Final Act of the Uruguay Round, the Brazilian President sent Presidential Message 498/1994 to Congress in order to seek approval of the Marrakesh Agreement that established the WTO.[302] Approving the bill for a legislative decree containing the Marrakesh Agreement and its annexes was then subject to discussions in Congress. On December 15, 1994, DLG 30/1994 was issued approving Brazilian accession to the WTO system and consenting to the Presidential ratification of the Marrakesh Agreement. On December 21, 1994, ratification of the Marrakesh Agreement was put into the Brazilian public record.[303] The Marrakesh agreement and its annexes were, then, incorporated into the Brazilian legislation upon enactment of Presidential Decree 1355/1994, on January 1, 1995.

According to Supreme Court case law dating back to 1971, upon enactment of a Presidential Decree, international agreements are immediately applicable and deemed law of the land.[304] After TRIPS was enacted in Brazil by means of Decree 1355/1994, it was recognized by the Superior Court of Justice as incorporated into the Brazilian legal system as of January 1, 1995.[305] As law of the land and directly applicable, TRIPS should have immediately revoked Law 5772/1971, the previous statute regarding

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tional Law Course, p. 180-187; *Rezek*, Public International Law, p. 69; *Rodas*, The Publicity of International Treaties, p. 200-201; and the Supreme Court decisions on HC 2.280, RE 71.154 and Rogatory Letter 8.279.

302 Presidential Message to the National Congress n. 498, of July 1, 1994.

303 See *WTO*, Status of Legal Instruments, p. 8.

304 See *Supreme Court*, RE 71.154 and RE 80.004.

305 As per article 102 of the Federal Constitution of 1988, the Supreme Court shall have jurisdiction over cases in which a violation of the Constitution may exist. Article 104 of the Federal Constitution created a second high court, the Superior Court of Justice, primarily competent for hearing cases where there may be a violation of the federal legislation (article 105 of the Federal Constitution).

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patents, and should have become the applicable law until Law 9279/1996 entered into force.[306]

Despite existing precedents, the Superior Court of Justice in REsp 960.728 (known as the DuPont case) rendered an important decision on March 17, 2009. It established that TRIPS is not applicable to private parties and would only obligate States; therefore, companies and private individuals could not invoke the Agreement in order to protect their own rights. TRIPS was no longer considered the law of the land and directly applicable.[307] The decision was based on a distinction that was made regarding the nature of international treaties, according to which there is a difference between international treaties, whose provisions regulate private relationships and may be directly applicable, and other agreements with provisions which serve as parameters for statutes to be enacted by States. These national statues would in turn regulate private relationships.[308] TRIPS fell in the category of the former as its provisions are directed to legislatures in Member States and not private parties.[309]

The DuPont case also addressed the date on which TRIPS became effective in Brazil.[310] TRIPS would not be applicable in the country beginning on January 1, 1996 – one year after the Marrakesh Agreement entered into force and the date on which TRIPS became generally applicable.[311] DuPont claimed that Article 33 of TRIPS would allow for an extension of patent term from fifteen to twenty years even prior to the enactment of Law 9279/96 (which foresees a twenty-year patent term in compliance with TRIPS)[312] The court understood that at the time Congress approved TRIPS, Brazil's unique waiver concerning delayed applicability of the Agreement under Article 65 was related to the possibility of postponing the patentability of inventions in certain technological areas (i.e., areas that were excluded as patentable subject matter under the old statute, such

306 See *Superior Court of Justice*, REsp 423.240, REsp 661.536 and REsp 667.025, following the long established understanding of the Supreme Court in RE 71.154 and RE 80.004.

307 See *Superior Court of Justice*, REsp 960.728, p. 1-2.

308 See *Barbosa*, Intellectual property: TRIPS Agreement application, p. 18; *Basso*, TRIPS application date in Brazil, p. 13-22; *Sichel*, TRIPS, p. 311-322.

309 See *Superior Court of Justice*, REsp 960.728, p. 6-9.

310 See *Superior Court of Justice*, REsp 960.728, p. 3.

311 Article 65.1 of TRIPS.

312 The previous statute, Law 5772/1971, established a patent term of fifteen years.

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as chemical and pharmaceutical products) for five years.[313] When Congress approved the international agreement, it rejected the option of an additional five-year term established by Article 65.4 of TRIPS and did not make reference to its use in order to delay the application of the Agreement.[314] According to the court, Article 65.4 of TRIPS is a faculty given to Member States that should decide to use it or not.[315] On the other hand, the term established in Article 65.2 of TRIPS is a right, and as such, was taken for granted by Member States and not subject to expressed discussion regarding its use, resulting in an additional four-year term for TRIPS to be applied in Brazil and other developing countries.[316]

Despite the controversy raised by this decision, it still recognizes that Brazil did not make use of the right to postpone the applicability of TRIPS provisions until January 1, 2000.[317] The enactment of Law 9279/1996 meant the right set forth in Article 65.2 of TRIPS had been renounced.[318]

It is important to consider that the Superior Court of Justice decision in the DuPont case was influenced by the argument that there was a lack of direct applicability of the treaty in countries of the European Union.[319] This position ignores the decision by the European Court of Justice in case C-431/05 and its effects on Portuguese and Spanish jurisdictions, where their respective national courts may directly apply international treaties.[320]

The Brazilian Superior Court of Justice issued other decisions according to what was established in the DuPont case.[321] Nevertheless, the Supreme Court still has to rule on the later understanding by the Superior Court of Justice regarding the indirect applicability of TRIPS and the date the Agreement entered into force in Brazil. It is up to the Supreme Court

313 See *Superior Court of Justice*, REsp 960.728, p. 9-19.
314 *Id.*
315 *Id.*
316 *Id.*
317 See *Superior Court of Justice*, REsp 960.728, p. 17.
318 *Id.*
319 This influence may be inferred in the text of the decision. See *Superior Court of Justice*, REsp 960.728, p. 9, quoting *Barbosa*, Intellectual property: TRIPS Agreement application, p. 85.
320 *European Court of Justice*, Merck Genéricos – Produtos Farmacêuticos Ltda v. Merck & Co. Inc. and Merck Sharp & Dohme Ltda, Case C 431/05, judgment of Sep 11, 2007, para. 47-48.
321 See *Superior Court of Justice*, REsp 806.147, REsp 642.213 and AgRg no REsp 1.105.155.

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to give the final word on whether TRIPS will be given differentiated treatment and, unlike other international agreements, not be considered the law of the land. The appeal against REsp 960.728 filed before the Supreme Court has been withdrawn and, thus, decision on this matter by the country's highest court has been delayed.[322]

322 See status of case RE 626.368 before the Brazilian Supreme Court at <http://www.stf.jus.br/portal/processo/verProcessoAndamento.asp> (Last visited May 9, 2012).

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III. CHAPTER. THE BRAZILIAN PATENT SYSTEM

A. Overview

1. The Constitutional Clause

Article 5, XXIX of the Brazilian Federal Constitution of 1988 safeguards the protection of inventions. This provision sets forth that the law shall ensure temporary privileges for the use of industrial inventions by their authors, as well as the protection of industrial creations, keeping in mind the interests of society and national technological and economic development. The constitutional clause also provides for the mandatory protection of property rights related to trademarks, company names and other distinctive signs. The clause instructs the infra-constitutional legislature to enact a statute regulating the granting and enforcement of industrial property rights.[323]

The industrial property clause is established as a fundamental right in Article 5, reflecting the commitment of the constitutional legislature to guarantee rights of inventors.[324] Because of their aspects in relationship to patrimony, intellectual property rights could be considered separate from the Bill of Rights, where individual rights are established in the Constitution, and placed among the provisions regarding economic order.[325] However, it is important to note that property rights for tangible goods are also deemed a fundamental right in Article 5, XXII of the Federal Constitution and there is no justification for intangible property to be excluded from similar protection.

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323 In the Brazilian Law, the Federal Constitution enjoys supremacy in the hierarchy of laws. Laws and statutes enacted by Congress would follow in the hierarchical scale, together with the Provisional Measures enacted by the President (according to Article 62 of the Federal Constitution). Presidential Decrees regulating the law enacted by Congress would come after. Ordinances and Resolutions from the governmental institutions would be at last. All the legislation, which in the hierarchical scale is subordinated to the Federal Constitution, is referred as infra-constitutional legislation.

324 See *Oswald, Leonardos*, Patent Law: Constitutional Aspects, p. 8.

325 See *Silva*, Constitutional Law, p. 276-277.

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The clause has been interpreted as finalistic and, accordingly, the infra-constitutional legislature should enact laws that take social, technological and economic interests into account. Industrial property law cannot aim (or have as a material effect) only to serve external government policies to the detriment of the interests of society and technological development of the country.[326] These are conditions that are inherent to the existence of industrial property rights, otherwise the law would be rendered unconstitutional.

Under a different interpretation, this clause has been regarded as the foundation for the patent system, reflecting a compromise between inventors and society. On the one hand, inventors obtain property rights and, on the other hand, society benefits from the contents of the patent either directly (having access to the new product) or indirectly (enjoying new economic activities related to the new product in the market). Also, the governments – representing the States – profit from economic activity that fosters technological development through the transfer of technology.[327] The conditions for granting of patents would be regulated in infra-constitutional legislation, which then guide public administration's activities.

Because the exercise of property rights is not unlimited, the Brazilian Federal Constitution establishes in Article 5, XXIII that property will conform to its social function. In the case of patent rights, any abuse would be inhibited or remedied by measures also foreseen in law such as granting compulsory licenses, which will be discussed later in this text.

In this context, it is also necessary to mention Article 170 of the Constitution dealing with economic order, which is founded on valuing individual work and free initiative. The regulation of Brazil's economic order should respect private property, the social function of property and freedom of competition, as foreseen in Article 170, II, III and IV respectively. However, Article 173 paragraph 4 of the Constitution establishes that the law will reprehend abuse of economic power aiming to domination of markets, elimination of competition and abusive profit increases.

Therefore, patent rights should always be analyzed in light of their objective of advancing society, technological and economic development, and the principles of free initiative and competition. The Constitution provides exclusivity rights for inventors as long as this privilege serves social

326 See *Barbosa*, Unconstitutionality of the Pipeline Patents, p 13-14.
327 See *Oswald, Leonardos*, Patent Law: Constitutional Aspects, p. 11.

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interests and fosters economic and technological development. Since patent rights enable the exclusion of third parties, which affects free initiative and competition, they should not be absolute in order to prevent abuses.[328] Through a systematic analysis of Articles 5, XXIX, 170 and 173 of the Brazilian Constitution, it is possible to conclude that whenever the Constitution authorizes law to provide for patents to be granted, there will be a balance between the principles of free private initiative and free competition. Additionally, case of abuse should be combated through competition laws. [329]

Patents constitute monopoly rights by the exclusion of third parties to exploit an invention. In light of this alone, patent rights would run counter to freedom of competition. In a balancing exercise, the constitutional assembly concluded that the monopoly rights of patents are in fact beneficial to society. It is also important to consider that patent rights do not totally exclude competition. Patents foster competing activities among innovative companies who invest in the development of new types of technology that surpass existing knowledge and replace old technologies.

2. General Provisions on Patentability

Brazilian Law 9279/1996 establishes the main set of provisions regulating the constitutional rights of inventors, providing for industrial property rights and seeking to implement TRIPS obligations into Brazilian legislation. The basic requirements for patentability – novelty, inventive step and industrial application – are foreseen in Article 8 of Law 9279/1996 pursuant to Article 27.1 first sentence of TRIPS. The Brazilian statute defines that an invention will be deemed new when not included in the state of the art as per Article 11 of Law 9279/96. Everything made accessible to the public before the application filing or priority dates will be considered part of the state of the art.[330] The contents of pending applications before the INPI, but not yet published, should also be taken into consideration provided that such applications are subsequently published.[331] There is also a

328 See *Ferraz Jr.*, Industrial Property and Competition Law, p. 11.
329 See *Rosenberg*, Patents on Medicines and International Trade, p. 131-132; *Salomão Filho*, Antitrust Law, p. 132.
330 Article 11, paragraph 1, of the patent statute.
331 Article 11, paragraph 2, of the patent statute.

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twelve-month grace period foreseen in Article 12 of Law 9279/96, which establishes that the disclosure of an invention within twelve months preceding the filing or priority dates will not consist in bar of novelty, as long as disclosure is carried out either by the inventor, by the INPI in an official publication without the inventor's consent, or by third parties on the basis of information obtained from the inventor.

The inventive step requirement as legally defined states that an invention will be regarded as such when not deriving from the state of the art in an evident or obvious way for a person skilled in such art, as per Article 13 of Law 9279/96. Inventive step, thus, depends on the knowledge of the person skilled in an art, which will serve as a parameter for the examination of inventive step. The person skilled in an art must possess general education in the field of technology and should dominate the general principles of analogous industries – that is to say the person is not a beginner.[332] The criteria for determining the level of knowledge and skills required should also vary according to the technology assessed. In some areas of highly advanced studies such as biotechnology, the person skilled in the art should have a high level of knowledge and education that generally includes doctoral titles.

Inventive step is a requirement that was introduced expressly in Brazilian law only through the enactment of Law 9279/1996. However, this concept has always underlined the basic notion of an invention in Brazil.[333] Novelty and inventive step combined are part of the foundation of the patent system, as the State affords exclusivity to inventors in exchange for the disclosure of their inventions. In case the invention is not new, already exists in the state of the art, or derives obviously from therein, such exclusivity would consist in an unfair monopoly.[334]

Article 15 of Law 9279/1996 broadly defines the industrial application requirement as being fulfilled when an invention can be made or used in any kind of industry. Industry comprises any branch of production activity and includes agricultural and extractive industries, as already established in Article 1(3) of the Paris Convention.[335] Article 1(3) seeks to avoid bar-

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332 See *Wolff*, Written Description, p. 25-26.

333 See *Miranda*, Treatise of Private Law, p. 274.

334 See *Cerqueira*, Industrial Property Treatise, p. 305-306.

335 "Article 1(3). Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for exam-

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ring patentability of activities and products, e.g. those related to agriculture, which would otherwise be at risk of not being assimilated by the industry itself, instead of obligating countries to grant patents on products such as wines, animals or fruits.[336]

Relating to more formal aspects of requirements for patentability, disclosure and written description should also be fulfilled before a patent is granted. As stated in Article 24 of Law 9279/1996, applicants are required to describe the invention clearly and sufficiently, so as to enable a person skilled in the art to carry it out and to indicate, when applicable, the best mode of execution. For the purposes of fulfilling disclosure and written description requirements of inventions involving biological material, sole paragraph of Article 24 allows for the deposit of such biological material in an institution authorized by the INPI as a means to supplement the specification.[337] In addition, Article 25 establishes that patent claims must be based on the specification, characterizing the particularities of the application and defining clearly and precisely the subject matter to be protected. The limitations of the claimed invention must be clearly set. The same figure of a person skilled in the art as foreseen in the inventive step requirement is present for examining disclosure and written description. These requirements seek to conform legislation to Article 29.1 of TRIPS.[338] That is to say, it is based on the foundation of patent system as a negotiated relationship between the State and inventors, ensuring that an invention can actually be carried out by someone skilled in the art as described in the

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ple, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour".

336 See *Bodenhausen*, Guide for the Paris Convention, p. 26.

337 Although Brazil is not a member of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, the INPI has been recognizing the deposit with one of the international depositary authorities accredited by this international treaty for the purposes of article 24, sole paragraph, of Law 9279/1996 (see Normative Act 127/97, item 16.1.1.2). The INPI has issued Resolution 82, of November 22, 2001, which defines the requirements for accrediting a Brazilian institution as a depository authority. As of April 3, 2006, the creation of a national depository authority in the city of Xerém in the State of Rio de Janeiro in cooperation with the Instituto Nacional de Metrologia, Normalização e Qualidade Industrial (INMETRO) has been announced by the INPI, but until the present date it has not started its operations. See *Brendler*, Storage center of biological material is likely to be created in Rio until October, para. 1-4.

338 See *Dannemann*, Commentaries on the Industrial Property Law, p. 55.

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specification. Written description and disclosure are complemented by Article 25, which was clearly inspired by Article 84 of the EPC, so as to ensure that exclusivity deriving from a patent does not extend beyond the actual contribution of the invention to the state of the art as described in the specification.[339]

Although patents may be granted for inventions that meet the novelty, inventive step, industrial application and disclosure requirements, set forth in Articles 8, 24 and 25 of Law 9279/1996, they should not be subject to the statutory bars established in Articles 10 and 18 of Law 9279/1996.

Article 10 of Law 9279/1996 defines ineligible subject matter for its inability to meet patentability requirements. The following are not considered inventions: a) discoveries, scientific theories and mathematical methods; b) purely abstract concepts; c) schemes, plans, principles or methods of a commercial, accounting, financial, educational, publishing, lottery or fiscal nature; d) literary, architectural, artistic and scientific works or any aesthetic creation; e) computer programs per se; f) the presentation of information; g) rules of games; h) operating or surgical techniques and therapeutic or diagnostic methods, for use on the human or animal body; and i) natural living beings, in whole or in part, and biological material, including the genome or germplasm of any natural living being, when found in nature or isolated therefrom, as well as natural biological processes.

Article 18 of Law 9279/1996, in turn, lists the following subject matter as expressly excluded, despite fulfilling patentability requirements: a) which is contrary to morals, good customs and public security, order and health; b) substances, matter, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes of obtaining or modifying them, when they result from the transformation of the atomic nucleus; and c) living beings, in whole or in part, except transgenic microorganisms meeting the three patentability requirements – novelty, inventive activity and industrial application – in Article 8 of Law 9279/1996 and which are not mere discoveries. In the sole paragraph of Article 18, transgenic microorganisms are defined as organisms, except the whole or part of plants or animals, which exhibit, due to direct human intervention in their genetic composition, a characteristic that cannot normally be attained by the species under natural conditions.

339 *Id.*, p. 56-57.

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At first glance, one would say that the exclusions from patentable subject matter established in the Brazilian statute would conform to Article 27.2 and 27.3 of TRIPS (as articles 10 and 18 of Law 9279/1996 seem to have been modeled after Articles 52 and 53 of the EPC 1973).[340] Nevertheless, TRIPS mandates Member States to provide for patentability of microorganisms in general, whereas Article 18 of Law 9279/1996 establishes that only transgenic microorganisms may be afforded patent protection.

The current industrial property law in Brazil, unlike the previous statute (Law 5772/1971), does not prohibit patents for products in the chemical and pharmaceutical fields. However, Article 10, VIII of Law 9279/1996 does not recognize operating or surgical techniques and therapeutic or diagnostic methods for use on the human or animal body to be inventions. These general provisions on patentability requirements must be kept in mind when analyzing issues that specifically concern patents on pharmaceutical inventions under Brazilian law.

3. Term of Protection and Rights Conferred by Patents

In order to be in harmony with Article 33 of TRIPS, the patent term in Brazil under Article 40 of Law 9279/1996 was extended from fifteen to twenty years as of the filing date. A minimum period of ten years of protection as of the granting of the patent is safeguarded by sole paragraph of Article 40 of Law 9279/1996, in light of the extensive backlog at the INPI.

As discussed in the previous chapter, TRIPS was enacted in Brazil by means of Decree 1355/1994 and patent owners have sought term extensions from courts for their patents, alleging that patents granted after January 1, 1995 (the date in which Decree 1355/1994 entered in force in Brazil) should be subject to Article 33 of the treaty and be granted for twenty, rather than fifteen, years.[341] Arguments were based on long-established case law from the Brazilian Supreme Court that says international agreements could be applied directly as laws and statutes passed by Congress that establish rights and obligations for citizens and residents in

340 New plant varieties are protected in Brazilian law by means of rights granted to plant breeders and is regulated by Law 9456/1997.

341 The previous statute, Law 5772/1971, established a patent term of fifteen years.

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the country.[342] The fact that Brazil had not made use of the transitional provisions in Article 65 of TRIPS also contributed to arguments on the immediate applicability of the Agreement. Initially, the Superior Court of Justice granted the requests for term extensions, accepting the arguments raised by the patent holders.[343] However, in 2009, the court reversed its previous ruling and decided that private parties may not invoke TRIPS in defense of their rights, since the treaty establishes obligations only towards States.[344] The court also determined that TRIPS would only be applicable in Brazil as of January 1, 2000, pursuant to Article 65.2 and, consequently, Article 33 would not apply.[345] Only when Law 9279/1996 entered in force entitlement to a twenty-year patent term began to apply.[346] The Superior Court of Justice rendered other decisions following this interpretation, which continues to prevail,[347] yet until today the Supreme Court has not been compelled to decide on the direct applicability of TRIPS.[348]

The extension of protected subject matter is defined by the claims, which will be interpreted by taking into consideration the specification and drawings as per Article 41 of Law 9279/1996. This provision should be combined with Article 25 of Law 9279/1996, which determines that claims must be based on the specification characterizing the particularities of the application and clearly and precisely defining the subject matter to be protected. The content of claims is the basis for an infringement analysis or for the validity of the patent in light of the prior art. Specification

342 See *Supreme Court*, RE 71.154, judgment of August 4, 1971 and RE 80.004, judgment of June 1, 1977.

343 See *Superior Court of Justice*, REsp 423.240, REsp 661.536 and REsp 667.025.

344 See *Superior Court of Justice*, REsp 960.728, p. 6-9.

345 See *Superior Court of Justice*, REsp 960.728, p. 9-19.

346 See *Superior Court of Justice*, REsp 960.728, p. 17.

347 See *Superior Court of Justice*, REsp 806.147, REsp 642.213 and AgRg no REsp 1.105.155.

348 Brazil is a country following civil law tradition, where decisions issued by courts are non-binding even if rendered by higher courts, the Supreme Court included. So, trial and appellate courts may decide differently and are not bound by any obligation to follow any previous established understanding, although the latter may have strong influence. Exceptions to this rule are generally reiterated cases in which the highest courts issue a common and general applicable judgment and appeals will have certiorari denied based on such judgment. See Brazilian Federal Constitution, article 103-A.

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and drawings are the primary parameters for the correct interpretation of claims.[349]

Article 42 of Law 9279/1996 specifies that the patent holder has the right to prevent unauthorized third parties from manufacturing, using, offering for sale, selling or importing for such purposes a product or a process that is the subject matter of a patent, or a product directly obtained by a patented process in conformity with Article 28.1 of TRIPS. Unlike the old statute, which granted the right of exclusive use of the patented subject matter to a patentee,[350] the current law provides for the right to exclude others even if they have independently developed the invention (with due exception for the prior user provided in Article 45 of Law 9279/1996 that will be discussed later on). Paragraph 1 of Article 42 further determines that the patentee is also entitled to inhibit acts carried out by third parties that contribute to the practice of infringing acts by other parties, thus prohibiting indirect infringement. Paragraph 2 determines that the burden of proof is reversed in the case of infringement of a patented process. It will be up to the alleged violator to prove that the product was not manufactured according to the patented process. It is important to note that unlike Article 34.1(a) of TRIPS, the Brazilian statute does not require that the product obtained by the patented process be new in order to reverse the burden of proof of infringement. The Brazilian provision is based on the presumption that the patentee is unable, through reasonable efforts, to determine the process actually used and the reversal is obtained by means of a specific judicial ruling, which should analyze whether there is a substantial likelihood that the product was manufactured by means of the patented process. Despite the absence of a specific provision in the Brazilian statute safeguarding the legitimate interests of the defendant in protecting their manufacturing and business interests, Article 34.3 of TRIPS and the principles of equity and proportionality are applicable and the defendant should not be obligated to reveal more than necessary to prove that the process used differs from the patented process. Defendants are allowed to exclude some specific details of the process that was used, as long as such omission does not interfere in the defense.[351]

Article 43 of Law 9279/1996 provides for exemptions to patent rights, which should conform to the three-step-test of Article 30 of TRIPS. As ex-

349 See *Dannemann*, Commentaries on the Industrial Property Law, p. 79.
350 See article 5 of Law 5772/1971.
351 See *Dannemann*, Commentaries on the Industrial Property Law, p. 86.

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ceptions to any right, they should be narrowly interpreted, especially taking into consideration that patent rights are constitutionally safeguarded; however, on behalf of the promotion of public interest and stimulation of technical and social progress, also contained in the constitutional clause, infringement defenses may be interpreted in a more permissive manner influenced by an anti-patent environment that may still prevail in Brazil. As per Law 9279/1996, the rights of patent holders will not be violated by the following: a) acts carried out privately and without commercial ends, provided they do not harm the economic interests of patent holders (Article 43, I); b) acts carried out for experimental purposes, related to studies or to scientific or technological research (Article 43, II); c) compounding drugs and their preparation following a medical prescription for an individual patient (Article 43, III); d) products manufactured according to a patented process or patented product that have been placed in the internal market directly by the patentee or with consent, leading to exhaustion (Article 43, IV); e) in the case of patents concerning living matter, the use of the patented product as the initial source of variation or propagation for obtaining other products (Article 43, V); f) to use, place in circulation or commercialize a patented product that has been legally introduced into the market by the patentee or licensee, provided that the patented product is not used for commercial multiplication or propagation of the living matter at stake (Article 43, VI); and g) acts carried out exclusively with the purposes of producing information, data and test results seeking marketing approval in Brazil or abroad so as to commercialize or exploit the patented product after the patent term has expired (Article 43, VII).

Article 43, I of Law 9279/1996 should protect acts from infringement that are carried out by unauthorized third parties solely with private non-commercial purposes and with no harm to the economic interests of the patentee. This classically refers to acts carried out directly by consumers when using goods – falling within the scope of patent protection – in a private manner as long as they do not result in harming the patent owner.[352] This protection does not apply to resale by consumers. In this case, there is

352 Although such exception was not expressly foreseen in the previous statute, Brazilian courts have already found that consumers of counterfeited goods do not infringe any patent right when using the products according to their own end. See Habeas Corpus 44.580, Impetrante: Bel. Lanir Orlando, Pacientes: Gabriel Dias Baeta e outros, publ. RT, 459/349-50, jan 1974. In: *Dannemann*, Commentaries on the Industrial Property Law, p. 87, footnote 150.

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a commercial purpose, even if no large commercial scale actually occurs, and the exhaustion principle does not apply since the product was not marketed by the patentee or with consent – that is to say the product it is counterfeited.[353]

The second exception foreseen in Article 43 of Law 9279/1996 provides for what is generally referred to as the "experimental use exception." The German interpretation of this exception as the scope of the experimental acts has not been addressed by the Brazilian legislature or by courts. The provision should exempt experimental acts from infringement that are performed by researchers on the subject of the invention in order to produce scientific knowledge or investigate the patented subject matter, which could result in finding additional uses or further data on the product or process.[354] Also, this defense against infringement should not encompass the use of a patented invention in experiments relating to a different subject matter, that does not expand the knowledge concerning the invention itself, under the penalty of rendering patents covering research tools unenforceable.[355] This provision only applies to acts of non-commercial and non-profit purposes, which is based on the argument that there would be unreasonable damage to the patent holder's rights if third parties could obtain commercial advantages through the use of the patent, even if such use has an experimental character.[356] A trial court decision endorsed this position, establishing that this exemption is applicable solely for cases in which there is no commercial interest. The court stated the actions carried out by a foundation or a not-for-profit organization could be exempted, whereas a company would have essentially commercial interests and, therefore, its activity would fall outside the scope of the provision.[357] Nevertheless, it is important to consider that the wording of the provision does not contain the restriction for "non-commercial purposes," which may jeopardize research activities in specific fields of technology, in which R&D activities are sponsored by the interest of large private companies, and such interpretation may also reduce the applicability of Article 43, I of

353 See *Dannemann*, Commentaries on the Industrial Property Law, p. 88.
354 See Clinical Trials I and II, German Federal Supreme Court cases.
355 See Clinical Trials I (IIC 1997, 103), German Federal Supreme Court case.
356 See *Philipp*, Patent of invention, p. 71-74; *Dannemann*, Commentaries on the Industrial Property Law, p. 88-92.
357 See *Abbott v. Aurobindo et al*., Trial Court Judgement, para. 3. Abbott v. Aurobindo et al., 13rd State Court of Sao Paulo, Case n. 00.5.020816-0, p. 1.

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Law 9279/1996 where express reference to "non-commercial ends" may be found.

Article 43, III of Law 9279/1996 applies to activities carried out by compounding pharmacies, addressing compounded medications and their preparation by qualified professionals. This defense against infringement applies to the use of a patented process or product whenever there is a medical prescription for individual cases. Accordingly, there is no exemption for infringement if medicine is prepared in large scale even if commercialization is subject to prescription. It is the act of preparing the compounding drug – and not the act of commercializing the compounding drug – that is conditioned to prescription in order to be exempted from infringement and thus stockpiling is prohibited.[358]

Pursuant to Article 43, IV of Law 9279/1996, exhaustion of patent rights is found whenever a product, either patented or obtained through a patented process, is placed in the Brazilian internal market by the patent holder or with consent. Because the wording of this provision specifically mentions placement of the product in the *national* market, it is possible to conclude that Brazil applies the national exhaustion rule. Parallel importation of a patented product purchased in a foreign market is not allowed, even through the patentee or with consent abroad. However, the Appellate Court of the State of São Paulo rendered a decision affirming that the placement of a product in the market leads to exhaustion of patent rights, and the patentee or its licensee cannot prevent importation.[359] The court understood that the patentee receives compensation with the first placement of the product in the market, even when abroad, and patent rights are consequently exhausted.[360] The decision cites a trademark case in the Superior Court of Justice[361] to ground this ruling, which appears to be in clear conflict with the wording of the law. Article 43, IV refers to products placed in the internal market "directly by the patentee or *with his consent*," implying that the party authorized to market the patented product under a

358 See *Dannemann*, Commentaries on the Industrial Property Law, p. 92-93.

359 See *Galena v Pharmaspecial*, Appeallate Court Judgement, p. 7.

360 *Id*., p. 6.

361 See Superior Court of Justice, REsp 609.047, *American Home Products Corp. v LDZ.* In this case, the Superior Court of Justice affirmed that parallel importation is allowed whenever the product was placed in the foreign market by the patentee or with consent and the trademark rights are exhausted.

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compulsory license would not have the consent of the patentee and the related patent rights would not be exhausted.

Article 43, V of Law 9279/1996 establishes that the owner of a patent on living matter may not prevent use by third parties for non-economic purposes, when the patented product constitutes the initial source of variation or propagation for obtaining other products. The provision addresses a hypothesis in which a third party acquires samples of the living matter from the authorized depositary where the patentee had deposited it in order to fulfill the written description requirements.[362] In such a case, the use of living matter should have no economic purpose and should be related to scientific research to develop new products deriving from such living matter. Nevertheless, the earlier discussion on interpreting "non-commercial" purposes continues to apply for cases involving private companies.

Whenever a patented product related to living matter has been lawfully introduced into the market by the patentee or licensees,[363] third parties may circulate or commercialize the patented product as per Article 43, VI of Law 9279/1996. This is the case as long as it is not used for commercial multiplication or propagation of such living matter. Accordingly, if a third party acquires a patented microorganism from the patentee, it may resell the acquired samples themselves (such as any other case where exhaustion applies) or multiply them for generating derived products which will then be commercialized because there is no multiplication of the microorganism for marketing of the multiplied samples.[364] The provision prohibits *commercial* multiplication, relating to the act of marketing, which should be interpreted in a stricter manner than multiplication for "economic use," which, in turn, comprises any activity resulting in an economic advantage for those using the patented microorganism.[365]

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362 If a third party produced himself the patented living matter, there may be patent infringement in light of article 42 of Law 9279/1996. Acquisition of samples put into the market by the patentee or licensee is covered by item VI of article 43 of Law 9279/1996. See *Dannemann*, Commentaries on the Industrial Property Law, p. 97-98.

363 Different than article 43, IV of Law 9279/1996, this provision employs specifically the term "licensee" (rather than the expression "with consent" of the patentee), implying that even in cases of compulsory license, the rights would be exhausted. See *Dannemann*, Commentaries on the Industrial Property Law, p. 100.

364 See *Dannemann*, Commentaries on the Industrial Property Law, p. 99.

365 *Id.*

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Article 43, VII of Law 9279/1996 establishes that acts relating to the patented invention performed by unauthorized third parties do not constitute infringement when they are carried out exclusively to produce information, data and test results used to seek marketing approval domestically or abroad, in order to exploit or commercialize patented subject matter after the patent term has expired. This provision was added to Law 9279/1996 through an amendment by Provisional Measure 2.014-7, of June 26, 2000, and was approved by Congress as Amending Law 10196, of February 14, 2001. The amendment provides for regulatory review exception, which allows research activities whose results are submitted with the purposes of obtaining marketing approval of a product that is covered by a patent, such as a generic version, prior to the patent expiration, provided that the product is marketed only after the protection term ends. A trial court decision determined that regulatory trials for obtaining a marketing approval of generic products are allowed. However, the act of submitting the data package to regulatory authorities seeking the registration and the act of granting registration by authorities, which would consequently authorize marketing of the generic product, is not covered by the provision.[366] The trial court emphasized that regulatory authorities may grant registration only upon expiration of a patent[367] because once registration is granted all the conditions enabling marketing of the product have been fulfilled.[368]

Article 44 of Law 9279/1996 authorizes patent holders to receive compensation for unauthorized use of patented subject matter during the period between the publication and the granting of an application. This provision aims to protect patent holders, to a certain extent, against unfair use of their invention by competitors taking advantage of delays in the patent granting procedure. In exchange for publishing an application prior to the granting of a patent, the patent holders are given this benefit. In the patent granting procedure, inventors disclose the invention as the application is

366 See *Nippon Soda Co. Ltda. v União Federal and Agripec Química Farmacêutica S/A,* Trial Court Judgement p. 4-5. The appeal filed against this decision is pending before the Federal Court of Appeals for the 1st Circuit. See *Nippon Soda Co. Ltda. v União Federal and Agripec Química Farmacêutica S/A,* Appeallate Court Proceeding, p. 1.

367 *Id.*, p 4.

368 *Id.*, p. 5. See also *Dannemann*, Commentaries on the Industrial Property Law, p. 106.

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published even before having the guarantee of a patent. Early publication allows society and competitors to have access to the invention and be aware of the latest developments in technology and the eventual proprietary rights that are to be granted. In order to balance this relationship, the provision provides the right of compensation to the patentee. Brazilian courts have already clarified that infringement may only occur upon the granting of a patent by the INPI. Prior to granting, applicants have a mere expectation and may not prevent exploitation of the invention; however, they are entitled to damages for the undue exploitation carried out between the date of publication and granting.[369] Paragraph 1 of Article 44 determines that the period of undue exploitation for the effect of compensation should start on the date in which the exploitation began, when the infringing party had access to the invention prior to the application's publication. For cases related to biological material deposited under sole paragraph of Article 24 (fulfillment of disclosure and written description requirements), compensation is possible only if the biological material has been made available to the public (see paragraph 2 of Article 44 of Law 9279/1996). Paragraph 3 of Article 44 states that the right of compensation should follow the same logic of infringement analysis and should depend on the content of the claims to determine the extent of protection pursuant to Article 41 of Law 9279/1996.

Prior user rights are also guaranteed in Article 45 of Law 9279/1996, enabling a person who exploited the patented subject matter in good faith prior to the filing or priority date to continue such use under the previous conditions without payment of royalties or further burden. Continuation of such exploitation is allowed as long as the previous conditions of use remain the same. The prior user is not allowed to increase the volume of manufactured products, for instance, or start selling goods which were initially manufactured only for personal needs.[370] Prior user rights may be transferred, but only together with the business or undertaking, or the part of the latter, directly related with the exploitation of the respective patented invention (paragraph 1 of Article 45 of Law 9279/1996). This provisions aims at safeguarding the right for those who have developed the in-

369 See *Emplal v. Mil Past*, Appellate Court Judgement; *Isaías Júnior v. Gobi Refrigeração*, Appellate Court Judgement, p. 1.

370 See *Dannemann*, Commentaries on the Industrial Property Law, p. 110, 114.

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vention in an independent manner and exploited it, secretly or not,[371] prior to the patent filing, to be able to continue their activities without being considered infringement. However, paragraph 2, establishes that those with access to an invention through disclosure under the conditions foreseen in Article 12 of Law 9279/1996 which provide for a grace period (i.e. disclosure carried out by the inventor, by the INPI in an official publication without the inventor's consent, or by third parties on the basis of information obtained from him) may not enjoy prior user rights as long as a patent application is filed within one year from disclosure. Restrictions imposed by the law entitling prior user rights have compliance with Article 30 of TRIPS precisely in mind. Prior user rights are exceptions to the rights conferred by a patent. They are limited in order not to unreasonably conflict with normal use of patents and not unreasonably prejudice the legitimate interests of patent owners while still taking into account the legitimate interests of third parties.

Law 9279/1996 also establishes that patent infringement is a statutory felony. Article 183 of Law 9279/1996 criminalizes the manufacturing of a patented product or the use of a patented means or process without authorization, under the penalty of three months to one year detention or fine. Article 184 of Law 9279/1996 establishes the same penalty for those who export, sell, exhibit or offer for sale, maintain in stock, hide or receive, use for economic purposes, a product manufactured in violation of a patent or one that is obtained by a patented means or process without due authorization. Article 184 also refers to those who import patented subject matter or products obtained by a patented process, for the above purposes, that has not been placed in the external market directly by or with consent from the patent holder. Since importation of goods marketed in foreign countries by the patentee or licensees is not considered a criminal offense by Article 184, only civil remedies may be taken for parallel importation (which may

371 A public use of the patented subject matter would render the patent invalid, but the prior user may be authorized by an interlocutory decision to continue using the invention based on prior user rights before a final decision on the invalidity. On the other hand, it is unlikely that a secret use will be subject to claims of prior user rights before courts, either because the user feels himself safe from an infringement accusation due to the secret nature of his activities, or because it is hard for a patentee to become aware of secret activities carried out by non-authorized parties. See *Dannemann*, Commentaries on the Industrial Property Law, p. 110.

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be regarded as patent infringement through the interpretation of Article 43, IV of Law 9279/1996 as discussed earlier).[372]

Not only acts of direct infringement are considered a crime under Articles 183 and 184 of Law 9279/1996, but also acts of indirect infringement can be prosecuted. Article 185 of Law 9279/1996 determines that supplying a component of a patented product, material, or equipment for executing a patented process is a crime, provided that the final application of the component, material, or equipment results in an unauthorized use of the patent.

Pursuant to Article 186 of Law 9279/1996, a crime has occurred even when the violation does not relate to all of the claims or if it is restricted to the use of means equivalent to the patented subject matter. The provision sets statutory grounds for the doctrine of equivalence in Brazilian patent law. When Article 41 of Law 9279/1996 establishes that extension of protection will be determined by the contents of the claims, it does not mean that interpretation of claims should be restricted to the literal wording used, but should also encompass any means deemed equivalent to those referred to in the claims. The concept of infringement by equivalence, although not expressly foreseen in national legislation, has underlined the system for a long time as scholars and case law have established that infringement may be found even if the manufactured product is not identical to the patented subject matter or if the employed process is not exactly the same as described in the patent.[373] However, it is important to note that infringement by equivalence usually refers to the invention concept contained in the patent without a careful consideration of the methodology that is used when examining infringement. There is no provision in the law, nor developed case law, such as in the US[374] and Germany,[375] regarding possible criteria to be used in determining equivalence.

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372 See *Dannemann*, Commentaries on the Industrial Property Law, p. 355.

373 See *Cerqueira*, Industrial Property Treatise, p. 542. *Taurus Blindagens Ltda. v Pier Luigi Nava*, Appellate Court Judgement, p. 1. *Elter Engenharia v. Coelma Construções*, Appellate Court Judgement, p. 1. Supreme Court, AG 19621, p. 1.

374 See *US Supreme Court*, Winam v. Denmead; *US Supreme Court*,Graver Tam & Mfg. v. Linde Air Products.; *Supreme Court*,Warner-Jenkinson Company v. Hilton Davis Chemical.; *US Supreme Court,* Festo Corp., v. Shoketsu Kinzoku Kogyo Kabushiki.

375 See *German Federal Supreme Court*, Molded Curbstone; *German Federal Supreme Court*, Cutting blade I; *German Federal Supreme Court*, Cutting blade II; *German Federal Supreme Court*, Plastic pipe; *German Federal Supreme*

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B. Patents on Pharmaceuticals

Law 9279/1996 was enacted on May 15, 1996, seeking to incorporate TRIPS obligations into Brazilian legislation and allowing patents for pharmaceutical products and processes. A new player was later introduced into the Brazilian patent granting system in 1999, through an amendment to this Law, namely the Agência Nacional de Vigilância Sanitária (ANVISA), whose role has been intensely debated. The discussion below will analyze the potential impact of ANVISA in light of the framework established by TRIPS.

1. The Prior Consent Requirement

1.1) Introduction of Article 229-C in the Patent Statute and Competence of the ANVISA

The Instituto Nacional da Propriedade Industrial (INPI) was founded in 1970 with the institutional purpose of implementing Brazilian industrial property legislation and is therefore the patent granting authority.[376] In 1999, when the new governmental agency, Agência Nacional de Vigilância Sanitária (ANVISA) started intervening in the patent granting procedure, Brazil's patent system experienced an unusual situation. The ANVISA is primarily the regulatory office competent for granting the marketing approval of drugs.[377] The Brazilian President enacted a provisional measure on December 15, 1999,[378] determining that patent applications in the pharmaceutical area must be submitted to *prior consent* by the ANVISA before being issued.[379] The prior consent requirement was ultimately inserted into Law 9279/1996 as Article 229-C by the amending Law

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Court, Custodiol I; *German Federal Supreme Court*, Custodiol II. See also *Pagenberg, Cornish*, Interpretation of Patents in Europe, p. 91-95.

376 Article 2 of Law 5648/1970.

377 Article 6 of Law 9782/1999.

378 Article 62 of the Federal Constitution empowers the President to legislate in case of relevance and urgency by enacting Provisional Measures.

379 See Provisional Measure 2006/1999, succeeded by Provisional Measure 2014-1/1999 (and its several re-editions) and, ultimately, Provisional Measure 2105-14/2000.

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10196 of February 14, 2001.[380] Pursuant to the statute's amendment by this provisional measure, Ordinance 593/2000 was published so as to change the internal regulations of the ANVISA to include, among the agency's competences, in addition to regulating the marketing of drugs, consent (prior consent) on the granting of patents for pharmaceutical products and processes. On May 21, 2001, the Intellectual Property Division was created within the agency, accounting for prior consent analysis, after Ordinance 239/2001 entered into force (which once again changed internal regulations of the ANVISA).

The origin of Article 229-C was a recommendation sent to the President by the Ministries of Health, Foreign Affairs, Industry and Management,[381] yet no records remain of the pursued intention of this communication. Unlike other pieces of legislation, there were not heated debates and discussions held in Congress over the approval of this provisional measure and its purposes. It was supported through a general justification that was related to the need for better technical standards when deciding on granting of pharmaceutical patents and for reflecting procedures existing in the patent and sanitary surveillance systems of other developed countries.[382] The provision was created without parameters concerning its basis and rationale. Legal criteria for prior consent or any regulatory implementation of Article 229-C has not been established, resulting in legal uncertainty regarding the role of the ANVISA.

A legal opinion issued by the Attorney's Office at the INPI first established that the ANVISA should examine the industrial application requirement or regular applications for prior consent purposes.[383] It excluded "pipeline" patent applications from the ANVISA's assessment under Article 229-C of Law 9279/1996, as this type of patent does not undergo examination of the patentability requirements set forth in Article 8 of the statute (novelty, inventive step and industrial application).[384] However, the

380 "Article 229-C. The granting of patents in connection with pharmaceutical products or processes shall be dependent on prior consent from the ANVISA".

381 EM Interministerial 92, of December 14, 1999.

382 It must be observed that the author is not aware of any other country with requisite similar to the prior consent, that conditions the granting of a patent in the pharmaceutical field to the approval of an authority equivalent to the ANVISA.

383 INPI, PROC 003/00.

384 "Pipeline" patents or patents of revalidation consist in a validation in Brazil of a patent issued abroad, ratifying the examination done by the foreign patent office, provided that the product covered by the patent application was not made com-

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INPI decided that the applications finally would be sent to the ANVISA following the end of examination by the patent office, which concludes for the granting of the patent.[385] This procedure has been applied to all patent applications, regular or "pipeline" since 2001, without establishing any definition or legal criteria for "prior consent."[386]

As a result of these changes, the ANVISA began to fully re-examine the patent applications pursuant to its own understanding of what prior consent should include. The patentability requirements such as novelty, inventive step and industrial applications, which were already analyzed by the INPI, are assessed for a second time by the ANVISA.[387] Also the agency provides an analysis of public health aspects, i.e. access to medicine, and a technical evaluation of compounds which makes the granting of patents subject to policy making considerations.[388] According to the policies for drug regulation, the granting of patents demands a rigorous analysis because it is a privilege with direct impact on the final cost of a drug.[389] On June 24, 2008, the ANVISA adopted a procedure for examining applications for prior consent by means of Resolution-RDC 45/2008. The Resolution established that the ANVISA should examine the patentability legal requirements established and may issue office actions

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mercially available (novelty, inventive step and industrial application are not examined by the INPI). They are foreseen by the statute in Articles 230 and 231, as a transitory mechanism to allow pharmaceutical patent applications to be filed between 1996 and 1997, regardless compliance with the novelty requirement (since these applications could not benefit from Paris Convention priority any longer and already belonged to the state of the art) taking into consideration that the previous legislation did not allow patents on pharmaceutical products. For more, see *Licks, Leonardos*, Article 229-C of the Industrial Property Law. The constitutionality of pipeline patents was challenged in a lawsuit currently pending before the Brazilian Supreme Court (ADIN 4234). The country's highest court must now decide *en banc* whether pipeline patents are contrary to the constitutional clause because afford exclusivity for subject matter deemed to be already in public domain. It is out of the scope of the present work to discuss in further details pipeline patents.

385 INPI, Comunicado INPI/DIRPA 02/2001.

386 The corresponding decision is published in the Official Gazette under codes 9.1, for regular applications, and 23.17, for "pipeline" applications. The issuance of these decisions means that the INPI concluded examination, and the applications meet the respective patentability requirements, be it regular or "pipeline".

387 See *ANVISA*, Current Policies for Regulating Medicines in Brazil.

388 *Id.*

389 *Id.*

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demanding applicants to submit documents, clarifications and amendments.[390] Resolution-RDC 45/2008 may be regarded as having been issued with ten years of delay.[391] Since the introduction of the prior consent requirement, even without proper regulation, the ANVISA has taken crucial decisions including the granting of patents on pharmaceuticals based on policy evaluations. It is important to note that the Resolution clearly and expressly establishes that ANVISA's activities should be bound to the law, with no room for other considerations. As a consequence, the ANVISA has been increasing barriers to patentability for some applications based on the lack of novelty, inventive step, disclosure or enablement, consisting of different criteria from the INPI and reflecting evaluations based on policy, which is theoretically forbidden. This has been the case regarding inventions of second medical uses and will be discussed in the following section.

The Associação Brasileira da Propriedade Intelectual (ABPI)[392] maintains the position that prior consent should be applicable only to "pipeline" applications, because both are inserted as transitory provisions of the statute.[393] In addition, the ANVISA is the authority for approving the marketing of the drugs, and would be better entitled to assess compliance with the non-commercialization requirement for granting "pipeline" patents. The ANVISA's interference in the patent granting procedure may be regarded as a way for the Executive Branch of the Brazilian Government to implement policy control of patents covering inventions related to pharmaceuticals.[394] In implementing the minimum standards required by TRIPS, the Brazilian industrial property law created legal grounds for the development of a sound patent system. As part of this evolving process, it is possible to consider that the INPI has been moving towards a patent-

390 Until the enactment of Resolution-RDC 45/2008, communications with applicants were done through the INPI.

391 Article 1, Paragraph 1 of Resolution-RDC 45/2008 establishes that the provisions of this resolution are retroactively applicable to all patent applications for pharmaceutical products and processes which were pending on December 15, 1999 or filed afterwards, regardless if already granted in the meantime. This provision creates acquired rights problems that have not yet been dealt by the Brazilian courts.

392 The ABPI is the Brazilian group of the Association Internationale pour la Protection de la Propriété Intellectuelle (AIPPI).

393 See *ABPI*, ANVISA's Technical Information.

394 See *Souza*, Should Brazil Allow Patents on Second Medical Use?, p. 53.

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friendly interpretation and application of the statute. As a result, the Brazilian government saw that it was necessary to establish political control of the granting of pharmaceutical patents by means of the ANVISA.

The ANVISA's political control of pharmaceutical patents would be justified under the government's discretionary power to act in defense of human rights, by enhancing access to medicines, through the right to health contained in Article 196 of the Federal Constitution.[395] Article 197 of the Federal Constitution entitles public administrators to act in order to safeguard public health. The supremacy of public welfare over individual rights is established in Articles 5, XXIII and 170, III of the Federal Constitution, which require that private property observes its social function.[396] Accordingly, prior consent should represent a measure that is adopted in order to guarantee social welfare and justice, as well as access to medicine by limiting intellectual property rights and specifically patent rights.[397]

On the other hand, it is often forgotten that Article 5, XXIX of the Federal Constitution also relates to the public interest, also supporting the argument that public interest should prevail over private interests. Denying patents in the pharmaceutical field, because they are considered harmful to the public interest, does not follow the principle of proportionality.[398] Without investments in R&D that result from the existence of the patent system, the development of new drugs would be at stake. Following this logic, the ANVISA's political control is unconstitutional because patents are a fundamental guarantee and must be granted upon the fulfillment of patentability requirements as set forth in the statute.[399]

The activities of public administration are subject to the principle of legality and there should be no space for the discretionary power of the ANVISA or any other public entity.[400] The constitutional clause contained in Article 5, XXIX of the Federal Constitution represents a justification giv-

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395 See *Basso*, The Brazilian Practice of the Prior Consent, p. 60.

396 *Id.*

397 See *Rodrigues Jr., Murphy*, Brazil's Prior Consent Law, p. 437.

398 See *Oswald, Leonardos*, Patent Law: Constitutional Aspects, p. 4-5.

399 See *Barbosa*, ANVISA's Prohibition of Claims on Pharmaceutical Use, p. 733.

400 The principle of legality established in Article 37 of the Federal Constitution orders that public administrators must act strictly in accordance with the law, i.e. the statutory acts originating from Congress. The public administration is only allowed to act when the law so establishes. Any ordinance or resolution enacted by the public administrator must conform to the laws originated from Congress. In this case, the activities of both the INPI and the ANVISA – when granting or

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en by the legislators to enact the patent statute and is the legal instrument to which public administrators (in this case represented by the ANVISA and the INPI) are bound. Therefore, once it is verified that the invention is new, inventive, industrially applicable, supported by the description and not prohibited subject matter (Articles 10 and 18 of Law 9279/1996), the patent must be granted upon payment of the applicable fees. Otherwise, the actions of public administrators would be *contra legem*, as per the opinion of the public attorneys from the INPI.[401] Another interesting argument made by the public attorneys from the INPI relates to the social function of patents. They argue that patents should be granted provided the legal requisites are observed, but as property rights they should respect the principle of social function of property of Article 5, XXIII and 170, III of the Federal Constitution.[402] The limitations to the use of patent rights should be determined in favor of society in order not to unduly restrict competition, also a guarantee of Article 170, IV of the Constitution, and policy evaluations should be used to avoid an abusive exercise of patent rights.[403]

Therefore, policy considerations should not be part of the patent granting procedure, which is strictly linked to law. Matters of governmental policy should be considered at the stage when patent rights are enforced, such as the example of granting compulsory licenses as per the so-called flexibilities of TRIPS. In fact, the Brazilian government has already granted a compulsory license for Merck's drug Efavirenz for the treatment of AIDS, having declared that it is of public interest in Decree 6108, of May 4, 2007.[404]

The ANVISA has been defending itself from criticism against prior consent, alleging that it has contributed to enhance the quality of patent examinations. The INPI reviewed its position following ANVISA's assessment of the patentability of some applications.[405] The agency also ar-

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denying applications or regulating procedures – must not contravene the patent statute.

401 See *INPI*, Legal Opinion on Incremental Inventions, p. 14.

402 *Id.*, p. 16.

403 *Id.*

404 This case will be analyzed in detail in the following chapter.

405 The ANVISA states that 5.4% of the patent applications submitted to the ANVISA have been rejected or shelved by the INPI following the ANVISA's analysis identifying irregularities. See *ANVISA*, Report on ANVISA's role in the exam os pharmaceutical patent filings, p. 3. This work provides an analysis of the

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gues that it should not be held responsible for increasing the country's existing backlog (only 5.9% of 1100 applications are pending examination by the agency for prior consent purposes).[406] In addition, the ANVISA presents statistics to support that it has not been assessing patentability requirements with an anti-patent bias. By December 31, 2008, the ANVISA had assessed 1047 patent applications and 89.4% were granted prior consent, while 36.6% were granted prior consent following restrictions to the claims, and only 10.6% were denied.[407]

The role of the ANVISA within the patent granting procedure has also been discussed at the political level. On July 9, 2008, Bill of Law 3709/2008 was presented in the House of Representatives to modify Article 229-C.[408] According to the proposal, prior consent by the ANVISA would be restricted to "pipeline" patent applications.[409] The Bill's justification states that "pipeline" patents consist of re-validating patents that are granted abroad, and should, therefore, be subject to more stringent analysis regarding whether the object of the patent was made available in the international market.[410] Because "pipeline" applications are allowed only for one year after the enactment of the patent statute, Article 229-C represents a transitory provision connected to the transitory nature of the existence of "pipeline" patents in the Brazilian system.[411] These restrictions to the ANVISA's activities have prompted protests from within the agency against losing the power to intervene in patent granting proceedings. The agency argues that the INPI is too lenient when examining patents and favors industry too much.[412] The INPI, on the other hand, argues that the concomitant work of the two governmental institutions extends the period of patent examinations and opens doors to conflicting interpretations, leading to legal uncertainty – such as the case of the patentability of second medical uses.[413]

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patent applications submitted to the ANVISA's analysis for prior consent purposes from June 2001 until July 2010.

406 *Id.*, p. 7.

407 *Id.*, p. 4.

408 See Bill of Law 3709/2008, p. 1.

409 *Id.*, p. 1.

410 *Id.*, p. 2-3.

411 *Id.*

412 See *Formenti*, ANVISA Resists in Restricting their Role during Patent Examination.

413 *Id.*

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Bill of Law 3943/2012 was proposed on May 2012 also seeking to define the scope of prior consent by the ANVISA, but it adopted a different approach.[414] The Bill establishes that prior consent must analyze the requirements of novelty, inventive step, and industrial applications for inventions and utility models in the chemical-pharmaceutical areas, for medicine of any kind, and for healthcare products, in addition to the respective obtaining and modification processes.[415] Assessment should be made in light of technical and scientific knowledge in chemistry, biochemistry and pharmacology, as well as clinical experience and public health uses. Also, patents should only be granted upon consensus between the ANVISA and the INPI.[416] The report justifying the Bill revolves around the argument that the INPI does not have the technical capacity to examine patents in the pharmaceutical area as patents for pharmaceutical arts had been prohibited for many years and due to the fact that it has granted patents which did not comply with requirements in Article 8 of Law 9279/1996.[417] It also states that patents covering second medical uses and new crystalline forms of compounds are not innovative and are artificial tools used by big pharmaceutical companies for extending the shelf life of their patent portfolio.[418] Both Bill of Law 3709/2008 and Bill of 3943/2012 have not been submitted yet to the House of Representatives' approval, pending being voted attached to each other.

The very first trial court decision addressing the scope of prior consent by the ANVISA rejected the agency's interpretation and application of Article 229-C of Law 9279/1996. The court stated that the ANVISA lacks the statutory authority to examine the requirements of inventive step, novelty, and industrial application of pharmaceutical patent applications, and any activities by the ANVISA should be free from political bias.[419] Never-

414 See Bill of Law 3943/2012, p. 1.
415 *Id.*
416 *Id.*
417 Id., p. 2.
418 *Id.*, p. 4-6.
419 See *F. Hoffmann-La Roche AG. v ANVISA and INPI*, Trial Court Judgment, p. 91-104. On November 3, 2004, the Trial Judge of the 37th Federal District Court of Rio de Janeiro rendered a judgment overruling the ANVISA's decision denying prior consent to patent application PI 9503468-4 (covering the drug Valcyte for the treatment of AIDS) owned by F. Hoffmann-La Roche A.G. Unlike the INPI's examination concluding for the patentability, the ANVISA considered that the invention was already part of the state of the art and argued that the granting

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theless, after this case, the Federal Court of Appeals for the 2nd Circuit rendered a decision in which a different understanding prevailed, according to which both the INPI and the ANVISA should coordinate examination of patentability requirements. Hence, the patent granting procedure for pharmaceutical applications became a complex act, requiring two administrative bodies. The court decided that patent applications in this field should be submitted to more stringent examination in order to avoid undue patent protection for drugs which are of high importance to the public health.[420]

More recently, a shift in position within Brazilian courts may be observed. The Federal Court of Appeals for the 1st and the 2nd Circuit have rendered decisions, according to which the prevailing understanding is that ANVISA has to limit analysis to the agency's institutional duty. This is to say, it must assess the subject matter of patent applications for pharmaceutical products and process only in connection to public health issues. The agency should not examine patentability requirements (which should be under the exclusive scope of action of the BPTO) and could only indicate possible technical obstacles for granting patents related to public health matters under Article 18, I of Law 9279/1996.[421]

The discussions gained another round when the limits of prior consent by the ANVISA raised controversy within the Attorney General's Office (AGO). The legal offices of both the ANVISA and the INPI are part of the broader structure of the AGO. On October 16, 2009, the AGO issued a first legal opinion against the ANVISA's practice of analyzing patentabili-

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of "bad patents" are harmful to the public health. This district court decision was nullified by the decision of the Court of Appeals rendered on December 11, 2007, for non-compliance with procedural requirements in the lawsuit. It was found that the trial court erred in denying the ANVISA's request for a technical expert to assist the courts in assessing if the invention was part of the state of the art. However, the appellate court decision does not address issues concerning the ANVISA's competence for intervening in the patent granting procedure and the scope of the prior consent See *F. Hoffmann-La Roche AG. v ANVISA and INPI*, Appellate Court Judgment, p. 1.

420 See *Aventis Pharma S.A. v ANVISA and INPI*, Appellate Court Judgment, p. 1778-1779.

421 See *Merck Frosst v. ANVISA*, Appellate Court Judgement, p. 197153; *Novartis v. ANVISA*, Appellate Court Judgement, p. 861-862; *Max-Planck and Zentaris AG v INPI and ANVISA*, Appellate Court Judgement. See also *Takeda v. ANIVSA,* Trial Court Judgment, p. 791-795; *Max-Planck and Zentaris AG v INPI and ANVISA*, Trial Court Judgement, p. 5.

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ty requirements, stating that the agency's activities under Article 229-C should be limited to the sanitary control of production and marketing of products and services harmful to human health; it is not for the agency to examine patentability requirements.[422] A final legal opinion was issued by the AGO, on January 7, 2011, rejecting a request for reconsideration filed by the ANVISA and upholding its previous understanding that the ANVISA's analysis should be restricted to investigating potential harmful effects to human health in light of Article 18, I of Law 9279/1996 and working in collaboration with the INPI. The latter should be provided with technical information to make the final decision regarding the granting of the patents.[423]

Following the two legal opinions issued by the AGO, a working group formed by representatives of the Ministry of Health, Ministry of Development, Industry and Foreign Trade, the AGO, the ANVISA and the INPI was created in order to analyze and suggest criteria, mechanisms, procedures and obligations regarding an articulated work between the ANVISA and the INPI under Article 229-C of Law 9279/1996.[424] On May 25, 2012, the working group published a report suggesting criteria and procedures to be adopted for the analysis of patent applications in the pharmaceutical field.[425] The report proposes a new prosecution process according to which applications filed before the INPI will be formally examined and upon identification of the subject matter as a pharmaceutical product or process, they will be sent to the ANVISA. Then, the ANVISA will carry out its analysis and publish its decision in the Official Gazette and return the application to the INPI.[426] If the ANVISA grants prior consent, the INPI will proceed to technical examination of the application. In the case that prior consent is denied, said decision is also published in the Official Gazette and the INPI will receive the application for shelving.[427] The scope of ANVISA's analysis for prior consent purposes should consider the impact of a pharmaceutical product or process in light of public health,

422 See *AGO,* Opinion 210/2009, p.13.
423 See *AGO,* Opinion 337/2010, p. 5.
424 See Interministerial Ordinance 1956/2011 and Interministerial Ordinance 2584/2011.
425 See Interministerial Ordinance, 1065/2012, p. 35.
426 See *ANVISA*, Report on criteria and procedures to be adopted for the analysis of article 229-C of Law 9279/1996, p. 8-9.
427 *Id.*

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taking into consideration Article 18, I of Law 9279/1996 and pursuant to the constitutional guiding principles of universal access, integrality and equity in health.[428] The proposal seeks better interaction between the INPI and the ANVISA, establishing the role of each institution in the procedure for granting patents in the pharmaceutical field.

Following the AGO report, a new resolution regulating the procedure for prior consent was opened by the ANVISA on October 17, 2012, for public consultation.[429] According to the proposed resolution, the ANVISA's prior consent would be defined as the agency's decision that a patent application is contrary to public health.[430] Patent applications deemed contrary to public health relate to a) subject matter consisting of products and processes which presents sanitary risks, comprising or resulting in a substance forbidden in the country, or b) a product or process that is of interest for policies concerning medicine or pharmaceutical assistance within the public healthcare system and do not fulfill patentability requirements.[431]

The ANVISA announced to the public on April 8, 2013, the criteria for evaluating patent applications. The agency will analyze applications only in the following two cases: 1) whenever the molecule is analogous to products already prohibited in the country, or 2) whenever the patent subject matter claims substances that may relate to drugs considered strategic to public health.[432] Any other applications will be sent back to the INPI, which will conduct the full examination.[433] The first criterion regarding substances prohibited in the country already presented during the public hearing corresponds with the AGO's and court's understanding of the ANVISA's role. The second criterion, however, evidences that political elements still permeate the ANVISA's assessment of prior consent. It does not expressly state that denial of prior consent will result from not meeting patentability requirements, rather says that applications concerning drugs deemed of strategic importance for the public health are subject to the ANVISA's assessment. This position is expressed in a statement by the

428 *Id.,* p. 6.
429 See *ANVISA*, Public Consultation 66/2012.
430 *Id*., p. 2.
431 *Id.*
432 *Estado de São Paulo*, ANVISA establishes criteria for pharmaceutical patents, para. 2.
433 *Id.*

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Commissioner of the ANVISA during a public hearing held on March 20, 2013, clarifying there may be cases in which prior consent will be denied even if the application fulfills the requirements of patentability.[434]

On April 15, 2013, the ANVISA published Resolution-RDC 21/2013 in the Official Gazette, regulating the prior consent procedure by modifying Resolution-RDC 45/2008. It defines prior consent as the examination of patent applications in the pharmaceutical area carried out by the ANVISA in light of public health.[435] A patent application will be deemed contrary to public health when a) the pharmaceutical product or process contained in the application presents a risk to health, which is characterized when the product comprises of or the process results in a substance which use has been prohibited in the country, or b) the pharmaceutical product or process is of interest for policies concerning medicine or pharmaceutical assistance within the public healthcare system and do not fulfill the patentability requirements established by Law 9279/1996. (Interest concerns substances listed as strategic medicines by the government or pertaining to the same therapeutic class as those listed by the government).[436] The Resolution further determines that the parameters for analyzing risks to health and interest for policies concerning medicine or pharmaceutical assistance within the public healthcare system will be detailed in a specific act.[437]

After the first legal opinion issued by the AGO, a public lawsuit was filed by the Office of the General Solicitor seeking to halt its effects. The purpose of this action was to determine that the ANVISA's activities, when assessing patent applications submitted to prior consent under Article 229-C of Law 9279/1996, in fact examine patentability requirements. Quoting the existing case law from the Federal Court of Appeals for the 1st Circuit, the trial court Judge denied the preliminary injunction request stating that the ANVISA's job should be protecting the population's

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434 The report made by the ABAPI's representative during the public hearing held at the ANVISA on March 20, 2013, transcribes Commissioner Dirceu Barbano declaration as follows: "A patent application that fall into one of the categories proposed in the new resolution will be analyzed by the agency in depth, which does not mean that prior consent will be automatically denied. Furthermore, there may be a situation in which the consent is denied even if the application fulfills all the patentability requirements." A copy of the ABAPI's report may be found in possession with the author.

435 Resolution-RDC 45/2008, article 2, I, as modified by Resolution-RDC 21/2013.

436 *Id*., article 4, para. 1-3.

437 *Id*., article 4, para. 4.

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health and not examining the requirements that will be analyzed by the INPI.[438] Despite the report published establishing the new prosecution process and the scope of prior consent following the final opinion of the AGO, a final unappealable decision on the merits in the public lawsuit will have *erga omnes* effects and will solve these disputes stemming from the lack of regulation of Article 229-C of Law 9279/1996 and pertaining to the ANVISA's legal mandate for examining patentability requirements.[439]

The ANVISA's role in the patent granting procedure tends to include an analysis of all patent applications for pharmaceutical products and processes, independent of being regular or pipeline. The discussions mentioned above relate to the scope of such analysis (including examination of patentability requirements) for the granting of prior consent. With the new procedure and the scope of prior consent by the ANVISA restricted to the evaluation of public health matters, even after the agency's latest resolution, it is still not clear how the agency will carry out assessments for prior consent. It is difficult to tell how evaluating the impact of pharmaceutical products or processes in light of public health will occur without being discretionary – if this is even possible – as patentability requirements remain as one of the items to be examined by the ANVISA when assessing applications for the purposes of prior consent.

2. Second Medical Use Inventions

2.1) INPI Examination Guidelines, ANVISA Policies and Debates on New Examination Guidelines

Second use inventions, in the pharmaceutical or other fields, are deemed patentable subject matter by the INPI provided that novelty and inventive step have been ascertained for this second use. The INPI Examination Guidelines in the Biotechnology and Pharmaceutical Field currently in force define second medical use in general as new use of a product known outside the medical field as a medication (referring to *first medical use*) or new medical use of a product already applied in the medical field (refer-

438 See *Federal Prosecution Office v. Federal Union,* Preliminary injunction decision, p. 2.

439 A final decision at the trial court level is still pending.

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ring to *second medical use* in strict sense).[440] The Examination Guidelines state that claims may be permitted when drafted as "use of product X characterized in that it is for the preparation of a medication to treat illness Y" or "use of product X characterized in that it is for the preparation of a medication to treat illness Y, which treatment consists of such and such."[441] These claims make use of the so-called *Swiss-type* form,[442] so as to avoid the prohibition of patenting methods of medical treatment present in Article 10, VIII of Law 9279/1996. In contrast, claims such as "product

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440 "2.39 Second use invention 2.39.1 Inventions of this nature can be of two types: (i) a new use, as medication, of a known product with use outside the medical field (first medical use); (ii) a new medical use of a product already known as medication (second medical use)".

441 "2.39.2 Typical claims of this type of invention would be: 2.39.2.1 Claim type: a. Product X characterized by the fact that it is used as a medication. b. Product X characterized by the fact that it is used for the treatment of illness Y shall not be granted on account of the fact that its purpose does not present newness, as, per definition (i) above, it comprises a known product which, obviously, is not new in the sense of Article 11. (...) 2.39.2.2 Claims of the type: a. Pharmaceutical preparation characterized for containing product X (occasionally with other components). b. Preparation for the treatment of illness Y characterized for containing product X (occasionally with other components). c. Preparation in the form of (tablet, gel, injected solution, etc.), characterized for containing product X (occasionally with other components) for use in the treatment of illness Y, may be granted as long as the preparations encompassed be new and display inventive activity. (...) 2.39.2.4. Claims of type: a. Use of product X characterized in that it is for the preparation of a medication to treat illness Y. b. Use of product X characterized in that it is for the preparation of a medication to treat illness Y, which treatment consisting of such and such, known as "Swiss formulas", being almost always used in second medical use inventions. They are entitled to privilege, in view of the considerations contained in item 2.23 above. (...)".

442 Swiss-type claims consist of using a wording formula for claiming inventions on second medical uses. The form of a usual Swiss-type claim is "use of a substance or composition X for the manufacture of a medicine for therapeutic application Z". The purpose of this wording is to avoid that use claims for pharmaceutical products are considered therapeutic methods, falling in the statutory prohibition against patenting this subject matter, which is foreseen in several national legislations, such as the Brazilian one. It was first adopted by the Swiss Patent Office, and afterwards by the practices of the European Patent Office. It is unlikely that the decision issued on February 19, 2010 by the Enlarged Board of Appeals of European Patent Office in case *EPO*, Dosage regime/ABBOTT RESPIRATORY, case G2/08, determining that Swiss-type claims are not going to be accepted any more, will have any impact in Brazil, since it was based on an amendment of the EPC text, which now allows patents for second medical uses in an express way.

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X characterized in that it is for the treatment of disease Y" would lack novelty; and claims such as "use of product X characterized in that it is for the treatment of disease Y" or "process to treat disease Y, characterized by the administration of product X" are considered to describe therapeutic methods.[443]

Despite all of the issues surrounding the use of the Swiss-type form for drafting claims, the official position of the INPI is that second medical use inventions are patentable. Nevertheless, the ANVISA holds the opposite opinion in this regard. On August 25, 2004, the ANVISA published information on its website about procedures concerning patent applications on pharmaceutical-related inventions.[444] It published the decision of the ANVISA Collegiate Board from November 23, 2003, which established that the agency will not grant prior consent to patent applications for second medical uses.[445] According to this decision, such patents are harmful to public health, to the country's scientific and technological development, and may hinder access to medicines.

The denial of prior consent to applications claiming second medical uses by the ANVISA may be in violation of TRIPS as it represents discrimination of a field of technology, which is prohibited by Article 27.1 of TRIPS,[446] since applicants in the pharmaceutical field are submitted to a second round of examination, while inventors in other fields are not. In addition, Article 27.2 of TRIPS cannot be used to justify the denial of such patents, because this provision's goal is to prevent proprietary rights only for inventions contrary to the interest of society.[447] Exclusions from

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443 "2.39.2.3 Claim of type: a. Use of product X characterized in that it is for the treatment of illness Y. b. Process for treating illness Y characterized by administering of product X (or preparation containing product X), are not granted on account of the fact that they comprise a therapeutic method (...)".

444 See *ANVISA*, Clarifications about Patent Applications for Pharmaceutical Products and Processes, para. 2.

445 "IV – Regarding the applications which have as claim the 'new use' of substances – The Collegiate Board, at a meeting held on 23 November 2003 stated as thus: 'The Collegiate Board considers that the institute is harmful to public health, to the country's scientific and technological development, and that it may hinder access to medication by the population. In this respect, it has decided for not granting prior consent to cases of patent applications claiming second use'".

446 See *ABPI*, ANVISA's Technical Information; and *Souza*, Should Brazil Allow Patents on Second Medical Use?, p. 62-63.

447 See *Rodrigues Jr., Murphy*, Brazil's Prior Consent Law, p. 451.

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patent protection could occur only if the commercial exploitation of these inventions is not allowed.

For those that support the ANVISA's interpretation, the agency's denial of patents on second medical uses would be legitimized by Articles 7 and 8 of TRIPS, as well as by the Doha Declaration.[448] These provisions entitle WTO Member States to adopt any measures they consider necessary to promote social welfare and protect public health. Specifically, Article 8.1 of TRIPS would expressly allow countries to exclude from patentable subject matter inventions like second medical uses that are needed to protect the public health.[449] Such patents would not contribute to technological innovation, since they are the result of empirical observation and not of investments in R&D, nor would they contribute to the dissemination of technology because artificially extend the exclusive rights of patent holders.[450] Moreover, Article 27 of TRIPS does not speak to inventions for second medical use when it deals with patentable subject matter and, therefore, Member States are free to decide if they are allowed or not.[451] From this perspective, intervention in the patent granting process by the ANVISA is an important tool to ensure the implementation of public health policies by adopting more stringent criteria for patentability.[452]

The conflicts between the INPI and the ANVISA prompted heated debates during the review of the INPI Examination Guidelines. The INPI organized meetings that were open to representatives of the two government institutions, associations from innovative and generic industries, as well as practitioners.[453] During the discussions, the difference in opinion between the ANVISA and the INPI was obvious. The Head of the Chemical Patent Division of the INPI believed that a second medical application for a known substance consists in an invention and the scope of the new guidelines is to define the criteria for granting patents.[454] In contrast, representatives of the ANVISA contended that such inventions mostly consist of methods for treatment by therapy.[455] Additionally, the ANVISA affirmed

448 See *Basso*, The Brazilian Practice of the Prior Consent, p. 63.
449 See *Arruda, Cerdeira*, Patents on Medicines and Public Health, p. 124.
450 See *Basso*, The Brazilian Practice of the Prior Consent, p. 63.
451 See *Correa*, Guidelines for the Examination of Pharmaceutical Patents, p. 1; and *Rodrigues Jr., Murphy*, Brazil's Prior Consent Law, p. 430.
452 See *Correa*, Pharmaceutical Inventions, p. 17.
453 See *INPI*, Second Medical Use.
454 See *INPI*, Minutes of the First Meeting about Second Medical Use.
455 *Id.*

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that a *Swiss-type* claim per se cannot be enabled in the specification. Based on what is disclosed in the application, it is not possible to manufacture a medication only for the treatment of a certain disease. Since descriptions do not usually refer to the process of manufacturing the medicine, the written description requirements would not be fulfilled.[456] These arguments are the same as those used decades ago to challenge the patentability of second medical use inventions, as if there were no advance in the debate, revealing the political considerations behind "technical" reasons to deny patents on this matter.

The debates at the INPI concluded favorably for patents on second medical use inventions, reiterating the institute's position under the current Examination Guidelines. The first draft of the new Examination Guidelines recognizes that an invention of second medical use is based on the report of a new therapeutic activity of a known chemical compound for the production of a medicine with a different purpose from the one that is already part of the state of the art.[457] The invention would be deemed new when the already known pharmaceutical product is used to treat a different disease.[458] Inventive step would be verified when the new medical use is not obvious to a person skilled in the art, taking into account the mode of action of the chemical compound, the relationship between therapeutic activity and chemical structure and the etiology of the targeted diseases.[459] However, the first draft of the guidelines does not suggest any parameters for disclosure requirement or for the wording of admissible claims. Since the last meeting on October 9, 2007, the INPI has been working on a final proposal for the new Examination Guidelines; in the meantime, the previously discussed regulations are still in force, as the publication of the final version still pends.

Within the context of the Brazilian pharmaceutical industry, it is important to note the remarks of a representative of the Associação dos Laboratórios Farmacêuticos Nacionais (Association of the National Pharmaceutical Laboratories – ALANAC) during the meetings for reviewing the Examination Guidelines, according to which the little research that is done in Brazil mostly consists of already known substances and any developments

456 *Id.*
457 See *INPI*, Draft Examination Guidelines for Applications Claiming Second Medical Use.
458 *Id.*
459 *Id.*

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therefrom would be new medical uses.[460] The innovation done by Brazilian companies is incremental innovation.[461] National industry does not have the means to finance R&D activities or the clinical trials needed for new drugs containing new chemical compounds. In contrast, the expenses needed for development of a drug based on new uses of known chemical compounds are comparatively lower, since the initial tests for proving the safety of the substance have already been performed. Brazilian inventors and industry would be harmed by the ANVISA's policy that blocks second medical use patents. Examples of Brazilian inventors who could be affected by such policy have also been identified.[462]

Until today, the INPI has not issued its new guidelines. It is most likely because the debate with the ANVISA on the patentability of second medical uses, and the discussion concerning the scope of prior consent, have led the INPI to refrain from publishing new guidelines so as to avoid political conflict within the government.

2.2) Discussions in Congress and Court Decisions

The conflict between the ANVISA and the INPI has also been seen in Congress during the debate on Bill of Law 2511/2007 (proposed on November 29, 2007)[463] to amend Law 9279/1996 and bar the patentability of second medical indications of pharmaceuticals in Article 18 of Law 9279/1996. Bill of Law 2511/2007 justifies the prohibition of patents on second medical uses stating that the lack of definition of therapeutic method within the law has led to the granting of patents for new medical

460 See *INPI*, Minutes of the Second Meeting about Second Medical Use.

461 *Id.*

462 See *Souza*, Should Brazil Allow Patents on Second Medical Use?, p. 67, for patent applications PI9908664-6, filed by Henrique Chvaler; PI9806330-5-8, filed by Edson Claro do Nascimento; PI9805654-9, filed by Edson Claro do Nascimento; PI9902178-1, filed by Edson Claro do Nascimento (BR/SP); PI9806331-6, filed by Edson Claro do Nascimento; PI0202647-3, filed by José Carlos Barbosa Vosgerau; PI0202539-6, filed by Marcus Keche Weber; PI0102184-2, filed by Laboratório Catarinense S/A; PI0102186-9, filed by Laboratório Catarinense S/A; PI0102185-0, filed by Laboratório Catarinense S/A; PI0004106-8, filed by Laboratório Sintofarma S/A; PI0004105-0, filed by Laboratório Sintofarma S/A; PI9702841-0, filed by Laboratório Sintofarma S/A; and PI9802893-6, filed by Eurofarma Laboratórios Ltda.

463 See Bill of Law 2511/2007, p. 1.

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indications, which consist of mere discoveries and do not fulfill patentability requirements. It states that the unjustified extension of protection hinders access to generic drugs by the population. It is important to note that the relationship between second medical uses being mere discoveries and the lack of definition of therapeutic methods is not clear.

In the first round of debates in the House of Representatives, each institution took opposite stances on the patentability of second medical use inventions. The ANVISA reiterated that patenting second medical uses is contrary to the public health policies because it hinders the production of generics and increases the costs of purchase of medicines.[464] In the opposite camp, the INPI affirmed their patentability upon fulfillment of requirements, based on the absence of such prohibition in the current statute.[465]

Inserted together in Congress legislative proceedings with Bill of Law 2511/2007, the new Bill of Law 3995/2008 proposed on September 3, 2008 has led to further debate in the House of Representatives.[466] Bill of Law 3995/2008 intends to modify Article 10 of Law 9279/1996 and exclude from patentability new crystalline forms of substances already in the state of the art, as well as new uses of products or therapeutic substances already subject to patent protection. The reason stated is that these kinds of patents would be in the interest of foreign pharmaceutical companies because they are an extension of the term of protection for already existing patents and they would serve as a barrier to other companies from entering the market. Second medical use includes the discovery of side effects and research is only related to adapting already existing drugs to treatment of new pathologies, which, in contrast, would constitute a therapeutic method – excluded from patentability by Article 10, VIII of Law 9279/1996.

During the political debates, the Commissioner of the INPI once again affirmed the position in favor of the patentability of second medical use inventions, as they may foster national research in the pharmaceutical field, and a number of Brazilian scientists were quoted in this regard.[467] According to the Commissioner, the INPI criteria for examining such patent applications would avoid undue extension of already existing

464 See *Agência Câmara*, Government Diverges about the Granting of Patents on Second Uses.

465 *Id.*

466 See Bill of Law 3995/2008, p. 1.

467 See *INPI*, Patentability of Pharmaceutical Incremental Innovation.

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patents by clearly delimiting the scope of protection.[468] He recognized that such patents may serve as a tool for technological development and attended to concerns of the representative of the Ministry of Industry, where the INPI is housed.[469] On the other hand, the representative of the Ministry of Health, to which the ANVISA is affiliated, advocated for the absolute ban of patents on second medical uses.[470] This debate shed light on the fact that conflicts between the ANVISA and the INPI reflect divergent positions between two different sectors of the Executive Branch, the Ministry of Industry and the Ministry of Health.

The INPI's position was legally grounded in an opinion by its public attorneys which considered that, in absence of a restriction in the statute against the patentability of second medical uses, patents on such subject matter must be granted if the requirements of novelty, inventive step and industrial application are met.[471] In not doing so, the INPI would be acting contrary to the law because policy evaluations should be reserved for the enforcement stage.[472]

Regarding the technical aspects that justify the criteria used by the INPI, an opinion prepared by examiners was presented to confirm the understanding already revealed in the first draft of the new Examination Guidelines. The new use of a known pharmaceutical product may be protected under a *Swiss-type* claim ("use of compound X characterized in that it is for the preparation of a medication to treat illness Y") because the protection would not be directed to the already known product, but to the use of the known product to manufacture medicine for a new therapeutic use.[473] In this manner, there would be no barriers to third parties to use the product or the process, in case they are already in the public domain and are not used for the new indication.[474] In addition, therapeutic methods comprise the steps necessary for the cure or prevention of a disease, or for alleviating pain and suffering, aiming at the reestablishment of normal conditions of health. *Swiss-type* claims would not cover such steps.[475] Novelty

468 *Id.*
469 *Id.*
470 *Id.*
471 See *INPI*, Legal Opinion on Incremental Inventions, p. 14.
472 *Id.*, p. 16.
473 See *INPI*, Technical Opinion on New Crystalline Forms and New Medical Uses, p. 22.
474 *Id.*
475 *Id.*

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would be verified when the second use is different than the one already part of the state of the art, meaning the treatment or prevention of a different disease.[476] When analyzing the prior art, side effects that are duly documented may destroy novelty.[477] The inventive step requirement would be fulfilled when a person skilled in the art does not understand the new application as obvious, taking into consideration that the invention provides a different mode of action of the pharmaceutical substance than the one described for the first use, the etiology of new diseases to be treated is also not the same, and the new therapeutic effect is not evidently derived from a molecular structure analogous to compounds presenting similar activities.[478] With regard to disclosure and enablement, *in vivo* tests are required and the disease to be treated should be specifically mentioned in the description. It is not enough to include a reference to the conditions to be treated (the mode of action of the pharmaceutical substance).[479]

Bill of Law 2511/2007 and Bill of Law 3995/2008 both seek to prohibit patenting of new therapeutic uses of pharmaceutical products and new crystalline forms of substances. These bills have received support from the Ministry of Health and the ANVISA.[480] Nevertheless, in further discussions, during a public hearing held by the House of Representatives on June 27, 2012, the INPI and the ABPI explained to congressmen that all patent applications, including ones covering new medical uses, undergo a patent examination on novelty, inventive step and industrial application and that remedies against eventual abuses are already available in the current legislation.[481] Members of the House of the Representatives have issued two opposing opinions concerning the approval of a bill modifying the statute so as to prohibit patenting of second medical uses in a congressional procedure that started in 2007.

Even though it is not likely that, this debate will be resolved in the short term, Bill of Law 5402/2013 was more recently proposed on April 18, 2013 also seeking to amend Law 9279/1996. The bill consists in another attempt to exclude subject matter comprising new properties or uses of

476 *Id.*
477 *Id.*, p. 23.
478 *Id.*, p. 23-24.
479 *Id.*, p. 24-25.
480 See Opinion of the House of Representative's Commission for Economic Development, Industry and Trade, p. 7.
481 *Id.*, p. 6-7.

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known substances, as well as new forms such as salts, polymorphs, metabolites and isomers from patent protection by including them in Article 10 of Law 9279/1996.[482] Bill of Law 5402/2013 is also pending examination by Congress together with the previous discussed bills.

Brazilian courts have already dealt with the issue of second medical use inventions. The trial judge of the 35th Federal District Court of Rio de Janeiro rendered a decision on December 3, 2007 in a leading case, related to the patent application PI9606903-1, covering the active ingredient tomoxetine.[483] The applicant claimed a new use for tomoxetine in the treatment of attention deficit and hyperactivity disorder; although, this compound had been known for decades, it had not been used medically for this purpose. The trial court judge affirmed that the new application of a product is patentable when the already known object is inventively used towards obtaining a new result and the novelty consists of the relationship between the means and the result.[484] The judge stated that there is no specific provision in the Brazilian patent statute prohibiting the patentability of second uses in pharmaceutical arts (second medical uses are not prohibited by Articles 10 and 18 of Law 9279/1996) and they should be patentable provided that the new use is not part of the state of the art, and inventive step and industrial application are shown.[485] Furthermore, the judge clarified that new uses of pharmaceutical products are not therapeutic methods and are not prohibited by Article 10, VIII of Law 9279/1996.[486] Finally, the judge considered *Swiss-type* claims that are used to describe second medical use inventions should not be seen as process claims; the nature of a *Swiss-type* claim relates to a product and its purpose.[487] It is important to note that this case did not address the ANVISA's peremptory prohibition on patents for second medical use. The

482 In addition, Bill of Law 5402/2013 seeks to revoke sole paragraph of article 40 (eliminating the ten year period of minimum term of protection) and to modify articles 13 (bringing a new definition of inventive step), 31 (introducing opposition proceedings before the granting of patents) and 229-C (including the criteria according to which the ANVISA must deny prior consent) among other amendments. The contents of the proposed Article 229-C are exactly the same as in the text of Resolution-RDC 21/2013 issued by the ANVISA.

483 See *Eli Lilly and Company v INPI*, Trial Court Judgment.

484 *Id.*, p. 6.

485 *Id.*

486 *Id.*, p. 7.

487 *Id*.

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INPI considered that the patent application lacked novelty, whereas in the court proceedings it was deemed to be new. This same judge rendered a second decision reiterating that there is no prohibition in the Brazilian legal system for claims covering a pharmaceutical use that presents a new and inventive use.[488]

In the tomoxetine case, the Federal Court of Appeals for the 2nd Circuit decided that patents for second medical uses do not fulfill the basic requirement of novelty, as the compound already belongs to the state of art. The use of the same compound for another end does not result in patentable subject matter as it does not involve inventive step.[489] According to the decision, this case would be at most a simple discovery of a new therapeutic use, which is not considered invention pursuant to Article 10 of Law 9279/1996.[490] A minority opinion was expressed in the dissenting vote, affirming that there is no legal prohibition in the country for second medical use patents. A distinction was made between a) a new medical application for a chemical compound already used as a medicine (with no novelty or inventive step, as no significant changes are carried out for obtaining the new medical application, consisting in discovery); b) a new medical application for a chemical compound already used as medicine through changing dosage, composition or administration periods (if such changes are new and not obvious, the new medical application may be patentable upon examination of specific cases); and c) medicinal use of a compound which already exists in the state of the art but was not used as a medicine until then (there is novelty in such use as medicine and inventiveness derives from the observation of the therapeutic effects).[491] Tomoxetine falls under the latter condition and should be patentable.[492] The dissenting opinion further stated that the claim covering tomoxetine's new use was not to be deemed process claim, but rather product claim.[493] The appellate court decision was issued by a majority vote that was confirmed by the enlarged panel of the Federal Court of Appeals for the 2nd Circuit and the current case law of the Court of Appeals for the 2nd Circuit pre-

488 See *Max-Planck and Zentaris AG v INPI and ANVISA*, Trial Court Judgement, p. 25.
489 See *Eli Lilly v INPI*, Appellate Court Judgement, p. 7.
490 *Id.*
491 *Id.*, p. 10-12.
492 *Id.*, p. 25.
493 *Id*.

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vails against the patentability of second medical use inventions. [494] No further appeal has been made so far to the Superior Court of Justice, compelling the higher court to decide specifically on the patentability of second medical uses in the country.

2.3) Further Remarks

Whether the ANVISA's system of prior consent is illegal under WTO law is an issue to be evaluated before the WTO Dispute Settlement Body. This would only occur after many other considerations have been made by a Member State that were to plead against Brazil and, therefore, it is likely to never occur. Despite this, it is important to consider that the right to protect public health is not totally unlimited. Patent rights are recognized by TRIPS and the Doha Declaration to be important for encouraging the development of new life-saving medicines.[495] A balance should always be struck between public health and technological development, seen as two social interests to be taken into consideration along with any related private and public interests.

For the Brazilian pharmaceutical industry, which struggles to establish itself in the national market, the prohibition of patents on second medical uses may be prejudicial. Most of the costs involved in the development of drugs occur during the stages before clinical trials, when molecules are still being studied and before human testing. Second medical uses, in contrast, relate to already known molecules so the costs are relatively lower. With this tool, national industry may have the chance to generate new technology in this area. It is crucial for the Brazilian government to reeval-

494 See *Novartis v. ANVISA*, Appellate Court Judgement, dealing with the scope of the ANVISA's prior consent; although the patentability of second medical use inventions has not been addressed in this case, the dissenting vote states clearly that new use of medicines does not fulfill the constitutional and legal patentability requirements, specifically novelty and inventive step. See also *Max-Planck and Zentaris AG v INPI and ANVISA*, Appellate Court Judgement, p. 12, reversing the trial court decision. However, the appellate court states that a second medical use patent does not necessarily lack novelty, being possible that new therapeutic effects originate from research of complete innovative character without consisting in mere discovery, which might show that a shift in the appellate court's understanding should not be disregarded.

495 See *Rodrigues Jr., Murphy*, Brazil's Prior Consent Law, p. 448.

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uate its policies when dealing with pharmaceutical patents under the risk of jeopardizing national industry and economic progress. The argument that the Brazil's public health and technological development are hindered by patents on second medical uses may be too simplistic. The risks related to undue extension of already existing patents would be minimized by the criteria adopted in the examination of the applications. Only when presenting novelty, inventiveness, industrial applicability, and are supported by the description (within the parameters presented by the INPI), exclusivity rights would be granted. Furthermore, any errors are subject to a reassessment within the INPI structure under appeal proceedings, in addition to a judicial review.

In light of the new prosecution process established, patent holders and applicants must wait to see how the ANVISA will assess public health matters and if this agency and the INPI will coordinate their jobs without prejudice to the patent system. Interpreting what is contrary to public health, as contained in Article 18, I of Law 9279/1996, is now going to be carried out by the ANVISA and should not be done to incorporate policy making considerations, which has been the case for inventions related to second medical uses. Policy making considerations at this level should be a topic for Congress, rather than for public administrators when applying the law. In this case, compliance with TRIPS should also be assessed. Finally, any disagreement with the ANVISA's decision, or even the INPI, on the granting of patents may be brought before courts in order to establish a final word on the matter.

C. Provisions on Compulsory License

According to Article 42 of Law 9279/1996, a patent holder has the right to prevent third parties from manufacturing, using, offering for sale, or importing for such purposes, without consent, a product or process that is subject matter of a patent, or a product directly obtained by a patented process. Compulsory licenses are thus regarded as a limitation to patent rights because the patentee is obligated to license patented subject matter to third parties.

As an exception to a right, compulsory licenses are always granted on a non-exclusive basis and sub-licensing is not permitted (Article 72 of Law 9279/1996). Accordingly, there are conditions imposed on the licensee. In the absence of legitimate reasons, Article 74 of Law 9279/1996 mandates

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that the licensee begin exploiting the patented subject matter within one year from the date the license was granted (interruption is also allowed for an equal period) under the penalty of the possibly having the license revoked upon the patent holder's request.[496]

The licensee will be vested with all powers to act in defense of the patent.[497] This is different from other cases of non-exclusive licenses, where the licensee is not usually entitled to proceed in this manner. In addition, after a compulsory license is granted, its assignment will be only permitted together with transfer or leasing of that part of the undertaking that exploits the patented subject matter under the granted license.[498]

1. Previous Law

Compulsory licenses were introduced in Brazilian legislation by DL 7903/1945. Article 53 of this law established that a patentee who has not exploited patented subject matter in the country for two years from the granting date, or has interrupted use for longer than two years, would be obligated to give licenses to third parties. Article 64 of the statute also provided for expropriation of the patent in the case of national interest, as well as for waiving of patent rights when insufficient effective local use of the invention occurred for more than three consecutive years, as per Article 77, paragraph 1 of DL 7903/1945.[499] Later legislation regulating industrial property rights (DL 254/1967, DL 1005/1969 and Law 5772/1971) had similar provisions.

Law 5772/1971 also raised the public interest as statutory grounds for the granting of compulsory licenses for the exploitation of an unused patent or of a patent whose exploitation in the country does not fulfill the market demands. Since Law 5772/1971 was in force, two compulsory licenses were granted. The first was grounded in public interest for a patent covering a vaccine.[500] The second was a landmark case granted in 1984

496 Article 74, paragraph 1 of Law 9279/1996.
497 Article 74, paragraph 2 of Law 9279/1996.
498 Article 74, paragraph 3 of Law 9279/1996.
499 It has not been found any decision or scholar work dealing with the expressions non-exploitation and lack of effective use under the previous law. To date, there is no clear definition towards the precise use of those expressions.
500 Compulsory license for patent PI 71767, published in the Industrial Property Gazette of November 29, 1977, p. 152.

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due to the non-use of the patented subject matter that covered the manufacturing process of the Monsanto Company's agrochemical *Round-up*.[501] The license was granted to the Brazilian company Nortox Agroquímica S.A. who was interested in exploiting *Round-up* technology and understood that three years after the patent was issued, it was not being duly exploited in the country. Nortox requested the license on March 1983 and, upon Monsanto's silence, had it granted on November of the same year.[502] Monsanto later challenged the granting of compulsory license before courts, but the license was maintained in a final decision on April 25, 1984.[503] In order to avoid the effects of the compulsory license, Monsanto sought to waive its patent rights over the production process of *Round-up*. The company believed that this strategy would exempt it from the obligation to use the patent's subject matter and, thus, no compulsory license could be granted. Such strategy did not prevail.[504] It is important to note that Nortox developed its own technology in the area of agrochemicals and the company was not dependent on the patent holder's know-how, which was considered crucial in determining the efficacy of the license granted.[505]

2. Provisions of Law 9279/1996

The current patent statute removed the possiblity to expropriate patents for national interest and to waive patent rights when there is lack of local use of the invention. However, under the new law, the situations in which compulsory licenses may be conferred were broadened. According to Articles 68, 70 and 71, compulsory licenses may be granted on the following grounds: a) abusive exercise of patent rights or abuse of economic power by means of patent rights,[506] b) non-exploitation in Brazilian territory because of lack or incomplete manufacture of the product or lack of com-

501 Compulsory license for patent PI 7107076, Process DIRCO/1649/83, published in the Industrial Property Gazette of May 29, 1984.
502 *Id.* For more see *Ash*, The Nortox v. Monsanto Case on Compulsory Licensing.
503 *Id.*
504 See *Barbosa*, Notes on the Monsanto Compulsory License of 1983.
505 *Id.*
506 Article 68 of Law 9279/1996.

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plete use of a patented process,[507] c) insufficient commercialization,[508] d) dependence of one patent on another[509] and e) national emergency or public interest.[510]

2.1) Abuse of Economic Power and Lack of Local Exploitation

2.1.1) Abusive Exercise of Rights or Abuse of Economic Power

Compulsory licenses based on abuse of economic power were introduced into Brazilian legislation by Law 8884/1994, which regulated the competitive practices of private companies in Brazil. Law 8884/1994 was revoked by Law 12529/2011, which currently establishes the framework of Competition Law in the country. The Conselho Administrativo de Defesa Econômica (CADE), the government institution responsible for controlling the competitive practices of private companies in the marketplace, can impose punitive measures to parties violating laws relating to competition. Article 38, IV(a) of Law 12529/2011 foresees the granting of compulsory licenses of patents as a possible statutory sanction against acts characterized as anti-competitive and deemed to be grave or affecting the public interest. When violation of competition law is verified, the CADE would make a recommendation to the INPI that a license be compulsorily granted, provided that the decision issued by the CADE regarding anti-competitive practices by a patentee is not subject to an appeal within that institution or to a pending lawsuit before courts.

After consultation requested by the Ministry of Health,[511] the CADE issued a legal opinion on March 31, 1999, regarding the sort of conduct that would be characterized as anti-competitive and would justify the granting of compulsory licenses.[512] The Ministry of Health wanted clarification on the type of activities that would be considered infringement of competition

507 Article 68, paragraph 1, I of Law 9279/1996.
508 Article 68, paragraph 1, II of Law 9279/1996.
509 Article 70 of Law 9279/1996.
510 Article 71 of Law 9279/1996.
511 See Consulta Prévia 031/1999, in *Dias*, Compulsory Licenses of Patents and the Antitrust Law, p. 6-7.
512 Even though the CADE's legal opinion was written under the revoked Law 8884/1994, the concepts underlying this understanding are fully applicable, since Law 12529/2011 has not modified the contents of the relevant provisions.

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law by companies that act in markets dealing with essential products such as medicine.[513]

The CADE understood that compulsory licenses as a sanction would be granted when nexus between the use of the patent and the activity violating the competition law were verified.[514] Article 36 of Law 12529/2011 describes the situations that consist in anti-competitive practices.[515] In or-

513 *Id*.

514 See *Dias*, Compulsory Licenses of Patents and the Antitrust Law, p. 6-7.

515 "Article 36 Law 12529/2011. Acts manifested in any form consist in anti-competitive practices, independent of guilt, if they have as scope or may produce the following effects, even if not achieved: (i) to limit, distort or in any form harm free competition or free access to market; (ii) to dominate a relevant market of goods or services; (iii) to arbitrarily increase the profits; (iv) to abuse a dominant position. Paragraph 1. Domination of a market resulting from a natural process by the most efficient economic agent in relation to its competitors does not characterize the offense provided for in section II.
Paragraph 2. The dominant position is presumed whenever a company or group of companies is capable of unilaterally or coordinately alter the market conditions or when it controls 20% (twenty percent) or more of the relevant market, being this percentage changeable by the CADE for specific sectors of the economy.
Paragraph 3. The following acts, among others, as they configure the hypothesis set forth in the caput of this article and its sections, characterize anti-competitive practices: (i) to accord, combine, manipulate or adjust with competitors, under any form: a) the price of goods or services individually offered; b) the production or commercialization of a restricted or limited quantity of goods or the provision of services in a restricted or limited number, volume or frequency; c) the division in parts or segments of a current or potential market of goods or services, by, among other, the distribution of clients, suppliers, regions or periods; d) prices, conditions, advantages or abstention in public competitions; (ii) to obtain or influence the adoption of uniform business practices or concerted action by competitors; (iii) to limit or prevent access for new companies into the market; (iv) to create difficulties for the establishment, operation or development of a competitor company or supplier, purchaser or financier of goods or services; (v) to prevent competitor from accessing inputs, raw materials, equipment or technology and distribution channels; (vi) to require or grant exclusivity for the dissemination of advertising in mass media; (vii) to use deceitful means to cause price oscillation of third parties; (viii) to regulate markets of goods or services by establishing agreements to limit or control research and technological development, the production of goods or services, or to dampen investments for the production of goods or services or their distribution; (ix) to impose on trade of goods or services, distributors, retailers and representatives, wholesale price, discounts, payment terms, minimum or maximum quantities, profit margins or any other marketing conditions related to their business with third parties; (x) to discriminate against purchasers or suppliers of goods or services by establishing different

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der to be sanctioned with a compulsory license under Article 38, IV(a) of Law 12529/2011, the patentee must have incurred one of the hypothesis described in Article 36 which is regarded in the concrete case as grave or that affects the public interest. All the cases which are an infringement of competition law are regarded as affecting the public interest.[516] Furthermore, market power will be considered abusive for this purpose when it derives directly from the exercise of patent rights.[517] This would be the case, for instance, of pricing patented products much higher than the sum of the costs of production, research investments and a reasonable margin for profit, and could amount to abusive use of patent rights in violation of Article 36, paragraph 3, XIX of Law 12529/2011.[518]

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prices, or operating conditions of sale or provision of services; (xi) to refuse to sell goods or provide services within the standard payment conditions for trade uses and customs; (xii) to hamper or disrupt the continuity and development of business relations indefinitely because the other party refuses to abide by unjustifiable trade or anticompetitive terms and conditions; (xiii) to destroy, discard or hoard raw materials, intermediate or finished goods, as well as destroy, disable or impair the operation of equipment to produce, distribute or transport them; (xiv) to take possession or prevent the exploitation of industrial property, intellectual or technology rights; (xv) to sell goods or provide services for unjustly below the price of cost; (xvi) to retain production or consume goods, except for guaranteeing the coverage of production expenses; (xvii) to interrupt totally or partially the company activities without proven good cause; (xviii) to condition the sale of an good to the acquisition of another or the use of a service, or to condition the provision of a service to the use of another or to the acquisition of a good; (xix) to abusively exceed or explore the industrial or intellectual property rights or technology or copyright.

516 *Id.*

517 *Id.*

518 For more see *Barbosa*, Compulsory Licenses: Abuse, National Emergency and Public Interest, p. 3-22.
"Article 21. The following acts, among others, will be deemed a violation of the economic order, to the extent applicable under article 20 and items thereof: XXIV – to impose abusive prices, or unreasonably increase the price of a product or service.
Sole Paragraph. For the purpose of characterizing an imposition of abusive prices or unreasonable increase of prices, the following items shall be considered, with due regard for other relevant economic or market circumstances: I – the price of a product or service, or any increase therein, vis-à-vis any changes in the cost of their respective input or with quality improvements; II – the price of a product previously manufactured, as compared to its market replacement without substantial changes; III – the price for a similar product or service, or any improvement thereof, on like competitive markets; and IV – the existence of agreements

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The INPI would then act in complement based on Article 68 of Law 9279/1996, which states that "a patentee will be subject to have his patent compulsorily licensed if the rights resulting therefrom are exercised in an abusive manner or by means of the patent rights he practices abuse of economic power that is proven under the terms of the law by an administrative or court decision." It must be noted that the Article 68 does not provide for a case of compulsory licenses granted *ex officio*.[519] The procedure included in Article 73, paragraph 2 of Law 9279/1996 must be applied,[520] and a third party should apply for the license before the INPI by presenting documentary proof of the patent holder's abusive conduct (resulting from abuse of patent rights or of economic power).

According to the CADE legal opinion, after it recommends granting of a compulsory license as a sanction, the INPI would have to publish such recommendation and offer licenses to third parties in order to impose the sanction as foreseen in Article 68 of Law 9279/1996.[521] Third parties would then file for an application of license in accordance with their particular interests. This would be a reasonable way to balance the application of both laws (Law 12529/2011, which imposes compulsory licenses as a sanction for anti-competitive practices by patent holders, and Law 9279/1996 which does not foresee the exercise of patent rights in abuse of economic power as a ground for granting compulsory licenses *ex officio*) and would maintain respect for the principle of legality to which every entity of public administration is bound.[522]

Moreover, in the case that a compulsory license has been granted due to abuse of economic power, Article 68, paragraph 3 of Law 9279/1996 establishes that to the licensee proposing to locally manufacture the product in question will be given up to one year to continue importation of the licensed subject matter provided it has been placed in the foreign market directly by the patentee or with consent. This presumes that importation is

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or arrangements in any way, which cause an increase in the prices of a product or service, or in their respective costs".

519 *Id.*

520 The compulsory license procedure of Article 73 will be discussed further on in this chapter.

521 See Consulta Prévia 031/1999, in *Dias*, Compulsory Licenses of Patents and the Antitrust Law, p. 6-7.

522 See *Dias*, Compulsory Licenses of Patents and the Antitrust Law, p. 7.

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necessary while the licensee makes the preparations for local production.[523]

Under competition law perspectives, Articles 8.2, 31(k) and 40 of TRIPS allow Member States to adopt adequate measures to restrict the rights of patent holders whenever a judicial or administrative decision determines existence of abusive use of IP rights with adverse effects on competition. Compulsory license granted under these provisions is an available tool to limit abusive conduct of patent holders, assuring a balanced and efficient patent system without creating unnecessary social costs such as price increases. In the pharmaceutical sector, patents have the potential to bring an undertaking into a dominant position and limiting abusive conducts is in conformity with TRIPS standards. Although it is seen as a measure which could be useful for reducing the price of medications, compulsory licenses based on abuse of economic power have never been granted, either for pharmaceutical patents or for other products.[524]

2.1.2) Insufficient or Non-Exploitation in Brazilian Territory

Article 68, paragraph 1 of Law 9279/1996 establishes the conditions that may also serve as grounds for a compulsory license, as follows: a) non-exploitation of the patented subject matter in Brazilian territory due to lack of or incomplete manufacturing of the product or, furthermore, due to incomplete use of a patented process (except in the case of non-exploitation due to lack of economic viability, when importation is admitted)[525] or b) commercialization that does not meet the needs of the market.[526] However, compulsory licenses will not be granted if the patentee justifies non-use for legitimate reasons,[527] proves that serious and effective preparations for exploitation have been carried out,[528] or justifies the lack of manufacture or commercialization due to legal obstacles.[529]

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523 See *Dannemann*, Commentaries on the Industrial Property Law, p. 139.
524 See *Curzel*, Access to Medicines: the Brazilian Case, p. 43.
525 Article 68, paragraph 1, I of Law 9279/1996.
526 Article 68, paragraph 1, II of Law 9279/1996.
527 Article 69, I of Law 9279/1996.
528 Article 69, II of Law 9279/1996.
529 Article 69, III of Law 9279/1996.

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Despite regular manufacturing of a patented product or making use of a patented process in the country, patent holders will continue to be subject to compulsory licensing when commercialization is deemed insufficient, as per Article 68, paragraph 1, II of Law 9279/1996. It is important to note that patent holders who completely manufacture a patented product or use a patented process in the national territory may import the product in order to meet the needs of the market and, thus, avoid licensing granted under this provision.

In the situations outlined in Article 68, paragraph 1 (lack of or incomplete manufacture of a patented product, incomplete use of a patented process, or insufficient commercialization), if based on lack of local exploitation of a patent, the interested third party may apply for a compulsory license only after three years from the date the patent was granted (paragraph 5, Article 68 of Law 9279/1996).[530]

One example is the request for compulsory license that was filed for patent PI 8704197-9, covering a process of vacuum packing owned by Interprise-Brussels.[531] The company Vacuum Pack Services Limited requested compulsory license of this patent based on lack of use of the patent, as per the notification published in the Industrial Property Gazette N. 1460, of December 29, 1998. There are no reports of a decision granting or not the license and patent PI 8704197-9 expired on August 13, 2002.

2.1.2.1) Analysis under TRIPS

Article 27.1 of TRIPS reads that "patents shall be available and *patent rights enjoyable without discrimination* as to the place of invention, the field of technology and *whether products are imported* or locally produced." The Agreement establishes that rights should be enjoyed without distinction towards a product's place of manufacture.

In the panel instated by the European Communities against Canada, the WTO Dispute Settlement Body determined that the word discriminate relates to the "results of the unjustified imposition of differentially disadvan-

530 The compulsory license procedure of Article 73 will be discussed further on in this chapter.

531 See *INPI*, Patent PI 8704197-9.

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tageous treatment."[532] In addition, the panel found that Article 27.1 of TRIPS prohibits discrimination regarding the enjoyment of patent rights in absolute terms, being applicable to the "exceptions to the exclusive rights conferred by a patent" under Article 30 of TRIPS.[533] This latter provision does not contain any suggestions for exemption from the non-discrimination principle in Article 27.1.[534]

As described above, Article 68, paragraph 1, I of Law 9279/1996 requires that a patent be exploited within Brazilian territory under the penalty of subjection to compulsory licensing. Exploitation must be done through the complete manufacturing of the product or the complete use of a patented process, and importation is allowed only in cases that are economically non-viable. Upon reading this provision, it is clear that discrimination against importation occurs in order for patent rights to be fully exercised.

The local working requirement is justified by the Paris Convention, which establishes in Article 5A(2) the right of Member States to provide for compulsory licenses to prevent any abuse resulting from patent rights including "failure to work." Each Member State is free to define their understanding of "failure to work."[535] In this context, Article 2(1) of TRIPS establishes that the Paris Convention provisions must be complied with by Member States and, therefore, the provision of Article 5A(2) of the Paris Convention should be considered part of TRIPS.

By mandating that patented subject matter be completely manufactured or used in Brazil, the local working requirement aims to propagate transfer of technology into the country as a counter-payment for the privilege associated with granting a patent. The mere importation of patented goods would not achieve this goal. Transfer of technology as an objective can find its international foundations in Articles 7 and 8.2 of TRIPS. Article 7 of TRIPS provides that the protection and enforcement of intellectual property rights should contribute to promotion of technological innovation

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532 See *Canada – Patent Protection of Pharmaceutical Products*. Complaint by the European Communities and their Member States. Report of the Panel, March 17, 2000 (WT/DS114/R), p. 172.

533 *Id.*, p. 171.

534 This decision invalidated the argument that, under a systematic interpretation of TRIPS, the non-discrimination principle of Article 27.1 is related only to the granting of patents, and not to the maintenance – and enjoyment – of rights.

535 See *Bodenhausen*, Guide for the Paris Convention, p. 71.

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and to transfer and dissemination of technology. More specifically, Article 8.2 of TRIPS states that appropriate measures should be taken by Member States to prevent abuse of intellectual property rights, which could adversely affect international transfer of technology.

Developing countries can make use of the local working requirement to promote building their industrial and technological capacity, as well as create employment and foster the general economy. Since transfer of technology is imperative for these countries, any action to hinder this objective would qualify as an abuse of patent rights. Most patents in these countries are owned by foreign companies from developed regions and mere importation could come at social costs. In this situation, non-local working should be regarded as an abuse of patent rights. Compulsory license would be a measure to prevent such an abuse, positively affecting the international transfer of technology.

As discussed previously, the former Brazilian statute (Law 5772/1971) mandated exploitation of patented subject matter within the country by patent holders under the penalty of compulsorily licensing or waiver of patent rights.[536] Through an interpretation of the old law, the INPI concluded that an invention must be used according to the description and claims, and exploitation should fall on the patented subject matter as a whole. This means that the patent holder must use all the patent claims in the country. The INPI position was also affirmed by courts.[537]

According to the wording of Article 68, paragraph 1, I of Law 9279/1996 and in light of the interpretation established under the previous law, the patent holder is obligated to manufacture the complete content of the patent, meaning each of the independent claims, within the national territory. Production, importation or distribution of most of the patented subject matter is not enough to satisfy the law and the manufacture of most of the parts of the product is also insufficient.[538] This provision puts a large burden on the patentee, but not on the licensee, who is obligated by Article 68, paragraph 2 of Law 9279/1996 to exploit the patented subject matter only in an efficient way and not to complete manufacture or make complete use of the patented product or process.[539]

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536 Articles 33 and 49 of Law 5772/1971.
537 See *Levy, Licks*, The Local Working Requirement, p. 5-7.
538 *Id.*
539 *Id.*

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By mandating patented subject matter to be completely manufactured or used in Brazil, the local working requirement disregards the reality of the globalized economy. Production of goods usually follows the rules of the market, which demand efficiency with minimum costs, meaning that goods are very often not completely manufactured in a single country. In this regard, the manufacture of all the elements of every independent claim of a patent would lead to an increase in costs – due to exchange rates, economy of scale or even lack of electricity.[540] The requirement of the Brazilian statute potentially jeopardizes not only the producer/patentee, but also the final consumer who will need to pay higher prices to cover higher costs.

It is important to remember that TRIPS is only a part of the WTO system, and the expansion of international trade and optimization of global resources is one of its main principles.[541] Accordingly, the WTO Agreement and its annexes (TRIPS being Annex 1C) should be understood as a harmonious and indivisible group of principles and rules; TRIPS integrates intellectual property into the rules related to free trade of goods and services.[542] Article 27.1 of TRIPS should be interpreted together with Article III, paragraph 4 of GATT 1994, which determines that imported goods should receive the same treatment as locally produced goods.[543] In consonance, the application of Article 5A(2) of the Paris Convention – giving freedom to countries to define "failure to work" when regulating compulsory licenses – is limited by Article 27.1 of TRIPS and Article III paragraph 4 of GATT 1994. Imported goods should not receive discriminatory treatment relative to locally manufactured goods; hence, the grounds for granting compulsory licenses are restricted.[544] Mandating that patented subject matter be completely manufactured or used in Brazil goes against the spirit of free trade under the WTO system and, worse, may be impossible to put into practice and may be an insurmountable obstacle for patent holders.

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540 *Id.*

541 See *WTO*, Principles of the Trading System, para. 1-2.

542 See *Carvalho*, Controversial Issues in the Patent Field, p. 92.

543 *Id.*

544 See *Gervais*, The TRIPS Agreement: Drafting History and Analysis, p. 148; *Blakeney*, TRIPS: A Concise Guide, p. 90-91; and *Otten, Wager*, Compliance with TRIPS, p. 401.

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Therefore, in order to reconcile Article 68, paragraph 1 of Law 9269/1996 with the logic of TRIPS and world free trade, specificity of the technology involved and Article 69 of Law 9279/1996 must be taken into account. The later provision establishes an exception to mandatory local and complete manufacturing when there is a legitimate reason. The logic of the specific business related to the patented subject matter should be considered when determining if a compulsory license should be granted or rejected. A lack of economic viability, material or technological resources for the local manufacture of a component of a patented product, for instance, may justify importation of such component.

In the case of the pharmaceutical industry, most active ingredients are manufactured and imported from China. This is not only the case for Brazil, but also many other countries. If a pharmaceutical product were required to be completely manufactured locally, it would demand that the active ingredient be manufactured locally as well. This would require infrastructure that Brazil had not been capable of building for decades even considering the prohibition of patents on pharmaceuticals. In addition, the generic industry would also be required to manufacture the active ingredient. Allowing importation would certainly harm the principles underlying the use of compulsory licenses.

2.1.2.2) The Panel filed by the USA before the WTO

On May 30, 2000, according to Article 4 of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes and Article 64 of TRIPS, the USA requested consultations with Brazil about the local working requirement. Enjoying exclusive patent rights could only be satisfied by local production, not importation, of patented subject matter.[545] According to their understanding, by stipulating that a patent is subject to compulsory licensing if not "worked" in the territory of Brazil, the local working requirement is inconsistent with Articles 27 and 28 of TRIPS and Article III of the GATT 1994.[546] The Brazilian law would be discriminatory when not recognizing importation as one of the ways to exploit

545 See *Brazil – Measures Affecting Patent Protection.* Request for Consultations by the United States, June 8, 2000 (WT/DS199/1), p. 1.

546 *Id.*

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patented subject matter and the granting of compulsory licenses would violate the exclusive rights of patent holders.

According to the Brazilian government, the granting of compulsory licenses as foreseen in the patent statute is in accordance with the conditions established by Article 31 of TRIPS for the use of a patent without the authorization of the patent holder.[547] In addition, Article 5(A) of the Paris Convention would admit the possibility of granting compulsory licenses based on the lack of exploitation of the patent and each country would be allowed to define its own understanding of failure to work.[548] US law also includes a type of "local working" requirement, according to which patented inventions developed with the use of public money must be exploited in United States territory.[549]

Because no mutual understanding between the two parties was reached, on January 8, 2001, the USA requested the establishment of a panel before the WTO Dispute Settlement Body.[550] In response, the Brazilian government started a campaign affirming that the US complaint at the WTO would jeopardize the Brazilian anti-HIV/AIDS program, which was considered the best in the world by the United Nations and the World Bank.[551] Brazil's strategy was to establish its moral high ground and gather the support of the NGOs such as the Médecins sans Frontière and Oxfam.[552] For the first time the Brazilian government mobilized public opinion in developed countries by publishing articles and interviews in The New York Times, Washington Post and on CNN.[553]

On July 5, 2001, the dispute came to an end, when both the US and Brazil filed a notification before the Dispute Settlement Body informing that the two governments had reached a mutually satisfactory solution to the matter.[554] The US agreed to withdraw the WTO panel if the Brazilian government committed itself to holding prior talks with the US govern-

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547 See *Basso et al.*, The Brazilian Patent Statute and the WTO Rules, p. 37-40.
548 See *Scholze*, Local Manufacture, Compulsory Licenses and Parallel Importation in the Industrial Property Law, p. 10.
549 See *Curzel*, Access to Medicines: the Brazilian Case, p. 42.
550 See *Brazil – Measures Affecting Patent Protection.* Request for Establishment of a Panel by the United States, January 9, 2001 (WT/DS199/3).
551 See *Cepaluni*, Patent Regime: Brazil x USA, p. 67-69.
552 *Id.*
553 *Id.*
554 See *Brazil – Measures Affecting Patent Protection.* Notification of Mutually Agreed Solution, January 9, 2001 (WT/DS199/4), p. 1.

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ment before applying Article 68 to grant compulsory licenses for patents held by US companies.[555] No decision from the WTO Dispute Settlement Body on the interpretation of the local working requirement had been rendered.

2.1.3) Economic Capacity of the Licensee and the Importation Exception

In order to be entitled to a compulsory license based on the grounds mentioned above (exercise of patent rights in an abusive manner or abuse of economic power, non-exploitation in the Brazilian territory, by lack of or incomplete manufacture of the product, lack of use of a patented process, and insufficient commercialization) the licensee must have legitimate interests and the technical and economic capacity to carry out efficient exploitation of patented subject matter.[556] Such exploitation should be predominantly for the internal market.

This requirement aims to ensure that licensing results in an effective use of the patent. For this purpose, the licensee does not need to possess the complete technical and economic capacity to exploit the whole invention; it is possible to sub-license to third parties who could supply the licensee with necessary goods and services.[557] As already mentioned, the law does not require that the licensee manufacture or use the patented subject matter completely in Brazil. It only requires that its exploitation be performed efficiently.

In this context, it is important to remember that as a condition to the licensee, Article 74 paragraph 3 of Law 9279/1996 establishes that assignments of compulsory licenses are only allowed together with transfer or leasing of the associated part of the undertaking, since the characteristics of the undertaking (the technical and economic capacity) were decisive for granting the compulsory license.

Even in the case that a compulsory license is granted as a sanction for the abuse of economic power, the licensee must satisfy the requirement of technical and economic capacity. The aim of the license is to make use of

555 *Id.*
556 Article 68, paragraph 2 of Law 9279/1996.
557 See *Barbosa*, An Introduction to Intellectual Property, p. 522.

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the patent in an adequate manner, be it to supply market demand or to maintain competition in the market.[558]

Importation by third parties of goods manufactured according to patented processes or products is allowed by Article 68, paragraph 4 of Law 9279/1996, provided that the goods have been placed in the market directly by the patentee or with consent. This provision allows for parallel importation as an exception to the rights conferred to patent holders in Article 42 of Law 9279/1996,[559] when exploitation occurs through importation by the patentee (when the local manufacture of the product or complete use of the patented process is not economic viable, as per Article 68, paragraph 1, I of Law 9279/1996) or by the licensee (of a compulsorily license that is granted based on the abuse of economic power while assuming that preparations for local manufacture of the goods are being made, as per Article 68, paragraph 3).

2.2) Dependent Patents

According to Article 70 of Law 9279/1996, the exploitation of a patent may require the use of a part or all of a subject matter already claimed in a previous patent belonging to third parties, creating a dependent relationship.[560] Dependency occurs when the use or exploitation of the second patent can occur only by infringing on the claims of the first.[561] In this case, the owner of the first patent may be obligated to allow the second patent to be exploited upon payment of royalties, which are arbitrated by the INPI. The owner of the dependent patent must file an application under Article 73 before the INPI.[562]

License will be granted when cumulatively a) one patent is dependent on another, b) the subject matter of the dependent patent constitutes a substantial technical advance in relation to the earlier patent, and c) the first

558 See *Dias*, Compulsory Licenses of Patents and the Antitrust Law, p. 7-8.
559 See *Dannemann*, Commentaries on the Industrial Property Law, p. 139-140.
560 Article 70, paragraph 1 of Law 9279/1996.
561 See *Dannemann*, Commentaries on the Industrial Property Law, p 143.
562 The compulsory license procedure of Article 73 will be discussed further on in this chapter.

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patentee does not come to an agreement with the owner of the dependent patent for the exploitation of the first patent.[563]

The notion of "substantial technical advance" should not be reduced to the analysis of inventive step.[564] Inventiveness is required for granting a patent, but at this stage there should be an evaluation of public needs that could be satisfied by the dependent technology.[565] "Substantial" should not be interpreted as revolutionary, but rather as of relevance, which in turn should be assessed following needs of society.

For the purposes of the law, the dependent relationship may also occur in the case of a process patent for the respective product, or in the case of a product patent for a previous process patent.[566] Furthermore, as per Article 70, paragraph 3, the owner of the patent licensed under this provision is also entitled to a compulsory cross license. There has yet to be any compulsory license granted in Brazil on these grounds.

2.3) Procedural Aspects

Granting compulsory licenses based on the above mentioned grounds (exercise of patent rights in an abusive manner or abuse of economic power, non-exploitation in the Brazilian territory, by lack of or incomplete manufacture of the product, lack of use of a patented process, insufficient commercialization and the dependency of one patent upon another) is subject to the procedural rules established in Article 73 of Law 9279/1996, requiring administrative judgment by the INPI. The INPI cannot grant *ex officio* compulsory licenses and due process must be respected, especially in light of its character as an exception to rights.

Accordingly, an interested (private) party must file an application for a compulsory license indicating the conditions offered to the patentee,[567] who will be notified to respond within sixty days, at the end of which the proposal will be considered as accepted in the absence of manifestation by the patent holder.[568] As mentioned earlier, the allegation of abuse of patent

563 Article 70, I, II and III of Law 9279/1996.
564 See *Barbosa*, An Introduction to Intellectual Property, p. 548.
565 *Id.*
566 Article 70, paragraph 2 of Law 9279/1996.
567 Article 73 of Law 9279/1996.
568 Article 73, paragraph 1 of Law 9279/1996.

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rights or abuse of economic power must be proven and documented by the applicant for a license on these grounds.[569] In case of insufficient exploitation, the burden of proof lies on the patent holder.[570]

If a patent holder contests, the INPI may take the necessary steps, including the establishment of a committee (which may include specialists that are not part of the INPI) aimed at arbitrating the remuneration that will be paid to the patent holder.[571] Public administration entities will assist the INPI in arbitrating the remuneration by providing all necessary information requested.[572] In arbitrating remuneration, the circumstances of each case will be considered and the economic value of the license granted must be taken into account.[573] Once provided with the necessary information, within sixty days the INPI will come to a decision regarding the approval and the conditions of the compulsory license.[574] Appeals from decisions granting compulsory licenses may be filed to the President of the INPI and will not suspend the effects of the first decision.[575] That is to say that the license will already produce legal effects. As any decision within public administration, the decision on approval or denial of compulsory licenses is subject to judicial review.

2.4) Cases of National Emergency or Public Interest

In the case of national emergency or public interest, the Brazilian government may grant compulsory licenses for the exploitation of a patent insofar as the patentee or the licensee cannot meet the needs raised during such a situation, based on Article 71 of Law 9279/1996. This provision embodies Article 31 of TRIPS, which provides the standards to be implemented by WTO Member States when regulating the use of patented subject matter without the authorization of the patent holder.[576] Unlike the cases of abuse of economic power or insufficient use of patented subject matter, where licenses are justified as sanctions to correct abuse or benefit the

569 Article 73, paragraph 2 of Law 9279/1996.
570 Article 73, paragraph 3 of Law 9279/1996.
571 Article 73, paragraph 4 of Law 9279/1996.
572 Article 73, paragraph 5 of Law 9279/1996.
573 Article 73, paragraph 6 of Law 9279/1996.
574 Article 73, paragraph 7 of Law 9279/1996.
575 Article 73, paragraph 8 of Law 9279/1996.
576 See *Dannemann*, Commentaries on the Industrial Property Law, p. 146.

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market (needed goods or transfer of technology by local production), in this case justification is the mere predominance of public need over private interests.[577]

National emergency and public interest must be declared by the Executive Branch of government. The license granted is non-exclusive and temporary and will not jeopardize other normal rights held by the respective patentee. Sole paragraph of Article 71 of Law 9279/1996 further establishes that the act granting the license will establish its term of validity and the possibility of extension. Unlike the other possibilities for granting compulsory licenses, the government may grant it *ex officio*, i.e. without an interested party applying for it under Article 73 of Law 9279/1996. Article 71 of Law 9279/1996 is further regulated through Decree 3201/1999 enacted by the President on December 22, 1999, and amended by Decree 4830/2003.

It is important to note that granting compulsory licenses under Article 71 of Law 9279/1996 is a power given to public administrators. Once circumstances characterized as national emergency or public interest have emerged, the Minister charged with this power is not obligated to grant a license.[578] This issue stands as a policy judgment, with space for discretionary action by representatives of government.[579] The convenience and opportunity of the act of granting a license is not subject to judicial review, which is only possible in case of abuse or failure to accomplish procedural rules.

Nevertheless, Article 71 clearly states that the power of granting a compulsory license cannot be used if the patentee or the licensee are able to meet the demands generated by the emergency or public interest.[580] Consequently, the patent holder must be given the right of defense, a principle established in Article 5, LIV of the Federal Constitution, taking into account the specific emergency and situation that may justify a postponed exercise of this right.[581]

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577 See *Barbosa*, Compulsory Licenses: Abuse, National Emergency and Public Interest, p. 15.
578 See *Curzel*, Access to Medicines: the Brazilian Case, p. 37.
579 See *Scudeler*, Compulsory Licenses for Lack of Local Exploitation, p. 8.
580 See *Barbosa*, Compulsory Licenses: Abuse, National Emergency and Public Interest, p. 16.
581 *Id.*

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Decree 3201/1999 that regulates the law allows compulsory licenses for cases of national emergency or public interest and covers all kinds of patents, including pharmaceuticals. It defines national emergency as imminent public danger, even if it occurs in one part of the territory.[582] This short definition does not give examples of cases which would be considered national emergencies. Facts of public interest are, among others, related to the public health, nutrition, defense of the environment, as well as those of significant importance to technological and socioeconomic development.[583] These hypothetical situations are only exemplary and others might be found regarding the notion of public utility, as foreseen in DL 3365/1941 regulating the expropriation of private property.[584]

It is clear in Decree 3201/1999 that compulsory licenses based on public interest cannot lead to commercial use of the licensed patent and they are restricted to only non-commercial public uses. According to the wording of Articles 1 and 2 of Decree 3201/1999, this limitation does not apply in cases of national emergency. As per Article 3 of Decree 3201/1999, national emergency or public interest cases will be declared by an act from the Minister responsible for the subject matter in question and is to be published in the Official Gazette. Once it has been verified that the patentee or the licensee are unable to address the situation of national emergency or public interest, as per Article 71 of Law 9279/1996, the public administration will grant ex officio the compulsory license of non-exclusive character, and the act shall be immediately published in the Official Gazette.[585] *Ex officio* granting does not originate from the INPI, but rather from the respective ministry. The INPI will be responsible only for recording such licenses, as well as amendments and termination.[586]

Among other stipulations, the act granting the compulsory license will specify the term of validity of the license, the possibility for extension,[587] and the conditions offered by the government, i.e. remuneration for the

582 Article 2, paragraph 1 of Decree 3201/1999.
583 Article 2, paragraph 2 of Decree 3201/1999.
584 Article 5 of DL 3365/1941 foresees the cases of public utility justifying the expropriation of private property, such as national security, defense of the State, public help in case of calamity, public salubrity, among several others. See *Barbosa*, Compulsory Licenses: Abuse, National Emergency and Public Interest, p. 15-16.
585 Article 4 of Decree 3201/1999.
586 Article 13 of Decree 3201/1999.
587 Article 5, I of Decree 3201/1999.

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patent.[588] It may also establish the obligation of the patentee to give information that is necessary and sufficient to effectively reproduce the protected subject matter, as well as other technical features applicable to the case in question.[589] The enablement requirement of Article 24 of Law 9279/1996 should be taken into consideration, according to which the specification of the patent must describe the subject matter clearly and sufficiently so as to enable a person skilled in the art to carry it out and indicate, when applicable, the best mode of execution. The patent holder's obligation to give information about other technical features might be considered compulsory licensing of know-how, which could be deemed as abusive.[590]

The relevant economic and market circumstances, the price of similar products and the economic value of the authorization will all be considered when determining the remuneration to be paid to the patent holder.[591] The respective authority may request the necessary information for other public administration entities in order to substantiate the granting of the license or to determine the suitable remuneration.[592] In cases of national emergency or public interest that are characterized by extreme urgency, a compulsory license may be implemented, and the use of the patent subject matter may be effectively exploited regardless of previous compliance with the conditions established in Articles 4 and 5 of Decree 3201/1999 (publication of the act in the Official Gazette as well as the stipulation on the conditions of the license).[593]

The Decree clearly determines that the patent holder's agreement with the conditions of the license is not a prerequisite for beginning the exploitation of a patent licensed on such grounds.[594] Exploitation may be carried out either directly by the government or by duly hired third parties.[595] The use of the patent for other purposes is deemed illegal and hired third parties must also respect principles that regulate public administra-

588 Article 5, II of Decree 3201/1999.
589 Article 5, paragraph 1 of Decree 3201/1999.
590 See *Dannemann*, Commentaries on the Industrial Property Law, p. 146.
591 Article 5, paragraph 2 of Decree 3201/1999.
592 Article 6 of Decree 3201/1999.
593 Article 7 of Decree 3201/1999.
594 Article 8 of Decree 3201/1999.
595 Article 9 of Decree 3201/1999.

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tion activities, as foreseen in Article 37 of the Federal Constitution, including the principle of legality, publicity and efficiency.[596]

In cases where it is not possible to address situations of national emergency or public interest with a product placed in the internal market, or if manufacturing patented subject matter by a third party or by the government is not viable, importation of the patented product is allowed.[597] Preference should be given to the acquisition of products which have been placed in the market directly by patent holders or with their consent, whenever this procedure does not hinder the purposes of the license.[598] Once the national emergency or public interest conditions have been addressed, the respective compulsory licenses should terminate, respecting the terms of the contract executed with the licensee.[599]

Granting compulsory licenses based on public interest will be discussed in further detail in the following chapter analyzing actual cases in which the Brazilian government made use of this instrument.

596 Article 9, sole paragraph of Decree 3201/1999.
597 Article 10 of Decree 3201/1999.
598 Article 10, sole paragraph of Decree 3201/1999.
599 Article 12 of Decree 3201/1999.

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IV. CHAPTER. ANALYZING THE BRAZIL CASE

A. General Overview: Brazilian statistics and the public healthcare system

Brazil is the fifth largest country in the world both in geographical area and population. The country is 8.5 million square kilometers and had 194.9 million people in 2010. It is growing at a 1% rate[600] and reached more than 199 million people in July 2012.[601] The country's nominal gross domestic product (GDP) at US$2.476 billion made it the sixth largest economy in the world in 2011.[602] Brazil economy is characterized by large and well-developed agricultural, mining, manufacturing and service sectors, as well as a large labor pool. With a GDP per capita of US $12,594 in 2011,[603] the World Bank classifies Brazil as an upper middle level country.[604]

As one of the BRICS countries, Brazil's booming economy has gone into overdrive with biofuels and deep-water oil reserves, providing energy independence, expanding the country's presence in international financial and commodities markets, and increasing exports of aircraft, electrical equipment, automobiles, ethanol, textiles, footwear, iron ore, steel, coffee, orange juice, soybeans, corn and beef[605] After becoming a net external creditor in 2008, the country was hit by the global financial crisis the following year. Nevertheless, Brazil was the first emerging market to recover from the crisis and experienced a 7.5% growth rate in July 2010, the highest rate in the past twenty-five years, leading the government to take measures to cool down the economy in response to rising inflation.[606] The country's expected rate of growth for 2013 was 4%.[607] Agriculture and related sectors like forestry, logging and fishing accounted for 5.5% of

600 See *World Bank*, Brazil's Profile, lines 1-2.
601 See *CIA*, Brazil, item 3.
602 See *World Bank*, Gross Domestic Product 2011, line 6.
603 See *World Bank*, GDP per capita, line 27.
604 See *World Bank*, Brazil's Data, table 1.
605 See *The Economist*, The Economy of Heat, table.
606 See *CIA*, Brazil, item 5.
607 See *Banco Central,* Inflation Report, p. 19.

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GDP, illustrating the importance of agribusiness in the country's trade balance. 27.5% of GDP was from industrial activity including automobiles, steel, petrochemicals, computers, aircraft, and consumer goods. Services were responsible for 67% of GDP in 2011.[608]

Brazil was placed in eighty-fifth position among the group of developed countries with high human development according to the rank by the Human Development Index published in the United Nations Development Program's Human Development Report released on November 2, 2011.[609] This classification takes into account that public expenditures on education represented 16.8% of total government expenditure in 2009, higher than the US 13.1%.[610] However, health represented 9% of GDP in 2010 similar to the Congo and Sierra Leone, African countries with low human development.[611]

Despite the relatively good classification by the UN Development Program, 21.4% of the Brazilian population still were living below the poverty line in 2009 and illiteracy rates reached 11.4%.[612] This is indicative of the long-existing unequal distribution of wealth in Brazil – one of the worst in the world. In 2008, 24.8 % of the country's workforce had a monthly income per capita below half of the local official minimum wage, which amounted to $410 reais (approximately US$242), whereas the population earning more than $2,050 reais (around US$1,206) corresponds to only 5.5% of Brazilians.[613]

The Brazilian Gini coefficient for income, which measures unequal distribution of family income in a country and ranges worldwide from approximately 23.0 to 70.9 (referring to Sweden and Namibia respectively)[614] was at 51.9 in 2012.[615] The Gini coefficient was only worse for Haiti, Central African Republic, Sierra Leone, Botswana, Lesotho, South Africa and Namibia.[616] In 2008, the index was reduced by 0.505 for Brazil and represented a 7% decrease in income disparities.[617] The improvement

608 See *CIA*, Brazil, item 5.
609 See *UN*, HDI rankings, column 2.
610 See *World Bank*, Spending on Education, line 27.
611 See *World Bank*, Spending on Health, line 27.
612 See *CIA*, Brazil, item 3.
613 See *IBGE*¸ Income Search, p. 192.
614 See *CIA*, Gini Index, lines 87, 116.
615 See *Holanda et al.*, Gini Index, p. 5.
616 See *CIA*, Gini Index, lines 14, 22, 49, 70, 87, 108, 112.
617 See *Schlindwein*, IPEA's measurements of Gini coefficients, p. 48.

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may reflect governmental long-term investments in social programs, such as the so called "Bolsa Família" which provides income to poor families and mandates children schooling in exchange,[618] within the context of general economic development.

The United Nations and the World Bank estimate that a quarter of the Brazilian population has no access to drinking water, living in very poor conditions without basic sanitation. Diseases typically found in poor countries, such as tuberculosis and Hansen's disease, still afflict Brazilian people.[619] However, some specific campaigns have proven successful including the eradication of Poliomyelitis since 1994, after nationwide vaccination campaigns organized by the Ministry of Health.[620]

In spite of social and economic inequities, Brazil was the tenth largest market for pharmaceutical products in 2008 and it was expected to be the eighth largest in 2013, representing 2% of the worldwide market.[621] Pharmaceutical industry sales in the country were around US$15.7 billion in 2009.[622]

Brazil's strategic importance in the global pharmaceutical market takes into consideration the publicly funded healthcare system, entitled "Sistema Único de Saúde" (SUS). The system was created through the Federal Constitution of 1988, which mandates the government to provide universal healthcare differing from the previous public system, which only provided healthcare to those who paid social security taxes.[623] However, currently there is a two-tier healthcare system in Brazil. 73.7% of the population depends on the public system to have access to medical treatment, and only 26.3% (around 49.1 million people) are able to afford a private insurance.[624] The SUS is a unified system and encompasses the three levels of government – federal, state and municipal – each with its own attributes, and working in coordination under the national guidelines established by the federal government. The SUS budget is part of the annual social secu-

618 The "Bolsa Família" social program is sponsored by the Brazilian federal government and was created by Law 10836 in 2004, aiming to reduce social inequalities.
619 See *IBGE*, Municipal Social Figures, p. 113, 116.
620 See *Schatzmayr*, Eradication of polyomielitis in Brasil, p. 12.
621 See *Interfarma*, Market Trends; *ABAMEC*, Pharmaceutical Industry Wins Millions, para. 2.
622 See *Interfarma*, Pharmaceutical industry sales in Brazil, table.
623 See *Martins*, Social Security Law, p. 6-15.
624 See *IBGE*¸ Overview of the Brazilian Health Care System, table 11.

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rity budget. In 2008, the federal government financed 45.51% of the system, whereas states and municipalities contributed 25.28% and 29.21% of the $110.5 billion reais respectively (around US$53 billion).[625] In the same year, the federal government allocated $54.1 billion reais (around US$26 billion) to health expenses and, in 2009, $59.8 billion reais (around US$30 billion). In 2010, the amount increased to $62.5 billion reais (around US$32 billion), representing 13.7% of the total of $456.7 billion reais for social security.[626] Brazilian healthcare expenditures (7.5% of GDP) are below the world average (9.7%), with an even lower public share (3.6% of GDP), which is inconsistent with a public universal healthcare system.[627]

Public expenditures for medicine represent only 0.33% of GDP, whereas the average for OECD countries amounts to 0.92%.[628] Despite this, 12% of the Ministry of Health budget – $77,1 billion reais in 2011[629] – is allocated to purchase medicine[630] and the total Brazilian drug market amounts to 28 billion reais,[631] and it could reach $87 billion reais in 2017.[632] These absolute figures in economy of scale make the Brazilian market for pharmaceutical products very attractive, possibly one of the most attractive in the world, since the Brazilian government may be deemed one of the biggest individual purchasers.

Public lawsuits have reached the Brazilian Supreme Court that address the extension of the constitutional right to universal healthcare. According to the highest national court, the right to health comprises the right of having government policies to promote and protect health, as well as the right of individual citizen's to request the guarantee of this right before a court.[633] Accordingly, individuals can seek judicial orders to obtain medications from the government, which were not initially supplied by the

625 See *Interfarma*, Health access and funding, p. 7.
626 *Id.*
627 See *Interfarma*, Health access and funding, p. 14-15.
628 See *Interfarma*, Health access and funding, p. 16.
629 See *MoH*, Health budget, para. 1.
630 See *MoH*, Expenditure in medicines, p. 2.
631 See *MoH*, Industrial numbers, line 5.
632 See *Data Mark*, Brazilian Pharmaceutical Industry, para. 2.
633 See *Supreme Court*, AR on Liminar Suspension 47, p. 8-28.

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SUS, illustrating further how appealing the Brazilian government is as a large purchaser of pharmaceutical products.[634]

B. AIDS in Brazil

1) Statistics

The first case of AIDS in Brazil was reported in 1980. Data from June, 2011 shows that there are 656,701 registered cases of the illness and the government estimates that there are around 530,000 people living with HIV in the country. From the start of this epidemic until 2011, 253,706 deaths related to the disease have been reported and 38,800 new cases have been identified each year.[635] The growth of the AIDS epidemic is considered stable, with 20.2 cases for each 100,000 inhabitants.[636]

In the period from 2002 to 2011, the rate of AIDS in the Southeast area of the country, where most of the instances are concentrated (58%), dropped from 27.5 to 21 cases for each 100,000 inhabitants. In other regions the rate increased or stabilized. There was a drop from 33.7 to 30.9 in the South and from 18.5 to 17.5 in Central-West, and an increase from 9.3 to 13.9 in the Northeast and from 10.9 to 20.8 in the North. The age group of 20-59 is where most occurrences in both genders are concentrated.[637]

Although it is currently considered stable, the infection rate grew exponentially in Brazil during the 1980s. In 1990, the World Bank predicted there would be 1,200 thousand cases by 2000.[638] The Brazilian Ministry of Health later published numbers that arrived at about half of this prediction.[639] The stabilization of the AIDS epidemic in Brazil was possible only through government policies that have provided universal access to an-

634 *Id.*, p. 23-31; see also *Supreme Court*, AR on STA 361, p. 7-8; *Supreme Court*, AR on STA 328, p. 6-8.
635 See *MoH*, Aids in Brazil, para. 1.
636 *Id.*
637 *Id.*, para. 2.
638 See *World Bank*, AIDS in Brazil result story, para. 1.
639 See *IBS*, fighting AIDS, para. 2.

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tiretroviral drugs and prevention campaigns. The UN recognizes Brazil as a model to be followed by developing countries.[640]

Since the mid-1990s, the Brazilian government has granted universal access to antiretroviral treatment for AIDS. This has been the key to success of the Brazilian program against AIDS, which includes other preventive measures such as providing one billion condoms for free.[641] Data from the Ministry of Health reports that between 1997 and 2004, after the introduction of universal access to antiretroviral treatment, which combines drugs with different modes of action, there was a 40% drop in mortality, a 70% drop in morbidity and an 80% drop in hospital admissions.[642] As a result of this successful program, costs of hospital admissions and medical and ambulatory care have been reduced by over US$2.3 billion between 1997 and 2004.[643] These healthcare expenses have been replaced by the cost of the anti-AIDS program at around US$200 million.[644]

Even though the program has been successful, because of the constant but increasing number of patients, the enlarged life expectancy of treated patients, the need to administer second and third generation drugs – which are more expensive and often subject to patent protection – has led to a significant increase in government expenditures. On average there are an estimated 33,000 new diagnosed cases in the country and each year almost 20,000 new patients are incorporated into the program.[645] From 2004 to 2005, expenditures on antiretroviral drugs increased 60%, raising spending by the Ministry of Health from US$250 million to US$490 million, yet the number of patients rose less than 10%.[646]

640 See *The Economist*, Brazil AIDS programme, para. 2; and *World Bank*, AIDS in Brazil result story, para. 3.
641 See *World Bank*, AIDS in Brazil result story, para. 6, item 14.
642 See *MoH*, 2008 Brazilian Health, p. 139.
643 *Id.*
644 See *Teixeira, Vitoria, Barcarolo*, Antiretroviral treatment: the Brazilian experience, para. 9.
645 See *Greco, Simão*, Brazilian policy of universal access to AIDS treatment, p. 37-45.
646 See *MoH*, Antiretroviral drugs expenditure report.

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2) The Anti-AIDS Program

After the first diagnosis in the early 1980s, AIDS in Brazil quickly evolved as an epidemic and demanded the attention of government at the national level. In 1986, the Ministry of Health created the National Sexually Transmitted Diseases and AIDS Program, by means of Ordinance 236/1985, and demanded that AIDS be treated as a public health priority. The National Program comprised policies and strategies to prevent and provide assistance in this area under the umbrella of Articles 6 and 196 of the Federal Constitution that guarantee the right to health and that mandate universal healthcare, as well as Law 8080/1990 that regulates government obligations regarding public health.

Despite unorthodox and controversial measures, the Brazilian national program combating HIV and AIDS was able to reach many different groups, including those that represented a high level of transmission. In contrast to many other countries, early on, priority was placed on an aggressive campaign promoting the use of condoms, which included free distribution during the carnival festival. This initiative resulted in an increase from 4% in 1986 to 48% in 1999, and 55% in 2003, of the use of condoms during first sexual encounters.[647] Groups of prostitutes were targeted and received informational material and condoms.[648] The program has included also supply of disposable syringes, resulting in a decrease of HIV infections among users of illicit injected drugs from 52% in 1999 to 41.5% in 2001.[649] One of the program's principal measures, seeking to reduce mortality and enhance the quality of life of patients, is free treatment within the SUS.

Pharmaceutical assistance under the SUS system is provided by Article 6 of Law 8080/1990, which establishes statutory access to medicine. By means of Ordinance 3916/1998, the Ministry of Health approved the National Drug Policy, aiming to guarantee safe, effective and quality drugs at the lowest cost possible, as well as to promote access to essential medicines. The guidelines of the Policy include a) adoption of a list of essential medicines, b) sanitary regulation of drugs, c) broadening the scope of pharmaceutical assistance, d) promotion of rational use of medicines, e) scientific and technological development, f) promotion of drug production,

647 See cited: *Levi*, *Vitória*, Fighting against AIDS, p. 2374.
648 See *Reel*, Where Prostitutes Also Fight AIDS, para. 5-6.
649 See cited: *Levi*, *Vitória*, Fighting against AIDS, p. 2375.

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g) guarantee of safety as well as efficacy and quality of drugs, and h) development and enablement of human resources. The Policy must meet constant changes in the Brazilian epidemiological profile, which encompasses diseases typically found in developing countries as well as those often found in developed countries. Adopting a national list indicating what pharmaceutical active ingredients are deemed basic and indispensable for the treatment of a broad spectrum of diseases is important within the context of the National Sexually Transmitted Diseases and AIDS Program. Since antiretroviral drugs are on this list, their acquisition is managed by the federal government by means of the Ministry of Health.

The key to combating mortality and enhancing quality of life of patients is the universal and free distribution of antiretroviral drugs as of the enactment of Law 9313/1996. The statute embodies the National Sexually Transmitted Diseases and AIDS Program and mandates that carriers of HIV and AIDS receive every medication needed for their treatment free of charge through the SUS. The Ministry of Health is responsible for issuing standards indicating the drugs to be used in each stage of the infection and disease, so as to guide the purchase of the medications by the SUS managers.[650] The drugs purchased by the federal government are, then, combined (commonly referred to as the anti-AIDS cocktail) and distributed to patients registered in the program in accordance to the prescribed treatment and they are not sold in pharmacies.[651]

Despite positive results, increasing expenditures for purchasing antiretroviral drugs have posed a threat to the long-term existence of the Brazilian program. From 1996 until 2005, around US$2.5 billion were spent to purchase antiretroviral drugs: six of them, namely, AZT, lamivudina, tenofovir, efavirenz, atazanavir and lopinavir/r, were responsible for the increase of US$284 million in expenditures between 2001 and 2005.[652] In 2005, the National Program's effective expenditure of US$500 million exceeded the expected budget of US$250 million, which already repre-

650 See article 1 of Law 9313/1996.

651 The current drugs used in the program are: Abacavir, Didanosina, Estavudina, Lamivudina, Tenofovir, Zidovudina (AZT), Efavirenz, Nevirapina, Etravirina, Atazanavir, Darunavir, Fosamprenavir, Indinavir, Lopinavir/r, Nelfinavir, Ritonavir, Saquinavir, Tipranavir, Enfuvirtida and Raltegravir. See *MoH*, Antiretrovirals. For more information on the treatment, see *MoH*, HIV Infected Adults Antiretroviral Therapy Recommendation, p. 126-128.

652 See *Nunn*, *et al.*, Anti-retroviral Drug Cost in Brazil, p. 4-6.

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sented almost 2% of the entire budget of the Ministry of Health. Importation of nelfinavir, efavirenz, lopinavir/r and tenofovir was responsible for 50% of these expenditures.[653] In 2005 and 2006, the government spent 11% of the Ministry's total expenditures only on the purchase of efavirenz.[654]

The increase in cost for the National Sexually Transmitted Diseases and AIDS Program is due to a combination of factors: a) each year there are more HIV carriers and AIDS patients initiating treatment; b) the treatment itself extends the lives of patients and, consequently, the term during which they will receive treatment; c) the longer the treatment period, the higher the risk and probability that patients will develop resistance to administered drugs, leading to the need for second and third generation antiretroviral drugs, which are more expensive and often patented; d) as of the enactment of Law 9279/1996, patenting pharmaceutical products is permitted, which restricts production of generic versions of drugs until patents expire; e) the national pharmaceutical industry does not have the technological capacity to produce generic versions of drugs covered by patents if compulsory licenses are granted; and f) more types of antiretroviral drugs are being used in order to include more innovative drugs in the anti-AIDS cocktail.[655] In order to maintain financial sustainability in the National Program, which reached its pinnacle in 2005,[656] the Brazilian government has adopted measures including national production of antiretroviral drugs, negotiations with the international pharmaceutical industry for price reductions, and granting of a compulsory license for efavirenz.

C. The Cases of Kaletra and Efavirenz

At the beginning of 2001, the Brazilian government announced that it was considering issuing compulsory licenses for the patents covering nelfi-

653 See 2005 Annual Budget Law; *MoH*, Antiretroviral drugs expenditure report; *MoH*, HIV Infected Adults Antiretroviral Therapy Recommendation, p. 129; See *Nunn*, *et al.*, Anti-retroviral Drug Cost in Brazil, p. 4-6.

654 See *MoH*, Antiretroviral drugs expenditure report.

655 See *Hoirisch*, Drugs Compulsory License as a Public Policy:_Efavirenz case, p. 64.

656 See *MoH*, Antiretroviral drugs expenditure report.

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navir (marketed in Brazil by Roche under the brand Viracept) and efavirenz (owned by Merck, Sharp & Dohme and marketed under the brand Stocrin), two drugs used in the anti-AIDS cocktail administered to patients in the National Sexually Transmitted Diseases and AIDS Program.[657] In March 2001, the Ministry of Health and Merck started negotiations and in November of the same year agreed to an additional price discount of 59% (the new cost of daily treatment was reduced to US$2.52 from US$6.96 when the drug was first launched). This discount was in addition to the price already reduced by 11.7% in exchange for not granting compulsory licenses of the patented efavirenz drug.[658] In August 2001, a settlement was also reached between the government and Roche for a 40% discount after threatening to give a compulsory license for nelfinavir patents, which would be then manufactured by the state-owned laboratory FarManguinhos.[659]

On June 24, 2005, the Ministry of Health enacted Ordinance 985, declaring the medicine containing the combination of the active ingredients lopinavir and ritonavir to be in the public interest. The combination of the antiretrovirals lopinavir and ritonavir is marketed by Abbott under the brand Kaletra, which is also part of the cocktail of drugs used in the treatment of AIDS. The Ordinance affirms that its declaration of public interest follows Article 71 of Law 9279/1996, which allows the government to grant *ex officio* compulsory licenses in cases of national emergency and public interest, citing the impact of the drug's price on the public budget and the maintenance of the National Sexually Transmitted Diseases and AIDS Program.[660]

After publication of Ordinance 985/2005, the National Health Council issued Resolution 352 of August 11, 2005, stating that negotiations with the laboratories owning the patents covering efavirenz, lopinavir and tenofovir have failed to result in a significant price reduction. The Resolution ended negotiations, enabling compulsory licensing of the respective patents and determining the local manufacturing of the drugs by investments that would strengthen state-owned laboratories and increase resources for research and development. The Resolution's preamble alleges that the high cost of the drugs may jeopardize the long-term existence of

657 See *Rodrigues*, *Soler*, Efavirenz compulsory license in Brazil, p. 553-554.
658 See *Sanches*, Compulsory licenses: facts and myths, p. 5.
659 See *Roche*, Roche and Brazilian Ministry of Health agreement, para. 3.
660 See Ordinance 985/2005, Preambles, para. 4-5, 8.

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the National Program,[661] but does not point out that the patent owners were using their economic power in an abusive manner. Nevertheless, on November 9, 2005, during a meeting of the National Health Council, the Minister of Health declared in a technical note that he would not ratify Resolution 352/2005, despite having initially signed it. Thus, the compulsory license for Kaletra, tenofovir and efavirenz patents would not be granted, since, contrary to Resolution 352/2005, negotiations with the patent owners were generally positive and should be reinstated.[662] It is important to note that the government's modus operandi always consists of threatening to grant compulsory licenses in order to obtain discounts on drug prices.

The settlement reached between the government and Abbott provided that Kaletra be supplied at a price of US$0.63 per tablet, as of February 26, 2006 and should be maintained until December 31, 2011. The new price represented a 46% reduction in the original price.[663] The agreement also established that Kaletra's new formulation, branded Meltrex, would be supplied at a 10% price increase.[664] The settlement with Abbott was shown to be more favorable for the government, since the national production of the drug would take at least two years and the lowest offer to the government for importing the drug was US$0.72, a higher price than Abbott's proposal.[665]

A civil class action was filed on December 1, 2005, by the Office of the Attorney General and NGOs against this settlement between Abbott and the Ministry of Health, seeking the granting of compulsory license of the Kaletra patents, arguing that national laboratories would be able to product the pills at US$0.41.[666] On May 8, 2006, the preliminary injunction was denied by the judge of the 15th Federal Trial Court of Brasilia. The decision was based on the lack of evidence concerning feasibility of the US $0.41 price and insufficient data regarding how the government would be able carry out the compulsory license, considering the investments needed

661 See Resolution 342/2005, Preambles, para. 4.
662 See *MoH*, 160ª CNS Ordinary Meeting Record, p. 4.
663 See *MoH*, Government and Abbott agreement, p. 2.
664 See *Id*., p. 3.
665 See *MoH*, Kaletra counterproposal, para. 4.
666 See *Ministério Público Federal v Abbott*, Initial Appeal, p. 11, 46-48.

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to enable national facilities for production.[667] The Federal Court of Appeals for the 1st Circuit confirmed this decision, rejecting the preliminary injunction and affirming that the Brazilian government acted according to its best judgment with no evidence showing violation of the law simply because it is possible to have the drugs purchased at a lower price.[668] On June 25, 2010, the trial court judge rendered a final decision rejecting the granting of compulsory licenses.[669] The appeal filed before the Court of Appeals for the 1st Circuit is now pending.[670]

Since efavirenz was introduced in the anti-AIDS cocktail in 1999, its use has progressively increased from 2,500 patients in 1999 to 75,000 patients in 2007, or 42,29% of patients treated in that year.[671] Due to such a high number of patients, efavirenz was seen as a threat to public finances and expenditures with the anti-AIDS cocktail. In 2006, the Brazilian government started to negotiate the price of efavirenz with Merck, arguing that the international laboratory marketed the drug at a lower price in countries like Thailand with the same Human Development Index,[672] yet demand in those countries would not be as big as in Brazil. The government alleged that while only 17,000 people in Thailand were submitted to treatment, 75,000 patients in Brazil were taking efavirenz, and, in spite of this, the price the Brazilian government was being charged was US $1.5920 per tablet – much higher than the US$0.65 offered in Thailand due to generic competition after a compulsory license had been granted in that country.[673] Brazil requested a discount so as to obtain the same US $0.65 price as Thailand; Indian generic versions would be much cheaper

667 See *Ministério Público Federal v Abbott*, Preliminary Injunction Trial Court Judgment, p. 3.

668 See *Ministério Público Federal v Abbott*, Preliminary Injunction Appellate Court Judgment.

669 See *Ministério Público Federal v Abbott*, Process Consultation on Trial Court Judgment, para. 34.

670 To see, insert "200601000227328" on *Federal Court of Appeals for the 1st Circuit*, Process Consultation.

671 See *MoH*, UNGASS – HIV/AIDS: Brazilian progress in 2005/2007, p. 86-87.

672 Merck makes use of price differentiation for determining efavirenz price based on a country's Human Development Index or HIV patient number. The price of the drug ranges from US$277.40 to US$697.00 per patient each year. See *Hoirisch*, Drugs Compulsory License as a Public Policy: Efavirenz case, p. 77; *MoH*, compulsory licensing of Efavirenz, item 4; and *Merck*, Commitment to HIV/AIDS, p. 3-4.

673 See *MoH*, compulsory licensing of Efavirenz, item 4.

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at a cost of US$0.427 to US$0.443 per tablet.[674] Negotiations with Merck evolved until the end of April 2007, when the laboratory's final proposal was a price of US$1.10, reducing 84% of its initial US$6.96 price in 2000,[675] which was deemed unacceptable by the Brazilian government.[676]

Unable to obtain the same discount offered to the Thai government, the Brazilian Minister of Health enacted Ordinance 886 of April 24, 2007, declaring that efavirenz was of public interest. The objective was to grant a compulsory license for non-commercial public use in order to guarantee feasibility of the National Sexually Transmitted Diseases and AIDS Program and safeguard the continuity of free and universal access to all medications needed for the treatment of HIV and AIDS.[677] The Ordinance expressly mentions the Doha Declaration and the recognition that WTO Member States are entitled to make full use of flexibilities in TRIPS when adopting measures to protect public health.[678] Despite new attempts at negotiation, in which Merck's US$1.10 offer was refused,[679] Decree 6108, of May 4, 2007, was enacted granting *ex officio* compulsory licenses of Brazilian patents PI1100250-6 and PI9608839-7 for public interest,[680] upon payment of royalties at 1.5% over the cost production or the price of the drug delivered to the Ministry of Health.[681] Patent PI1100250-6, a pipeline patent entitled "benzoxazinones as inhibitors of HIV reverse transcriptase" was granted on August 9, 1999, with expiration on August 7, 2012, composed of claims covering efavirenz compounds and pharmaceutical compositions.[682] Patent PI9608839, entitled "compound and compound N-(4-methoxybenzyl)-6-chloro-2[(R)-cyclopropylethynyl-hydroxy-trifluoromethyl]-methyl chiral aniline" was granted on June 21, 2005, with expiration on May 21, 2016, covering intermediate compounds in the process of obtaining efavirenz.[683]

The compulsory license has been granted for a five-year term (ending on May 7, 2012), but is renewable for an equal period without exclusivity

674 See *MoH*, UNGASS – HIV/AIDS: Brazilian progress in 2005/2007, p. 87.
675 See *Sanches*, Compulsory licenses: facts and myths, p. 5.
676 See *MoH*, Explanatory note, item 4.
677 Article 1 of Ordinance 886/2007.
678 See Ordinance 886/2007, Preambles, para. 6.
679 See *Sanches*, Compulsory licenses: facts and myths, p. 6.
680 Article 1 of Decree 6108/2007.
681 Article 2 of Decree 6108/2007.
682 To see, insert "PI1100250-6" on *INPI*¸ Patent Process Database, claims 1-5.
683 To see, insert "PI9608839-7" on *INPI*¸ Patent Process Database, claims 1-2.

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and for non-commercial public use within the National Sexually Transmitted Diseases and AIDS Program and pursuant to Law 9313/1996 in order to provide for universal and free distribution of antiretroviral drugs.[684] Decree 6108/2007 determines that the license will be terminated by means of an act from the Ministry of Health once the circumstances of public interest cease to exist.[685] The royalties to be paid to Merck were established at 1.5% of the drug production cost or of the drug price upon delivery to the Ministry of Health.[686] Merck is obligated to supply all the necessary and sufficient information for the effective reproduction of the licensed patents[687] under the penalty of having the patents declared invalid for lack of enablement.[688] The exploitation of licensed subject matter should be primarily carried out directly by the federal government or by duly hired third parties.[689] Nevertheless, if it is not possible to satisfy the needs of public interest through the products placed in the domestic market, or if the total or partial production of the licensed subject matter by the government shows to be unfeasible, importation is allowed upon due payment of royalties.[690] For record keeping purposes, the Ministry of Health must inform the INPI of the granting of the compulsory license by means of Decree 6108/2007 as well as any modifications and termination.[691]

Brazil has not immediately started national production of efavirenz. At first, it imported the drug from Indian laboratories Aurobindo and Ranbaxy,[692] by means of the UNICEF and the Pan American Health Organization (PAHO – the regional office of the WHO for the Americas) respectively.[693] The first batch arrived in the country on June 2, 2007, at a final

684 Article 1, paragraph 1 of Decree 6108/2007.
685 Article 1, paragraph 2 of Decree 6108/2007.
686 Article 2 of Decree 6108/2007.
687 Article 3 of Decree 6108/2007. Article 3 of the Decree 6108/2007 was outlined pursuant to paragraph 1 of article 5, item II of Decree 3201/1999.
688 Article 3, sole paragraph of Decree 6108/2007.
689 Article 4 of Decree 6108/2007.
690 Article 5 of Decree 6108/2007.
691 Article 6 of Decree 6108/2007.
692 The two Indian laboratories were selected among the manufacturers which already had efavirenz in the pre-qualification system established by the World Health Organization (WHO) meeting certain quality, safety and efficacy standards. See *Hoirisch*, Drugs Compulsory License as a Public Policy: Efavirenz case, p. 79; and *MoH*, compulsory licensing of Efavirenz, item 7.
693 See *MoH*, UNICEF and PAHO mediation; and *MoH*, UNGASS – HIV/AIDS: Brazilian progress in 2005/2007, p. 87.

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cost between US$0.4270 and US$0.4430 per tablet.[694] The Ministry of Health initially estimated that national production would start by 2009 in the state-owned laboratories Farmanguinhos and LAFEPE.[695] The first batch manufactured by Farmanguinhos has not fulfilled the bioequivalence requirement after a change was introduced in the original formulation as an alternative to avoid importing one of the original ingredients; this eventually resulted in the need to import the ingredient and caused further delay for delivering a nationally manufactured efavirenz.[696] LAFEPE has not fulfilled a regulatory requirement of the ANVISA and Farmanguinhos remains the only laboratory manufacturing efavirenz in the country.[697] The first efavirenz pills produced by Farmanguinhos were sold at 45% of Merck's price (approximately US$0.67) before the compulsory license.[698] Farmanguinhos supplied 60% of the Brazilian demand and, until 2010, the remainder was still imported from India. This stock lasted until 2011, when the Brazilian supply became fully domestic.[699] The Ministry of Health ordered 57 million pills of efavirenz from Farmanguinhos in 2012 at approximately US$38.5 million.[700] It is estimated that around 50% of people in treatment (about 104,000 people) make use of efavirenz in their therapeutic regimen.[701]

On May 7, 2012, Decree 7723/2012 was published extending the term of the compulsory license of patents 1100250-6 and 9608839-7 covering efavirenz for public non-commercial use for another five years.[702]

Decree 4830/2003 was issued on September 5, 2003, amending the existing Decree 3201/1999 regulating the *ex officio* granting of compulsory licenses in the cases of national emergency and public interest, and specifically allowed the importation of the licensed patent subject matter in case the government or duly authorized third parties are not able to manufac-

694 See *MoH*, Positive Response; and *Hoirisch*, Drugs Compulsory License as a Public Policy:_Efavirenz case, p. 78-79.
695 See *Agência Brasil*, Brazil starts producing generic against AIDS in 2009, para. 1.
696 See *Hoirisch*, Drugs Compulsory License as a Public Policy:_Efavirenz case, p. 108-110.
697 See *Globo*, Nacional production of generic AIDS, para.7.
698 See *Estado de São Paulo*, Efavirenz price, para. 1.
699 See *MoH*, compulsory licensing of Efavirenz renew, para. 3.
700 *Id.*
701 *Id*., para. 1.
702 See article 1 of Decree 7723/2012.

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ture it in the country. The provisions of the Decree should apply to the antiretroviral drugs used in the treatment of AIDS as facts of public interest should be understood to comprise issues related to public health.[703] The use of these antiretroviral drugs in the National Program does concern Brazilian public health, and the granting ex officio of compulsory licenses for public non-commercial use whenever the patent holder does not meet the needs of the public interest should be allowed. In the case of efavirenz, the public interest consisted in the government's budget for maintaining the National Program. With immediate savings of US$31.5 million,[704] pharmacoeconomic numbers in the Ministry of Health budget has illustrated the public interest. The primary interests of society are related to the budget and are reflected in the National Program context. Five years after the compulsory license was granted, foreign investments have not yet diminished in the country as the Brazilian government is still an important player for the global pharmaceutical industry because it remains a major purchaser of drugs (not only antiretroviral drugs).

The settlement between Abbott and the Brazilian government regarding the price of Kaletra has not brought an end to discussions revolving around patent PI1100397-9 covering lopinavir. In 2009, the Brazilian pharmaceutical company Cristalia filed a lawsuit before the 9th Federal Trial Court of Rio de Janeiro against Abbott seeking to invalidate pipeline patent PI1100397-9, entitled "compounds to inhibit retroviral proteases".[705] According to Cristalia, patent PI1100397-9 should be declared null because it was granted without examination of the patentability requirements including novelty, inventive step and industrial application (like the other pipeline patents), and without the prior consent of the ANVISA, in violation of Article 229-C of Law 9279/1996.[706] As a pipeline patent, it was granted in disrespect to the Brazilian constitutional provisions protecting acquired rights (society would have already acquired the right to use PI1100397-9 related subject matter as it would have already entered the public domain).[707] Cristalia argues that patent PI1100397-9 prevents competitors from manufacturing lopinavir until 2016, which would result in

703 See article 2, paragraph 2 of Decree 3201/1999.
704 See *MoH*, compulsory licensing of Efavirenz renew, para. 2.
705 *Cristália v INPI*, Trial Court Process.
706 *Cristália v INPI*, Trial Court Process, p. 2.
707 *Id.*

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damages to the government's budget by increasing costs for the National Program and would restrict universal access to medications.[708]

The trial court judgment rendered on February 29, 2012, established that the patent was allowed by the INPI on November 23, 1999, prior to the enactment of Provisional Ruling 2006 on December 14, 1999, which first introduced Article 229-C into Brazilian legislation.[709] Accordingly, pipeline application PI1100397-9 should not be subject to the prior consent of ANVISA for final granting, as only the issuance of the letters patent upon payment of the due fees were still pending.[710] However, it declared that pipeline patents were unconstitutional; since novelty, which is one of the main requirements for granting a patent that justifies the existence of a patent system within the context of fostering innovation, cannot be found in this type of application.[711] The legal monopoly represented by a patent would be extremely detrimental to free competition, which is highly important in the pharmaceutical sector, a sensitive area regarding the welfare of society.[712] The judgment declared the unconstitutionality of patent PI1100397-9,[713] which only affects Abbott's patent that was under discussion, regardless of the constitutional lawsuit pending before the Supreme Court (ADIN 4234).[714] The appeal filed by Abbott against this judgment is currently pending before the Court of Appeals for the 2nd Circuit.

D. Impacts of the WTO Free Trading System on Brazil

As a result of Brazil's accession to the WTO free trading system, the country's commodities exports have experienced a boost. Total exports reached US$197.942 million in 2008 as a result of the increased volume of the country's participation in international trade since 1994.[715] Basic goods contributed at 36.9%, manufactured goods had a share of 46.8% and semi-

708 *Id.*
709 *Id.*, p. 8.
710 *Id.*
711 *Id.*, p. 12, 18.
712 *Id.*, p. 14, 18.
713 *Id.*, p. 18.
714 See footnote 384.
715 See *MDIC*, Evolution of Brazilian exports, line 55.

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manufactured goods were at 13.7%.[716] During the global economic crisis, Brazilian exports experienced a small decline, but remained high in the amount of US$152.995 million with basic and manufactured goods maintaining a very close 40.5% and 44% respectively.[717]

In addition, the country has learned how to make use of the WTO system for its benefit as seen in the complaint against the United States for subsidies on upland cotton, which led to threats of retaliation regarding intellectual property rights.[718]

1. The Panel Against the US for Cotton Subsidies

On September 27, 2002, the Brazilian government requested consultations with the US under the WTO system of Dispute Settlement Understanding, questioning the consistency of US subsidies and export credit guarantee programs with the WTO Agreement on Agriculture and the Agreement on Subsidies and Countervailing Measures.[719] The panel that was established on March 18, 2003, issued its final report on September 8, 2004, finding that US subsides and export credit guarantee programs for unscheduled agricultural products, which include upland cotton and rice, circumvented the provisions of the Agreement on Agriculture and were not covered by the exemptions provided by the Agreement on Subsidies and Countervailing Measures.[720] The decision was confirmed by the Appellate Body, which issued its report on March 3, 2005.[721]

In compliance with the decision of the WTO Dispute Settlement Body (DSB), the US ceased their export credit guarantee programs, but continued to provide subsidies on upland cotton. Upon a Brazilian request to adopt countermeasures suspending its obligations to the US, a panel was established and found that the US had failed to comply with the recom-

716 *Id.*
717 *Id.*
718 The WTO dispute settlement mechanisms should be considered a check and balance means for controlling the international legal order after the WTO and TRIPS has a key functional role with direct impacts in the balance of the global economy. See *Straus*, A Marriage of Convenience: World Economy and Intellectual Property, p. 662-666.
719 See *United States – Upland Cotton*, Key Facts, para. 1.
720 See *United States – Upland Cotton*, Report of the Panel, p. 347-351.
721 See *United States – Upland Cotton*, Report of the Appellate Body, para. 763.

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mendations and rulings adopted by the DSB in the original procedure, as per a report issued on December 18, 2007.[722] On appeal, this understanding was confirmed by the report issued by the appellate body on June 2, 2008.[723]

As a result, Brazil requested authorization to implement countermeasures as well as to adopt retaliation measures on importation of goods, services and intellectual property rights.[724] An arbitration decision was rendered on August 31, 2009, establishing that Brazil was allowed to retaliate to the amount of US$829 million, authorizing cross-retaliation on services and intellectual property rights (under GATS and TRIPS respectively) for US$238 million.[725] The remaining US$591 million would result from retaliation on goods (under GATT 1994) by increasing tariffs for imports of US products such as cars, boats, wheat, ketchup and paracetamol, as listed by the Brazilian Chamber of Foreign Trade (CAMEX) in Resolution 15, of March 5, 2010.[726]

1.1. Cross-retaliation on IP rights

Article 22 of the DSU provides for retaliation in case official recommendations by the WTO Dispute Settlement Body have not been implemented in due course. Retaliation measures may consist of compensation and halting concessions or obligations deriving from WTO treaties and are considered temporary measures aimed at securing the implementation of the decision instated by the panel or appellate body. The general principle establishes that the concessions or obligations to be halted should first be within the same area in which the original violation of WTO provisions occurred; in case this is unfeasible or ineffective, sanctions should pertain to another section of the violated agreement.[727] In the latter case, as a sub-

722 See *United States – Upland Cotton*, Recourse to Article 21.5 of the DSU by Brazil, Report of the Panel, p. 188-190.
723 See *United States – Upland Cotton*, Recourse to Article 21.5 of the DSU by Brazil, Report of the Appellate Body, p. 175-178.
724 See *United States – Upland Cotton*, Communication from Brazil, para. 3.
725 See *United States – Upland Cotton*, Recourse to Arbitration by the United States under Article 22.6 of the DSU and Article 4.11 of the SCM Agreement, Decision by the Arbitrator, p. 124.
726 See *Brasil*, Brazilian retaliation list of products, para. 4.
727 See article 22.3 (a) and (b).

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sidiary measure, cross-retaliation is possible, when other options are ineffective and the circumstances are serious enough, enabling suspension of concessions or obligations that fall under a completely different WTO agreement.[728]

Even before the end of the dispute settlement proceedings on US subsidies on cotton, following the favorable report published in 2007, bills of law were submitted to the Brazilian Congress aimed at establishing a procedure that would enforce an eventual cross retaliation. The most important piece was Bill of Law 1893/2007, which aimed at establishing measures to temporarily suspend or remove IP rights in Brazil in case of noncompliance with multilateral obligations under the WTO by a foreign State, and was conceived as a tool for commercial pressure. This measures affected copyrights including software, trademarks, geographical indications, patents, plant varieties, integrated circuit topographies and trade secrets comprising confidentiality of data packages.

The Brazilian President enacted Provisional Measure 482/2010 on February 10, 2010, which provided for measures suspending obligations related to the TRIPS Agreement as a form of retaliation under the WTO Dispute Settlement Understanding. This provisional measure was based on Bill of Law 1893/2007 and established measures against IP rights (copyrights including software, trademarks, geographical indications, patents, plant varieties, integrated circuit topographies and trade secrets comprising confidentiality of data packages) upon authorization by the WTO Dispute Settlement Body including a) reducing the term of protection for IP rights, b) providing compulsory licenses, c) allowing parallel importation of patented products, d) increasing official fees for obtaining and maintaining IP rights, e) temporarily prohibiting that royalties are remitted abroad, and f) creating a registration requirement for obtaining and maintaining IP rights.

Natural persons who are nationals or residents of countries against which Brazil has been authorized to retaliate, as well as companies therein headquartered or established, are affected by cross-retaliation. In the cotton dispute scenario, the measures would be applicable against US residents or nationals with IP rights in Brazil. Provisional Measure 482/2010 was fully approved by Congress, converted into Law 12279/2010, and came into force as of June 22, 2010.

728 See article 22.3 (c).

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Following the enactment of Provisional Measure 482/2010, the Brazilian Chamber of Foreign Trade (CAMEX) published Resolution 16, on March 12, 2010, opening public consultation proceedings to hear interested parties regarding cross-retaliation measures against IP rights in the US cotton dispute. Following the general lines of the provisional measure, Resolution 16/2010 suggests a range of IP-related measures to be taken. They include: a) reduction of the term of protection for a certain period of time for patents covering medications for human and veterinary use, chemical and biotechnological products and processes for agriculture, IP rights on plant varieties, as well as copyright over public performance of musical works; b) royalty-free compulsory license of patents covering medications for human and veterinary use, chemical and biotechnological products and processes for agriculture, IP rights on plant varieties, as well as copyright over literary works and public display of audio-visual works; c) importation without consent of the patent holder of products protected by patents covering medications for human and veterinary use, chemical and biotechnological products and processes for agriculture, allowing parallel importation of branded drugs and importation of generics; d) increase of official fees charged by the INPI regarding patents, trademarks, utility models, industrial designs, software registration, geographical indications, integrated circuit topographies and record of licenses, as well as the fees charged by the Plant Variety Protection Office and by the entities responsible for copyright registration; e) application of commercial rights over royalties to be paid to owners of patents, trademarks and copyrights including software; and f) creation of mandatory registration as a requirement for obtaining and maintaining copyrights.

The enactment of Provisional Measure 482/2010 (at the time Bill of Law 1893/2007 was still pending in Congress) and the issuance of Resolution 16/2010, served as a tool for political maneuvering. US companies or citizens who owned or licensed IP rights in Brazil, as well as foreign companies located or with principal place of business in the US could be affected. Under assessment of the Brazilian government, retaliation on goods could pose trouble, but threatening to suspend patent protection for pharmaceutical products could result in pressure from the industry to push the US government to halt subsidies and to negotiate.[729] Moreover, sus-

729 See *Varella*, Effectiveness of DSB, p. 15-17; *Hoirisch*, Drugs Compulsory License as a Public Policy: Efavirenz case, p. 82-85.

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pending IP rights would lead to a decrease in prices, benefiting consumers, whereas retaliating on goods would lead to price increase of products imported from the US.[730]

The provisions in the TRIPS Agreement were part of the package that developing countries had to accept in order to benefit from a multilateral trading system.[731] Thus, Brazil has been using all means available under the WTO system in order to ensure that the rulings by the Dispute Settlement Body are enforced.

1.2. Ongoing Discussions

As negotiations evolved with the US government, Brazil decided to postpone retaliations both on goods and IP rights until 2012, when the US Congress would vote on an agricultural reform bill (the Farm Bill), provided that a fund was created to support Brazilian cotton producers to the amount of US$147 million per year,[732] representing compensation, partial reduction and annual limitations on US subsidy programs.[733] The defeat of the governing party in the US congressional election on November 11, 2010, resulted in uncertainties regarding the approval of a new US Farm Bill that would reduce subsidies. In fact, the approval of an amendment to the 2012 agriculture budget by the US House of Representatives on June 16, 2011, posed a more serious threat to the agreement reached between the two countries. The amendment ended the US$147 million annual payments in order to reduce US public expenditures.[734] Nevertheless, the US Senate decided to maintain the payments.[735]

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730 See *Varella*, Effectiveness of DSB, p. 15-17.

731 For more on the relationship between GATT, TRIPS and the use of the WTO dispute settlement mechanism, see *Straus*, A Marriage of Convenience: World Economy and Intellectual Property, p. 642-654, referred by this author as a "marriage of convenience".

732 The Instituto Brasileiro do Algodão (IBA) has been discussing with the state associations of cotton producers the management of the and the activities and measures to be implemented, such as investments in environmental sustainability, infrastructure and training. See *Dinheiro Rural*, Interview with IBA president, p.1.

733 See *Id*.

734 See *Estado de São Paulo*, Resumption of the cotton case?, p. 1.

735 See *Farm Policy*, Senate Farm Bill Issues, p. 1.

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As the new Farm Bill was being been discussed in the US Congress, the subsidies contested by the Brazilian government have been replaced by an income protection program named Stax, which is an insurance policy for cotton growers that assures the income of farmers will not fall below the expected regional revenues.[736] According to the statement by the Brazilian ambassador to the WTO, Roberto Azevedo, no program covering for such income losses is compliant with WTO and challenging IP rights seems to be the only way to engage the US.[737] In June 2012, the CAMEX decided to reactivate the working group that had been evaluating the issue of cross-retaliation.[738] A progressive reduction in the US federal budget as of March 2013 opened a new round of debates and the US Secretary for Agriculture announced that the US would suspend monthly payments to Brazilian cotton producers as of October 2013.[739] In response, the Brazilian Ministry of Foreign Affairs announced that cross-retaliation relating to IP rights and services was still on the table.[740]

With the final approval of the US Farm Bill providing for the Stax income protection program by the US Congress at the beginning of 2014 after several years of discussions,[741] and consequently the end of the temporary agreement reached with the US to postpone retaliations, it is now up to Brazilian officials to assess whether or not to exercise the right to cross-retaliate[742] and, hence, establish a precedent within the WTO trading system.[743]

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736 See *The Guardian*, Cotton subsides in farm bill, para. 12.

737 *Id*., para. 13, 17.

738 See *Brazil – US Business Council*, CAMEX, assess retaliation to US, para. 1, 3.

739 See *Estado de São Paulo*, the US suspend payment of indemnification to Brazilian producer, para. 3, 7.

740 See *Exame*, Brazil does not discard retaliating the US in the cotton case, p. 1.

741 See *Fox* News, Congress approves farm bill, sends to Obama for signature, para. 1, 7.

742 Already envisaging the approval of the US Farm Bill, the working group of CAMEX intensified its discussions on cross-retaliation and, on December 19, 2013, re-opened public consultations about the measures foreseen in Resolution 16/2010 by means of Resolution 105/2013. This new resolution seeks to reinstate internal proceedings within the CAMEX for a recommendation regarding the adoption or not of cross-retaliation in intellectual property rights, which should be established until February 28, 2014 pursuant to its article 4.

743 Cross-retaliation was also requested by Ecuador against the European Communities (see *European Communities – Regime for the Importation, Sale and Distribution of Bananas.* Recourse to Arbitration by the European Communities under

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Despite settlements eventually reached, cross-retaliation against IP rights may run against some considerations regarding Constitutional Law. As discussed in the previous chapter, IP rights in Brazil are guaranteed under Article 5, XXVII and XXIX of the Constitution. Intellectual property is granted protection to be statutory regulated, keeping in mind the interests of society and technological and economic development of the country. This constitutional finalistic clause must underline the granting of patents along with any limitations to them.

Laws restricting fundamental constitutional guarantees are subject to limitations – entitled "limitations to limitations" – and requirements in order to safeguard such guarantees, which could otherwise become void.[744] The governing principle is the prohibition against excesses, according to which limitations should a) enable the intended purposes, b) be needed since there is not a less cumbersome way to achieve such purpose and c) be proportional demanding a reflected analysis of the burden caused and benefit brought.[745] Any law restricting a constitutional guarantee should comply with the three requirements; even if adequate and needed, it should be deemed unconstitutional if it adopts measures constraining rights that are excessive and are not proportional to the obtained results. The proportionality principle acts as a mechanism to limit and control ordinary laws passed by Congress.

Any legislation limiting IP rights, which are safeguarded as fundamental guarantee in the Constitution, should only be pursued in order to defend any other constitutionally protected rights or values. Limits should also comply with the following two requisites. 1) They should be proportionate, connecting the restriction with constitutionally foreseen goals. 2) The restriction should also aim at the economic and technological development of the country. Nevertheless, limits should respect the proportionality principle, paying attention to its adequacy, need, burden imposed, and benefits brought.[746]

Article 22.6 of the DSU, Decision by the Arbitrators, March 24, 2000 (WT/DS27/ARB/ECU), para. 173) and by Antigua against the US (see *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Service.* Recourse to Arbitration by the United States under Article 22.6 of the DSU, Decision by the Arbitrator, Deceber 21, 2007 (WT/DS285/ARB), para. 1.5). Upon the threat of cross-retaliation, these cases also reached a settlement.

744 See *Canotilho*, Constitutional Law and theory of the Constitution, p. 451.

745 See *Barroso*, Interpretation and application of the constitution, p. 209-234.

746 See *Leonardos, Maior*, Opinion on Bill of Law 1893/2007, p. 5.

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Inasmuch as cross-retaliation on IP rights may be legally available under the WTO system and may be useful as a tool for political pressure, restriction of IP rights as foreseen in Law 12279/2010 are not directly linked to public interest, economic and technological development of the country, or any social function pertaining to these rights. The measures implementing retaliation on IP rights should be shaped by the Brazilian constitutional system. In this case, compulsory license of a certain patented technology with a provision mandating transfer of technology would retaliate on IP rights and serve the purposes of development, without being too excessive in case due royalties must be paid to the patentee.

2. Remarks on the Overall Pharmaceutical Scenario

The main argument against patent rights is the high prices of drugs. Since patents establish the right to exclude competitors, patents are not regarded as competition friendly; rather, they are an option taken for policy making reasons with the goal of fostering technological development. In reality, no extensive and corroborated empirical studies have been able to show the direct correlation between price increase with the introduction of patents covering pharmaceutical products and processes in Brazil.[747] A study carried out in 2003 pointed out that the average drug price in Brazil increased from US$1.31 to US$6.04 between 1989 and 1998.[748] Since patents for pharmaceutical have only begun to be effectively granted in the country as of the enactment of Law 9279/1996,[749] it is not possible to conclude that such increase is a direct result of patent protection in this field of technology.

Availing itself of the flexibilities provided by TRIPS, the Brazilian government has not stopped with the granting of compulsory licenses for efavirenz in the context of the National Sexually Transmitted Diseases and AIDS Program. Ordinance 681 of April 8, 2008, was issued by the Ministry of Health declaring tenofovir to be of public interest, taking into ac-

747 The author has carried out an extensive search and, to the best of her knowledge, no study has been published in this regard.

748 See *Valentim*, Generic Drugs Policies: a study of the Brazilian case, p. 21.

749 Studies indicate that the first patent for medicines in Brazil was granted in 1884. See *Assumpção*, Chemistry Patent in Brazil: A Troubled History, penultimate para.

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count that the drug is an important component of the anti-AIDS cocktail. Tenofovir was the subject matter of patent application PI9811045-4, pending examination by the INPI since 1998, and the declaration sought to have the application subject to priority examination pursuant to INPI Resolution 132/2006.[750] The Resolution mentions that Fiocruz had already filed third party observations supporting the lack of novelty and inventive step of the application's subject matter, and that an application belonging to the same family was rejected in the US for lack of inventive step.[751] Acceleration of the application through priority examination was clearly a measure for having the patent denied by the INPI. The INPI ultimately rejected the patent due to unfulfilled patentability requirements of Articles 8 and 13 of Law 9279/1996.[752] Patent applicant Gilead Sciences, Inc. filed a lawsuit in Brazilian federal court on January 26, 2010, seeking to revert the decision by the INPI, which is currently pending a trial court decision.[753] National production of tenofovir began in 2011 by the state-owned laboratory Fundação Ezequiel Dias (Funed), and the first batch was put on the market in March 2011. According to estimates by the Ministry of Health, it could represent an economy of $410 million reais (approximately US$242 million) in five years.[754]

Current Brazilian President Dilma Rousseff gave a speech to the United Nations on September 20, 2011, in which she declared that Brazil defends access to medicine as part of the human right to health, as a strategic element for social inclusion, equity and strengthening of public health systems. She also stated that Brazil respects its commitments and obligations concerning IP rights, but is convinced that TRIPS and the Doha Declaration provide flexibilities that are indispensable for policies that safeguard the right to health. The President indicated that the government may make use of compulsory licenses for drugs for the treatment of non-transmissible chronic diseases such as cancer, hypertension, diabetes, and lung dis-

750 INPI's Resolution 132/2006 establishes in article 3 that patent applications which subject matter is declared by the government of national emergency or public interest – under the cases described in paragraphs 1 and 2 of article 2 of Decree 3201/1999 – will be subject of priority examination *ex officio*.

751 See Ordinance 681/2008, Preambles, para. 6-7.

752 See *RPI*, 1964, p. 114; and *RPI*, 2008, p. 23.

753 See *Gilead Sciences Inc. v INPI and ANVISA*, Process Consultation on Trial Court Judgment.

754 See *MoH*, AIDS and Hepatitis National Production.

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eases.[755] Following the Brazilian President's speech, the Minister of Health Alexandre Padilha declared that such diseases are also public health concerns, as there should be no differentiation between transmissible and non-transmissible diseases and 72% of non-violent deaths among people under 70 are caused by such diseases. However, the Minister affirmed that it would not be a case of general issuance of compulsory licenses, and there are no upcoming plans or needs for compulsory licenses to be issued for medications used in the treatment of such diseases.[756]

On April 9, 2013, the INPI published Resolution 80/2013, which established rules on prioritized examination for patent applications of pharmaceutical products and processes as well as equipment and material relevant to public healthcare. Prioritized examination may be granted to requests by the Brazilian Ministry of Health for any application concerning products, processes, equipment or material for healthcare related to public assistance policies and regarded to be strategic to the SUS.[757] Any interested party, which includes applicants and third parties, may request prioritization whenever the patent application's subject matter is directed at diagnosis, prophylaxis and treatment of AIDS, cancer or neglected diseases.[758] The grounds for prioritization requested directly by the Ministry of Health are not restricted to patent applications covering diagnosis, prophylaxis and treatment of the diseases listed in the attachment.[759] Entitlement of the Ministry is broader so as to encompass any application regarded as strategic to the public healthcare system. Therefore, in the tenofovir case, the speech at the UN and the INPI Resolution 80/2013 serve as evidence that the Brazilian government will make use of the tools available in the patent system to implement public health policies.

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755 See *MoH*, Clipping – Chronic Diseases and Patents Breaks.

756 See *Id*.

757 Article 1, paragraph 1 and article 3 of Resolution 80/2013.

758 Article 1, paragraph 2 and article 5 of Resolution 80/2013. The neglected diseases are listed in Attachment 1 of Resolution 80/2013 as follows: Chagas disease; dengue, hemorrhagic dengue; schistosomiasis; hanseniase; leprosy; leishmaniasis; malaria; tuberculosis; Buruli ulcer; neurocysticercosis; echinococcosis; yaws; fascioliasis; paragonimiasis; filariasis; rabies; helminthiasis; manifestations originated from intoxications or poisonings caused by poisonous and venomous animals.

759 Article 3, paragraph 1 of Resolution 80/2013.

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V. CHAPTER. CONCLUDING REMARKS

The body of provisions on patents in the WTO TRIPS Agreement clearly seeks to harmonize the general principles that should embody national legislations. Implementation by Member States must always be placed within the context of international trade. Different standards of protection and enforcement have been proven to represent non-tariff barriers to international trade and each of the principles and rules locally governing patents must now be interpreted in light of TRIPS. The present text has aimed to provide an analysis of the TRIPS framework for patents and the implementation of its provisions in Brazilian law. The analysis has been driven by the provisions and context surrounding compulsory licenses for pharmaceutical products, but has also aimed to illustrate the discussions surrounding the accession of Brazil into the international trading system.

Since the WTO negotiations, policy specialists had already foreseen the need to study the impacts of raising IP protection standards in developing countries. Many empirical studies have yet to evaluate such effects, whilst there is a consensus that this should be a case sensitive analysis – such as in the public health area. On the one hand, without patent protections, it is possible that there would not be enough incentive for investment in research and development. Moreover, a lack of patent rights may serve as a non-tariff barrier to trade in addition to being a violation of TRIPS. On the other hand, the absolute right to exclude third parties from using a patented subject matter should be reviewed in a case by case manner, especially in developing countries. The main challenge is to achieve a balance, which assures necessary protections in order to foster technological development yet does not consist in overwhelming protection that creates non-proportional social costs resulting from patent exclusivity. This was the conclusion that derived from the discussions among WTO Member States and is reflected in the Doha Declaration on the TRIPS Agreement and Public Health.

Compulsory licenses should not be regarded as the only way to promote access to medicine. The indiscriminate use of such a mechanism, which would serve to hide structural problems in healthcare systems, should be avoided. For those that defend compulsory licensing, it is a measure that has marginal negative effects on research and development and there is no

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evidence that such effects jeopardize other policies such as price control. Any negative effects would be minimal in developing countries, whose markets are less important for industry profits. Increased use of compulsory licenses in developing countries may lead to a reduction in social costs, especially in the patented pharmaceuticals market, while allowing a high level of patent protection to be maintained. Ultimately, the pharmaceutical industry may charge higher prices in developed countries, while practicing price differentiation in order to charge lower prices in developing countries with lower incomes. Furthermore, local industry could benefit as well from transfer of technology, which would allow for drugs to gradually be manufactured locally.

This text has shown that the Brazilian market does not present typical characteristics of a developing country. The Brazilian government plays a strategic role as a major consumer in the pharmaceutical area. In Brazil, universal access to healthcare is constitutionally safeguarded and should be implemented through social and economic policies, which include access to medications distributed by the SUS.

When implementing TRIPS into national legislation, Brazil adopted a rather friendly approach towards higher standards of protection, as the country understood them to be favorable to international trade, from which the Brazilian economy has been benefiting. The country's patent provisions mostly fulfill the minimum standards of protection in TRIPS. For pharmaceutical products and processes, intervention in the patent granting procedure by the ANVISA plays a peculiar role and the question remains why the research-based industry has not questioned the legality of prior consent by the ANVISA on a more general basis – rather than case by case – or even lobbied for the exclusion of the provision from the statute.

However, as a developing country, Brazil has been struggling to balance its interest in protecting technology mostly developed abroad with its interest in fostering local technology while at the same time assuring that social policies are implemented. In the pharmaceutical context, the dispute between these interests is clear. The healthcare system demands more access to medication at cheaper prices and at the same time investments are fostered for innovation by means of private-public partnership with local industry. Investing in innovation could ultimately be translated into protecting such innovation through patents so as to assure a continual investment process. In the compulsory licensing case of efavirenz, the declaration of public interest based on the cost of the drug used in the anti-AIDS

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cocktail shows one side of this dichotomy, whereas the public-private partnership for national production of the drug reveals the other.

It is important to consider that compulsory licensing is a measure restricting exclusivity rights derived by a patent, which is a constitutionally safeguarded right in Brazil, and its granting must follow the principle of proportionality. Accordingly, licenses must not only be shaped by the principles of the international treaty, but also follow national mechanisms for controlling legality and constitutionality. Licenses should not be granted when the demands of public interest may be satisfied through different means after balancing all the interests involved. In the case of compulsory licenses for efavirenz, the discussions went beyond compliance with TRIPS or the legality and constitutionality of the measure, which were satisfied in general. In fact, the case concerned how the Brazilian government made use of the available tools and mechanisms to implement a policy making decision. The other cases, such as Abbott's Kaletra and Gilead's Tenofovir, are also examples of such use in the area of public health. The use of the legal mechanisms available as of WTO/TRIPS have also been illustrated by the cross-retaliation in IP rights after Brazil won the case on cotton subsidies against the US in the WTO Dispute Settlement Body.

Another possible solution concerns government control of prices, which could be proposed as a measure to balance the social costs imposed by patents without jeopardizing the patent system and its incentives for investment in research and development. In Brazil, the government controls prices of products that are subject to medical prescription or that are in a more concentrated relevant market. As a major purchaser of drugs, the Brazilian government could also adopt a system that benefits from its power as a big consumer of the drugs. Prices could be based on government control of marginal profits of companies and industry would be obligated to submit accurate data on their profits under the penalty of having their products removed from the government's general purchasing list. Such price control would give the Brazilian government the power to minimize the social costs of patents without creating general suspicion among industry against the country's IP enforcement policies, jeopardizing long-term investments in research and development and the direct transfer of technology into the country. Of course, upon implementing this suggestion, one should take into account that price control administration is not an easy task, especially considering that profit information submitted by the companies may not be accurate and may require extensive negotiations with industry. Also, a deep and careful analysis should be carried out in

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relation to the constitutional principle of free enterprise and the restraints that such measures could impose on this freedom. How to best implement this or other alternatives is a challenge that this work leaves up to future studies.

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ANNEX: Law 9279, of May 14, 1996

as amended by Law 10196, of February 14, 2001*

THE EXECUTIVE BRANCH OF THE PRESIDENCY OF THE REPUBLIC

Civilian Household
Department for Legal Matters
Law No. 9,279, of May 14, 1996
Regulating Industrial Property Rights and Obligations

THE PRESIDENT OF THE REPUBLIC

Let it be known that the National Congress has enacted and I approve the following Law:

PRELIMINARY PROVISIONS

Art. 1 – This law regulates rights and obligations relating to industrial property.
Art. 2 – In view of the interest of society and the technological and economic development of the country, the protection of rights relating to industrial property shall be assured by means of:

I – the grant of patents for inventions and utility models;
II – the grant of industrial design registrations;
III – the grant of trademark registrations;
IV – the suppression of false geographical indications; and
V – the suppression of unfair competition.

Art. 3 – The provisions of this law shall apply to:

I – applications for patents or registrations filed in Brazil by a person holding protection under a treaty or convention in force in Brazil; and
II – nationals of, or persons resident in a country that affords the same or equivalent rights, in a reciprocal manner, to Brazilians or persons resident in Brazil.

Art. 4 – The provisions of treaties in force in Brazil shall apply, under the same conditions, to natural

* Unofficial English version prepared by the firm Dannemann, Siemsen, Bigler & Ipanema Moreira. Available at <http://www.dannemann.com.br/dsbim/manager.aspx?ID_LAYOUT=237&ID=47> (Last visited February 25, 2014).

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and legal persons who are nationals of, or resident in Brazil.
Art. 5 – For all legal effects, industrial property rights shall be deemed movable property.

TITLE I – PATENTS

CHAPTER I – OWNERSHIP

Art. 6 – The author of an invention or utility model shall be afforded the right to obtain a patent securing him or her the property, under the terms set out by this Law.

§ 1 – Unless otherwise proven, the applicant shall be presumed to be entitled to obtain a patent.
§ 2 – A patent may be applied for by the author, his or her heirs or successors, by an assignee or by any person designated the owner by law or a contract of either employment or provision of services.
§ 3 – If an invention or utility model is created jointly by two or more persons, a patent may be applied for by all or any one of such persons, safeguarding the rights of the others by providing their names and particulars.
§ 4 – The inventor shall be named and his or her particulars given, but he or she may request that his or her name not be disclosed.

Art. 7 – If two or more authors created the same invention or utility model independently of each other, the right to obtain a patent shall belong to the person proving the earliest filing date, irrespective of the invention or creation date.

Sole Paragraph – The withdrawal of an earlier filing that has not had any effect shall give priority to the filing that immediately follows.

CHAPTER II – PATENTABILITY

SECTION I – Patentable Inventions and Utility Models

Art. 8 – An invention shall be patentable if it meets the requirements of novelty, inventive step and industrial application.

Art. 9 – An object of practical use, or part thereof, susceptible of industrial application, that presents a new form or arrangement and involves inventive step that results in functional improvement in its use or manufacture shall be patentable as a utility model.

Art. 10 – The following shall not be considered inventions or utility models:

I – discoveries, scientific theories and mathematical models;
II – purely abstract concepts;

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III – schemes, plans, principles or methods of commerce, accountancy, finance, education, advertising, lotteries or inspection;
IV – literary, architectural, artistic and scientific works or any aesthetic creation;
V – computer programs in themselves;
VI – presentations of information;
VII – rules for games;
VIII – techniques and methods for operations and surgery or therapeutic or diagnostic methods for application to the human or animal body; and
IX – all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germplasm of any natural living being or natural biological processes.

Art. 11 – An invention or utility model shall be considered to be new if it does not form part of the prior art.

§ 1 – Prior art shall constitute everything made available to the public by written or verbal description, use or any other means, before the filing date of the patent application, in Brazil or abroad, except as provided for in articles 12, 16 and 17.
§ 2 – For the purposes of determining novelty, the full contents of an application filed but not yet published in Brazil shall be deemed part of the prior art from the filing or claimed priority date, provided that it is published, even if this happens subsequently.
§ 3 – The provisions of the previous paragraph shall apply to an international patent application filed in accordance with the provisions of a treaty or convention in force in Brazil, provided that there is a national phase.

Art. 12 – The disclosure of an invention or utility model occurring during the 12 (twelve) months preceding the application filing date, or priority date, shall not be deemed to be part of the prior art if made by:

I – the inventor;
II – the Brazilian Patent and Trademark Office (BPTO), through the official publication of an application filed without the consent of the inventor, based on information obtained from the inventor or as a result of his or her acts; or
III – third parties on the basis of information obtained directly or indirectly from the inventor or as a result of his or her acts.

Sole Paragraph – The BPTO may require a statement from the inventor relating to the disclosure,

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accompanied by evidence or not, under the requirements established in the regulations.

Art. 13 – An invention shall be considered as involving inventive step if, to a person skilled in the area, it does not derive evidently or obviously from prior art.

Art. 14 – A utility model shall be considered as involving inventive step if, to a person skilled in the area, it does not derive in a common or usual way from prior art.

Art. 15 – Inventions or utility models shall be considered as susceptible of industrial application if they can be used or made in any kind of industry.

SECTION II – Priority

Art. 16 – Priority rights shall be assured, within the time limits set out in the agreement, for a patent filed in a country that has an agreement with Brazil or with an international organization that has the effect of a national filing, and the filing shall neither be invalidated nor prejudiced by events occurring within such time limits.

§ 1 – A priority claim shall be made at the time of filing, and may be supplemented within sixty (60) days by other priorities that precede the filing date in Brazil.

§ 2 – A priority claim shall be supported by a legal document of origin with number, date, title, description and, where appropriate, claims and drawings together with an uncertified translation of the filing certificate or equivalent document containing data identifying the application, the contents of which shall be under the full responsibility of the applicant.
§ 3 – If not submitted on filing, evidence shall be submitted within one hundred and eighty (180) days from the filing date.
§ 4 – For international applications filed under a treaty in force in Brazil, the translation referred to in § 2 shall be filed within 60 (sixty) days from the entry date into the national phase
§ 5 – If an application filed in Brazil is faithfully reproduced in the document of origin, a statement to this effect by the applicant shall suffice to replace the uncertified translation.
§ 6 – If priority is obtained by assignment, the corresponding document shall be filed within one hundred and eighty (180) days of the filing date or within sixty (60) days of the entry date into the national phase, where appropriate, consular legalization in the country of origin not being required.
§ 7 – Failure to provide evidence within the time limits set out in this article shall result in the loss

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of the priority.
§ 8 – If an application has been filed with priority claim, any request for early publication shall be made with evidence of the priority.

Art. 17 – An application for a patent for an invention or a utility model originally filed in Brazil without priority claim and not yet published shall afford a priority right to a subsequent application on the same subject matter filed in Brazil by the same applicant, or his or her successors, within a period of one (1) year.

§ 1 – Priority shall be granted only for the subject matter that is disclosed in the earlier application, and shall not be extended to any matter newly introduced.
§ 2 – The pending earlier application shall be deemed definitively withdrawn.
§ 3 – An application resulting from the division of an earlier application shall not serve as the basis for a priority claim.

SECTION III – Non-patentable Inventions and Utility Models

Art. 18 The following shall not be patentable:
I – anything contrary to morality, decency, and public safety, order and health;
II – substances, materials, compounds, elements or products of any kind, including the modification of their respective physical-chemical properties and the respective processes for obtaining or modifying them, when they result from the transformation of the atomic nucleus; and
III – living beings, in whole or in part, except for transgenic microorganisms meeting the three requirements for patentability – novelty, inventive step and industrial application – listed in

Art. 8 and which are not mere discoveries.

Sole Paragraph – For the purposes of this law, transgenic microorganisms are organisms, except for plants and animals, in whole or in part, that due to direct human intervention in their genetic composition express a characteristic that cannot normally be achieved by the species under natural conditions.

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CHAPTER III- PATENT APPLICATIONS

SECTION I – Application Filing

Art. 19 – In accordance with the requirements established by the BPTO, patent applications shall contain:

I – a request;
II – a specification (descriptive report);
III – claims;
IV – drawings, where applicable;
V – an abstract;
VI – proof of payment of the filing fee.

Art. 20 – Once the application has been submitted, it shall be subject to a formal preliminary examination, and if found in order shall be recorded and the filing date shall be taken as the submission date.

Art. 21 – An application that does not formally meet the requirements of article 19, but which contains data relating to the subject matter, the applicant and the inventor, may be submitted to the BPTO in return for a dated receipt which sets out the requirements to be met within a period of 30 (thirty) days, failing which the documentation shall be returned or withdrawn.

Sole Paragraph – Once the requirements have been met, the filing shall be considered to have been made on the receipt date.

SECTION II – Application Requirements

Art. 22 – A patent application for an invention shall relate to a single invention or to a group of inventions linked in such a way as to form a single inventive concept.

Art. 23 – A patent application for a utility model shall relate to a single principle model which may include a plurality of distinct, additional elements or structural or configurative variations, provided that the technical-functional and material unity of the object is maintained.

Art. 24 – The specification shall clearly and sufficiently describe the subject matter thus enabling a person skilled in that area to be able to carry it out and, where appropriate, to indicate the best way to execute it.

Sole Paragraph – In the case of biological material essential for the practical execution of the application subject matter, which cannot be described in accordance with this article and which is not acces-

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sible to the public, the specification shall be supplemented by depositing the material at an institution authorized by the BPTO or determined in an international agreement.

Art. 25 – The claims shall be based on the specification, characterizing the special features of the application and clearly and precisely defining the subject matter for which protection is sought.

Art. 26 – An application may be divided into two or more applications until the end of the examination, ex officio or at the request of the applicant, provided that the divided application:

I – makes specific reference to the original application; and
II – does not extend beyond the subject matter contained in the original application.

Sole Paragraph – Divisional applications that do not meet the requirements of this article shall be deemed withdrawn.

Art. 27 – Divisional applications shall have the filing date of and, where applicable, enjoy any benefit of priority of the original application.

Art. 28 – Each divisional application shall be subject to the payment of the corresponding fees.

Art. 29 – A withdrawn or abandoned patent application must be published.

§ 1 – Withdrawal requests shall be filed within 16 (sixteen) months from the filing date or that of earliest priority.
§ 2 – Withdrawal of an earlier filing that has not produced any effect shall give priority to the immediately subsequent filing.

SECTION III – Application Prosecution and Examination

Art. 30 – Patent Applications shall be kept secret for a period of 18 (eighteen) months from the filing date or that of the earliest priority, where applicable, at which time they shall be published, except as provided for in article 75.

§ 1 – If requested by the applicant, the application may be published early.
§ 2 – Publication shall include data identifying the application, a copy of the specification, the claims, the abstract and the drawings shall be available to the public at the BPTO.
§ 3 – In the case referred to in the sole paragraph of article 24, the biological material shall be made available to the public at the time

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of the publication referred to in this article.

Art. 31 – Documents and information supporting the examination may be submitted by interested parties from the time of application publication until the end of examination.

Sole Paragraph – Examination shall not begin earlier than 60 (sixty) days from application publication.

Art. 32 – In order to better clarify or define his or her application, an applicant may make amendments up to the time of the request for examination, provided that the amendments are limited to the subject matter initially disclosed in the application.

Art. 33 – Examination of a patent application shall be requested by the applicant or by any interested person within 36 (thirty six) months from the filing date, under penalty of the application being deemed withdrawn.

Sole Paragraph – A patent application may be reinstated, at the request of the applicant, within 60 (sixty) days from having been withdrawn and upon payment of a specific fee, uder penalty of the application being deemed definitively withdrawn.

Art. 34 – Once examination has been requested, the following documents shall be filed within 60 (sixty) days, whenever requested, under penalty of the application being deemed withdrawn.

I – objections, prior art searches and results of examination for the grant of corresponding applications in other countries, where there is a priority claim;
II – documents necessary to regularize the application procedure and examination; and
III – an uncertified translation of the legal document referred to in § 2 of article 16 in those cases where the translation has been replaced by the statement referred to in § 5 of the same article.

Art. 35 – During the technical examination a search report and an opinion shall be prepared with respect to:

I – the patentability of the application;
II – suitability of the application to the claimed nature;
III – amendment or division of the application; or
IV – technical requirements.

Art. 36 – When the opinion is that the application is non-patentable or not suitable for the claimed nature or if the opinion sets any requirements, the applicant shall be

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notified to reply within a period of 90 (ninety) days.

§ 1 – Failing a reply to a requirement, the application shall be deemed definitively withdrawn.
§ 2 – In the event of a reply to a requirement, even if the requirement is not met, or if its formulation is contested, the examination shall be continued irrespective of the submission or arguments concerning patentability or suitability.

Art. 37 – On conclusion of the examination a decision to allow or deny the application shall be issued.

CHAPTER IV – PATENT GRANT AND TERM

SECTION I – Patent Grant

Art. 38 – A patent shall be granted upon approval of the application and, on supply of proof of payment of the corresponding fee, the respective patent certificate shall be issued.

§ 1 – Payment of the fee and proof of payment shall be supplied within 60 (sixty) days from the approval of the application.
§ 2 – The fee referred to in this article may be paid and proof of payment supplied within the time limit specified in the previous paragraph, regardless of any notice, on payment of a specified fee, on penalty of the application being deemed definitively withdrawn.
§ 3 – A patent shall be deemed granted from the publication date of the relevant decision.

Art. 39 – The patent certificate shall contain the relevant number, title and nature, inventor name, in accordance with the provision § 4 of article 6, and the particulars and place of residence of the patent owner, the term of validity, specification, the claims and the drawings, as well as any data relating to priority.

SECTION II – Patent Term

Art. 40 – The patent term for an invention shall be 20 (twenty) years and for a utility model 15 (fifteen) years from the filing date.

Sole Paragraph – The term shall be not less than 10 (ten) years for inventions and 7 (seven) years for utility models from the grant date, except where the BPTO is prevented from carrying out the application substantive examination due to pending litigation or for reasons beyond its control.

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CHAPTER V PROTECTION CONFERRED BY PATENT

SECTION I – Rights

Art. 41 – The scope of the protection conferred by the patent shall be determined by the contents of the claims interpreted on the basis of the specification and drawings.

Art. 42 – A patent shall afford to its owner the right to prevent others from producing, using, offering for sale or importing for such purposes without his or her consent:

I – a product that is the subject matter of a patent;
II – a process or a product directly obtained by a patented process.

§ 1 – A patent owner shall further enjoy the right to prevent others from assisting other parties from carrying out the acts referred to in this article.
§ 2 – The rights in a process patent, as referred to in item II, shall be deemed to have been infringed if the holder or owner of a product fails to prove, by a specific judicial ruling, that his product was obtained by a manufacturing process different from the process protected by the patent.

Art. 43 – The provision of the previous article shall not apply to:

I – acts carried out privately and without commercial purposes by unauthorized third parties, provided that these acts do not prejudice the economic interests of the patent owner;
II – acts carried out by unauthorized third parties for experimental purposes, related to studies or scientific or technological research;
III – the preparation of a medicine in accordance with a medical prescription in individual cases and carried out by qualified professional, as well as the medicine thus prepared;
IV – a product manufactured in accordance with a process or product patent that has been placed on the internal market directly by the patent holder or with his or her consent;
V – third parties who, in the case of patents related to living matter, use the patented product, without economic purpose, as an initial source of variation or propagation in order to obtain other products; and
VI – third parties who, in the case of patents related to living matter, use, place in circulation, or market a patented product that has been lawfully introduced into the market by the patent owner or his

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or her licensee, provided that patented product is not used for the commercial multiplication or propagation of the living matter concerned.
VII – acts practiced by unauthorized third parties, related to the invention protected by a patent, for the sole purpose of producing test information, data and results in order to obtain a marketing registration, in Brazil or abroad, for the exploitation and marketing of the product that is the subject matter of the patent, following expiry of the time limits set out in article 40. (Item included by Law 10,196 of 14/02/2001).

Art. 44 – A patent owner shall be entitled to compensation for the unauthorized exploitation of the subject matter of the patent, including exploitation that occurs between the application publication date and the patent grant date.

§ 1 – If an infringer becomes aware, by any means, of the contents of a filed application prior to the publication, the period of unlawful exploitation for compensation purposes shall be from the date on which exploitation began.
§ 2 – If the subject matter of a patent application relates to biological material, deposited in accordance the sole paragraph of article 24, the right to compensation shall be granted only when the biological material has been made available to the public.
§ 3 – The right to compensation for unlawful exploitation, including that relating to the period before the patent grant, shall be limited to the subject matter of the patent, in accordance with article 41.

SECTION II – Prior User

Art. 45 – A person who, in good faith, prior to the filing or priority date of a patent application, exploits its subject matter in Brazil, shall be entitled to continue such exploitation in the same way and condition without any liability.

§ 1 – The right conferred by this article may only be assigned together with the business or company, or part thereof that is directly related to the exploitation of the subject matter of the patent, by transfer or leasing.
§ 2 – The right conferred by the article shall not be enjoyed by a person who obtained knowledge of the subject matter of the patent as a result of disclosure, in accordance with article 12, provided that the application was filed within 1 (one) year from the disclosure.

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CHAPTER VI – NULLITY OF PATENT

SECTION I – General Provisions

Art. 46 – A patent granted contrary to the provisions of this Law shall be null and void.

Art. 47 – Nullity may apply to only some claims, a condition for partial nullity being that the remaining claims constitute patentable subject matter in themselves.

Art. 48 – Patent nullity shall become effective from the application filing date.

Art. 49 – Where the provisions of article 6 have not been complied with, the inventor may, alternatively, commence proceedings to decide patent ownership.

SECTION II – Administrative Procedure for Nullity

Art. 50 – Administrative nullity of a patent shall be declared if:

I – any of the statutory requirements have not been met;
II – the specification and claims do not meet the requirements of articles 24 and 25, respectively;
III – the subject matter of the patent extends beyond the contents of the application as originally filed; or
IV – any of the essential formalities that are indispensable for grant were omitted during prosecution.

Art. 51 – Proceedings for nullity may be instituted ex officio or at the request of any person having a legitimate interest, within 6 (six) months from the patent grant.

Sole Paragraph – Proceedings for nullity shall continue even if the patent has lapsed.

Art. 52 – The patent owner shall be notified to make his or her comments within a period of 60 (sixty) days.

Art. 53 – Irrespective of a response having been filed, on expiry of the time limit specified in the previous article, the BPTO shall issue an opinion and notify the patent owner and the applicant to submit within a common time limit of 60 (sixty) days.

Art. 54 – On expiry of the time limit set out in the previous article, even if no responses have been received, the procedure will be decided by the President of the BPTO, and the administrative procedure shall be concluded.

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Art. 55 – The provisions of this Section shall apply, as appropriate, to certificates of addition.

SECTION III – Nullity Proceedings

Art. 56 – Nullity proceedings may be instituted at any time during the term of a patent by the BPTO or any party with a legitimate interest.

§ 1 – Patent nullity may be alleged at any time as a defense plea.
§ 2 – As a preventive or incidental measure, the judge may decide to suspend the effects of a patent, provided that the relevant procedural requirements are met.

Art. 57 – Nullity proceedings shall be heard by Federal Courts and the BPTO shall participate in the proceedings when the BPTO is not the plaintiff.

§ 1 – The time limit for the defendant patent owner to reply shall be 60 (sixty) days.
§ 2 – Once the final decision on nullity proceedings has been made, the BPTO shall publish a notification to inform third parties.

CHAPTER VII – ASSIGNMENT AND ENTRIES

Art. 58 – A patent application or a patent, the contents of which are indivisible, may be assigned in whole or in part.

Art. 59 – The BPTO shall make the following entries:

I – assignment, stating the full particulars of the assignee;
II – any limitations or requirements placed on the application or patent; and
III – changes to the name, headquarters or address of the applicant or owner.

Art. 60 – The entries shall have an effect in relation to third parties from the publication date.

CHAPTER VIII- LICENSES

SECTION I – Voluntary Licenses

Art. 61 – A patent owner or applicant may enter into a licensing agreement for exploitation.

Sole Paragraph – The patent owner may afford on the licensee full powers to act in the defense of the patent.

Art. 62 – The licensing agreement shall be recorded at the BPTO in

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order to produce an effect in relation to third parties.

§ 1 – The record shall become effective with regard to third parties from its publication date.
§ 2 – The record of the licensing agreement at the BPTO is not needed for the purposes of validity of proof of use.

Art. 63 – An improvement to a licensed patent shall belong to the person who has made the improvement and the other contracting party shall be afforded a preferential right to license.

SECTION II – License Offer

Art. 64 – A patent owner may request the BPTO put his patent up for offer with a view to its exploitation.

§ 1 – the BPTO shall publish the offer.
§ 2 – No exclusive voluntary license shall be recorded at the BPTO unless the patent owner has withdrawn his or her offer.
§ 3 – No patent under an exclusive voluntary license may be put up for offer.
§ 4 – A patent owner may withdraw his or her offer at any time, prior to the express acceptance of its terms by the interested party, in which case the provisions of article 66 shall not apply.

Art. 65 – In the absence of an agreement between the patent holder and the licensee, the parties may request that the BPTO arbitrate the remuneration.

§ 1 – For the purposes of this article, the BPTO shall comply with the provisions of § 4 of article 73.
§ 2 – The remuneration may be reviewed 1 (one) year after it has been determined.

Art. 66 – The renewal fees for a patent subject to offer shall be reduced by one-half during the time between the offer being made and the first license granted.

Art. 67 – The patent owner may request cancellation of a license if the licenses does not begin effective exploitation within 1 (one) year from the license being granted, if exploitation is interrupted for more than 1 (one) year or if he or she does not comply with the conditions for exploitation.

SECTION III – Compulsory Licenses

Art. 68 – A patent owner shall be subject to compulsory licensing of his patent if he exercises his or her rights thereof in an abusive manner or uses it to abuse economic power, as evidenced under

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the terms of the law by an administrative or court decision.

§ 1 – The following may also be the grounds for compulsory licensing:

I – failure to exploit the subject matter of the patent within Brazilian territory or failure to manufacture the product or failure to use a fully patented process, except in the case of economic unfeasibility, in which case import shall be permitted; or
II – marketing that does not satisfy the needs of the market.

§ 2 – A license may only be requested by a party having a legitimate interest and having the technical and economic capability to exploit effectively the subject matter of the patent, which should predominantly be intended for the internal market, in which case the exception contained in item I of the previous paragraph shall not apply.
§ 3 – If a compulsory license is granted on the grounds of abuse of economic power, a time limit, set out in the provisions of article 74, shall be guaranteed to a licensee to import the subject matter of the license, provided that it has been placed on the market directly by the patent owner or with his or her consent.

§ 4 – In the event of an import to exploit a patent or an import as set out in the previous paragraph, third parties shall also be allowed to import a product manufactured according to a process or a product patent, provided it has been placed on the market by the patent owner or with his or her consent.
§ 5 – A compulsory license as described in § 1 may only be requested 3 (three) years after patent grant.

Art. 69 – A compulsory license shall not be granted if, on the request date, the patent owner:

I – justifies failure to use for legitimate reasons;
II – proves that serious and effective preparations for exploitation have been made;
III – justifies the failure to manufacture or to market on the grounds of legal obstacles.

Art. 70 – A compulsory license shall also be granted when the following conditions are cumulatively met:

I – there is a situation of dependency of one patent on another;
II – the subject matter of the dependent patent constitutes a substantial technical progress in relation to the earlier patent; and
III – the owner fails to reach agreement with the owner of the

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dependent patent on the exploitation of the earlier patent.

§ 1 – For the purposes of this article, a patent is dependent if its exploitation absolutely depends on the use of the subject matter of a previous patent.
§ 2 – For the purposes of this article, a process patent may be deemed dependent on a patent for the relevant product, and likewise a product patent may be dependent on a process patent.
§ 3 – The owner of a patent subject to a license according to the provisions of this article shall have the right to a compulsory license of the dependent patent.

Art. 71 – In cases of national emergency or of public interest, declared in an act by the Federal Executive Department, provided that the patent holder or licensee does not satisfy such a need, a temporary non-exclusive compulsory license to exploit the patent may be granted ex officio without prejudicing the rights of the patent owner.

Sole Paragraph – The instrument granting the license shall set out its term of validity and the possibility of extension.

Art. 72 – Compulsory licenses shall always be non-exclusive and sub-licensing shall not be permitted.

Art. 73 – An application for a compulsory license shall set forth the conditions offered to the patent owner.

§ 1 – On filing of the license application, the patent owner shall be notified to reply within the time limit of 60 (sixty) days, on expiry of which, in the absence of a reply from the patent owner, the proposal shall be deemed accepted under the conditions offered.
§ 2 – An applicant for a license who alleges abuse of patent rights or the abuse of economic power shall be required to submit documentary proof.
§ 3 – If a compulsory license is applied for on the grounds of failure to exploit, the patent owner shall prove the exploitation of the patent
§ 4 – If contested, the BPTO may take necessary measures, as well as appoint a committee that may include independent experts, in order to arbitrate the remuneration to be paid to the patent owner.
§ 5 – The bodies and entities of direct and indirect federal, state and municipal public administration shall provide the BPTO with such information as requested to assist in the arbitration of the remuneration.

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§ 6 – In the arbitration of remuneration, the circumstances of each case shall be taken into consideration, the inclusion of the economic value of the granted license being compulsory.
§ 7 – Once the case has been examined, the BPTO shall decide on the grant and on the conditions of a compulsory license within a time limit of 60 (sixty) days.
§ 8 – Appeals against decisions granting a compulsory license shall not have a suspensive effect.

Art. 74 – In the absence of legitimate reasons, the licensee shall begin exploitation of the subject matter of the patent within a time limit of one (1) year from the grant of the license, interruption for an equal period of time being permitted.

§ 1 – A patent owner may request cancellation of the license if the provisions of this article are not complied with.
§ 2 – The licensee shall have full powers to defend the patent.
§ 3 – Once a compulsory license has been granted, assignment thereof shall only be permitted together with the assignment, transfer or leasing of that part of the enterprise that exploits it.

CHAPTER IX – PATENT OF INTEREST TO NATIONAL DEFENSE

Art. 75 – A patent application originating in Brazil, the subject matter of which is of interest to national defense shall be prosecuted subject to secrecy and shall not be subject to the publications provided for in this Law.

§ 1 – the BPTO shall promptly forward the application to the competent Executive Power body, which shall issue a decision on secrecy within a time limit of 60 (sixty) days. If such a period of time expires without the competent body giving a decision, the application shall be prosecuted normally.
§ 2 – Filing of a patent application of which the subject matter is deemed to be of interest to national defense shall not be made abroad, nor shall any disclosure thereof be allowed, except if previous consent is given by the competent body.
§ 3 – Exploitation and assignment of the application or patent of interest to national defense shall be subject to prior authorization from the competent body, compensation being guaranteed whenever this implies a restriction to the rights of the applicant or patent owner.

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CHAPTER X – CERTIFICATE OF ADDITION

Art. 76 – On payment of a specific fee, the applicant or patent owner may request a certificate of addition to protect an improvement in or development of the invention subject matter, even if it lacks inventive step, provided that the matter is included in the same inventive concept.

§ 1 – Where the main application has already been published, the application for a certificate of addition shall be published at once.
§ 2 – An application for a certificate of addition shall be examined in accordance with the provisions of articles 30 to 37, except where provided for in the previous paragraph.
§ 3 – An application for a certificate of addition shall be rejected if its subject matter does not share the same inventive concept.
§ 4 – An applicant may, within the time limit for appeal and on payment of the applicable fees, request the conversion of an application for a certificate of addition to a patent application, enjoying the filing date of the certificate application.

Art. 77 – The certificate of addition shall be accessory to the patent, shall have the same expiry date and shall accompany it for all legal effects.

Sole Paragraph – In nullity proceedings, the patent holder may request that the subject matter contained in the certificate of addition be examined to verify if it may subsist without prejudice to the protection term of the patent.

CHAPTER XI – PATENT LAPSE

Art. 78 – A patent shall lapse on:

I – expiry of the protection term;
II – waiver by the patent owner, without prejudice to the rights of other parties;
III – cancellation;
IV – failure to pay the annual fee, within the time limits set out in article 84, § 2, and article 87; and

V – failure to comply with the provisions of article 217.

Sole Paragraph – On patent lapse, its subject matter shall fall into the public domain.

Art. 79 – Waiver shall only be allowed if it does not prejudice the rights of third parties.

Art. 80 A patent shall be canceled, ex officio or at the request of any party with a legitimate interest if, after 2 (two) years from the grant

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of a first compulsory license, this time limit has not been sufficient to prevent or remedy abuse or misuse, except for legitimate reasons.

§ 1 – A patent shall be canceled if, on the date of application for cancellation or on that of the ex officio commencement of the relevant proceedings, its exploitation has not yet begun.
§ 2 – In cancellation proceedings initiated by request, the BPTO may pursue the proceedings if the applicant desists.

Art. 81 – The patent owner shall be notified by publication to respond within a 60 (sixty) day period, and shall bear the burden of proof of exploitation.

Art. 82 – A decision shall be issued within 60 (sixty) days from the end of the time limit referred to in the preceding article.

Art. 83 – A decision in proceedings for forfeiture shall take effect as from the day of the request or of the publication of ex officio institution of proceedings.

CHAPTER XII – ANNUAL FEES

Art. 84 – The applicant and patent owner shall be required to pay annual fees from the beginning of the third year after the filing date.

§ 1 – Advance payment of annual fees shall be regulated by the BPTO.
§ 2 – Payment shall be made within the first 3 (three) months of each annual period, but it may also be made within the following 6 (six) months, independently of any notification, on payment of an additional fee.

Art. 85 – The provisions of the previous article shall apply to international applications filed under a treaty in force in Brazil, and payment of annual fees due prior to the entry date into the national phase shall be made within a time limit of 3 (three) months from that date.

Art. 86 – Failure to make payment of the annual fee, in accordance with the provisions of articles 84 and 85, shall result in the application being deemed withdrawn or patent being deemed lapsed.

CHAPTER XIII – RESTORATION

Art. 87 – A patent application or a patent may be restored on request by the applicant or patent owner within 3 (three) months from notification of having been deemed withdrawn or the patent having

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lapsed, on payment of a specific fee.

CHAPTER XIV – INVENTIONS OR UTILITY MODELS MADE BY EMPLOYEES OR SERVICE PROVIDERS

Art. 88 – An invention or utility model shall belong exclusively to the employer when it results from a contract of work being performed in Brazil and whose subject matter is the research or inventive activity or if such results from the nature of the services for which the employee was contracted.

§ 1 – Except as otherwise stipulated by contract, the remuneration for the work this article refers to shall be limited to the agreed salary.
§ 2 – In the absence of proof to the contrary, an invention or utility model for which a patent is sought by an employee within 1 (one) year from termination of the employment contract shall be deemed to have been developed during the term of the contract.

Art. 89 – An employer who is the patent owner may award the employee who is the author of the invention or improvement, participation in the economic gain resulting from the exploitation of the patent, by negotiating with the interested party or as provided for by the rules of the company.

Sole Paragraph – The participation referred to in this article shall not be incorporated in any way into the salary of the employee.

Art. 90 – An invention or utility model developed by an employee shall belong exclusively to the employee, provided that it is in no way connected to his employment contract and if it does not result from the use of resources, means, data, materials, facilities or equipment of the employer.

Art. 91 – An invention or utility model shall be joint property, in equal shares, if it results from the personal contribution of the employee and from the resources, data, means, data, materials, facilities or equipment of the employer, without prejudice to express contrary contractual provisions.

§ 1 – If more than one employee is involved, the part due to each shall be divided equally between all of them, except as agreed to the contrary.
§ 2 – The employer shall be entitled to exclusive right to the exploitation license and the employee shall be entitled to fair remuneration.

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§ 3 – The exploitation of the patent subject matter, if agreement has not been reached on the issue, shall be started by the employer within 1 (one) year from the grant date, failing which the patent ownership shall be transferred as an exclusive right to the employee, except where there are legitimate reasons for the failure to exploit.
§ 4 – In the event of an assignment, any of the joint owners, under the same conditions, may exercise preference rights.

Art. 92 – The provisions of the preceding articles shall apply, as appropriate, to the relationship between an independent worker or a trainee and the contracting company and between contracting and contracted companies.

Art. 93 – The provisions of this Chapter shall apply, as appropriate, to entities of Public Authorities, whether direct, indirect or foundational and federal, state or municipal.

Sole Paragraph – Under the terms of article 88, the inventor shall be entitled to an award corresponding to a share of the value of the benefits obtained due to the application, subject to the terms and conditions set out by the statutes and internal regulations of the entity to which this article refers.

TITLE II – INDUSTRIAL DESIGNS

CHAPTER I – OWNERSHIP

Art. 94 – The author shall be afforded the right to obtain an industrial design registration securing him or her the ownership of the design, under the terms set out by this Law.

Sole Paragraph – The provisions of articles 6 and 7 shall apply, as appropriate, to industrial design registrations.

CHAPTER II – REGISTRABILITY

SECTION I – REGISTRABLE INDUSTRIAL DESIGNS

Art. 95 – An industrial design shall be deemed to be any ornamental 3-dimensional form of an object or any ornamental arrangement of lines and colours which may be applied to a product, resulting in a new and original appearance in its external configuration and that may serve as a model for industrial manufacture.

Art. 96 – An industrial design is deemed new if it is not comprised in the prior art.

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§ 1 – The prior art shall comprise everything made available to the public before the application filing date, in Brazil or abroad, by use or by any other means, without prejudice to the provisions of § 3 of this article and of article 99.
§ 2 – For the sole purpose of determining novelty, the full contents of a patent application or registration filed but not yet published in Brazil shall be deemed part of the prior art from the filing or claimed priority date, provided that it is published, even if this happens subsequently.
§ 3 – An industrial design that is published during the 180 (one hundred and eighty) days preceding the application filing date or claimed priority date shall not be deemed part of the prior art, provided publication was made in the situations referred to in items I and III of article 12.

Art. 97 – An industrial design is deemed to be original if it results in a visual configuration that is distinctive in relation to existing objects.

Sole Paragraph – The original visual result may be the result of a combination of known elements.

Art. 98 – Works of a purely artistic nature shall not be considered industrial designs.

SECTION II – Priority

Art. 99 – The provisions of article 16, except for the time limit referred to in § 3 of that article which shall be 90 (ninety) days, shall apply, as appropriate, to registration applications.

SECTION III – Non-registrable Industrial Designs

Art. 100 – An industrial design shall not be registrable if:

I – it is contrary to morality and decency or if it offends the honor or image of persons, threatens the freedom of conscience, belief, religions or ideas and feelings deserving respect and veneration;
II – it is the necessary common or ordinary shape of the object or even, a shape that is essentially determined by technical or functional considerations.

CHAPTER III – REGISTRATION APPLICATIONS

SECTION I – Application Filing

Art. 101 – A registration application, in accordance with the conditions set out by the BPTO, shall contain:

I – a request;
II – a specification (descriptive report), where applicable;
III – claims, where appropriate;

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IV – drawings or photographs;
V – the field of application of the object; and
VI – proof of payment of the filing fee.

Sole Paragraph – Documents comprised in a registration application shall be filed in Portuguese.

Art. 102 – On submission, an application shall be subject to a formal preliminary examination and, if found in order, shall be recorded and the submission date shall be taken to be the filing date.

Art. 103 – An application that does not formally meet the requirements of article 101, but which contains sufficient data relating to the applicant, industrial design and the author, may be submitted to the BPTO in return for a dated receipt which sets out the requirements to be met within a period of 5 (five) days, failing which the documentation shall be deemed non-existent.

Sole Paragraph – Once the requirements have been met, the filing shall be considered to have been made on the application submission date.
SECTION II – Application Requirements

Art. 104 – An application for an industrial design registration shall refer to a single object, of which a plurality of variations shall be permitted, provided that they are intended for the same purpose and all possess the same distinctive characteristic, each being limited to a maximum of twenty (20) variations.

Sole Paragraph – The drawing shall clearly and adequately represent the object and its variations, where applicable, in such a manner as to enable its reproduction by a person skilled in the art.

Art. 105 – Where secrecy is requested under § 1 of article 106, the application may be withdrawn within a period of up to 90 (ninety) days from the filing date.

Sole Paragraph – Withdrawal of an earlier application that produces no effect, shall confer priority to the first subsequent application.
SECTION III – Application Prosecution and Examination

Art. 106 – Once the application for an industrial design has been filed and the provisions of articles 100, 101 and 104 have been met, it shall automatically be published, registration shall be simultaneously granted and the relevant certificate shall be issued.

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§ 1 – At the request of the applicant at the time of filing, an application may be kept secret for a period of 180 (one hundred and eighty) days from the filing date, following which it shall be prosecuted.
§ 2 – If an applicant avails himself of the provisions of article 99, the application shall not be prosecuted until the priority document is filed.
§ 3 – If the provisions of 101 and 104 are not met, a notification shall be issued, and the applicant shall be given 60 (sixty) days to submit his or her reply, on penalty of which the application shall be deemed definitively withdrawn.
§ 4 – If the provisions of article 100 are not complied with, the registration application shall be rejected.

CHAPTER IV – REGISTRATION GRANT AND TERM

Art. 107 – The certificate shall contain the number and title, author name, in accordance with the provision of § 4 of article 6, the name, nationality and country of residence of the owner, the term of validity, the drawings, data relating to foreign priority, and where applicable, the specification and claims.

Art. 108 – Registrations shall have a term of 10 (ten) years from the filing date. This term shall be renewable for 3 (three) successive 5 (five) year periods.

§ 1 – Applications for renewal shall be made during the last year of the registration term and shall be accompanied by proof of payment of the corresponding fee.
§ 2 – If renewal has not been applied for before the end of the registration term, the owner may request renewal within the following 180 (one hundred and eighty) days, on payment of an additional fee.

CHAPTER V – PROTECTION CONFERRED BY REGISTRATION

Art. 109 – Ownership of an industrial design shall be acquired by means of a valid registration.

Sole Paragraph – The provisions of article 42 and § 1, 2 and 4 of article 43 shall apply, as appropriate, to an industrial design registration.

Art. 110 – Any person who, in good faith, prior to the filing date or priority date of a registration application used to exploit the subject matter in Brazil, shall be entitled to continue such exploita-

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tion in the same way and condition without any liability.

§ 1 – The right conferred by this article may only be assigned together with the business or company, or part thereof that is directly related to the exploitation of the subject matter of the registration, by transfer or leasing.
§ 2 – The right conferred by the article shall not be enjoyed by a person who obtained knowledge of the subject matter of the registration as a result of publication, in accordance with § 3 of article 96, provided that the application was filed within 6 (six) months from the publication.

CHAPTER VI – SUBSTANTIVE EXAMINATION

Art. 111 – The owner of an industrial design may at any time during the registration term request the examination as to novelty and originality of the subject matter of the registration.

Sole paragraph – the BPTO shall issue a substantive opinion which, if it is established by the absence of at least one of the requirements referred to in articles 95 to 98, shall serve as a basis for the commencement of ex officio nullity proceedings for registration.

CHAPTER VII – REGISTRATION NULLITY

SECTION I – General Provisions

Art. 112 – A registration shall be deemed null and void if granted contrary to the provisions of this Law.

§ 1 – Registration nullity shall take effect from the application filing date.
§ 2 – When the provisions of article 94 have not been complied with, the author may, alternatively, institute proceedings to decide registration ownership.

SECTION II – Administrative Procedure for Nullity

Art. 113 – Registration nullity shall be declared administratively if it has been granted contrary to the provisions of articles 94 to 98.

§ 1 – Registration nullity may be instituted ex officio or at the request of any person having a legitimate interest, within 5 (five) years from the registration grant date, without prejudice to the case referred to in the sole paragraph of article 111.
§ 2 – Commencement of proceedings on request or ex officio shall suspend the effects of the registration grant if submitted or pub-

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lished within 60 (sixty) days from the grant.

Art. 114 – The owner of the registration shall be notified to submit his or her comments within 60 (sixty) days from the publication date.

Art. 115 – Irrespective of a response having been filed, on expiry of the time limit specified in the previous article, the BPTO shall issue an opinion and notify the owner and the applicant to submit a reply within 60 (sixty) days.

Art. 116 – On expiry of the time limit set out in the previous article, even if no responses have been received, the procedure will be decided by the President of the BPTO, and the administrative procedure shall be concluded.

Art. 117 – Nullity proceedings shall continue even if the registration has lapsed.

SECTION III – Nullity Proceedings

Art. 118 – The provisions of articles 56 and 57 shall apply, as appropriate, to nullity proceedings of an industrial design registration.

CHAPTER VIII – REGISTRATION LAPSE

Art. 119 – A registration shall lapse on:

I – expiry of the protection term;
II – waiver by the owner, without prejudice to the rights of third parties;"
III – failure to pay the fee referred to in articles 108 and 120; or
IV – failure to comply with the provisions of article 217.

CHAPTER IX – FIVE-YEAR FEE

Art. 120 – The registration owner shall be required to pay a five-year fee from the second five-year period after the filing date.

§ 1 – Payment for the second five-year period shall be made during the fifth year of the registration term.
§ 2 – Payment for all other five-year periods shall be made at the time of application submission for renewal referred to in article 108.
§ 3 – Payment of five-year fees may also be made subsequently within 6 (six) months following the period set out in the preceding paragraph, on payment of an additional fee.

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CHAPTER X – FINAL PROVISIONS

Art. 121 – The provisions of articles 58 to 63 shall apply, as appropriate, to the subject matter covered by this Title and employee and service provider rights shall be governed by articles 88 to 93.

TITLE III – TRADEMARKS

CHAPTER I – REGISTRABILITY

SECTION I – Signs Registrable as Trademarks

Art. 122 – Any distinctive visually perceivable signs, if not prohibited by law, shall be eligible for trademark registration.

Art. 123 – For the purposes of this Law the following definitions shall apply:

I – product or service mark: a mark used to distinguish a product or service from an identical, similar or related product or service of different origin;
II – certification mark: a mark used to attest that a product or service complies with established standards or specifications, particularly regarding its quality, material used and methodology employed; and
III – collective mark: a mark used to identify goods or services produced by members of a certain entity.

SECTION II – Signs Non-registrable as Trademarks

Art. 124 – The following shall be non-registrable as trademarks:

I – official, public, national, foreign or international coats of arms, armorial bearings, medals, flags, emblems, decorations or monuments, as well as any designations, figures or imitations thereof;
II – an individual letter, number or date, on its own, except when sufficiently distinctive;
III – expressions, figures, drawings or any other sign contrary to morality and decency or which offends the honor or image of a person or which offends freedom of conscience, belief, religions or ideas and feelings that deserve respect and veneration;
IV – designations or initials of public entities or bodies, where registration is not required by the public entity or body;
V – reproductions or imitations of a characteristic or differentiating element of a third party establishment name or company name, likely to mislead or cause confusion with such distinctive signs;

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VI – signs of a generic, necessary, common, ordinary or simply descriptive nature when related to the product or service to be distinguished, or those commonly used to designate a characteristic of a product or service with respect to its nature, nationality, weight, value, quality and period of production or provision of a service, except where presented in a sufficiently distinctive form;
VII – signs or expressions used merely as a means of advertising;
VIII – colours and their names, except where arranged or combined in an unusual and distinctive way;
IX – geographical indications, or their imitations likely to mislead or signs that might wrongly suggest a geographical indication;
X – signs that induce a false indication of their origin, source, nature, quality or usefulness of the product or service to which the trademark is applied;
XI – reproductions or imitations of official seals normally used to guarantee a standard of any type or nature;
XII – reproductions or imitations of signs registered as collective or certification marks by a third party, without prejudice to the provisions of article 154;
XIII – names, prizes or symbols of official or officially recognized sporting, artistic, cultural, social, political, economic or technical events, or imitations likely to cause confusion, except when authorized by the competent authority or entity promoting the event;
XIV – reproductions or imitations of securities, bonds, coins or bank notes of the Union, States, Federal District, Territories, Municipalities or any other country;
XV – personal names or signatures, family names and surnames and images of third parties, except with consent of the owner, or his or her heirs or successors;
XVI – widely known pseudonyms or nicknames, singular or collective artistic names, except with the consent of the owner, or his or her heirs or successors;
XVII – literary, artistic or scientific work, as well as titles protected by copyrights and likely to mislead or cause confusion, except with the consent of the author or owner;
XVIII – technical terms used in industry, science and art that are related to the product or service to be distinguished;
XIX – reproductions or imitations, in whole or in part, even with additions, of a trademark registered by a third party, to distinguish or certify an identical, similar or related product or service, which is likely to cause confusion or association with a third party's trademark;

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XX – duplication of trademarks of a single owner for the same product or service, except where, in the case of trademarks of the same nature, they are presented in a sufficiently distinctive manner;
XXI – the necessary, common or usual shape of a product or packaging, or even, shapes that cannot be dissociated from a technical effect;
XXII – objects that are protected by an industrial design registration owned by a third party; an
XXIII – signs that imitate or reproduce, in whole or in part, a trademark which the applicant could not fail to have knowledge of in view of his or her activities and of which the owner is established or resident in Brazil or in a country with which Brazil has an agreement or affords reciprocal treatment, if the trademark is intended to distinguish a product or service that is identical, similar or related, and likely to cause confusion or association with such a third party's trademark.

SECTION III – Famous Trademarks

Art. – 125 – Trademarks registered in Brazil and deemed to be famous shall be afforded special protection in all fields of activity.

SECTION IV – Well-known Trademarks

Art. 126 – Trademarks that are well-known in their field of activity in accordance with article 6 bis (I) of the Paris Convention for the Protection of Industrial Property shall enjoy special protection, irrespectively of whether they have been previously filed or registered in Brazil.

§ 1 – The protection afforded by this article shall apply also to service marks.
§ 2 – the BPTO may reject ex officio an application for a trademark registration that, in whole or in part, reproduces or imitates a well-known trademark.

CHAPTER II – PRIORITY

Art. 127 – Priority rights shall be afforded to a trademark registration application filed in a country with which Brazil has signed an agreement or with an international organization that has the effect of a national filing, within the time limits set out in such an agreement, the filing not being invalidated or prejudiced by events occurring within such periods of time.

§ 1 – A priority claim shall be made at the time of filing and may be supplemented within 60 (sixty)

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days by other priorities that precede the filing date in Brazil.
§ 2 – A priority claim shall be supported by means of a suitable document of origin containing the number, date and reproduction of the registration application or registration, together with a simple translation, the contents of which shall be the full responsibility of the applicant.
§ 3 – If not provided at the time of filing, proof shall be provided within 4 (four) months from the filing date, under penalty of losing priority.
§ 4 – Where priority is obtained under an assignment, the relevant document shall be submitted together with the actual priority document.

CHAPTER III – REGISTRATION APPLICANTS

Art. 128 – Public law or private law natural or legal persons may apply for a trademark registration.

§ 1- Private law persons may only apply for trademark registrations relating to the activity they effectively and lawfully exercise, either directly or through companies they directly or indirectly control, and they shall state such fact on the actual request, under penalty of the law.

§ 2 – A collective mark registration may only be applied for by a legal person representing a group who may exercise an activity different from that of its members.
§ 3 – A certification mark registration shall only be applied for by a person with no direct commercial or industrial interest in the certified product or service.
§ 4 – A priority claim shall not exempt an application from being subject to the provisions of this Title.

CHAPTER IV – TRADEMARK RIGHTS

SECTION I – Acquisition

Art. 129 – Ownership of a trademark shall be acquired by a valid registration, according to the provision of this Law, the owner having exclusive use of the trademark throughout national territory, without prejudice to the provisions of articles 147 and 148 with respect to collective and certification marks.

§ 1 – Any person who, in good faith, at the priority or application date, has been using an identical or similar trademark for at least 6 (six) months in Brazil to distinguish or certify an identical, similar or related product or service, shall have preferential rights to registration.

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§ 2 – Preferential rights shall only be assigned, together with the business of the company, or part thereof that is directly related to the use of the trademark, by transfer or leasing.

SECTION II – Protection Afforded by the Registration

Art. 130 – The owner of a trademark shall also enjoy the right to:

I – assign his registration or registration application;
II – license its use;
III – ensure its material integrity or reputation.

Art. 131 – The protection afforded by this Law includes the use of the trademark on papers, printed matter, in advertising and in documents related to the activities of the owner.

Art. 132 – The owner of a trademark shall not prevent:

I – traders or distributors from using their own distinctive signs, together with the trademark of the product, for the purposes of promotion and marketing.
II – manufacturers of accessories from using the trademark to indicate the use of the product, provided they comply with the principles of fair competition.
III – free circulation of products placed on the internal market, by the owner or with his or her consent, without prejudice to the provisions of § 3 and 4 of article 68; and
IV – mention of the trademark in speeches, scientific or literary works or in any other publication, provided it is done without any commercial connotation and in no way prejudices its distinctive character.

CHAPTER V – TERM, ASSIGNMENT AND ENTRIES

SECTION I – Term

Art. 133 – A trademark registration shall have a term of 10 (ten) years, as from the grant date, and may be renewed for successive and similar periods.

§ 1 – A renewal application shall be filed during the last year of the registration term and shall be accompanied by proof of payment of the corresponding fee.
§ 2 – If no renewal request has been made by the end of the registration term, the owner may request renewal within the following 6 (six) months, on payment of an additional fee.
§ 3 – Renewals shall not be granted if the provisions of article 128 are not complied with.

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SECTION II – Assignment

Art. 134 – Registration applications and registrations may be assigned provided that the assignee meets the statutory requirements for requesting such registration.

Art. 135 – An assignment shall include all registrations or registration applications, in the name of the assignor for identical or similar trademarks with respect to a product or service that is identical, similar or related, under penalty of the registrations being canceled or the applications not assigned being withdrawn.

SECTION III – Entries

Art. 136 – The BPTO shall make the following entries:

I – of the assignment, giving the full particulars of the assignee;
II – of any limitation or burden on the application or registration; and
III – of changes in the name, headquarters or address of the applicant or the owner.

Art. 137 – Entries shall become effective with respect to other persons on their publication date.

Art. 138 – An appeal may be lodged against any decision which:

I – rejects assignment entries; or
II – cancels the registration or withdraws the application, according to the provisions of article 135.

SECTION IV – Use License

Art. 139 – A registration owner or applicant may enter into a licensing agreement for the trademark use, without prejudice to his or her rights, to exercise effective control over the specification, nature and quality of the respective products or services.

Sole Paragraph – The owner may afford the licensee full powers to take action to defend the trademark, without prejudice to his or her own rights.

Art. 140 – The licensing agreement shall be recorded at the BPTO in order to be effective in relation to third parties.

§ 1 – The record shall become effective with regard to third parties from its publication date.
§ 2 – The record of the licensing agreement at the BPTO is not needed for the purposes of validity of proof of use.

Art. 141 – Appeals may be lodged against any decisions rejecting the record of a licensing agreement.

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CHAPTER VI – LOSS OR RIGHTS

Art. 142 – The trademark registration shall lapse on:

I – expiry of the protection term;
II – waiver, either in whole or in part, of the products or services to which the trademark applies;
III – cancellation;
IV – failure to comply with the provisions of article 217.

Art. 143 – A registration shall be canceled, at the request of any person having a legitimate interest, if, on the actual request date:

I – trademark use has not begun in Brazil within 5 years of its grant;
II – trademark use has been interrupted for more than 5 (five) consecutive years, or if, within the same period, the mark has been used in a modified form that involves alteration to its original character in accordance with the registration certificate.

§ 1 – A trademark shall not be canceled if the owner gives legitimate reasons for failure to use it.
§ 2 – The owner shall be notified to reply within a time limit of 60 (sixty) days, and shall prove that the trademark has been used or justify failure to use it for legitimate reasons.

Art. 144 – Trademark use shall comprise the products or services referred to in the certificate, under penalty of partial cancellation of the registration with respect to those products or services which are not similar or related to those for which the trademark use was proven.

Art. 145 – Requests for cancellation shall not be admitted if the trademark use has been proven or if failure to use it has been justified in an earlier proceeding filed less than 5 (five) years previously.

Art. 146 – Appeals may be lodged against decisions which declare or deny cancellation.

CHAPTER VII – COLLECTIVE AND CERITIFICATION MARKS

Art. 147 – Registration applications for collective marks shall include the regulations for use, determining conditions and prohibitions regarding the mark use.

Sole Paragraph – If the regulations for use do not accompany the application, these regulations shall be filed within 60 (sixty) days from the filing date, under penalty of the application being deemed definitively withdrawn.

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Art. 148 – Applications for a certification mark registration shall contain:

I – the product or service characteristics to be certified; and
II – control measures to be adopted by the owner.

Sole Paragraph – If the documents referred to in items I and II of this article do not accompany the application, these documents shall be filed within 60 (sixty) days, under penalty of the application being deemed definitively withdrawn.

Art. 149 – Any changes in the regulations for use shall be notified to the BPTO by means of a duly filed request, stating the provisions that have been changed, under penalty of the changes being disregarded.

Art. 150 – Mark use shall not be dependent on a license and it shall be sufficient to have authorization in the regulations for use.

Art. 151 – In addition to the grounds for lapse referred to in article 142, collective and certification mark registration shall lapse if:

I – the entity ceases to exist; or
II – the mark is used under conditions that differ from those laid down in the regulations for use.

Art. 152 – Waiver of a collective mark registration shall only be accepted if requested in accordance with the articles of incorporation or statutes of the entity itself, or even the regulations for use.

Art. 153 – A registration shall be declared canceled if the collective mark is not used by more than one authorized person, without prejudice to the provisions of articles 143 and 146.

Art. 154 – Collective or certification marks which have already been used and the registrations of which have lapsed may not be registered in the name of another party before the 5 (five) year time limit from the registration lapse has expired.

CHAPTER VIII – FILING

Art. 155 – Applications shall refer to a single distinctive sign and, according to the conditions established by the BPTO, shall contain:

I – the application;
II – labels, where appropriate; and
III – proof of payment of the filing fee.

Sole Paragraph – The request and any supporting documents shall

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be filed in Portuguese and any document filed in a foreign language shall have an uncertified translation submitted at the time the application is filed or within the following 60 (sixty) days under penalty of the document not being taken into consideration.

Art. 156 – Once the application has been filed it shall be subject to a formal preliminary examination, and if found in order, the application shall be recorded and the submission date shall be taken to be the filing date.

Art. 157 – Applications that do not comply with the requirements of article 155, but which contain sufficient data about the applicant, the trademark sign and the class, may be filed with the BPTO in return for a dated receipt which shall establish the conditions to be complied with by the applicant within 5 (five) days, under penalty of not being taken into consideration.

Sole Paragraph – Once the conditions have been complied with, the filing date shall be taken to be that of the application submission date.

CHAPTER IX – EXAMINATION

Art. 158 – Once recorded, the application shall be published to enable oppositions to be filed within a time limit of 60 (sixty) days.

§ 1 – The applicant shall be notified of any opposition and shall be notified to reply within 60 (sixty) days.
§ 2 – Oppositions, the administrative procedure for nullity or nullity proceedings based on the provisions of item XXIII of article 124 or 126 shall not be admitted unless proof of registration application filing is supplied, in accordance with this Law, within the time limit of 60 (sixty) days from the opposition, administrative procedure for nullity or nullity proceedings filing date.

Art. 159 – On expiry of the opposition period, or if an opposition has been lodged, on expiry of the period for submitting comments, the examination shall be carried out during which conditions may be established which shall be complied with within 60 (sixty) days.

§ 1 – If no answer is received to the conditions, the application

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shall be deemed definitively withdrawn.
§ 2 – Once the reply to the conditions has been filed, even if the conditions have not been met, or if its formulation has been contested, the examination shall be continued.

Art. 160 – On completion of the examination, a decision shall be issued approving or rejecting the registration application.

CHAPTER X – ISSUE OF REGISTRATION CERTIFICATES

Art. 161 – A registration shall be issued once the application has been approved and proof of payment of the appropriate fees has been supplied.

Art. 162 – The payment of fees and proof of payment in respect of the issue of the registration certificate and to the first 10(ten) years of protection shall be made within the time limit of 60 (sixty) days from approval.

Sole Paragraph – The fees may also be paid and proof supplied within 30 (thirty) days from the time limit referred to in this article, independent of notification, on payment of a specific fee, under penalty of the application being definitively withdrawn.

Art. 163 – A registration certificate shall be deemed to have been issued on the publication date of the relevant decision.

Art. 164 – The certificate shall mention the trademark, the registration number and date, name, nationality and country of residence of the owner, the products and services, the registration characteristics and foreign priority.

CHAPTER XI – REGISTRATION NULLITY

SECTION I – General Provisions

Art. 165 – A registration granted contrary to the provisions of this Law shall be null and void.

Sole Paragraph – Registration nullity may be total or partial, and a condition for partial nullity shall be the fact that the remaining part is registrable.

Art. 166 – A trademark owner registered in a country that is a signatory of the Paris Convention for the Protection of Industrial Property may, alternatively, commence legal proceedings to claim registration ownership, in accordance with the provisions of article 6 septies (1) of that Convention.

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Art. 167 – A nullity declaration shall be effective from the filing date.

SECTION II – Administrative Procedure for Nullity

Art 168 – Registration nullity shall be declared administratively if the registration has been granted contrary to the provisions of this Law.

Art 169 – A nullity procedure may be instituted ex officio or at the request of any person with a legitimate interest within a time limit of 180 (one hundred ad eighty) days from the registration certificate issue date.

Art. 170 – The owner shall be notified to reply within a time limit of 60 (sixty) days.

Art. 171- After the time limit referred to in the previous article, even if no response has been submitted, the procedure shall be decided by the president of the BPTO, and the administrative procedure shall be closed.

Art. 172 – Nullity proceedings shall continue even if the registration has lapsed.

SECTION III – Nullity Proceedings

Art. 173 – Nullity proceedings may be commenced by the BPTO or by any person having a legitimate interest.

Sole Paragraph – During the course of the proceedings, the judge may grant an injunction suspending the registration effects and the trademark use, provided that the relevant procedural requirements are complied with.

Art. 174 – Proceedings to declare registration nullity shall prescribe in 5 (five) years from the registration date.

Art. 175 – Nullity proceedings shall be brought before the Federal Justice Courts and the BPTO shall participate in the proceedings when it is not the plaintiff.

§ 1 – A defendant owner of a registration shall have a time limit of 60 (sixty) days to reply.
§ 2 – When the final decision on nullity proceedings has been made, the BPTO shall publish a notification to inform third parties.

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TITLE IV GEOGRAPHICAL INDICATIONS

Art. 176 – A geographical indication shall be an indication of the source or origin denomination.

Art. 177 – Indication of the source shall mean the geographic name of a country, city, region or location in its territory, which has become known as the center of extraction, production or manufacture of a given product or of the provision of a given service.

Art. 178 – Denomination of origin shall be the geographical name of a country, city, region or locality in its territory, used to designate a product or service of which the qualities or characteristics are exclusively or essentially due to the geographical environment, including natural and human factors.

Art. 179 Protection shall extend to the graphical or figurative representation of a geographical indication, as well as the geographic representation of the country, city, region or location of which the name is a geographical indication.

Art. 180 – Where the geographical name has entered into everyday use designating a given product or service, it shall not be deemed a geographical indication.

Art. 181 – A geographical name that is not an indication of source or denomination of origin may be used as a characteristic element of a product or service mark provided it does not suggest a false origin.

Art. 182 – The use the geographic indication shall be reserved to the producers and service providers established in that locality and, regarding denominations of origin, quality requirements shall also be complied with.

Sole Paragraph – The BPTO shall establish the conditions for registration of geographic indications.

TITLE V – INDUSTRIAL PROPERTY INFRINGEMENT

CHAPTER I – PATENT INFRINGEMENT

Art. 183 – An infringement of a patent for an invention or utility model is committed by any person who:

I- manufactures a product which is the subject matter of a patent for an invention or utility model patent without the authorization of the patent owner; or
II – uses a means or a process that is the subject matter of a patent for an invention, without the authorization of the patent owner.

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Penalty – imprisonment, from one (1) to three (3) months, or fine.

Art. 184 – An infringement of a patent for an invention or utility model is committed by any person who:

I – exports, sells, exhibits or offers for sale, holds in stock, conceals or receives for use for commercial purposes, a product manufactured in infringement of a patent for an invention or utility model, or that was obtained by a patented means or process; or
II – imports a product that is the subject matter of a patent for an invention or utility model or which is obtained by a means or a process patented in Brazil, for the purposes referred to in the previous item, and that has not been placed on the external market directly by the patent owner or with his or her consent.

Penalty – imprisonment, from 1 (one) to 3 (three) months, or fine.

Art. 185 – Supplying a component of a patented product, or material or equipment for carrying out a patented process, where the end use of the component, material or equipment necessarily implies exploitation of the subject matter of the patent.

Penalty – imprisonment, from 1 (one) to 3 (three) months, or fine.

Art. 186 – The acts referred to in this Chapter shall constitute infringement even if they do not affect all claims of the patent or if they are limited to the use of means equivalent to the subject matter of the patent

CHAPTER II – INDUSTRIAL DESIGN INFRINGEMENT

Art. 187 – Manufacturing, without authorization of the owner, a product that incorporates a registered industrial design, or a substantial imitation thereof that is likely to mislead or cause customer confusion.

Penalty – imprisonment, from 3 (three) months to 1 (one) year, or fine.

Art. 188 – An infringement of an industrial design registration is committed by any person who:

I – exports, sells, exhibits or offers for sale, holds in stock, conceals or receives for use for commercial purposes, a product manufactured in infringement of a patent for an invention or utility model, or that was obtained by a patented means or process; or
II – imports a product that is the subject matter of a patent for an

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invention or utility model or which is obtained by a means or a process patented in Brazil, for the purposes referred to in the previous item, and that has not been placed on the external market directly by the patent owner or with his or her consent.

Penalty – imprisonment, from 1 (one) to 3 (three) months, or fine.

CHAPTER III – TRADEMARK INFRINGEMENT

Art. 189 – An infringement of a registered trademark is committed by any person who:

I – reproduces, in whole or in part, a registered trademark, without the authorization of the owner, or imitates it in a manner that may cause confusion; or
II – alters the registered trademark of another person already affixed to a product on the market.

Penalty – imprisonment, from 3 (three) months to 1 (one) year, or fine.

Art. 190 – An infringement of a registered trademark is committed by any person who imports, exports, sells, offers or exhibits for sale, conceals or keeps in stock:

I- a product bearing a trademark of another party which is unlawfully reproduced of imitated, in whole or in part; or
II – a product of his or her industry of commerce, held in a vessel, container or packaging bearing the legitimate trademark of another person.

Penalty – imprisonment, from 1 (one) to 3 (three) months, or fine.

CHAPTER IV – INFRINGEMENTS COMMITTED BY MEANS OF TRADEMARKS, ESTABLISHMENT NAMES AND ADVERTISING SIGNS

Art. 191- Reproducing or imitating, in whole or in part, in a manner that may mislead or cause confusion, official armorial bearings, coats of arms or decorations whether national, foreign or international without the necessary authorization, in a trademark, establishment name, trade name, insignia or advertising sign, or using such reproductions or imitations for commercial purposes.

Penalty – imprisonment, from 1 (one) to 3 (three) months, or fine.

Sole paragraph – Any person who sells, exhibits or offers for sale products branded with such marks shall be subject to the same penalty.

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CHAPTER V – INFRINGEMENT OF GEOGRAPHICAL AND OTHER INDICATIONS

Art. 192 – Manufacturing, importing, exporting, selling, exhibiting or offering for sale or having in stock a product that bears a false geographical indication.

Penalty – imprisonment, from 1 (one) to 3 (three) months, or fine.

Art. 193 – Using on a product, container, case, wrapper, label, invoice, circular, poster, or any other form of publicity or advertising, indicative terms such as "type", "sort", "kind", "system", "similar", "substitute", "identical", or the like, failing to clearly state the true source of the product.

Penalty – imprisonment, from 1 (one) to 3 (three) months, or fine.

Art. 194 – Using a trademark, commercial name, establishment name, insignia, advertising sign or expression or any other form that suggests a source other than the true source, or selling or exhibiting for sale a product bearing such signs.

Penalty – imprisonment, from 1 (one) to 3 (three) months, or fine.

CHAPTER VI – ACTS OF UNFAIR COMPETITION

Art. 195 – An act of unfair competition is committed by any person who:

I – publishes, by any means, a false statement, detrimental to a competitor, with the aim of obtaining an advantage;
II – supplies or publishes false information with respect to a competitor with the aim of obtaining an advantage;
III – uses fraudulent means to divert the customers of another party, for his or her own profit or that of another party;
IV – uses the advertising expression or sign of another party, or imitates it, in a manner liable to cause confusion between products or establishments;
V – makes undue use of another party's commercial name, establishment name or insignia or sells, exhibits, offers for sale or has in stock a product bearing those references;
VI – substitutes on the product of another party the name or company name of such party, without his or her consent, with his or her own name or company name;
VII – claims, by way of advertising, to have received a prize or distinction that he or she has not actually been awarded;

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VIII – sells, exhibits or offers for sale, in the container or packaging of another, an adulterated or counterfeit product, or uses such container or packaging to trade with a product of the same type, even if not adulterated or counterfeit, if such does not constitute a more serious offense;
IX – gives or promises money or other consideration to an employee of a competitor in return for which the employee, failing in his or her duties of employment, provides him or her with an advantage;
X – receives money or other consideration, or accepts a promise of payment or reward in return for providing an advantage to a competitor, thereby failing in his or her duties of employment;
XI – publishes, exploits or uses, without authorization, confidential knowledge, information or data which may be used in industry, commerce or service provision, except where such confidential knowledge, information or data are in the public domain or are obvious to a person skilled in the art, to which he or she has had access due to a contractual or employment relationship, even after termination of the contract;
XII – publishes, exploits or uses, without authorization, such knowledge or information referred to in the previous item, obtained by illicit means or to which he or she has had access by fraud;
XIII – sells, exhibits or offers for sale a product that he or she wrongly states to be subject of a patent filed or granted or of a registered industrial design or who wrongly states in a commercial announcement or paper that such product has been filed, patented or registered; or
XIV – publishes, exploits or uses without authorization, the results of tests or other undisclosed data that have been developed involving a considerable effort and which has been submitted to government entities as a condition for the approval of the marketing of products (Included by Law no. 10,1966 of 14/02/2001).

Penalty – imprisonment, from 3 (three) months to 1 (one) year, or fine.

§ 1 – The situations referred to in XI and XII include the employer, partner or administrator of a company who commits an act described in those items.
§ 2 – The provisions of item XIV shall not apply to the publication by a government agency competent to authorize the marketing of a product, where necessary to protect the public.

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CHAPTER VII – GENERAL PROVISIONS

Art. 196 – The terms of imprisonment provided for in Chapters I, II and III of this Title shall be increased by between one third and one half if:

I – the person is or was a representative, proxy, agent, partner or employee of the patent or registration owner or also of his licensee; or
II – the altered, reproduced or imitated trademark is famous, well-known, or a certification or collective mark.

Art. 197 – The fines provided for in this Title shall range between a minimum of 10 (ten) and maximum of 360 (three hundred and sixty) daily fines, in accordance with the provisions of the Penal Code.

Sole paragraph – The fines may be increased or reduced by up to ten (10) times, taking into consideration the personal situation of the agent and the size of the advantage obtained, regardless of the provisions set out in the previous article.

Art. 198 – At the time of clearance, customs authorities may seize, ex officio or at the request of an interested party, any products bearing falsified, altered or imitated marks or a false indication of source.

Art. 199 – Proceedings with respect to offenses referred to in this Title are only commenced upon complaint, except in the case of the offense referred to in article 191 which shall bring about public criminal proceedings.

Art. 200 – Criminal proceedings and preliminary measures of search and seizure, in cases of industrial property infringement, shall be governed by the provisions of the Code of Criminal Procedure, with the alterations provided for in the articles of this Chapter.

Art. 201 – During the execution of a search and seizure measure relating to a patent infringement of which the subject matter is a process invention, the bailiff shall be accompanied by an expert who shall make a preliminary verification of the existence of the unlawful act, enabling the judge to order seizure of the products obtained by the infringer using the patented process.

Art. 202 – In addition to the preliminary measures of search and seizure, the party interested party may request:

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I – seizure of a counterfeit, altered or imitated trademark where it is prepared or found, prior to use for criminal purposes; or
II – destruction of the counterfeit trademark on packaging or products that contain it, before distribution, even if this implies the destruction of the packaging or products themselves.

Art. 203 – In the case of a lawfully constituted industrial or commercial establishment operating in public, the preliminary measures shall be limited to inspection and seizure of the products as ordered by the judge, the lawful activity not being brought to a halt.

Art. 204 – If a search and seizure procedure was requested in bad faith, for reasons of competition, a mere whim or gross error, the person who requested the measure shall be liable for loss and damages.

Art. 205 – An allegation of a patent or registration nullity on which the proceedings are based may constitute a plea of defense in criminal proceedings. Acquittal of the defendant, however, shall not imply patent or registration nullity which may only be claimed in competent proceedings.

Art. 206 – If information that is of a confidential nature, either an industrial or trade secret, is disclosed during proceedings, the judge shall decide whether the proceedings should continue in secret, the other party being prohibited from using such information for other purposes.

Art. 207 – Independently of criminal proceedings, the injured party may commence civil proceedings as he considers necessary in accordance with the Code of Civil Procedure.

Art. 208 – Compensation shall be determined on the basis of the benefit that the injured party would have obtained if the infringement had not taken place.

Art. 209 – The injured party shall be entitled to compensation for loss or damages in respect of industrial property rights infringement and acts of unfair competition not provided for in this Law, but which are liable to prejudice one's reputation or business or to lead to confusion between commercial or industrial establishments or service providers, or between products and services placed onto the market.

§ 1 The judge may, in the record of the same proceedings, in order

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to avoid irreparable damages or damage that would be difficult to recover, grant an injunction to cease the infringement or act concerned, before summoning the defendant, subject to bail or other security where necessary.
§ 2 – In the case of flagrant reproduction or imitation of a registered trademark, the judge may order the seizure of all merchandise, products, articles, packaging, labels or other objects bearing the counterfeit or imitated trademark.

Art. 210 – Loss of profits shall be determined by the most favourable of the following criteria to the injured party:

I – the benefits the injured party would have obtained if the infringement had not taken place;
II – the benefits received by the infringer; or
III – the remuneration the infringer would have paid to the owner of the infringed rights for a license that would have permitted the lawful exploitation of the subject matter of the rights.

TITLE VI – TECHNOLOGY TRANSFER AND FRANCHISING

Art. 211 – The BPTO shall register the contracts that involve technology transfer, franchising agreements and the like in order that they may be effective with respect to third parties.

Sole Paragraph – Decisions regarding the application for the record of contracts of the type referred to in this article shall be issued within 30 (thirty) days from the record application date.

TITLE VII – GENERAL PROVISIONS

CHAPTER I – APPEALS

Art. 212 – Unless explicitly stipulated to the contrary, appeals may be lodged against decisions referred to in this Law within a time limit of 60 (sixty) days.

§ 1 – Appeals shall have suspensive and full devolutive effect and all provisions concerning first instance hearing shall be applied, where applicable.
§ 2 – No appeal may be lodged against a decision ordering the final refusal of a patent or design registration application or a decision granting a patent, certification of addition or a trademark registration application.
§ 3 – The president of the BPTO shall decide on appeals, and the administrative procedure shall be closed.

Art. 213 – The interested parties shall be notified to file counter-

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claims within a time limit of 60 (sixty) days.

Art. 214 – In order to supplement the appeal claims, the BPTO may formulate conditions that shall be complied with, within a time limit of 60 (sixty) days.

Sole Paragraph – On expiry of the time limit in the head of this article, a decision shall be taken on the appeal.

Art. 215 – An appeal decision shall be final and there shall be no appeal from the administrative procedure.

CHAPTER II – ACTS OF THE PARTIES

Art. 216 – The acts referred to in this Law shall be performed by the parties or their duly qualified attorneys.

§ 1 – Power of attorney in its original form, an official copy or a certified photocopy shall be in Portuguese, consular legalization and certification by a notary public not being required.
§ 2 – A power of attorney shall be filed within 60 (sixty) days from the performance of the first act by the party in the proceedings, irrespective of notification or requirement, under penalty of withdrawal, the withdrawal of a patent, industrial design registration or trademark registration application being final.

Art. 217 – A person resident abroad shall be required to appoint and maintain an attorney duly qualified and resident in Brazil, with powers to represent such person administratively and legally, and shall also be empowered to receive summons.

Art. 218 – Petitions shall not be taken into consideration if:

I – they are submitted after the statutory deadline;
II – they are not accompanied by proof of payment of the relevant fee applicable on submission.

Art. 219 – Petitions, oppositions and appeals shall not be taken into consideration if:

I – they are submitted after the time limit set out by this Law;
II – they are not based on legal grounds;
III – they are not accompanied by proof of payment of the relevant fee.

Art. 220 – Whenever possible, the BPTO shall take into account the acts of the parties and may impose any befitting requirements.

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CHAPTER III – TIME LIMITS

Art. 221 – The time limits laid down by this Law shall be continuous, and the right to perform an act shall automatically lapse on termination of the time limit unless the party concerned proves that the act was not performed for legitimate reasons.

§ 1 – Legitimate reasons mean an unforeseeable event, beyond the control of the party concerned which has prevented the party from carrying out the act.
§ 2 – Where legitimate reasons are accepted, the party concerned shall perform the act within the time limit determined by the BPTO.

Art. 222 – In calculating the time limits, the first day shall be excluded and the last day included.

Art. 223 – Time limits shall only begin to run on the first working day after legal notification is made by publication in the official BPTO communication.

Art. 224 – In the absence of express provision in this Law, the time limit for a party to perform an act shall be 60 (sixty) days.

CHAPTER IV – LIMITATION

Art. 225 – Proceedings for damages suffered by industrial property rights shall become prescribed after 5 (five) years.

CHAPTER V – ACTS of the BPTO

Art. 226 – Acts of the BPTO in administrative procedures relating to industrial property shall take effect only after publication in the respective official communication, except:

I – those which, under the provisions of this Law, expressly do not require notification or publication;
II – administrative decisions, where notification is made in the post or the interested party is made aware through the proceedings; and
III – internal opinions and decisions of which notification of the parties is not required.

CHAPTER VI – CLASSIFICATIONS

Art. 227 – Classifications relating to the subject matter of Titles I, II and III of this Law, shall be established by BPTO, in those cases where they were not laid down by an international treaty or agreement in force in Brazil.

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CHAPTER VII – FEES

Art. 228 – Fees shall be charged for the services provided in accordance with the provisions of this Law, the amounts of such fees and the form of collection shall be established by a decision made by the head of federal public administration body to which the BPTO is linked.

TITLE VIII – TRANSITIONAL AND FINAL PROVISIONS

Art. 229 – The provisions of this Law shall apply to all applications pending, except with regard to the patentability of applications filed until December 31, 1994, whose subject matter for protection are substances, materials or products obtained through chemical means or processes or foodstuff or chemical-pharmaceutical substances, materials, compounds or products and medicines of any kind, as well as to the respective processes for obtaining or modifying them and whose applicants have not been exercising their rights as set out in articles 230 and 231 of this Law which shall be considered rejected, for all effects, it being necessary for the BPTO to publish the communication of the said rejections. (Text given by Law no. 10,196 of 14/02/2001).

Sole paragraph – The criteria of patentability in this Law, on the effective application filing date or priority date, where applicable, shall apply to applications related to pharmaceutical and chemical products for agriculture filed between January 1, 1995 and May 14, 1997, thus ensuring protection from the patent grant date for the remaining term from the filing date in Brazil, limited to the term provided for in the heading of article 40. (Sole paragraph included by Law no. 10,196 of 14/02/2001).

Art. 229-A – Applications for process patents filed between January 1, 1995 and May 14, 1997, which enjoyed no protection under article 9, item "c" of Law no. 5,772 of December 21, 1971, shall be deemed rejected, and the BPTO shall publish the communication of the said rejections. (Article included by Law no. 10,1966 of 14/02/2001).

Art. 229-B – Applications for product patents filed between January 1, 1995 and May 14, 1997, which enjoyed no protection under article 9, items "b" and "c" of Law no. 5,772 of December 21, 1971, and whose applicants have not been exercising their rights as set out in articles 230 and 231, shall be decided on by December 31, 2004, in accordance with this

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Law. (Article included by Law no. 10,196 of 14/02/2001).

Art. 229-C – Patent grants for pharmaceutical products and processes shall depend on the prior consent of the National Agency for Sanitary Inspection (Agência Nacional de Vigilância Sanitária – ANVISA). (Article included by Law no. 10,196 of 14/02/2001).

Art. 230 – A patent application may be filed with respect to substances, materials or products obtained through chemical means or processes or foodstuff or chemical-pharmaceutical substances, materials, compounds or products and medicines of any kind, as well as to the respective processes for obtaining or modifying them, by any person entitled to protection under a treaty or convention in force in Brazil, the initial filing date abroad being recognized, provided that the subject matter thereof has not been placed on any market by direct initiative of the owner or by third parties with his or her consent, nor have third parties carried out serious and effective preparations in Brazil for exploiting the subject matter of the application or patent.

§ 1 – Applications shall be filed within a time limit of 1 (one) year from the publication date of this Law, and shall state the first filing date abroad.
§ 2 – Patent applications filed in accordance with the provisions of this article shall be automatically published, and the interested parties shall be entitled to submit comments within a time limit of 90 (ninety) days on whether the conditions set out in the head of this article have been met.
§ 3 – Without prejudice to articles 10 and 18 of this Law, and once the conditions set out in this article have been met and patent grant in the country where the initial application has been proved, the patent shall be granted in Brazil exactly as granted in the country of origin.
§ 4 – A patent granted on the basis of this article shall enjoy the remaining protection term of that granted in the country of first application from the filing date in Brazil and limited to the term set out in article 40, and the provision of the sole paragraph shall not apply.
§ 5 – An applicant that has filed a pending application with respect to substances, materials or products obtained through chemical means or processes or foodstuff or chemical-pharmaceutical substances, materials, compounds or products and medicines of any kind, as well as to the respective processes for obtaining or modify-

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ing them, may file a new application within the time limit and under the provisions of this article, submitting proof of withdrawal of the pending application.
§ 6 – The provisions of this Law shall apply where appropriate, to applications filed and to patents granted in accordance with the provisions of this article

Art. 231 – A patent application may be filed for the subject matters referred to in the previous article by a national or person resident in Brazil, and the invention publication date shall be guaranteed, provided that its subject matter has not been placed on any market on the direct initiative of the owner or by a third party with his or her consent, nor have third parties carried out serious and effective preparations in Brazil for exploiting the subject matter of the application.

§ 1 – The application shall be filed within 1 (one) year from the publication of this Law.
§ 2 – Patent applications filed in accordance with the provisions of this article shall be prosecuted under the terms of this Law.
§ 3 – A patent granted on the basis of this article shall enjoy the remaining protection term of 20 (twenty) years from the invention publication date, from the filing in Brazil.
§ 4 – An applicant with a pending application for a patent relating to a subject matter to which the previous article refers may file a new application within the time limit and under the conditions set out in this article, submitting proof of withdrawal of the pending application.

Art. 232 – The production or use, in accordance with the provisions of the previous legislation, of substances, materials or products obtained through chemical means or processes or foodstuff or chemical-pharmaceutical substances, materials, compounds or products and medicines of any kind, as well as the respective processes for obtaining or modifying them, even if protected by a product or a process patent in another country in accordance with a treaty or convention in force in Brazil, may continue under the same conditions that existed prior to the approval of this Law.

§ 1 – No retroactive or future claim of any value shall be admitted with respect to products manufactured or processes used in Brazil, in accordance with this article.
§ 2 – In the same way, no claim under the terms of the previous

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paragraph shall be admitted if, during the period prior to the entry into force of this Law, significant investment has been made for the exploitation of a product or a process as referred to in this article, even if protected by product or process patents in another country.

Art. 233 – Applications for the registration of advertising slogans and signs and declarations of notoriety shall be definitively rejected and the registrations and declarations already granted shall remain in force for the remainder of their term, but may not be renewed.

Art. 234 – Priority guarantees, in accordance with article 7 of Law no. 5,772 of December 21, 1971, shall be enjoyed by the applicants up to the expiry of the current time limit.

Art. 235 – Time limits granted under Law no. 5,772 of December 21, 1971 shall be guaranteed.

Art. 236 – Applications for industrial model and design patents filed under Law no. 5,772 of December 21, 1971, shall be automatically designated as industrial design registration applications, for all legal effects being deemed to have been published.

Sole paragraph – Payments made with respect to such adapted applications shall be taken into account in order to calculate the due five-year fee.

Art. 237 – The provisions of article 111 shall not apply to industrial model or design patent applications that have been examined in accordance with the provisions of Law no. 5,772 or December 21, 1971.

Art. 238 – Appeals filed under Law no. 5,772 of December 21, 1971, shall be decided in accordance with the provisions therein.

Art. 239 – The Executive Branch is authorized to carry out any changes within the BPTO necessary to ensure its financial and administrative autonomy, the BPTO being able to:

I – contract technical and administrative staff by way of public examination;
II – establish salaries for its employees, subject to the approval by the Government Department to which the BPTO is linked; and
III – propose a basic structure and internal regulations subject to the approval of the Government Department to which the BPTO is linked.

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Sole paragraph – Expenses resulting from the enforcement of this article shall be paid from the BPTO's own resources.

Art. 240 – Article 2 of Law no. 5,648 of December 11, 1970 shall be reworded as follows:

"Article 2 – The principal task of the BPTO shall be to execute at a national level the statutes that govern industrial property, taking into account its social, economic, legal and technical functions, as well as making pronouncements on the advisability of signing, ratifying and terminating conventions, treaties, and agreements about industrial property."

Art. 241 – The Judiciary is hereby authorized to establish special courts to hear matters relating to industrial property.

Art. 242 – The Executive Branch shall submit to the National Congress a bill intended to promote, where necessary, the harmonization of this Law with the industrial property policy adopted by other MERCOSUR member countries.

Art. 243 – This Law shall enter into force on its publication date with respect to the matters contained in articles 230, 231, 232 and 239, and 1 (one) year after its publication with respect to the remaining articles.

Art. 244 – Law no. 5,772 of December 21, 1971, Law no. 6,348 of July 7, 1976, articles 187 to 196 of Decree-Law no. 2,848 of December, 1940, articles 169 to 189 of Decree-Law no. 7,903, of August 27, 1945, and any other contrary provisions are hereby repealed.

Brasília, May 14, 1996; 175th year of Independence and 108th year of the Republic.

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