ALEBE LINHARES MESQUITA

THE DIALOGUE BETWEEN THE INTELLECTUAL PROPERTY PROVISIONS IN PREFERENTIAL TRADE AGREEMENTS AND THE BRAZILIAN LEGAL FRAMEWORK

Master Dissertation

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Master Dissertation presented to the Examining Committee of the Law Post-Graduate Program of the University São Paulo Law School, in the International Law concentration area, under the supervision of the Associate Professor Dr. Alberto do Amaral Júnior.

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ABSTRACT

The present work promotes a dialogue between the intellectual property provisions adopted in Preferential Trade Agreements (PTAs) and the Brazilian legal framework. In recent years, PTAs have become a major source of international intellectual property regulation. This happens in parallel to the multilateral trading system and rules established under the auspices of the World Trade Organization (WTO). The new intellectual property provisions established under PTAs advance significantly the rules established under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). In this scenario, Brazil is apart from the international economic trend of adopting intellectual property provisions in PTAs. Due to its inaction, the country cannot influence the direction in which the international intellectual property regulation is heading. This issue is analyzed in the light of the balance between private and public interests that the protection of intellectual property rights imposes. The general objective of the present work is to investigate how and to what extent the intellectual property rules established under PTAs differs from the Brazilian intellectual property regime. The specific objectives are to assess which are the legal issues and the possible effects that pervade the adoption higher standards of intellectual property protection in PTAs; to map and analyze the norms on patent and test data protection adopted in PTAs and to compare them with the TRIPS Agreement and the Brazilian intellectual property regime; and to investigate how intellectual property rules are diffused across international, regional and national levels. The methodology adopted in this research is characterized as bibliographic, descriptive and exploratory. The importance of this research resides in understanding the cross cutting trends in the establishment of new intellectual property rules. This work concludes that the intellectual property rules on patent and test data protection accorded under PTAs do not radically differ from the Brazilian intellectual property regime. Brazil already has several provisions in its national legislation that even exceed the level of patent and test data protection required under these PTAs and the TRIPS Agreement. On the one hand, the Brazilian intellectual property regime differs from the following TRIPS-Plus provisions on: patentability of methods of treatment, plants and animals; limitation of the grounds for compulsory license; restriction of the grounds for patent revocation; adjustment to compensate the curtailment of the patent term due to the marketing approval procedures; patent-linkage; and test data exclusivity of pharmaceutical products for human use submitted to marketing approval. On the other hand, the Brazilian intellectual property regime aligns with the following TRIPS-Plus provision: prohibition of parallel importation of patented products; patentability of “new uses” of known compounds; adjustment in the patent term of protection to compensate unreasonable delays in the granting process; disclosure of the origin of the national genetic resource and associated traditional knowledge in patent applications; test data exclusivity of pharmaceutical products for veterinary use and plant protection products.

Key Words: Preferential Trade Agreements. TRIPS-Plus. Patent. Test Data. Brazil.

Alebe Linhares Mesquita. O Diálogo entre os Dispositivos de Propriedade Intelectual nos Acordos Preferenciais de Comércio e o Quadro Jurídico Brasileiro. 2017. 269 p. Mestrado – Faculdade de Direito, Universidade de São Paulo, São Paulo, 2017.

RESUMO

O presente trabalho promove um diálogo entre as disposições sobre propriedade intelectual adotadas nos Acordos Preferenciais de Comércio (APCs) e o regime jurídico brasileiro. Nos últimos anos, os APCs se tornaram uma fonte importante de regulação internacional da propriedade intelectual. Isso acontece paralelamente ao sistema e as regras multilaterais de comércio estabelecidas sob os auspícios da Organização Mundial do Comércio (OMC). As novas disposições em matéria de propriedade intelectual estabelecidas no âmbito dos APCs avançam significativamente as regras estabelecidas no Acordo da OMC sobre Aspectos dos Direitos de Propriedade Intelectual Relacionados ao Comércio (Acordo TRIPS). Nesse cenário, o Brasil está à parte da tendência econômica internacional de adotar disposições sobre propriedade intelectual em APCs. Devido à sua inação, o país não pode influenciar a direção que a regulação internacional da propriedade intelectual se dirige. Essa questão é analisada à luz do equilíbrio entre os interesses privados e públicos que a proteção dos direitos de propriedade intelectual impõe. O objetivo geral do presente trabalho é investigar como e em que medidas as normas sobre propriedade intelectual estabelecidas em APCs diferem do regime de propriedade intelectual brasileiro. Os objetivos específicos são avaliar as questões legais e os possíveis efeitos que permeiam a adoção de padrões mais elevados de proteção da propriedade intelectual em APCs; mapear e analisar as normas sobre proteção de patentes e dados de teste adotadas em APCs e compará-las com o Acordo TRIPS e com o regime de propriedade intelectual brasileiro; e investigar como as regras de propriedade intelectual são difundidas nos níveis internacional, regional e nacional. A metodologia adotada nesta pesquisa é caracterizada como bibliográfica, descritiva e exploratória. A importância desta pesquisa reside na compreensão das tendências transversais no estabelecimento de novas regras de propriedade intelectual. Este trabalho conclui que as normas de propriedade intelectual sobre proteção de patentes e dados de teste acordadas nos PTAs não diferem radicalmente do regime de propriedade intelectual brasileiro. O Brasil já possui várias disposições em sua legislação nacional que até mesmo excedem o nível de proteção patentes e dados de teste exigido por esses APCs e pelo Acordo TRIPS. Por um lado, o regime de propriedade intelectual brasileiro difere dos seguintes dispositivos *TRIPS-Plus* sobre: patenteabilidade dos métodos de tratamento, plantas e animais; limitação dos motivos para licença compulsória; restrição dos motivos para revogação de patentes; ajuste para compensar a redução do prazo de patente devido aos procedimentos de aprovação para comercialização; vinculação entre patente e aprovação comercial; exclusividade de dados de teste de produtos farmacêuticos para uso humano submetidos à aprovação comercial. Por outro lado, o regime de propriedade intelectual brasileiro alinha-se com os seguintes dispositivos *TRIPS-Plus* sobre: proibição de importação paralela de produtos patenteados; patenteabilidade de "novos usos" de composições já conhecidas; ajuste no prazo de proteção de patente para compensar atrasos injustificados no processo de outorga; divulgação da origem dos recursos genéticos nacionais e do conhecimento tradicional associado nos pedidos de patente; exclusividade de dados de teste de produtos farmacêuticos para uso veterinário e produtos para proteção de plantas.

Palavras-Chave: Acordos Preferenciais de Comércio. *TRIPS-Plus*. Patente. Dados de Teste. Brasil.

Alebe Linhares Mesquita. Le Dialogue entre les Dispositions sur La Propriété Intellectuelle dans les Accords Commerciaux Préférentiels et le Cadre Juridique Brésilien. 2017. 269 p. Master – Faculté de Droit, Université de São Paulo, São Paulo 2017.

RÉSUMÉ

Cette étude développe un dialogue entre les dispositions relatives à la propriété intellectuelle adoptées dans les Accords Commerciaux Préférentiels (ACPs) et le régime juridique brésilien. Ces dernières années, les ACPs sont devenus une source majeure de la réglementation internationale de la propriété intellectuelle. Ce, parallèlement au système et aux règles multilatérales du commerce établies sous les auspices de l'Organisation Mondiale du Commerce (OMC). Les nouvelles dispositions en matière de propriété intellectuelle établies dans le cadre des ACPs avancent précisent considérablement les règles énoncées dans l'Accord de l'OMC sur les Aspects de Droits de Propriété Intellectuelle qui touchent au Commerce (l'Accord ADPIC). Dans ce schéma, le Brésil s'écarte de la tendance économique internationale qui adopte des dispositions sur la propriété intellectuelle dans les ACPs. De part son retrait, le pays ne peut influer l'orientation de la réglementation internationale de la propriété intellectuelle. Cette question est analysée à la lumière de l'équilibre entre les intérêts privés et publics que la protection des droits de propriété intellectuelle impose. L'objectif général du présent travail est d'examiner comment et dans quelle mesure les règles de propriété intellectuelle établies dans le cadre des ACPs diffèrent du régime brésilien de la propriété intellectuelle. Les objectifs spécifiques sont d'évaluer les questions juridiques et les potentiels effets qu'entraine l'adoption de normes de protection de la propriété intellectuelle plus élevées dans les ACPs; de cartographier et d'analyser les normes sur la protection des brevets et des données d'essai adoptées dans les ACPs pour les comparer avec l'Accord ADPIC et le régime brésilien de propriété intellectuelle; et d'examiner comment les règles de propriété intellectuelle sont diffusées aux niveaux international, régional et national. La méthodologie adoptée pour cette recherche fut à la fois bibliographique, descriptive et exploratoire. L'importance de cette recherche réside dans la compréhension des tendances transversales dans l'établissement de nouvelles règles de propriété intellectuelle. Ce travail conclut que les règles de propriété intellectuelle sur la protection des brevets et des données d'essai convenues dans les ACPs ne diffèrent pas radicalement du régime brésilien de la propriété intellectuelle. Le Brésil a déjà plusieurs dispositions dans sa législation nationale qui dépassent même le niveau de protection des brevets et des données d'essai requises par ces ACPs et par l'Accord ADPIC. Le régime brésilien de la propriété intellectuelle diffère des dispositions ADPIC-Plus suivantes : la brevetabilité des méthodes de traitement, des plantes et des animaux ; la limitation des motifs pour la licence obligatoire ; la restriction des motifs pour la révocation de brevet ; l'ajustement pour compenser la réduction de la durée du brevet en raison des procédures d'approbation de commercialisation ; le lien entre brevet et approbation commerciale; et l'exclusivité des donnés d'essai des produits pharmaceutiques à usage humain soumis à l'approbation de commercialisation. En revanche, le régime de propriété intellectuelle du Brésil s'aligne sur les dispositions ADPIC-Plus suivantes : l'interdiction de l'importation parallèle de produits brevetés ; la brevetabilité des « nouvelles utilisations » de composés déjà connus ; l'ajustement de la durée de la protection du brevet pour compenser les retards injustifiables dans le processus de délivrance ; la divulgation de l'origine de la ressource génétique nationale et des connaissances traditionnelles associées dans les demandes de brevet ; et l'exclusivité des donnés d'essai des produits pharmaceutiques à usage vétérinaire et de produits de protection des plantes.

Mots-Clés : Accords Commerciaux Préférentiels. ADPIC-Plus. Brevet. Donnés d'Essai. Brésil.

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LIST OF ABBREVIATIONS AND ACRONYMS

AB	Appellate Body
ABIFINA	Brazilian Fine Chemicals, Biotechnology and Specialty Industries Association
ACTA	Anti-Counterfeiting Trade Agreement
ANVISA	Brazilian Health Regulatory Agency
ARIPO	African Regional Intellectual Property Organization
ARV	Antiretroviral
BIRPI	*Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle*
BPCI	United States Biologics Price Competition and Innovation Act
CAFTA	Central American Free Trade Agreement
CBD	Convention on Biological Diversity
CDIP	Committee on Development and Intellectual Property
CETA	Comprehensive Economic and Trade Agreement
CGRFA	Commission on Genetic Resources and Agriculture
CGen	Genetic Heritage Management Council
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
CIPR	Commission on Intellectual Property Rights
CMC	Mercosur Common Market Council
COP	Conference of the Parties
CRTA	Committee on Regional Trade Agreements
CTCN	Climate Technology Centre and Network
DARs	Development Agenda Recommendations
DESA	UN Department of Economic and Social Affairs
DESTA	Design of Trade Agreements Database
DNA	Deoxyribonucleic Acid
DSB	Dispute Settlement Body
DSU	Dispute Settlement Understanding
ECA	Economic Complementation Agreement
EEA	European Economic Area
EFTA	European Free Trade Association
EPA	United States Environmental Protection Agency
EPO	European Patent Office
EST	Environmentally Sound Technology
EU	European Union
FAO	Food and Agriculture Organization
FDA	United States Food and Drug Administration
FDI	Foreign Direct Investment
FD&C	United States Federal Food, Drug and Cosmetic Act
FIFRA	United States Federal Insecticide, Fungicide and Rodenticide Act
FOAG	Swiss Federal Office for Agriculture
GATT	General Agreement on Tariffs and Trade
GATS	General Agreement on Trade in Services
IBAMA	Brazilian Institute of Environment and Renewable Natural Resources
ICT	Information and Communication Technologies
ICTSD	International Centre for Trade and Sustainable Development

IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources Traditional Knowledge and Folklore
IMF	International Monetary Fund
INNs	International Nonproprietary Names
INPI	National Institute of Industrial Property
IP	Intellectual Property
IPR	Intellectual Property Right
ITA	Information Technology Agreement
ITPGRFA	International Treaty on Plant Genetic Resources and Agriculture
ITT	International Technology Transfer
JPO	Japan Patent Office
LAIA	Latin American Integration Association
LDCs	Least-Developed Countries
MAPA	Brazilian Ministry of Agriculture, Livestock and Food Supply
Mercosur	Southern Common Market
MFN	Most-Favored-Nation
MMA	Brazilian Ministry of Environment
NAFTA	North American Free Trade Agreement
NDE	National Designated Entity
NGO	Non-Governmental Organization
OECC	Organisation for European Economic Cooperation
OECD	Organization for Economic Co-operation and Development
PCT	Patent Cooperation Treaty
PIC	Prior and Informed Consent
PTA	Preferential Trade Agreement
RCEP	Regional Comprehensive Economic Partnership
RNC	National Plant Variety Registry
RTA	Regional Trade Agreement
RTA-IS	Regional Trade Agreement-Information-System
R&D	Research and Development
SACU	The Southern African Customs Union
SCP	WIPO Standing Committee on the Law of Patents
SIPO	State Intellectual Property Office of the People's Republic of China
SisGen	National System for the Management of Genetic Heritage and Associated Traditional Knowledge
SME	Small and Medium-Sized Enterprise
SUS	Brazilian Health System
Swissmedic	Swiss Agency for Therapeutic Products
SNPC	National Service for Plant Variety Protection
SPC	Supplementary Protection Certificate
TEC	Technology Executive Committee
TFA	Trade Facilitation Agreement
TFEU	Treaty on the Function of the European Union
TM	Technology Mechanism
TNA	Technology Needs Assessment
TPA	Swiss Therapeutic Products Act
TPP	Trans-Pacific Partnership
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TTIP	Transatlantic Trade and Investment Partnership
UPOV	Union for the Protection of New Varieties of Plants

UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNFCCC	United Nations Framework Convention on Climate Change
UNICITRAL	United Nations Commission on International Trade Law
UNWTO	United Nations World Tourism Organization
US	United States of America
USPTO	United States Patent and Trademark Office
VCLT	Vienna Convention on the Law of Treaties
WCO	World Customs Organization
WESP	World Economic Situations and Prospects
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

SUMMARY

1 INTRODUCTION

The world economy is increasingly based on knowledge, information and technology. The advancement in these fields has transformed the national productive capacity, enabling the spread of the production chain all over the world. In order to reduce production costs, national frontiers are overcome through the establishment of regional and global value chains. In the current commercial transactions, a good is no longer designed, manufactured and sold nor a service is provided within a single country. Each of these stages can be executed in a different country and, accordingly, subject to a different national legal regime. By enabling the well-functioning of these production chains throughout the world, the protection and enforcement of intellectual property rights are key components in this process.

In this scenario, the World Trade Organization (WTO) stands out as the main international forum for regulating trade relations, settling trade disputes and monitoring its Member States' trade policy. The WTO is the primary international organization responsible for operating a global system of trade rules based on non-discriminatory principles. Its foundation is part of the historical efforts to establish international institutions aimed at ensuring world peace through multilateral cooperation and economic integration. Since its creation in 1995, the WTO has made great progress in the international trade governance.

However, the WTO is facing one of the most challenging moments in its recent history. The Doha Round of trade negotiations launched in 2001 has not yet been successfully completed. Its stalemate casts doubt on the WTO's capacity to deliver trade rules that reflect the current commercial transactions. Updating the rules demands consensus among all the WTO Members. Under the stewardship of the WTO Director General Roberto Azevêdo, the WTO Members have been able to find consensus in specific topics in the last ministerial conferences, such as the Trade Facilitation Agreement (TFA), the expansion of the Information Technology Agreement (ITA), the elimination of agricultural export subsidies and others measures to support least developed countries. However, this progress remains far below of what was established under the Doha negotiation's mandate.

Meanwhile, there has been a significant increase in the number of Preferential Trade Agreements (PTAs) adopted in parallel to the WTO's system. Nowadays, a large part of the international world trade happens, in addition to the WTO rules, under the frameworks of PTAs. The new generation of these bilateral and plurilateral treaties not only regulates issues already established under the WTO regime (WTO-In), but also advances (WTO-Plus) and creates (WTO-Extra) new rules. They go beyond the mere reduction of tariff barriers in trade in goods and include trade in services and other elements of economic integration, such as investment, regulatory coherence and convergence, labor standards and environmental protection.

In this sense, special attention has been drawn to the acceleration in the conclusion of PTAs with intellectual property (IP) provisions. The WTO 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) established minimum standards of intellectual property protection, allowing Member States to adopt higher standards of protection than that accorded in the TRIPS Agreement. Due to this possibility, PTAs have become a major source of international intellectual property regulation. They constitute the main instruments expanding intellectual property rules at the international level. This occurs in a period when intellectual property is increasingly becoming an area of global cooperation and conflict.

The proliferation of intellectual property rules through PTAs is a controversial subject that attracts both criticism and support from different countries. On the one hand, supporters allege that PTAs meet central aspects of the contemporary trade-related aspects of intellectual property rights. On the other hand, opponents argue that their expansion weakens much of the flexibilities provided by the TRIPS Agreements and prevent countries from implementing public policies aimed at their development.

In this context, Brazil is apart from the international economic trend of adopting intellectual property provisions in PTAs. Historically, the country has favored the multilateral sphere as the main forum for establishing any new international intellectual property commitment. It defends that the multilateral level offers the best conditions for developing countries to ensure more balanced results in their areas of interest. The country has refused to adopt any kind of IP provision or to increase the protection levels settled in the TRIPS Agreement in the framework of its PTAs.

During the 1990s and 2000s, Brazil has made little efforts to build a dense network of PTAs. The few PTAs adopted by Brazil regulate mainly issues already established under the WTO, not advancing nor creating new obligations. In addition, Mercosur, the main Brazilian regional integration project, endures a deep stagnation due to successive political and economic crises in its main State Parties.

For these reasons, part of the literature understands that the superficiality and the limited number of the Brazilian PTAs would be affecting the country's economic growth and its capacity to influence the creation of these new trade rules. The Brazilian refusal to adopt higher levels of commitment would be hindering the performance of its high value-added exports, frustrating greater attraction of foreign investments; and impeding its insertion in global value chains. As a result, the country would be having fewer resources to implement fundamental public policies for its development.

Therefore, the Brazilian inertia before this new dynamic of establishing new trade rules raises concerns among certain academics and policy-makers. Notwithstanding the historical position of Brazil, the expansion of the international intellectual property regime through PTAs is a fact and probably a long-lasting trend with which the country will be affected sooner or later. The intellectual property rules established under PTAs influence the direction by which the regulation in multilateral forums heads for. The consensus achieved under these frameworks is used as a base for instituting new norms in the multilateral realm.

In the light of the described scenario, the present work raises the following questions: How and to what extend the intellectual property rules that are being established under PTAs differs from the Brazilian intellectual property regime? Does Brazil provide for a higher or lower level of intellectual property protection than the required under PTAs? Which are the advantages or disadvantages related to the adoption of higher standards of intellectual property protection than the required under the TRIPS Agreement? How these intellectual property norms established in PTAs are diffused and interact with other international, regional and national legal spheres?

The interest for this problematic arose during the course "Developing Countries, Globalized Economies and the Challenges of International Regulation", thought by Professors Alberto do Amaral Júnior and Umberto Celli, in the master program at the

Faculty of Law of the University of São Paulo (USP). The curiosity for the subject was further incited by the studies undertaken by the Center for Global Trade and Investment Studies (CGTI) of the Getulio Vargas Foundation (FGV), under the coordination of Professor Vera Thorstensen. The motivation for the development of the present research resides in understanding how intellectual property provisions in PTAs could be designed to enhance the win-win relation between economic stakeholders and society.

The general objective of the present work is to investigate how and to what extent the intellectual property rules that are being established under PTAs differ from the Brazilian intellectual property regime. In order to achieve this main goal, this work has the following specific objectives: (i) to assess which are the legal issues and the possible effects that pervade the adoption of higher standards of intellectual property protection in PTAs; (ii) to map and analyze the norms on patent and test data protection adopted in PTAs and to compare them with the TRIPS Agreement and the Brazilian intellectual property regime; and (iii) to examine how intellectual property rules are diffused across international, regional and national levels.

These objectives aim not only to present a wider picture and facilitate future research on this subject, but also indicate the intricate challenges arising from the adoption of IP provisions in the PTAs' context. Although there is an extensive literature on TRIPS-Plus, relatively few comprehensive vertical analyzes have been undertaken between the PTAs' patent and test data provisions and the Brazilian intellectual property regime. The present work aims to make a contribution towards closing this gap.

The importance of this research resides in understanding the cross cutting trends in the establishment of new intellectual property rules. The analysis of the patent and test data provisions in PTAs involving parties from all regions and levels of development is key to understand adoption of intellectual property rules in the international level and how the different countries influence each other in this process. The elaboration of a study that analyzes the Brazilian patent and test data regime in the light of these major international trends is fundamental to formulate new legal strategies aimed at fostering innovation and development in the country. Moreover, the regulatory expansion of intellectual property rights through PTAs and its impacts in the multilateral trading system and in the developing countries innovative capacities is one of the greatest challenges to be faced by the WTO in the 21st Century.

Therefore, this study intends to investigate alternatives to render intellectual property right not a mere instrument of economic monopoly, but a device that promotes the generation of full employment, the increase of population's per capita income, contributing to poverty alleviation and environmental protection. It should be noted that intellectual property is one of the most important drivers of economic development. Its combination with human capital makes it a powerful vector in the current dynamics of the knowledge-based economy. Therefore, intellectual property is increasingly perceived as an important economic asset whose value can be enhanced through proactive and strategic legal design and the implementation of public policies.

When well-managed, intellectual property assets can bring several benefits, such as: generating revenue from the sale of products with IP content and royalties from their licensing, increasing high value-added exports, stimulating research and development industries, supporting teaching institutions, improving the evaluation of companies, attracting joint ventures, and encouraging and maintaining skilled workforce. Intellectual property lies at the heart of the contemporary business strategies. Their protection, however, should not be seen as an end in itself, but as a means to promote innovation and dissemination of knowledge.

As to the basic methodology, this research uses the categorical-deductive method. It departs from general premises on the proliferation of intellectual property rules through PTAs in order to arrive at pertinent and specific conclusions and arguments through logical derivations. The subjects that integrate the universe of this research are the States and customs territories inserted in the international trade dynamics, international organizations, multinational and national companies, non-governmental organizations and the human being as a rights holder.

As to the methodological objectives, the present research is characterized as exploratory, descriptive and explanatory. In the exploratory aspect, the objective is, through the collection of information, to create familiarity and, later, a deeper understanding of the international regulation of the intellectual property rights. This initial exploration will lead to a better understanding about the possibilities of intellectual property promotion, protection and enforcement. In the descriptive aspect, the present research describes the main peculiarities of the patent and test data provisions. It identifies their main characteristics in order to enable their comparison with the TRIPS Agreement

and the relevant Brazilian legislation. At last, in the explanatory aspect, this research aims to explain the possible differences and similarities between the new rules on patent and test data protection adopted under PTAs and the Brazilian intellectual property regime.

As to the methodological procedures, the research is characterized as bibliographical and documental. The proposal is to develop an extensive bibliographical research, encompassing the perspectives of several national and international authors on the subject. As to documental aspect, this research analyzes the text as primary sources of multilateral intellectual property agreements, PTAs and the several national laws and regulations on intellectual property. These documents are interpreted through data analysis, tables, reports and statistics. This provides an analytical treatment of the information contained in the documents under study.

The present research investigates the patent and test data provisions adopted in the PTAs signed from the entry into force of the TRIPS Agreement, 1st January 1995, to 1st January 2017. It examines 68 PTAs that together cover 93 countries and separate customs territories possessing full autonomy in the conduction of their external commercial relations. The reason for analyzing patent protection in conjunction with test data protection relies on the fact that TRIPS-Plus provisions are increasingly combining both categories of intellectual property. Therefore, they should be analyzed jointly, even though their object of protection is different.

This study integrates horizontal and vertical methodologies in legal comparison to investigate the complex phenomenon of the TRIPS-Plus provisions in PTAs. It maps and describes the PTAs provisions on patent and test data protection on the basis of carefully constructed classificatory schemes. It describes the similarities and differences between these provisions ant the TRIPS Agreement (horizontal comparison); and between these provisions and the Brazilian patent and test data regime (vertical comparison).

As to the methodological approach, the research is characterized as qualitative and quantitative. In the qualitative aspect, the research takes into consideration the author's subjective interpretation while observing the dynamics between the world and the subject. The quantitative technique is used in the mapping of the patent and test data provisions in PTAs. The research uses calculations and statistics to measure the participation of the patent and test data provisions in the total amount of analyzed PTAs. Hence, the

information and data collected during the development of the research will be analyzed in categorized way.

The present work proceeds in three main parts. First, it describes the main complexities and problems related to the preferential expansion of intellectual property rules through PTAs. It contextualizes this phenomenon from an historical perspective, demonstrating the international dynamics for the establishment of intellectual property rights in the international realm. It introduces the legal aspects that pervade the interaction between the WTO regime and the intellectual property rules adopted in PTAs. It also indicates the main problematic features of unbalanced IP provisions in PTAs for developing countries.

Second, it undertakes a literature review of studies that investigated the regulation of intellectual property provisions in PTAs. It analyzes the provisions on patent and test data protection accorded under PTAs, from 1st January 1995 to 1st January 2017. It maps and categorizes these provisions in order to compare them with the TRIPS Agreement and the Brazilian intellectual property regime. This chapter aims to assess how and to what extent the levels of patent and test data protection required under PTAs are higher or lower than the levels provided in Brazil.

Third, it explains how intellectual property policy and norms are diffused across different countries. It shows evidence of diffusion of intellectual property norms on patent and test data protection through PTAs. Moreover, it addresses the issue of the fragmentation of international law, which is aggravated by the proliferation of preferential trade agreements. It delineates possible mechanisms to provide greater coherence between these new intellectual property rules accorded under PTAs, the WTO regime and other international law subsystems.

This dissertation proposes the following hypothesis to be proven in the course of the research: the Brazilian intellectual property regime has a lower level of patent and test data protection than the ones required under the PTAs' TRIPS Plus provisions. Since Brazil refuses to adopt higher levels of intellectual property protection than the level required under the TRIPS Agreement in its PTAs, it is to be expected that the country also only provides for TRIPS-In rules on patent and test data protection in its national legislation.

In accordance with the above-described parameters, the present work intends to undertake the proposed research and accomplishment the stipulated objectives and the understanding of the object under study.

2 THE EXPANSION OF THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM THROUGH PREFERENTIAL TRADE AGREEMENTS

2.1 Introductory Remarks

The world has witnessed the increasing proliferation of Preferential Trade Agreements (PTAs)[1] accorded in parallel to the WTO system in the last decades. In the beginning of the 1990s, there were only around 70 of these agreements in force. By the end of 2010, this number more than quadrupled to nearly 300 (WTO, 2013a, p. 75). By the end of 2016, 643 PTAs had already been notified to the WTO, of which 431 were in force (WTO, 2017a, p. 89). These numbers demonstrate a shift in how international trade is being negotiated and regulated internationally (ELEOTERIO; MESQUITA, 2016, p. 107).

Among the factors that explain the multiplication of such agreements, Baccini and Dür (2011, p. 57) highlight "the stagnation of the process of multilateral trade liberalization, the search for economics of scale, the desire to signal commitments to specific trade and economic policies and the protection of foreign direct investments." In a similar vein, Baldwin (2011) understands this new wave of PTAs as a response to the demands of the 21st Century Regionalism, centered in the "trade-investment-service nexus." The author (BALDWIN, 2011, p. 5) uses this term to describe the growing complexity of the international commerce, characterized by the intertwining of: (i) trade in goods; (ii) international investment in facilities, training, technology and long-term business relationships, and (iii) the use of infrastructure services to coordinate the dispersed production, mainly services such as telecoms, internet, express delivery, air cargo, trade-related finance and customs clearance services.

[1] Researchers and policy-makers have often adopted the terms Preferential Trade Agreements (PTAs) and Regional Trade Agreements (RTAs) more or less interchangeably (WTO, 2013, p. 75). According to the WTO (2017b), the term RTA is defined as reciprocal trade agreements between two or more partners, including free trade agreements and customs unions, while the term Preferential Trade Arrangements (note, not agreements) refers to unilateral trade preferences, including no-reciprocal deals (BIRKBECK; BOTWRIGHT, 2015, p. 12). This work adopts, for now on, the term Preferential Trade Agreement (PTA) to refer to these both types of agreements, since the great majority of them are no longer regional in the sense of geographic proximity. The term PTA reflects more appropriately the objective functions of such schemes and the phenomenon that this work intends to depict (MAVROIDIS, 2007, p. 148).

The new generation of PTAs expresses this new production logic, constituting the legal framework that supports the internationalization of trade in tasks. The functioning of global and regional value chains relies heavily on intellectual property protection and enforcement rules (OKEDIJI, 2004, p. 130). As noted by Baldwin (2002, p. 9), the assurance that foreign knowledge-capital owners will be treated fairly and their rights will be respected facilitates the sharing of tacit and explicit technology and intellectual property.

As a result, PTAs are also increasingly incorporating intellectual property provisions in their frameworks. Among the reasons for countries to embed IPRs rules in PTAs, Fink (2001, p. 387) highlights the significant changes that have occurred in this field since the adoption of the TRIPS Agreement and their importance in the overall package of "this for that" (*quid pro quo*) necessary to strike a trade deal. Moreover, Fink (2001, p. 387) emphasizes that countries are using PTAs to clarify and update, according to their view, certain TRIPS standards in their international commercial relations. Normally, the tightening of intellectual property rules in PTAs is led by developed countries, which host substantial intellectual property rights producing industries. They pressure developing countries to commit to strong standards of intellectual property protection in exchange of preferential access to their markets for manufactured or agricultural goods (FINK, 2001, p. 387).

In this above described scenario, Brazil gave preference to the multilateral trade forum and concentrated in the adoption of PTAs with developing countries (THORSTENSEN; FERRAZ et al; 2015, p. 9). [2] On continental sphere, Brazil is a founding Member of Mercosur, embedded in the Latin American Integration Association (LAIA), and it has PTAs with Chile; Cuba; Bolivia; Mexico; Peru; Colombia, Ecuador and Venezuela; Guyana and St. Kitts & Nevis; and Suriname. On the extra-continental sphere, Brazil, within Mercosur, has PTAs with India, Israel, The Southern African Customs Union (SACU) Egypt and Palestine. From all of these PTAs, only the Mercosur-Palestine is not yet in force (MDIC, 2017; THORSTENSEN; FERRAZ et al, 2013, p. 1).

[2] More recently, Brazil, within Mercosur, reassumed the negotiations of a PTA with the European Union. This was a clear move from its South-South strategy towards a North-South Agreement (THORSTENSEN; FERRAZ, 2015, p. 5). The comings and goings of the Mercosur-EU PTA negotiations have lasted more than 15 years. Intellectual property may be one subject among the topics regulated by the agreement. However, since this Dissertation proposes to only examine the PTAs already signed, the EU-Mercosur will not be analyzed.

Another crucial element concerns the commitment of the Mercosur States to jointly negotiate PTAs with third countries or economic blocks in which tariff preferences are granted. As observed by Celli Júnior and Eleoterio (2015), this foreign policy position was instituted through The Common Market Council (CMC)'s Decision No. 32 in 2000. It is part of the Mecosur's efforts to establish a common market, which implies, among other things, the need for a common external trade policy (CELLI JÚNIOR, ELEOTERIO, 2015). As Mercosur is legally embedded in the Latin American Integration Association (LAIA),[3] its States Parties can negotiate PTAs with other LAIA countries on their own; but, since the CMC Decision No. 32/2000, they have agreed to negotiate PTAs only with other non-LAIA countries as one trading bloc (CELLI JÚNIOR et al, 2010, p. 20).[4]

The great majority of the Brazilian PTAs focus mainly on tariff-reductions. They do not advance significantly in the elimination of non-tariff barriers nor establish new rules on subjects not yet regulated under the WTO regime. Brazil has also traditionally opposed to adopt intellectual property commitments in the framework of its PTAs.

Under the Mercosur's regime, there is no legal instrument that exceeds the level of intellectual property protection established under the TRIPS Agreement. The Mercosur norms on this matter are restricted to the harmonization of intellectual property rights (POLIDO; DOS ANJOS, 2016, p. 293).[5] They include, for example, the 1995 Protocol for the Harmonization of Intellectual Property Norms in Mercosur with respect to Trademarks, Indications of Source and Denomination of Origin; [6] and the 1998 Protocol on Harmonization of Standards in the Matters of Industrial Designs (BARBOSA, 2003, p. 165). Notwithstanding the establishment of an intellectual property commission under the Mercosur's Sub-Working Group on Industry (SGT-7), its initiatives are very limited in this field.

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[3] The Economic Complementation Agreement (ECA) No. 18 confirms the Mercosur's institution within the LAIA's framework. The LAIA was created in 1980 to promote the economic and social development of Latin America through a progressive and gradual process of economic integration. Currently, LAIA has 13 Members: Argentina, Bolivia, Brazil, Chile, Colombia, Cuba, Ecuador, Mexico, Panama, Paraguay, Peru, Uruguay and Venezuela (MRE, 2017).

[4] For a deeper analysis on the Mercosur's insertion in global trend of adopting PTAs see: CELLI JÚNIOR, Umberto; SALLES, Marcus; TUSSIE, Diana; PEIXOTO, Juliana. **Mercosur in South-South Agreements**: in the Middle of Two Models of Regionalism. Geneva: UNCTAD, 2010. Available at: <https://vi.unctad.org/resources-mainmenu-64/digital-library?view=search>. Accessed on: 30 Nov. 2017.

[5] Polido and Dos Anjos (2016, p. 292) also stresses that the Mercosur's Protocols on investment, the 1994 *Protocolo de Colônia* and the 1995 *Protocolo de Buenos Aires*, consider intellectual property as type of investment. Nevertheless, these protocols are not yet in force, since they have not been ratified by different Mercosur Member States (POLIDO; DOS ANJOS, 2016, p. 293).

[6] At the time of writing, only Paraguay and Uruguay have ratified this 1995 Protocol (MERCOSUR, 2017).

Moreover, Polido and Dos Anjos (2016, p. 294) remind that these Mercosur instruments should be harmonized with the existing Brazilian legislation. According to Article 242 of the Brazilian Industrial Property Law, the Executive Power shall "submit to the National Congress a bill of law intended to accomplish, whenever necessary, the harmonization of this law with the industrial property policy adopted by the other countries that are members of Mercosur." The initiatives in this regard, however, have been reluctant.

In this perspective, this first chapter aims to describe the problematic addressed by this work, mainly the expansion of the intellectual property system through PTAs. Therefore, it will proceed in three parts. Firstly, it will contextualize this phenomenon in the international dynamics of IPRs rule-setting. Secondly, it will introduce the legal aspects that pervade the interaction between the WTO regime and the intellectual property rules adopted in PTAs. At last, it will indicate the main problematic features of unbalanced IP provisions in PTAs for developing countries.

2.2 The Evolving International Dynamics of Intellectual Property Rights Rule-Setting

The establishment of rules for the protection of intellectual property rights (IPRs) in the international level has historically moved in a pendulous way between bilateralism and multilateralism in accordance with national interests and internal demands. According to Yu (2014, p. 328), the development of the international intellectual property regime is "the product of repeated interactions between an evolving set of currents and crosscurrents. While the currents of multilateralism push for uniformity and increased harmonization, the crosscurrents of resistance […] protect national autonomy and international diversity."

The international intellectual property system encompasses a dense set of linkages and relationships among treaties, international organizations, and multilateral, regional and bilateral negotiating venues (HELFER, 2009, p. 39). In consonance with Drahos (1999, p. 15), the protection of intellectual property at international level can be roughly divided into three periods: the territorial period, the international period, and the global period.

The first one – territorial period – is based on the principle of territoriality, which determines that "intellectual property rights do not extend beyond the territory of the sovereign that has granted the rights in the first place" (DRAHOS, 1999, p. 16). This period is marked by the proliferation of national intellectual property regimes in Europe that, through cross-pollination and much of borrowing intellectual property laws, influenced other States and reverberated along colonial pathways (DRAHOS, 1999, p. 16).

As observed by Lowenfeld (2011, p. 338), "the origins of intellectual property rights are buried in a mixture of guild rules, censorship practices, and government activities aimed at stimulating local industry and ensuring commercial morality." This first period is essentially characterized by an absence of international protection (DRAHOS, 1999, p. 15).

The second period – international period – is characterized by the principle of national treatment, which secures that, when it comes to the regulation of intellectual property rights, nationals and foreigners shall not be treated in a discriminatory manner through reciprocal adjustments between States (DRAHOS, 1999, p. 17).

This cycle is marked by the greater interest in the possibility of international cooperation on intellectual property (DRAHOS, 1999, p. 16). National authors and inventors competed in a disadvantageous position as regards to foreign imports of functionally equivalent and cheaper products. The lack of international protection resulted in the organization of internal demands that led to the adoption of bilateral, regional and multilateral treaties, culminating in the 1883 Paris Convention for the Protection of Industrial Property and the 1886 Berne Convention for the Protection of Literary and Artistic Works (LOWENFELD, 2011, p. 338).

Each of these conventions was administered by a small bureau (secretariats) and they were merged in 1893 to form the United International Bureau for the Protection of Intellectual Property, known by their French initials as BIRPI[7] (LOWENFELD, 2011, p. 339; DRAHOS, 1999, p. 18). Due to the growing importance of intellectual property for the world economy and the multiplication of international agreements on this matter, the BIRPI was transformed into the World Intellectual Property Organization (WIPO) through the adoption of the 1967 Stockholm Convention. With headquarters in Geneva, WIPO

[7] *Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle*.

became a specialized agency of the United Nations in 1974, evolving into the leading international organization for the promotion of intellectual property rights worldwide (WIPO, 2004, p. 4).[8]

The conclusion of the two multilateral pillars reproduced in the Paris and Bern Convention in the 1880s constitutes, according to Dinwoodie (2001, p. 994), the beginning of the developed system of intellectual property law. These treaties were built around two basic principles that have persisted throughout the twentieth century. Those are the principle of national treatment (previously explained) and the so-called substantive minima, according to which signatory States had to provide in their domestic law certain minimum levels of intellectual property protection.

The second period also reflects a world in which a lot of free-riding was tolerated. Even though enforcement mechanisms – such as appeals to the International Court of Justice – were foreseen in various intellectual property agreements, most countries took reservations on such clauses (DRAHOS, 1999, p. 20).

The third period – global period – is built on the edifice of the principles of territoriality and national treatment, but their coverage is enhanced due to the globalization of intellectual property through its linking to international trade (DRAHOS, 1999, p. 21). According to Lowenfeld (2011, p. 339), the gaps in the ninetieth century conventions became increasingly apparent as global commerce increased in the twentieth century.

The beginning of the global period is marked by the adoption of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in April 15, 1994.[9] Through its trade linkage, the TRIPS Agreement encompasses all those States that are members of the multilateral trading system

[8] Currently, the WIPO is the main forum for intellectual property services, policy, information and cooperation. It is responsible for administering 26 international treaties and counts with a Membership of 189 States.

[9] In this regard, Drexl (2016, p. 54) highlights that "when the contracting Parties of GATT decided to bring intellectual property rights (IPRs) under the new umbrella of the World Trade Organization (WTO), they justified this by labeling the new IP rules contained in the TRIPS Agreement as 'trade-related'." The adoption of this term intended to address international law concerns regarding overlapping of competences between the recent created WTO and the already existing WIPO. Hence, the GATT Contracting Parties perceived the need to justify the inclusion of IP issues in the new WTO Law through its strictly linkage to trade (DREXL, 2016, p. 54).

(DRAHOS, 1999, p. 21).[10] The inclusion of the TRIPS Agreement under the WTO umbrella "linked IP protection to trade politics, and ushered in an era of new, powerful global IP law" (RAUSTIALA, 2007, p. 1022).

Even though the 1947 GATT[11] already had some references to intellectual property rights, the subject was only categorically introduced into the multilateral trading system during the Uruguay Round (1986 - 1994) of trade negotiations. For the first time, the TRIPS Agreement instituted the most-favored-nation principle in the area of intellectual property protection. None of the previous IP conventions contained such an obligation (VAN DEN BOSSCHE; ZDOUC, 2013, p. 952).

The adoption of the TRIPS Agreement was motivated by the deficiencies found in the previous intellectual property agreements, such as their fragmented coverage of IP rights, the lack of effective enforcement standards and systems for the settlement of disputes, and their limited membership that did not encompass notorious violators of IP rights (VAN DEN BOSSCHE; ZDOUC, 2013, p. 953). Due to the increasing importance of intellectual property component of goods and services, countries with IPR-producing industries demanded for substantial changes in the international intellectual property system (ABBOT, 2007, p. 452).

Nevertheless, there were substantive differences on how developed and developing countries perceived the level of intellectual property protection that should be granted under a multilateral trade agreement. India and Brazil led the coalition against the inclusion of this topic in the Uruguay Round negotiating mandate. They argued that the regulation of this matter would mainly benefit rich countries, hindering the development and the diffusion of new technologies in the poor ones (ROSENBERG, 2005, p. 276).

The United States, European Union (EU),[12] Japan, and their respective IP intensive industries were the strongest proponents for including the subject in the Uruguay Round

[10] The TRIPS Agreement was incorporated as the 1C Annex of the WTO Constitutive Agreement, signed in Marrakesh on April 15, 1994, binding all the Members of the newly created international organization (TAUBMAN; WAGER; WATAL, 2012, p. 8).

[11] The four GATT articles that refer to intellectual property rights are the following: XX(d); IX; XII:3(c)(iii); and XVIII:10.

[12] Until November 30, 2009, European Communities (EC) was the official name of the EU in the WTO. That name continues to appear in older WTO materials, documents and articles on the multilateral trade negotiations. Since December 1, 2009, European Union has been the official name of this international organization in the WTO as well as in the outside world (WTO, 2017c). From here on, this works adopts the acronym EU to refer to the European Union.

(HELFER, 2004, p. 2). They aimed to introduce systematic reforms in the regime of international intellectual property right in order to encourage the creation of an investment-friendly environment. In the final bargain, developing countries agreed to include the topic in the Uruguay Round, provided that some liberalization in the agricultural sector were granted (THORSTENSEN et al, 2012, p. 194).

Currently, the TRIPS Agreement constitutes the most comprehensive multilateral agreement of intellectual property in force (FRANKEL, 2012, p. 159). It represents the compilation of the previous intellectual property rights agreements and the advancement on new rules. By linking them to international trade, the TRIPS Agreement brings intellectual property rights into the realm of WTO dispute settlement procedures. This represents a major strengthening of the global system over the previously weakly enforceable conventions supervised by the WIPO (MASKUS, 2000, p. 6-7).

However, "multilateralism on intellectual property in the form of TRIPS Agreement has not worked to stabilize intellectual property standards" (DRAHOS, 2001, p. 805). The Agreement "was expressly negotiated as a floor – with 'minimum standards' – rather than as a ceiling" (RAUSTIALA, 2007, p. 1028). The main players, such as United States, European Union and Japan continued to push their agenda for ever-higher standards of IP protection through bilateral, regional and plurilateral negotiations (SELL, 2011, p. 448).

In this sense, the global period extends beyond the TRIPS Agreement and echoes in the increasing number international instruments regulating intellectual property. The subject has also become a highly politicized arena in which state and non-state actors continuously contest not only intellectual property rules, but also the roles of markets and government (DRAHOS, 1999, p. 22).

The architecture of the global intellectual property regime has become increasingly complex and includes a diversity of multilateral, regional[13] and bilateral agreements[14] (CIPR, 2002, p. 156). Most of the multilateral treaties are administered by the WIPO and they can be divided into three categories: (i) standard setting treaties, which determines

[13] The European Patent Convention, the Harare Protocol on Patent and Industrial Designs within the Framework of the African Regional Intellectual Property Organization (ARIPO) and the Andean Community Common Regime on Industrial Property are an example of regional treaties or instruments (CIPR, 2002, p. 156).

[14] Bilateral Agreements may regulate intellectual property rights exclusively or this subject may appear as one of several issues covered (CIPR, 2002, p. 156).

basic standards of protection;[15] (ii) global protection system treaties, which facilitate filing or registering intellectual property rights in more than one country;[16] and (iii) and classification treaties, which organize information regarding inventions, trademarks and industrial designs into catalogued, manageable frameworks for ease of consultation.[17]

Beyond the WTO and WIPO regimes, intellectual property rules can also be found directly or indirectly in other international institutions, such as International Union for the Protection of New Varieties of Plants (UPOV),[18] the Organization for Economic Co-operation and Development (OECD),[19] the World Customs Organization (WCO)[20] and the

[15] The Paris Convention, Bern Convention, the TRIPS Agreement and the Convention for the Protection of New Varieties of Plants are an example of standard setting treaties (CIPR, 2002, p. 156).

[16] The 1958 Lisbon Agreement for the Protection of Appellations of Origin and their International Registration, the 1891 Madrid Agreement Concerning the International Registration of Marks, the 1925 Hague Agreement Concerning the International Deposit of Industrial Designs, the 1970 Patent Cooperation Treaty (PCT) and the 1977 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure are examples of global protection treaties.

[17] The 1957 Nice Agreement Concerning the International Classification of Goods and Services for the Purpose of the Registration of Marks, the 1968 Locarno Agreement Establishing an International Classification for Industrial Designs, the 1971 Strasbourg Agreement Concerning the International Patent Classification and the 1973 Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks are examples of classification treaties.

[18] The UPOV is an intergovernmental organization with headquarters in Geneva, Switzerland. It was established by the 1961 Convention for the Protection of New Varieties of Plants and revised in 1972, 1978 and 1991. Its main goal is to provide and promote an effective system of plant variety protection, with the purpose of supporting the development of new plant varieties for the benefit of society (UPOV, 2017).

[19] The Organisation for European Economic Cooperation (OECC) was created in 1948 to run the US-financed Marshall Plan for reconstruction of the continent devastated by the Second World War. In 1961, the OECC was transformed into the Organisation for Economic Co-operation and Development (OECD) through the entering into force of the OECD Convention (14 December 1960). Its membership was extended to non-European countries, as such that currently 35 countries – mainly high-income economies – are OECD Members (OECD, 2017a). In the intellectual property field, the OCDE develop IP statistics and analysis, particularly, on the innovative output of top research and development (R&D) investors worldwide using patents and trademarks as proxy indicators; enquiries into intellectual property's economic impact; methodological work and publications on IP-related statistics; and a conference on IP statistics for decision making. These projects and studies are conducted in close cooperation with the Member's National IP Offices (OECD, 2017b).

[20] The WCO is an intergovernmental organization, headquartered in Brussels, Belgium, established in 1952 with the aim to enhance the effectiveness and efficiency of customs administrations. It represents today 181 customs administrations across the globe that together process approximately 98% of world trade (WCO, 2017a). In contrast to its origin when the international organization had a strictly technical profile, Arbix (2009, p. 84) highlights that the WCO became a soft law producer with the WCO Model IP Legislation, based on the TRIPS Agreement and to a significant extend influenced by the representatives of the private sector. Currently, the WCO provides "a set of intellectual property best practices to promote respect for IPR at borders by building customs capacity and strengthening cooperation between Customs and its international partners as well as rights holders" (WCO, 2017b). Among its initiatives and tools, one can highlight: WCO Risk Management Guidelines for more effective controls, Customs Enforcement Network (CEN) and its communication tools, IPR Diagnostic Survey, working methods tailored to suit the specific nature of anti-counterfeiting activities, and the establishment of a Counterfeiting and Piracy Group (CAP) (WCO, 2017b).

Conference of the Parties to the Convention on Biological Diversity (CBD)[21] (HELFER, 2009, p. 39).

Under the umbrella of the United Nations (UN), there are also some important organizations or programs that – in addition to the work developed by WIPO – deal with the regulation of intellectual property. They include the World Health Organization (WHO), [22] the United Nations Environment Programme (UNEP), [23] United Nations Educational, Scientific and Cultural Organization (UNESCO),[24] the Food and Agriculture Organization (FAO), [25] the United Nations Conference on Trade and Development (UNCTAD) [26] and the United Nations Commission on International Trade Law (UNICITRAL)[27] (ARBIX, 2009, p. 86).

[21] The interplay between CBD and intellectual property rights is addressed in the section 1.3.2 of this work.
[22] The WHO Member States established, in May 2003, the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) to conduct analysis of the interface between intellectual property rights, innovation and public health. In April 2006, the CIPIH published a benchmark report on Public Health, Innovation and Intellectual Property Rights with 60 recommendations aimed at promoting innovation and access to medicines. Since then, the WHO has produced a significant amount of material to guide its Member States in the process of designing their policies on public health and IP (WHO, WTO, WIPO, 2013, p. 21-22). Currently, the key CIPIH activities include: (i) formulating sustainable alternatives ways of coordinating and financing research and development for priority health technologies; (ii) developing policy guidance and providing technical assistance on IP management in order to promote needs based innovation and access to patent protected essential medicines and health products; and (iii) facilitating technology transfer to build manufacturing capacity in developing countries for strategically selected health products (WHO, 2017).
[23] The UNEP has conducted several studies on intellectual property rights and environmental protection, such as the "the Role of Intellectual Property in Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge" (2004) in cooperation with WIPO; and the "Patents and Clean Energy: Bridging the Gap between Evidence and Policy" (2010) in cooperation with the European Patent Office (EPO) and the International Centre for Trade and Sustainable Development (ICTSD).
[24] Under the auspices of UNESCO, the Universal Copyright Convention (UCC) was adopted in 1952, aimed at extend international copyright protection universally. It established an Intergovernmental Copyright Committee (Art. 11) that meets in ordinary sessions every 4 years (UNESCO, 2017).
[25] Under the FAO's auspices, countries adopted the International Treaty on Plant Genetic Resources and Agriculture (ITPGRFA) in 2001. Its main goal is to "facilitate the exchange of seeds and other germplasm to be used for research, breeding and crop development" (HELFER, 2004, p. 87). Its Article 12.3(d) prevents the recipients of genetic resources from claiming intellectual property rights that limit the facilitated access to plant genetic resources for food and agriculture. Moreover, FAO also has a Commission on Genetic Resources for Food and Agriculture (CGRFA) and code of conduct for plant germplasm collecting and transfer (ARBIX, 2009, p. 82).
[26] The UNCTAD's IP program aims to assist "developing countries to participate effectively in international discussions on intellectual property rights and, at the national level, to help ensure that their IP policies are consonant with development objectives" (UNCTAD, 2017a). Its activities include: "research and policy analysis, technical assistance and workshops/policy dialogues with negotiators, policy makers, the private sector, academia and civil society." This facilitates the construction of developing countries' negotiating position and, consequently the consensus-building in international discussions.
[27] The UNCITRAL developed a Legislative Guide on Secured Transactions: Supplement on Security Rights in Intellectual Property. Adopted in 2010, this legislative guide aims to "make credit more available and at a lower cost to intellectual property owners and other intellectual property rights holders, thus enhancing the value of intellectual property rights as security for credit" (UNCITRAL, 2011, p. 1). This work was carried out by the UNICITRAL Working Group VI (Security Interest).

Recently, intellectual property issues have become a top priority in the agenda of these intergovernmental organizations, programs and in international expert and political bodies. The expansion of intellectual property law-making into these diverse international forums is, in accordance with Helfer (2004, p. 6), "the result of a strategy of 'regime shifting' by developing countries and NGOs that are dissatisfied with many provisions in TRIPS or its omission of other issues and are actively seeking ways to recalibrate, revise, or supplement the treaty."

Moving negotiations to international regimes whose institutions, actors and subject matter mandates are more closely aligned with developing countries' interests reflects their willingness to have a more active role in shaping the international intellectual property regime (HELFER, 2004, p. 6). Because these forums have different rules of access, membership and participation, Raustiala (2007, p. 1027) emphasizes that they "empower and disempower distinct actors." States are no longer the only stakeholders who seek to use different forums to develop and elaborate international IP. Corporations, civil society and groups of IP users are also playing an active role in this sense.

The adoption of the Development Agenda within the WIPO's framework reflects the willingness of developing countries to influence the direction in which the international IP regulation is heading. The original proposal[28] was presented by Brazil and Argentina at the 2004 General Assembly and subsequently supported by 12 developing countries [29] (BIRKBECK; MARCHANT, 2011, p. 105).[30]

The primary goal of the Development Agenda's proponents was to make development a central concern for WIPO, which until then had "presented itself to the world as a merely technical agency with no political role in the global system" (MAY, 2007, p. 182). After long negotiations, the 2007 General Assembly agreed to 45

[28] See WIPO Document: Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO - WO/GA/31/11. Available at: <http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=31737>. Accessed on: 3. Apr. 2017.
[29] Argentina, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Iran, Kenya, Sierra Leone, South Africa, Tanzania and Venezuela.
[30] The proposal was further put forwarded by the Group of "Friends of Development" made up of the two original proposers, their cosponsors, Peru and Uruguay (MAY, 2007, p. 162).

Development Agenda Recommendations (DARs);[31] and to the establishment of the Committee on Development and Intellectual Property (CDIP) to oversee the implementation of the recommendations and undertake future work (BIRKBECK; MARCHANT, 2011, p. 106).[32]

Notwithstanding the developing countries' attempt to shift intellectual property rule setting to these multilateral forums, the most significant expansion of the international intellectual property regime is happening under the framework of preferential trade agreements. The development of international IP rules has in recent years moved back from multilateralism to bilateralism (DREXL, 2016, p. 55). The adoption of multilateral intellectual property agreements might even be seen as an instrumentalist "pause" in what has been an enduring feature of bilateral intellectual property international relations (OKEDIJI, 2004, p. 219). Even small and large developing countries, such as China and India, have also been busy negotiating their own PTAs with IP provisions (YU, 2015, p. 116).

Nevertheless, Okediji (2004) observes that there are fundamental differences in scope and substantive provisions of the bilateral intellectual property agreements adopted before the 1994 TRIPS Agreement and the ones adopted after it. While similar in form, the new bilateralism serves a different agenda in comparison with the old bilateralism (OKEDIJI, 2004, p. 134).

The old bilateralism relied "principally on commercial agreements as a means to stabilize, formalize and advance interests ostensibly mutual to the contracting parties" (OKEDIJI, 2004, p. 130). It was "aimed at facilitating access to foreign markets on grounds similar to what citizens would enjoy in the domestic context in a deliberate effort to, inter alia, maximize the gains of comparative and competitive advantage" (OKDIJI, 2004, p. 136). It did not require substantive intellectual property commitments from developing countries and did not deviate from the existing multilateral agreements (OKDIJI, 2004, p. 140).

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[31] The 45 recommendations were grouped into the following six clusters: (a) technical assistance and capacity building; (b) norm-setting, flexibilities, public policy and public domain; (c) technology transfer, information and communication technologies (ICT) and access to knowledge; (d) assessment, evaluation and impact studies; (e) institutional matters including mandate and governance: (f) other issues (WIPO, 2009, p. 2).

[32] See WIPO Document: WO/GA/34/16.

The new bilateralism, by its turn, is a "tool to effectuate the benefits of forum shifting, to overcome limitations imposed by the TRIPS Agreement, and to sustain the expansion of intellectual property rights at the expense of public interest both in developed and developing countries" (OKEDIJI, 2004, p. 141). It differs from the old by "utilizing the bilateral and regional processes primarily for strategic purposes" (OKEDIJI, 2004, p. 141). The new bilateralism extracts substantive intellectual property commitments from developing countries and deviates from existing multilateral agreements (OKDIJI, 2004, p. 140). PTAs have become, in accordance with Van Langenhove (2013, p. 109), "an instrument for strategic market access used by individual countries without real integration motives. They are used for preferential partnerships driven by political and economic drivers but unrelated to regional dynamics."

In a similar vein, Drexl (2016, P. 55) perceives that "this new 'IP bilateralism' does not at all express a shift from uniformity to a belief in the need for more differentiated IP standards." Rather, it reflects the conviction of certain trading nations that is easier to push for ever-higher standards of IP bilaterally. Hence, the motivations behind this phenomenon are better explained through a political economy perspective than solely through the legal systematic dogmatic (DREXL, 2016, p. 55).

Therefore, neither the TRIPS Agreement should be considered the endpoint in the development of intellectual property regime (OKEDIJI, 2004); nor the PTA's IP regulation be perceived as drastic derivations from the traditional path of regime development (YU, 2015, p. 116). Instead, all these agreements merely represent ups and downs of international intellectual property regime building (YU, 2015, p. 116). According to Cottier et al (2015, p. 466):

> Preferentialism and multilateralism are not two independent and distinct avenues for the pursuit of market access and regulatory policies. Historically, they build on each other in a dialectical process, closely related and linked through regulatory bridges of reference.

This shifting movement between multilateralism and preferentialism is what it is called by Cottier et al (2015, p. 467) as a dialectical relationship. As demonstrated above, history shows "movements occurring in waves, […] moving from preferentialism towards

multilateralism and then back again to preferentialism only to approach multilateralism over again" (COTTIER et al, 2015, p. 467). The proliferation of PTAs helps to form a critical mass that will provide "the basis for consolidation and further plurilateral and multilateral developments" (COTTIER et al, 2015, p. 468).

Hence, the advancement of intellectual property provisions in PTAs is neither good nor bad *per se* (YU, 2015, p. 97).[33] Their potential to be beneficial or harmful depends on how they are designed, the volume of trade covered, the participants, and to what extend significant progress proceeds in line with the WTO or other multilateral regimes (SCHOTT, 2004, p. 4-5).

In sum, both bilateralism and multilateralism shall be understood as integral parts of international dynamics of intellectual property rights rule-setting (OKEDIJI, 2004, p. 147). Intellectual property has become a foreign policy priority of our time and this is reflected in acceleration in the conclusion of PTAs with IP provisions (OKEDIJI, 2004, p. 104). This phenomenon, however, does not happen in a legal vacuum. The conclusion of PTAs shall be conducted in compliance with WTO rules. Therefore, it is important to depict the WTO legal background that enables the adoption of PTAs as well as the legal effects of this dialectical relation, specially, for trade-related intellectual property rules.

2.3 The WTO Regime and the Legal Effects of PTAs with IP Provisions

[33] In accordance with Yu (2015, p. 97), the negotiation of preferential trade agreements has both advantages (strengths) and disadvantages (weaknesses). On the one hand, PTAs have the ability to: (i) to drive reforms through the introduction of "multilateral-plus" and "multilateral-extra" provisions; (ii) to provide important entry points into regional or plurilateral networks; (iii) to enable the participating countries to speak with a louder voice and increase their leverage in multilateral negotiations; (iv) to foster common policy positions through the harmonization of their intellectual property standards, if the parties have equal bargaining strength; (v) to induce the less powerful counterpart to change laws, policies and standards, if the parties have unequal bargaining strength; and (vi) to practice a "divide and conquer" approach to international negotiations (YU, 2015, p. 88-92). On the other hand, PTAs are capable of: (i) undermining the existing multilateral system; (ii) enhancing the growing fragmentation of the international regulatory system; (iii) perpetuating, or even exacerbating, the already highly vulnerable position of less developed countries; and (iv) introducing provisions highly unpopular at home that the legislature would not have otherwise enacted through the outsourcing of the legislative process to an international forum of unelected representatives (YU, 2015, p. 92-97).

Notwithstanding their apparent incompatibility with the non-discrimination principles of the multilateral trading system, PTAs are not prohibited under WTO rules.[34] They are permitted as long as specific requirements are fulfilled. These are defined in the General Agreement on Tariffs and Trade (GATT)'s Article XXIV,[35] for trade in goods provisions; the General Agreement on Trade in Services (GATS)'s Article V,[36] for trade in services provisions; and the Enabling Clause,[37] for preferential arrangements among developing countries in trade in goods. No equivalent specific conditions for the formation of PTAs with IPRs provisions are found under the TRIPS Agreement (VALDÉS; McCANN, 2014, p. 3).

It is worth noting that these concessions made in the framework of PTAs constitute an exception to the application of the most-favored-nation (MFN) principle established under GATT Article I, GATS Article II and TRIPS Agreement Article IV. In simple terms, the MFN principle requires that Members shall not discriminate some countries over others, extending any advantage granted to one country to others WTO Members (VAN DEN BOSSCHE; ZDOUC, 2013, p. 316). Through this exception, WTO Members can offer trade concessions to individual countries in the framework of PTAs "without having to grant the same form of free trade to other WTO Members" (DREXL, 2016, p. 63).[38]

As observed by Mavroides (2007, p. 153), GATT's Article XXIV imposes three general obligations on WTO Members wishing to enter into a PTA. Namely, the

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[34] In this aspect, Marceau and Reiman (2001, p. 308) emphasize that PTAs existed even before the adoption of the 1947 General Agreement on Tariffs and Trade (GATT). Their legality was recognized by this first multilateral trade agreement (1947 GATT, Art. XXIV), and reaffirmed in the GATT 1994 (Art. XXIV).

[35] The 1994 GATT does not use the term "Preferential Trade Agreements". It instead refers to them as Free Trade Areas and Customs Union (MAVROIDIS, 2007, p. 148). As observed by Marceau and Reiman (2001, p. 302) the difference between these two is that while in the Free Trade Areas the intra-group trade barriers on nearly all trade between Members are abolished, in the Customs Unions a common external trade policy *vis-à-vis* non Members is also implemented.

[36] The GATS does not use the term "Preferential Trade Agreements", but "Economic Integration Agreements" to refer this kind of international instrument.

[37] The Enabling Clause is the term commonly used to refer to the decision entitled "The Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries", adopted in 1979 at the end of the Tokyo Round. It allows the GATT contracting parties to derogate the MFN principle in favor of preferential arrangements in trade in goods among developing countries (MARCEAU; REIMAN, 2001, p. 327). The Enabling Clause does not use the term "Preferential Trade Agreements". It instead adopts the term "partial scope agreements" to refer to them.

[38] There are two possible ways in the GATT to review the consistency of a PTA with the WTO rules: one multilateral and the other bilateral. As indicated by Mavroidis (2007, p. 153), through the multilateral track, WTO Members have to notify the PTAs they enter into to the WTO Committee on Regional Trade Agreements (CRTA); while through the bilateral track, WTO Members may challenge the consistency of a PTA with the multilateral rules under the Dispute Settlement Understanding (DSU).

contracting parties shall: (i) promptly notify the PTA to the WTO;[39] (ii) substantially liberalize all trade among them (internal requirement); and (iii) not raise the overall level of protection neither make the access of products from WTO Members not included in the PTA more onerous (external requirement) (MAVROIDIS, 2007, p. 153).[40]

In this regard, Pauwelyn and Alschner (2015, p. 499) remind that GATT's Article XXIV is not a prohibition, but an exception. That is to say, if a PTA does not meet GATT Article XXIV conditions, the PTA would not terminate or become invalided. It would only lead to the extension of the further liberalization agreed between the PTA's parties to all WTO Members. In other words, "not meeting these conditions do not invalidate the [PTA], it only invalidates Article XXIV exception to MFN" (PAUWELYN; ALSCHNER, 2015, p. 499).

Besides, it is also important to stress that matters not covered by the WTO (WTO-Extra) – such as competition, labor or environment – are not subject to WTO's MFN provisions. The arrangements in these topics can be preferential even though the PTA does not meet the conditions established under GATT Article XXIV, GATS Article V or the Enabling Clause (PAUWELYN; ALSCHNER, 2015, p. 501).

The purpose behind Article XXIV is to increase freedom of trade through the promotion of closer integration between the PTA's parties.[41] This provision originally established under the 1947 GATT was envisaged in a period when trade concessions were

[39] Seuba (2013, p. 240) reminds that PTAs are notified to the WTO under paragraphs 8 (a) and 8 (b) of article XXIV of GATT 1994 (customs union and free trade agreements); article V of GATS (economic integration agreements); and under paragraph 4(a) of the Enabling Clause (partial scope agreements). The TRIPS Agreement, however, has no requirement to notify relevant PTAs with IPR obligations. Nevertheless, many of PTAs with IPRs provisions end up being notified to the WTO due to their other provisions on trade in goods and services (VALDÉS; MACCANN, 2014, p. 3).

[40] The Appellate Body decision on the case Turkey – Restrictions on Imports of Textile and Clothing (DS34) is a landmark in regard to the relation PTAs and the WTO rules. It states clear that "the formation of an [PTA] may justify measures that are inconsistent with GATT rules, but only after having demonstrated […] the full compatibility of the [PTA] with Article XXIV:(5) and (8) of GATT and only […] if the formation of the formation of the [PTA] would have been prevented otherwise" (MARCEAU; REIMAN, 2001, p. 327).

[41] At the end of the Uruguay Round in 1994, the WTO Members adopted the Understanding on the Interpretation of Article XXIV of the General Agreement on Tariffs and Trade. Its preamble provides that: "the purpose of such agreements should be to facilitate trade between the constituent territories and not to raise barriers to the trade of other Members with such territories; and that in their formation or enlargement the parties to them should to the greatest possible extend avoid creating adverse effects on the trade of Members."

mostly related to the abolition of customs duties for certain products.[42] Nowadays, PTAs cover more complex subject matters, mainly on behind the border measures that, due to their regulatory nature, are not so simple to assess as tariff reduction. This demands a more careful analysis on whether a regulatory measure is discriminatory or not. Particularly for IP regulation, there are some TRIPS Agreement provisions that shall be taken into consideration when assessing the interplay between the multilateral and the preferential levels of regulation.

The TRIPS Agreement constitutes a minimum standard Agreement, since its Article 1:1 allows WTO Members to provide for a more extensive intellectual property protection than the one agreed in its text (WATAL, 1998, p. 282). This implies that Members are not only permitted to "recognize autonomously higher standards of protection in their domestic legislation, but also includes the possibility to enter into agreements with internationally binding obligations [that introduce higher] standards [of protection]" (DREXL, 2016, p. 63). Article 1:1 of the TRIPS Agreement reads, in the relevant part, that "members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement."

In accordance with Hilty (2016, p. 188), Article 1:1 stipulates a one-way system in which "deviations from any TRIPS provisions have to mandatorily lead to more extensive protection." Accordingly, WTO Members may agree on a more extensive approach, but they are not allowed to fall below the minimum protection requirement established under the TRIPS (HILTY, 2016, p. 195). In this sense, the TRIPS Agreement was designed in a way to allow "countries to adopt stronger protection of IPRs both unilaterally or in future PTAs" (COTTIER et al, 2015 p. 472).

However, Ruse-Khan (2012, p. 881) reminds that TRIPS Article 1.1 does not only set minimum standards, but also "functions as a regulatory framework that affects the ability of states to introduce additional IP protection." The second sentence of Article 1.1 allows WTO Members to introduce additional IP rules under the condition of not contravening TRIPS provisions (RUSE-KHAN, 2012, p. 882). This non-contravention

[42] In this regard, Van Langenhove (2013, p. 108) stresses that "originally the creation of [PTAs] were justified, in economic terms, as long as the trade creation induced by the tariffs removal between Members countries was exceeding the trade diversion brought by the displacement of imports from low-cost third countries producers to high-cost new [PTAs] partners."

obligation applies to "prohibit additional IP protection in conflict with a binding obligation in TRIPS that limits IP protection and enforcement" (RUSE-KHAN, 2012, p. 882). Article 1.1, however, "does not apply whenever a WTO Member chooses not to implement a flexibility TRIPS provides" (RUSE-KHAN, 2012, p. 882). Under these terms, the TRIPS Agreement "makes clear that any type of more extensive protection needs to be in harmony with the Agreements provisions" (ALEMAN, 2014, p. 63).

Another main issue regarding the adoption of higher standards of intellectual property protection in PTAs regards their subjection to WTO Dispute Settlement System. Since the TRIPS Agreement does not provide for a regional integration exception, such as provided in the GATT (Article XXIV) and in the GATS (Article V), any intellectual property advantage granted by a WTO Member to the nationals of any other country shall be extended to all WTO Members. Even if other WTO Members do not belong to the contracting parties of such agreements, they can bring complaints under the WTO Dispute Settlement System based on the TRIPS national treatment (Article 3) and most-favored-nation (Article 4) clauses. In effect, the TRIPS non-discrimination clauses end up "multilateralizing" intellectual property concessions made in PTAs (DREXL, 2016, p. 63).

Agreements that require a higher degree of protection than is required under the TRIPS Agreement should, in accordance with Yu (2007, p. 867), be distinguished into three different types of provisions: TRIPS-Plus, TRIPS-Extra and TRIPS-Restrictive.[43] Such provisions respectively require that: (i) countries increase the domestic IP protection above the standards established under TRIPS; (ii) countries add commitments in new areas not covered by the TRIPS; and (iii) the flexibilities provided under the TRIPS ought to be

[43] Some scholars generally define PTAs with higher standards of IP protection as merely TRIPS-Plus, not making a distinction between these three categories brought by Yu (2007). For example, Sell (2007, p. 52) defines TRIPS-Plus as "provisions that either exceed the requirements of TRIPS or eliminate TRIPS flexibilities." In a similar vein, Drahos (2001, p. 793) characterize them as provisions that "requires a Member to implement a more extensive standard; or which eliminates an option for a Member under a TRIPS standard." In consonance with Helfer (2004, p. 4), TRIPS-Plus Agreements "contain intellectual property protection standards more stringent than those found in TRIPS, obligate developing countries to implement TRIPS before the end of its specific transition period or require such to accede to or conform to the requirements of other multilateral intellectual property agreements." The adoption of the Yu's (2007, p. 867) concept is intended to better clarify the impact of different IP provisions in PTAs and to assess the necessary policy responses.

limited (YU, 2007, p. 867-869; JEFFERSON, 2014, p. 46).[44] This distinction between the types of intellectual property provisions is crucial to assess the interaction between the multilateral and the preferential regimes.

Even though TRIPS-Plus and TRIPS-Extra provisions appear quite similar, their distinction is of key importance (YU, 2015, p. 88). First, because the WTO only allows "the use of its mandatory process to settle disputes arising under its agreements, TRIPS-extra provisions are technically outside the WTO rules" (YU, 2015, p. 88). Therefore, TRIPS-Extra provisions can "be subjected to unilateral trade sanctions or alternative dispute resolution mechanisms" (YU, 2015, p. 88). Second, the classification of intellectual property provisions into TRIPS-Plus and TRIPS-Extra has meaningful implications for the application of the TRIPS's national treatment and MFN principles. Depending on the type of intellectual property right established under the PTA, those non-discrimination principles may apply or not. The reasons that based these understandings are the following.

The national treatment principle established under Article 3 of the TRIPS Agreement requires in essence that "nationals of other Members are given the same treatment as one's own nationals" (MALBON; LAWSON; DAVISON, 2014, p. 188).[45] By its turn, the MFN principle incorporated into the TRIPS Article 4 mandates that "any advantage granted by a Member to the nationals of any other country must be accorded immediately and unconditionally to the nationals of other Members" (CARVALHO, 2005, p. 94). In sum, Taubman, Wager and Watal (2012, p. 16) explain that "while the national treatment clause forbids discrimination between a Members' own national and the national of others Members, the MFN treatment clause forbids discrimination between the nationals of other Members."

It is worth recalling that the national treatment obligations in the TRIPS Agreement differ from the national treatment obligations provided for in the GATT (Article III) and in

[44] Aleman (2014, p. 68), for example, categorizes provisions that require a higher degree of protection than the TRIPS into four group of rules: (i) provisions that aim to clarify, interpret or narrow down a TRIPS flexibility, as well as provisions that go beyond the minimum standard of protection of TRIPS; (ii) provisions that develop new matters not covered by the TRIPS Agreement; (iii) provisions that repeat the text of TRIPS Agreement; (iv) provisions that contain an obligation to "apply" or "accede" to other treaties or to respect international commitments in force.

[45] In this regard, Abbot, Cottier and Gurry (2007, p. 46) clarifies that: "the national treatment principle does not prevent a government from establishing different rules that apply to foreigners and domestic nationals, that is rules that take into account legitimate differences. What is prohibited are measures that adversely affect foreigners without justification, thereby creating an imbalance in conditions of competition."

the GATS (Article XVII). While the GATT requires non-discriminatory treatment for like products (tangible assets), the GATS requires it for service suppliers, and the TRIPS for persons (whether natural or juridical) holding intellectual property rights (intangible assets) (UNCTAD-ICTSD, 2005, p. 62-63).[46] As noted by Gervais (2003, 88), "the WTO Membership is the fundamental element in the definition of 'nationals' to whom the treatment provided in TRIPS must be accorded."[47]

The application of the national treatment and MFN principle in the TRIPS's context is subject to a number of cautiously negotiated exceptions. They incorporate mainly the exceptions already provided in the Paris, Bern and Rome Conventions regarding respectively industrial property rights, copyright and related rights and add others specific cases (CORREA, 2004, p. 10; GERVAIS, 2003, p. 98). These exceptions, however, do not include "regional integration" itself (ALEMAN, 2014, p. 67). This means that, in principle, IP concessions agreed in PTAs shall be automatically extended to all WTO Members not just to those that participate in a given PTA (ELSIG; SURBECK, 2016, p. 2). In this manner, the TRIPS MFN principle knits closely the multilateral and preferential rules (COTTIER et al, 2015, p. 474). 2

The scope of these principles, however, has some nuances that are better explained in conjunction (CARVALHO, 2005, p. 94). The TRIPS Article 3.1 states that the national treatment obligation applies "with regard to the protection of intellectual property." In order to clarify the scope of this obligation, the footnote 3 to Article 3.1 provides an inclusive definition of the term "protection" as used in Articles 3 (National Treatment) and 4 (Most-Favored Nation). It reads as follows:

> For the purposes of Articles 3 [National Treatment] and 4 [Most-Favored Nation], "protection" shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights **specifically addressed in this Agreement** (emphasis added).

[46] On this view, Malbon, Lawson and Davison (2014, p. 119) explains that while under the GATT the first step is to identify whether the relevant imported product and the local product are similar for then examine whether the treatment of the important product is less favorable than that accorded to the local product, under the TRIPS we must compare the treatment of a particular IP right that a Member confers to its own nationals and to nationals of other Members.

[47] The footnote 1 to TRIPS Article 1.3 clarifies that the "concept of nationals extends to separate customs territories (such Macao, Hong Kong, Taipei and the European Communities and their Member States)" (CARVALHO, 2005, p. 70).

According to Carvalho (2005, p. 90-91), the purpose of Footnote 3 to Article 3.1 is twofold: (i) to define the word protection and (ii) to specify the coverage of such protection for the purposes of national treatment and most-favored nation principles. Drawing on his observation, only those intellectual property rights the use of which are **specifically addressed** in the Agreement are subject to the applicability of the two principles.

In this respect, Pauwelyn and Alschner (2015, p. 501) remind that not all WTO Agreements include an MFN clause.[48] Consequently, where these clauses are found, they only cover matters falling within the scope of the agreement (PAUWELYN; ALSCHNER, 2015, p. 501). This premise expresses the principle of *ejusdem generis*, which, according to the International Law Commission (1978, p. 27), mandates that "under the most-favored-nation clause the beneficiary State acquires, for itself or for the benefit of persons or things in a determined relationship with it, only those rights which fall within the limits of the subject matter of the clause."[49]

In light thereof, TRIPS Article 1.2 (Nature and Scope of Obligations) explains that, for the purposes of the TRIPS Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II. In other words, intellectual property in the TRIPS Agreement refers to: (i) copyright and related rights; (ii) trademarks; (iii) geographical indications; (iv) industrial designs; (v) patents; (vi) layout-designs (topographies) of integrated circuits; and (vii) protection of undisclosed information (MALBON; LAWSON: DAVISION, 2014, p. 86). This definition excludes from general TRIPS obligations forms of intellectual property not covered by Agreement (GERVAIS, 2003, p. 87). However, it is important to highlight that the term "intellectual property rights" also includes IP in the provisions of other IP conventions that were incorporated into the TRIPS, such as the Paris, Bern and Rome Conventions and the Washington Treaty (MALBON; LAWSON: DAVISION, 2014, p. 87).

Having this legal provisions and understandings in mind, we can conclude that the TRIPS Agreement's national treatment (Article 3) and MFN (Article 4) clearly apply to the 7 above-mentioned intellectual property rights' categories. This implies that IP provisions

[48] For example, the Agreement on Subsidies and Countervailing Measures (SCM) or the Agreement on Trade-Related Investment Measures (TRIMS) do not include a MFN clause.
[49] Article 9 of the International Law Commission Draft Articles on Most-Favored-Nation Clauses.

in PTAs that goes beyond the TRIPS minimum standard of protection of TRIPS (TRIP-Plus) in these intellectual property categories cannot discriminate between a Member's national and a foreigner (National Treatment) or between nationals of other WTO Members (MFN).

As such, this also means that IP provisions in PTAs that develop new aspects not covered by the TRIPS Agreement (TRIPS-Extra) are not subject to the TRIPS' national treatment and most-favored nation principles (MALBON; LAWSON: DAVISION, 2014, p. 90; ALEMAN, 2014, p. 76). According to Correa (2007, p. 66-67), the TRIPS-Extra rights recognized in the context of PTAs do not need to be extended by the contracting parties to non-contracting parties. There are a number of issues that are not covered nor specifically addressed by the TRIPS Agreement, falling outside of the scope of TRIPS Articles 1.2 and Footnote 3 to Article 3.1.[50] In such matters, the countries' decision to implement TRIPS-Extra provisions derives exclusively from national policy choices (ALEMAN, 2014, p. 73).

For example, since traditional knowledge is not defined as intellectual property under the TRIPS Agreement (Article 1.2) nor it is specifically addressed by it (Footnote 3 to Article 3.1), IP provisions on this subject granted in a PTA scheme are not subjected to TRIPS national treatment nor MFN principles (MALBON; LAWSON; DAVISION, 2014, p. 90). In this case, narrow reciprocity based national treatment would be valid under a PTA arrangement. However, if it is a provision referring to patent protection, for example, TRIPS national treatment and MFN principles shall apply, since it falls within the TRIPS definition of intellectual property right (Article 1.2), being its use specifically addressed by the TRIPS Agreement (Footnote 3 to Article 3.1).

The problematic feature about this reasoning is that there is no scholarly consensus[51] nor specific WTO jurisprudence that draws a clear line between which are the specifically addressed categories of intellectual property that constitutes TRIPS-Plus or TRIPS-Extra provisions. There are some grey areas, not as simple as patent and traditional knowledge, that are more difficult to discern whether it falls within the TRIPS Agreement's scope of protection or not.

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[50] Examples of TRIPS-Extra provisions include rules on traditional knowledge, traditional cultural expressions, genetic resources, domain names, protection of encrypted program-carrying satellite and cable signals.

[51] See Carvalho, 2015, p. 90; Correa, 2007, p. 61 and Malbon; Lawson; Davision, 2014, p. 86.

For example, there is a discussion whether national treatment and MFN should also apply not only to intellectual property right categories expressly listed in the headings of Sections 1 to 7 of Part II of TRIPS Agreement, but also to intellectual property categories found within the text of Sections 1 to 7, such as plant variety protection and unfair trade practices[52] (CARVALHO, 2005, p. 93).

Regarding plant variety protection, even though the TRIPS Article 1.2 does not list it as a category of intellectual property, Article 27.3.b states that: "Members shall provide for the protection of plant varieties either by patents of by an effective *sui generis* system or by any combination thereof." This passage raises the question whether the mere reference to an alternative *sui generis* system of protection in this provision could classify it as an intellectual property right "specifically addressed" by the TRIPS Agreement (Footnote 3 to Article 3.1) (CARVALHO, 2005, p. 91-92). As regard to unfair trade practices, even though their provisions are mainly located in Section 8 of Part II of the TRIPS Agreement, unfair competition is also mentioned by the text of Article 22.2 (b) of the TRIPS Agreement in Section 3 of Part II (CARVALHO, 2005, p 29).[53]

Another grey area refers to whether national treatment and MFN principle would also apply to the provisions from the Paris, Bern, Rome Conventions and Washington Treaty incorporated by the TRIPS Agreements. As noted by Carvalho (2005, p. 30), there are a number of areas of industrial property – such as utility models, trade names and collective marks – that the TRIPS provisions do not mention, but the Paris Convention expressly refers to them. This raises the question whether the term "specifically addressed" also comprises all these intellectual property rights that are not directly mentioned in the TRIPS agreement, but are identified as mandatory subject matter of protection under these incorporated multilateral IP agreements (CORREA, 2007, p. 62).

At the time of writing, there are only two cases under the WTO Dispute Settlement System that have directly addressed the interpretation of TRIPS Footnote 3 to Article 3.1: the Indonesia – Certain Measures Affecting the Automobile Industry (DS54, 55, 59, 64)[54]

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[52] Section 8 of Part II – Control of Anti-Competitive Practices in Contractual Licenses.

[53] As stated in TRIPS Article 2.2b: "in respect of geographical indications, Members shall provide the legal means for interested parties to prevent: (b) any use which constitutes an act of unfair competition within the meaning of Article 10bis of the Paris Convention (1967)."

[54] In the *Indonesia – Autos*, the complaints were raised by the European Union, Japan and United States. The panel was established on 12 June 1997, its report was circulated on 2 July 1998 and adopted on 23 July 1998 (WTO, 2015, p. 25).

and the EU – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs (DS174).[55] In addition to those, the United States – Section 211 Omnibus Appropriations Act of 1998 (DS176)[56] case adds an important understanding on the incorporation of the Paris Convention's obligations into the TRIPS Agreement (Article 2.1).[57] Their findings shed some light in the scope of the national treatment and MFN principles under the TRIPS Agreement.

In the Indonesia – Autos, the panel was requested, among other matters, to rule on whether the grant of "National Motor Vehicle" benefits only to motor vehicles bearing a unique Indonesian trademark owned by Indonesian nationals consisted a discriminatory measure against foreign-owned trademarks and their owners. The complaining parties argued that this measure characterized a breach of TRIPS Article 3 (National Treatment), Article 20[58] (Other Requirements) and 65.5[59] (Transitional Arrangements). On the interpretation of Footnote 3 to Article 3, the panel asserted that:

> As made clear by the footnote to Article 3 of the TRIPS Agreement, the national treatment rule set out in that Article does not apply to use of intellectual property rights in generally but only to "those matters affecting the use of intellectual property rights specifically addressed in this Agreement" (Paragraph 14. 275).

The complaining parties (more specifically, the United States) argued that the Indonesian law and practice at issue related to the use of an intellectual property right

[55] In the *EC – Trademarks and Geographical Indications*, the complaints were raised by the United States and Australia. The panel was established on 2 October 2003, its report was circulated on 15 March 2005 and adopted on 20 April 2005 (WTO, 2015, p. 70).
[56] In the *US – Section 211 Appropriations Act*, the complaints were raised by the European Union. The panel was established on 26 September 2000 and its report was circulated on 6 August 2001. The parties appealed and the Appellate Body (AB) completed the panel's analysis by circulating its report on 2 January 2002. The AB report was adopted on 1 February 2002 (WTO, 2015, p. 71).
[57] TRIPS Article 2.1 establishes that: "In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967)."
[58] TRIPS Article 20 on Trademarks (Other Requirements) reads as follows: "The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings. This will not preclude a requirement prescribing the use of the trademark identifying the undertaking producing the goods or services along with, but without linking it to, the trademark distinguishing the specific goods or services in question of that undertaking."
[59] TRIPS Article 65.5 on Transitional Arrangements reads as follows: "A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement."

"specifically addressed" by TRIPS Article 20.[60] On this topic, the panel ruled that it was not demonstrated that Indonesia was in breach of its obligations under TRIPS Article 3 in respect of the use of trademarks specifically addressed in TRIPS Article 20 (Paragraph 14.279).

In the EU – Trademarks and Geographical Indications (DS174) case, the panel was questioned, among other issues, to rule whether the European Union regulation on the protection of GIs and designations of origin violated the national treatment principle regarding the equivalence and reciprocity conditions of non-EU nationals (MALBON; LAWSON: DAVISION, 2014, p. 133). Regarding the interpretation of footnote 3 of Article 3.1 of TRIPS Agreement, the panel noted that:

> It is not disputable that 'designation of origin' and 'geographical indication', as defined in the European Union Regulation, fall within the category of "geographical indications", the subject of Section 3 of Part II, and therefore part of a category of intellectual property within the meaning of Article 1.2 of the TRIPS Agreement (Paragraph 7.178).
>
> Therefore, this claims concerns the protection of intellectual property, as clarified in footnote 3 to the TRIPS Agreement, within the scope of the national treatment obligation in Article 3 of that Agreement (Paragraph 7.179).

On this matter, the panel found that:

> The equivalence and reciprocity conditions in respect of GI protection under the EC Regulation violated the national treatment obligations under TRIPS Article 3.1 […], by according less favourable treatment to non-EC nationals and products, than to EC nationals and products (WTO, 2015, p. 70).

In the US – Section 211 Appropriations Act (DS176), the Appellate Body (AB) was requested, among other issues, to rule on whether trade names were covered by the TRIPS Agreement, given that Article 8 of Paris Convention[61] was incorporated into TRIPS

[60] TRIPS Article 20 regulates other requirements for the use of trademarks in the course of trade.
[61] Article 8 of Paris Convention (1967) provides that: "A trade name shall be protected in all the countries of the Union without the obligation of filling or registration, whether or not it forms part of a trademark."

Agreement through TRIPS Article 2.1.[62] On this matter, the AB reverted the panel's findings, under the reasoning that:

> Article 8 of the Paris Convention (1967) covers only the protection of trade names; Article 8 has no other subject. If the intention of the negotiators had been to exclude trade names from protection, there would been no purpose whatsoever in including Article 8 in the list of Paris Convention (1967) provisions that were specifically incorporated into the TRIPS Agreement. To adopt the Panel's approach would be to deprive Article 8 of the Paris Convention (1967), as incorporated into the TRIPS Agreement by virtue of Article 2.1 of that Agreement, of any and all meaning and effect (Paragraph 338).

On these grounds, the AB concluded that trade names are covered under the TRIPS Agreement and WTO Members do have an obligation to provide protection to trade names. On this view, the "the meaning of 'intellectual property' under the TRIPS is not limited to the Article 1.2 definition, and includes rights and obligations arising as a result of the operation of Article 2.1" (MALBON; LAWSON: DAVISION, 2014, p. 89). The AB also applied the TRIPS Articles 3.1 (national treatment) and 4 (MFN) to trade names in its ruling (WTO, 2015, p. 71).

From the analysis of the three above-mentioned cases, one can assert that the national treatment and MFN principles under the TRIPS Agreement does not apply to use of intellectual property rights in general, but only to those matters affecting the use of intellectual property rights specifically addressed in the Agreement. This does not mean that they are limited to the titles of provisions in Sections 1 through 7 of Part II, but that they apply to those intellectual property rights that are subject of those provisions (MALBON; LAWSON: DAVISION, 2014, p. 89-90). Furthermore, the TRIPS nondiscrimination principles also apply to the provisions of the 1967 Paris Convention – such as trade names – specifically incorporated into the TRIPS Agreement by its Article 2.1.

The clarification of the above-addressed points of the multilateral trade regime is of key importance to understand the interplay between the multilateral and preferential levels of regulation as well as the legal boundaries that countries should be aware when

[62] TRIPS Article 2.1 reads as follows: "In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention."

negotiating IP provisions in PTAs. After all, the adoption of PTAs has a substantial impact on domestic regulation, since "IP provisions covered by the TRIPS Agreement and contained in a particular [PTA] must be applied without discrimination to the nationals of countries that are not parties to the [PTA] in question" (VÁLDES; McCANN, 2014, p. 39). For this reason, it is so import to know the scope of TRIPS national treatment and MFN principles as well as whether the intellectual property rights under a PTA constitute a TRIPS-Plus or TRIPS-Extra regulation. These aspects will guide whether a WTO Member is obliged to extend an IP concession made in the framework of a PTA to all other Members or not (DRAHOS, 2001, p. 802).

As observe by Drexl (2016, p. 62), the concept of trade-relatedness of intellectual property rights is not just a label put on TRIPS to formally justify the inclusion of intellectual property in international trade law, but it constitutes "a one-way ticket that WTO Members have taken for a journey towards IP expansion." The fact that TRIPS embeds intellectual property under the umbrella of WTO has important consequences. The use of trade concessions as bargaining chip for higher standards of IP protection is not only accepted, "but even promoted by the legal design of the multilateral WTO trading system" (DREXL, 2016, p. 69).

However, the multilateralization of TRIPS-Plus provisions through the application of the TRIPS MFN clause and the advancement of the international IP regime through TRIPS-Extra provisions remain a controversial subject. It is argued that the majority of these provisions do not really address the needs of developing countries to build a sound, dynamic and sustainable innovation system. They usually disregard "local needs, national interests, technological capabilities, institutional capacities and public health conditions" (YU, 2015, p. 84). For that reason, the next section aims to highlight the most problematic features of unbalanced IP provisions in PTAs, more specifically in the patent law field.

2.4 Problematic Features of Unbalanced IP Provisions in PTAs

There is no conclusive evidence that the adoption of more stringent IPRs leads to a direct increase in trade, foreign investment and technology transfer (CORREA, 2007, p.

225; ELSING; SURBECK, 2016, p. 2). These are typically the benefits that developed countries present to developing countries to entice them to offer stronger protection and enforcement of intellectual property rights (YU, 2015, p. 105).

As shown by the World Bank publication on Intellectual and Development, the adoption of stronger intellectual property rights within preferential trade agreements does not directly and automatically results in an increase in foreign direct investment and technology transfer (FINK; MASKUS, 2005, p. 8-9). There are many other variables that determine the net benefit and impact of a particular intellectual property regime, such as: "countries endowments with factors and technologies, other business regulations, the efficiency of the judicial system, macroeconomic stability, and so on" (BRAGA; FINK, SEPULVEDA, 2000, p. 49). The adoption of higher standers might be seen at most as "a signal indicating that a country is willing to provide a more business-friendly environment" (SANDERS, 2007, p. 6).

As noted by Sanders (2007, p. 6), "countries with weak protection or enforcement of IPR like Brazil and China have been more successful in attracting FDI [foreign direct investment] than many developing countries that have made strong IPR central to their development strategy."[63] If stronger intellectual property protection always led to more foreign direct investment, recent capital flows would not have gone to high-growth and large-market developing countries, such as China and Brazil, but rather to Sub-Saharan Africa and Eastern European countries (YU, 2015, p. 105).

After more than 20 years since the adoption of the TRIPS Agreement, countries have begun to realize that the oft-presented advantages may be misleading (YU, 2015, p. 105). The higher degree of protection that is required under the PTAs may not be adequate for countries with less sophisticated innovation system. Like any other incentive, Correa (2007, p. 225) reminds that: "the impact of intellectual property rights will depend on the context in which they apply."

In this respect, Fink asserts that (2011, p. 388) while "most trade theories predict economic welfare gains as a result of reciprocal tariff liberalization, the same cannot be said about the adoption of the ever-higher protection standards for IPRs." This derives

[63] According to the 2017 World Investment Report, China, Singapore, Brazil, India, Russia, Mexico and Angola were, in this order, the main destination of FDI flows among developing countries in 2015-2016 (UNCTAD, 2017b, p. 12).

from the complexities that involve measuring the cost and benefits of higher standards of IP protection. As observed by Drexl (2016, p. 72), due to its static nature, this is much easier to be undertaken with regard to trade in goods, "which is typically expressed by a reduction of customs duties and corresponding increase in cross-border sales." In accordance with Abbot, Cottier and Gurry (2007, p. 42), there are mainly three reasons why it is complicate to assess the economic costs and benefits of stronger IP rules in PTAs.

First, "the traditional logic economists apply to mercantilist trade bargaining does not straightforwardly extend to intellectual property" (ABBOT, COTTIER, GURRY, 2007, p. 42). Intellectual property rights aim to give incentives for inventive and creative activities by granting intellectual property owners temporary market exclusivity. This enables them to generate revenues above competitive returns and thus recover the initial knowledge-generating investment (FINK, 2011, p. 388).

Pursuant to national policy objectives, governments "need to strike a proper balance between the interests of intellectual property holders and the public at large, which experiences market exclusivity as a barrier to the free dissemination of knowledge" (FINK, 2011, p. 388). In this way, intellectual property rights entail a trade-off between competitive access to new technologies and incentives for innovation. There is, however, no guarantee that stronger intellectual property rules will always be welfare enhancing (ABBOT, COTTIER, GURRY, 2007, p. 42). According to Abbot, Cottier and Gurry (2007, p. 42) "the direction and size of the welfare effect will depend on a country's level of economic development."

Second, stronger IPRs' commitments are permanent and likely to be implemented in a non-preferential basis. The TRIPS Agreement does not provide for an exception to the MFN principle for FTAs, such as provided in GATT (Article XXIV) and GATS (Article V) (ABBOT, COTTIER, GURRY, 2007, p. 42). Hence, if a country were to extend superior treatment to intellectual property rights covered by the TRIPS Agreement, "other WTO members could invoke the WTO's dispute settlement mechanism to request the extension of the special benefits to its own nationals" (FINK, 2011, p. 389). This has important bargaining implications, since it is not possible to offer the same IP concession twice (FINK, 2011, p. 389).

Third, “it is inherently difficult to quantify the implications of changing intellectual property standards, let alone to compare them in monetary values to the gains derived from improved market access abroad” (ABBOT, COTTIER, GURRY, 2007, p. 42). While the benefits of trade in goods liberalization are normally of a short-term nature, “the social costs of excessive IP protection will often materialize only in the long run” (DREXL, 2016, p. 72).

These reasons underline the risks that countries may incur when “importing” a standard of intellectual property protection that do not reflect their national efficiency trade-off (DREXL, 2016, p. 72). Therefore, it is important to evaluate the arguments regarding problematic features of unbalanced IP provisions in PTAs, especially those concerning patent regulation. This section addresses the debate involving innovation, public health, environment protection, biological diversity and food security.

2.4.1 Innovation

Innovation[64] is a key component of the current knowledge-based economy. There is no completely new and independent innovation. The innovative process is not a breakthrough one, but a cumulative one in which every innovation builds upon existing products or processes (SEARLE; BRASSELL, 2106, p. 56). Intellectual property rights were primarily instituted to incentivize innovation (SEARLE; BRASSELL, 2106, p. 14).

Patents work in this manner by providing rights holders “with limited monopolies over their innovation” (SEARLE; BRASSELL, 2106, p. 54). Innovation, however, is not conditional to patent protection. The intellectual property system is just one element among many others that help to improve the innovation environment.[65] As pointed out by Searle and Brassell (2016, p. 54), “humankind has long innovated while patents are relatively new addition to our economies.”

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[64] As defined by Searle and Brassell (2016, p. 14), “an innovation is an applied invention. An invention is the creation of a new product or process; whereas innovation is the use of application of the new product or process.”

[65] The WIPO Annual Global Innovation Index, for example, takes into consideration other figures other than intellectual property to construe its innovation indicator. It considers, for example, figures related to institutions, human capital and research, infrastructure, business and market sophistication, knowledge, technology and creative outputs.

It is worth noting that countries enjoyed considerable autonomy in setting national policies in the patent domain until the 1990s. Even though the Paris Convention required its signatories to abide by basic norms of non-discrimination and national treatment, countries preserved practically complete autonomy in respect to substantive aspects of national patent law. They could determine, for example, which technological areas were eligible for patent protection (SHADLEN et al, 2011, p. 3).

This completely changed with the adoption of the TRIPS Agreement in 1994. From then on, countries were required to make patent available for any inventions, whether products or process, in all fields of technology (Art. 27.1), for a minimum period of twenty years of protection (Art. 33). The already controversial and fiercely debate on the effects of strong patent regimes in industrialized countries were then also transferred to developing countries. The signing of the TRIPS Agreement extended to developing countries the same type of patent regime that was designed to developed countries (CORIAT, ORSENIGO, 2014, p. 229). This one-size-fits-all approach is argued to have delayed and hindered the innovation capacities and the technological catch-up of several developing countries.

It is important to stress that the commonly defended "the stronger patent protection, the better" does not faithfully reflect the dynamics of creative process. According to Hilty (2016, p. 194), the equation "more patent = more innovation" is by far too simplistic. This correlation depends on other factors, such as the developmental state of the national economy and to the field of technology (HILTY, 2016, p. 194). In fast-moving industries such as mobile phone technologies, for example, Searle and Brassell (2016, p. 55) argue that "patents can become market obsolete quickly and, therefore, longer durations would be inefficient."

In accordance with Hilty (2016, p. 192-193), "a lower protection standards during a certain transitional period tend to facilitated the evolution of a country's own, competitive industrial branches thanks to possible learning effects." In a similar vein, Abbot (2014, p. 160) asserts that "countries that have limited capacity for leading-edge technological innovation may be better off with weaker IP protection that provides more leeway for copying innovation undertaken elsewhere."

There are quite a few examples that support this understanding. The Netherlands abolished patents in the field of chemistry from 1869 to 1910 to catch up with other

European countries, such as Germany (EL-SAID, 2016, p. 374). Switzerland was the last Central European country to introduce patent protection in 1907, under the pressure from France and Germany (HILTY, 2016, p. 192). In the 1970s, Japan was heavily criticized for imitating electronic goods and cars from western industries. It used this tactic to close the gap between its national industry and the competition abroad.

The same strategy was followed by South Korea,[66] later on Taiwan and meanwhile China (HILTY, 2016, p. 192-193). Presently, it is just a matter of time until "Chinese industries reach the standard of US or European developers and producers" (HILTY, 2016, p. 193). India also used as long as it could all the TRIPS flexibilities to build a robust pharmaceutical industry focused on generics.

As these examples suggest, the accumulation of technical capabilities over time "can allow local actors to advance beyond absorption and imitation and undertake their own innovative activities" (SHADLEN et al, 2011, p. 6). Weaker patent rights can facilitate capability-development and enable the flourishing of strong local firms in a set of sophisticated industries (SHADLEN et al, 2011, p. 6-7).

According to Abbot (2014, p. 160), "there is a general theory of intellectual property rights suggesting that countries at different levels of economic development have different best interests in the strength of IP protection, and that these best interests change over time." There is a point in which countries "who previously benefited from weaker IPR system may develop an interest in stronger IPRs to protect their own innovations" (SHADLEN et al, 2011, p. 7). National stakeholders even start to request their governments to pursuit higher levels of protection in the international realm. As soon as this technological transition period is over, "higher protection standards may apply without harm for the strengthened domestic industries" (HILTY, 2016, p. 193).

The problematic feature regarding the adoption of higher standards of patent protection in PTAs by developing countries lies, precisely, in the adverse effects that this might have on their innovation capacities. An immediate, unconfined and unbalanced commitment to those standards "risks slowing down the development of domestic industries and thus domestic economic growth" (HILTY, 2016, p.193).

[66] El-Said (2016, p. 374) reminds us that "when South Korea introduced patent protection in 1961, the protection term was limited to only twelve years and protection did not extend to foodstuffs, pharmaceuticals, or chemicals."

In the words of Abbott (2014, p. 160), “a commitment to implement TRIPS-plus obligations prior to achieving a threshold level of innovation capacity may, in fact, impede economic and social development.” Strong patent laws “may not be enough to promote innovation in contexts where innovation capabilities are low or missing altogether” (CORIAT, ORSENIGO, 2014, p. 235). An overprotective patent system can even harm countries that have already achieved a high level of domestic innovation capacity (ABBOTT, 2014, p. 160).

2.4.2 Public Health

The intersections between international trade rules, the intellectual property system and public health is complex and multifaceted. Among the intellectual property elements relevant to medical innovation and access to medical technologies, one can highlight: (i) patents; which encourage invest in R&D; (ii) test data protection; which includes clinical trials and other information regarding quality, safety and efficacy of medicines; (iii) trademarks;[67] which serves to distinguish products and inform the consumer; and even (iv) copyrights, concerning covers of the package inserts and information leaflets that accompany pharmaceutical products (WHO; WIPO; WTO, 2012, p. 12-13).

Given the significant financial and technical resources required, in addition to the high risk of failure even at a late stage in product development, the above-mentioned intellectual property rights are particularly valuable for the development of new medical technologies (WHO; WIPO; WTO, 2012, p. 53). They provide the necessary incentives to different stakeholders to invest resources in the development and in the marketing of new therapeutic products (WHO; WIPO; WTO, 2012, p. 53).

[67] In this regard, Shadlen et al (2011, p. 2) reminds that: “pharmaceutical firms are also dependent on trademarks to preserve market shares in the absence of patents, but this concern is not just relevant to originator firms but can also pertain to producers of off-patent drugs.” Trademarks are used to label both original and generic products. In order to avoid confusion, trademarks for pharmaceutical products needs to be different from the international nonproprietary names (INNs) of the products (WHO; WIPO; WTO, 2012, p. 53). INNs are: “universally recognized as unique names that identify particular pharmaceutical substances or active pharmaceutical ingredients” (WHO; WIPO; WTO, 2012, p. 67). The WHO keeps a system of such generic names.

Due to the high costs of research and development, combined with the relative easy reverse-engineering, patent protection plays a central role for the pharmaceutical industry (SHADLEN et al, 2011, p. 2). Several therapeutic technologies are expensive to develop, but relatively cheap to reproduce (WHO; WIPO; WTO, 2012, p. 54). The pharmaceutical sector is, therefore, "intensively dependent on patents as a mechanism to ward off competition and thus appropriate the rents derived from technological innovation" (SHADLEN et al, 2011, p. 2). As stressed by Coriat and Orsenigo (2014, p. 219), this industry is "one of the few in which patents are recognized as being key instruments for privately appropriating the economic benefits of innovation and, therefore, serving as an important incentive for innovation."

In this perspective, Li (2011, p. 421) observes that intellectual property and public health are two sides of the same coin, inseparable and mutually dependent. On the one hand, "the patent system is crucial to provide necessary incentives to invest in discovery of essential drugs for public health as there is a long lead time, high investment and entry barriers in the drug discovery process" (LI, 2011, p. 415). No pharmaceutical company would be inclined to invest in a costly, lengthy and challenging drug discovery process without a financial return (LI, 2011, p. 416). On the other hand, the intellectual property system attains a higher and nobler objective by granting patent rights to inventors of new drugs that can save lives. A significant amount of patents has been granted for the discovery of essential medicines in the field of public health, benefiting and justifying the IP system itself (LI, 2011, p. 416).

However, it is important to notice that prior to the adoption of the TRIPS Agreement in 1994, countries were not required to grant patents on pharmaceutical products and/or processes. They enjoyed virtually complete autonomy in respect to substantive aspects of their national patent law, being able to exclude certain technological areas from patentability (SHADLEN et al, 2011, p. 3). This changed through the incorporation of TRIPS Article 27.1, which requires that "patents shall be available for any inventions, whether products or processes, in all fields of technology."

In accordance with Ruse-Khan (2016, p. 421), the global extension of patent protection to cover "all fields of technology" is the root of the debate on "TRIPS, the right (of states) to protect public health and the right (of individuals) to health and access to (patented) medications." Previously, pharmaceutical products had not been subjected to

patent protection in several countries[68] (RUSE-KHAN, 2016, p. 421). Since the entering into force of the TRIPS Agreement, WTO Members – mainly developing countries – have been trying to reaffirm their policy space to adopt measures to address public health concerns in accordance with their commitments made in the multilateral trading system.

After extensive negotiations,[69] this precept was reflected at the launch of the Doha Round of trade negotiations (2001), when its Ministerial declaration reiterated that the TRIPS Agreement is to be interpreted and implemented in a manner supportive of public health (WTO, 2001).[70] The Member States adopted a separated declaration entitled "The Doha Declaration on the TRIPS Agreement and Public Health"[71] that reaffirms their right to fully use the provisions in the TRIPS Agreement in order to protect public health, including by applying the flexibilities foreseen in the Agreement (VAN DEN BOSSCHE; ZDOUC, 2013, p. 956). Through this declaration, WTO members agreed to integrate "health concerns into TRIPS functions by means of implementation and interpretation of its individual norms" (RUSE-KHAN, 2016, p. 423).

Significant progress was enshrined in the Declaration's Paragraph 6, which recognized the problems faced by countries with insufficient or no manufacturing capacities in the pharmaceutical sector to make full use of compulsory licensing under the TRIPS Agreement. This paragraph also demanded the TRIPS Council to find an expeditious solution to this problem (MUSUNGU, 2008, p. 447).

On 30 August 2003, the WTO General Council approved the decision on "Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health"[72] (TAUBMAN; WAGER; WATAL, 2012, p. 232). This decision grants waivers

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[68] In accordance with Bartelt (2003, p. 285), 49 countries that were Members of the Paris Convention for the Protection of Industrial Property did not provide patent protection for pharmaceuticals products prior to the Uruguay Round.

[69] The background of this negotiation involves countries facing severe HIV/AIDS epidemic, high prices for drugs and overloaded health budgets. South Africa and Brazil, for example, adopted national legislation "that allowed the limitation of patent rights in order to facilitate affordable access to medication" (RUSE-KHAN, 2016, p. 421). Notwithstanding the legality of this measure under the TRIPS, they suffered fierce pressure from developed countries and pharmaceutical companies (RUSE-KHAN, 2016, p. 421). In this context, the African Group and other developing countries proposed a draft text on TRIPS and Public Health for the 2001 Doha Ministerial Declaration. The United States and other countries promptly opposed the proposal. However, due to the 9/11 terrorist attacks in the United States and the subsequently threat of an anthrax virus epidemic, the United States changed its position (RUSE-KHAN, 2016, p. 421-422).

[70] Article 17 of the 2001 Doha Ministerial Declaration.

[71] See Document WTO/MIN(01)/DEC/2.

[72] See Decision of the General Council of 30 August 2003 (WT/L/540 and Corr.1).

concerning the obligations outlined in TRIPS Article 31 (f),[73] "permitting a production for export under a compulsory license, and in [Article 31 (h), [74]], waiving the payment requirement in the eligible importing Member to prevent duplication of royalty fee payments" (KUANPOTH, 2007, p. 31). The decision on the Paragraph 6 implementation also included "procedural safeguards to prevent diversion of cheap medicines to rich countries markets" (SELL, 2007, p. 48-49). The waivers "would terminate on the date on which an amendment to TRIPS replacing them took effect" (MEY, 2010, p. 413).

On 6 December 2005, the WTO General Council accepted the protocol amending the TRIPS Agreement.[75] The amendment entered into force on 23 January 2017, after it was accepted by two thirds of the WTO membership. The incorporation of the Article 31*bis* (Paragraph 6 System) replaces by identical provisions the waiver decision (TAUBMAN; WAGER; WATAL, 2012, p. 232). It provides legal certainty that countries with limited or no pharmaceutical production capacity are allowed import generic versions of patent-protected medicines under compulsory license. For WTO Members that have not accepted the amendment yet, the waivers introduced by the 2003 Decision still apply.[76] The TRIPS Article 31*bis* was the first amendment to a WTO Multilateral Agreement.

At last, the Doha Declaration also takes an important step regarding transition periods for least-developed countries (LDCs). Its Paragraph 7 recognizes the LDC's legitimate right to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement.[77] In this spirit, the TRIPS Council agreed to extend the

[73] TRIPS Article 31 (f) reads as: "such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."
[74] TRIPS Article 31 (h) provides that: "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."
[75] See General's Council Decision of 6 December 2005 (WT/L/641).
[76] As observed by Ruse-Khan (2016, p. 425), it still hard to see how the Paragraph 6 System can become economically feasible for generic companies and practically relevant for patients, due to its "administratively complex and cumbersome procedures on top of an already long list of conditions for the grant of a [compulsory license] under Article 31."
[77] TRIPS Article 66.1 reads as: "In the view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3 [National Treatment], 4 [Most-Favored-Nation] and 5 [Multilateral Agreements on Acquisition or Maintenance of Protection], for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country member, accord extensions of this period."

LDC's transition period until 1 July 2021;[78] and until 1 January 2033 for certain obligations related to pharmaceutical products (WTO, 2017d).[79]

On the whole, the TRIPS Agreement's provisions leave significant room to maneuver (flexibilities)[80] for countries to tailor their intellectual property policies to suit public health goals (SELL; 2007, p. 58; KUANPOTH, 2007, p. 31). The WIPO Secretariat,[81] in collaboration with the Member States, identified four clusters of flexibilities: (i) the method of implementing TRIPS obligations; (ii) substantive standards of protection; (iii) mechanism of enforcement; and (iv) areas not covered by the TRIPS Agreement.[82] On public health, the feasible options include:

(i) Transition periods;
(ii) The adoption of the principle of international exhaustion of rights so as to facilitate parallel imports for cheaper drugs (Article 6);
(iii) Flexible interpretation of each o provision of TRIPS in light of the objectives and principles stipulated under Articles 7 and 8;
(iv) Exclusion of certain biotechnological inventions, as well as medical methods for the treatment of human and animals (Article 27);
(v) Exceptions to patent rights (Article 30);
(vi) Compulsory license (Art. 31);
(vii) Public non-commercial use of patents (Government Use); and
(viii) Implementation of Paragraph 6 System (KUANPOTH, 2007, p. 31; MUSUNGU; OH, 2006; RODRIGUES, 2014).[83]

Notwithstanding the recent progress made to reaffirm the compatibility between TRIPS rules and the States' right to protect public health, maneuvers are being carried out "to undermine these flexibilities that were so strongly recognized and endorsed [by the

[78] Decision of the Council for TRIPS of 11 June 2013 on the Extension of the Transition Period under Article 66.1 for Least Developed Country Members.
[79] Decision of the Council for TRIPS of 6 November 2015 on the 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.
[80] Notwithstanding the repeated references to "flexibilities" in the policy debate, "neither the TRIPS Agreement nor any later instrument have formally defined the exact meaning of this term." The word "flexibilities" only became part of the wider IP vocabulary after the Doha Declaration (WHO; WIPO; WTO, 2012, p. 71).
[81] The WIPO provides legal and technical assistance regarding the TRIPS Agreement based on the signed between WIPO and WTO on 22 December 1995 (WHO; WIPO; WTO, 2012, p. 71).
[82] See the WIPO database updated by Member States on flexibilities in the intellectual property system at: <http://www.wipo.int/ip-development/en/agenda/flexibilities/search.jsp>.
[83] For a broader analysis of the TRIPS Agreement's flexibilities, see MAX PLANCK INSTITUTE. **Declaration on Patent Protection**: Regulatory Sovereignty under TRIPS. Munich: Max Planck Institute for Innovation and Competition, 2014. Available at: <https://www.mpg.de/8133454/Patent-Declaration1.pdf>. Accessed on: 2 Jun. 2017.

Doha Declaration]" (ABBOTT, 2004, p. 2). This is happening, to the greatest extent, through the negotiation of PTAs "that include as one of their major elements provisions contradictory to the letter and spirit of the Doha Declaration" (ABBOTT, 2004, p. 2).

There is an increasing number of PTAs with IP provisions relevant to public health and pharmaceuticals. These provisions are referred by Váldes and Tavengwa (2012, p. 27) as pharma-related provisions, which include: (i) patentability criteria and exclusions; (ii) patentability of new uses; (iii) patenting of life forms; (iv) patent linkage; (v) exceptions to exclusive rights; (vi) data exclusivity; (vii) minimum period of data exclusivity; (viii) term extensions of patent protection; (iv) compulsory licensing; (x) exhaustion; (xi) safeguarding a trademark's function [84] (VÁLDES; TAVENGWA, 2012, p. 29). In analyzing 194 PTAs notified to the WTO by November 2010, Váldes and Tavengwa (2012, p. 32) identified that the United States PTA's have the most significant pharma-related provisions in terms of coverage and depth, followed by EFTA, EU and Mexico.[85]

In September 2016, the United Nations Secretary-General released the report of the High-Level Panel on Access to Health Technologies.[86] Created by Ban Ki-Moon in November 2015, the High-Level Panel's mandate aimed to "review and asses proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies" (UN, 2016, p. 7). Among its conclusions, the High-Level Panel's report states that:

> The proliferation of free trade agreements containing expansive patent and test data protection on health technologies, which exceed the minimum standards for intellectual property protection required by the TRIPS Agreement (so-called 'TRIPS-Plus' provisions), may impede access to health technologies (UN, 2016, p. 7).

[84] This type of provision demands that measures requiring the use of common names, "including requirements on size, placement or style of use of the trademark, do not impair the use or effectiveness of trademarks" (VÁLDES; TAVENGWA, 2012, p. 29).

[85] The high number of pharma-related provisions in the Mexico's PTAs is explained by the country's membership in the North American Free Trade Agreement (NAFTA). Under this framework, Mexico has already adopted a large number of pharma-related provisions that are, subsequently, passed on through its PTAs with non-NAFTA partners in Central America (VÁLDES; TAVENGWA, 2012, p. 29).

[86] The High-Level Panel brought together a diverse group of specialists from various backgrounds, experiences and continents (UN, 2016, p. 3). The Panel was co-chaired by Ruth Dreifuss, first female President of the Swiss Confederation in 1999, and Festus Gontebanye Mogae, President of the Republic of Botswana from 1998 to 2008.

Furthermore, the High-Level Panel's report recommends that WTO Members should commit themselves "to respect the letter and spirit of the Doha Declaration on TRIPS and Public Health, refraining from any action that will limit their implementation and use in order to promote access to health technologies" (UN, 2016, p. 9). More precisely, the report recommends that WTO Members should:

> (i) Make full use of the TRIPS flexibilities to promote access to health technologies when necessary;
> (ii) Adopt and apply rigorous definitions of invention and patentability, making full use of the policy space available in TRIPS's Article 27;
> (iii) Adopt and implement legislation that facilitates the issuance of compulsory licenses;
> (iv) Revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license;
> (v) Ensure that bilateral and regional trade and investment treaties do not include provisions that interfere with their obligations to fulfill the right to health (UN, 2016, p. 9).[87]

These conclusions and recommendations made by the High Level Panel[88] provides countries guidance on important aspects that they should take in consideration when entering into preferential trade arrangements. As highlighted, unbalanced IP provisions might have harmful effects on national public health policies relevant to access to medicines and medical technologies.

Particularly, rules that result on longer than normal periods of market exclusivity – such as data exclusivity, patenting of new uses and patent term extension – may delay the

[87] In addition to the recommendations directed to WTO Members, the High Level's report also made recommendations to multilateral organizations. It recommended that the WTO, WHO, WIPO, UNCTAD and the United Nations Development Programme (UNDP) should "cooperate with one another and with other relevant bodies […] to support governments to apply public health-sensitive patentability criteria" (UN, 2016, p. 9). They should also "strengthen the capacity of patent examiners at both national and regional levels to apply rigorous public health-sensitive standards of patentability taking into account public health needs" (UN, 2016, p. 9).

[88] Since its release, the High-Level Panel's report is being raised by developing countries in several international forums. The report has already been raised in the TRIPS Council (October, 2016); WIPO Standing Committee on the Law of Patents (SCP) (December, 2016); WHO (January, 2017) and the United Nations Human Rights Council (March, 2017).

entry of generic drugs [89] into the market (VÁLDES; TAVENGWA, 2012, p. 32). Pharmaceutical companies are the main supporters of incorporating these provisions into PTAs. As emphasized by Searle and Brassell (2016, p. 67), these companies have incentives to seek to restrict market for generics or prolong patent protection, since generics drastically reduce price of out-of-patent medicines, resulting in the decline of their sales. According to Coriat and Orsenigo (2014, p. 224), stronger IPRs "make life more difficult for local brands and generic producers, especially if data-exclusivity agreements and patentability are enforced."

Another problematic feature relates to the adoption of provisions that require highly flexible patentability standards (novelty, inventive step and industrial applicability). As explained by Seuba (2017, p. 6), flexible standards of patentability contribute to a large number of patented products. This consecutively leads to a lower level of competition, increase prices, reduce access to patented medicinal products and ultimately affect universal health coverage. By reversing this logic, one could say that countries should adopt more stringent patentability requirements to lower the number of patented products. This would lead to a higher level of competition, reduce prices and increase access to medicines.

Among other provisions that interfere with the population's right to health, Seuba (2017, p. 13) highlights those requiring countries: (i) to provide patents for new uses of known products (second-use patents); (ii) to grant patent protection for plants and animals; (iii) to limit the issue of compulsory license to national emergencies, antitrust remedies and for public non-commercial use; (iv) to link generic marketing approval to the expiration of the patent term (patent-linkage); and (v) to limit parallel import through licensing contracts.

It is also useful to note that the adoption of stronger intellectual property rights by developing countries will not necessarily be translated into incentives for research and development of drugs for local diseases, such as malaria, dengue or zika. According to Coriat and Orsenigo (2014, P. 224), the "decisions concerning the direction of innovative activities are still influenced by considerations of profitability, both by local and foreign innovators."

[89] Generic drugs include "medicines with expired patents, those that never received patent protection, and those that have been licensed for generic manufacturing by the patent owner" (SEARLE; BRASSELL, 2016, p. 67).

In brief, excessively high pharma-related standards in PTAs "have strong negative effects on prices and access to health, especially in developing countries" (CORIAT; ORSENIGO, 2014, p. 235).[90] In exchange for gains in other economic field, developing countries are giving up the long fought TRIPS flexibilities for the pharmaceutical sector. The problem of this approach is that net economic gains of textile or agricultural producers are not converted into higher public or private health expenditures (ABBOTT, 2005, p. 353). A possible way for developing countries to counterbalance this trend is to form coalitions committed to resisting pressures on public health (COTTIER et al, 2015, p. 474; ABOOTT, 2006, p. 33).

2.4.3 Environmental Protection

Intellectual property can play a major role in the efforts to develop new technologies and build innovative capacities to effectively address environmental challenges. These include climate change mitigation and adaptation, preservation of natural habitats and biodiversity, energy efficiency, water management, waste disposal and agricultural productivity (CURTIS, 2016, p. 10). The promotion of a balanced and dynamic intellectual property system can improve "environmental protection by securing a marketplace advantage for environmental innovators" (GOLLIN, 2014, p. 243).

The intellectual property's impact in environmental protection is argued to be twofold. On the one hand, intellectual property rights can encourage the innovative activity of domestic firms (HALL; HELMERS, 2010, p. 492). They "facilitate investment in research and development (R&D), reduce licensing costs, add to the knowledge base, and enhance follow-on inventive activity" (MASKUS; OKEDIJI, 2014, p. 392-393). On the other hand, they can discourage learning via imitation and, consequently, inhibits technological catch-up (HALL; HELMERS, 2010, p. 492). According to Hall and Helmers (2010, p. 492), the dominant effect "depend on the level of technological development

[90] However, it is important to stress that pharmaceutical patents are just one element among many that influences the prices of medicines. El-Said (2016, p. 442) reminds that public procurement, taxes, production ability and public health insurances also contributes to the overall prices of medicines.

already attained in the host country as technology transfer requires absorptive capacity in the recipient country."

The intellectual property system, as any other system, is not good or bad *per se*. Its success and failures depends on how the different stakeholders make use of it. This also applies to how and to what extent the system could enhance environmental protection. As observed by Reichman et al (2014, p. 360), given the early stage of research and the relatively nascent stage of much of the environmental technology, there is little compelling empirical evidence to support either of the above-mentioned points of views (REICHMAN et al, 2014, p. 360). This is why is important to identify its advantages and disadvantages in order to seek a more environmental friendly intellectual property system.

Patents, for example, can provide many incentives to the development of pollution control equipment and others environmental technologies[91] (GOLLIN, 2014, p. 243). Several national intellectual property offices[92] worldwide have already put in place measures to fast track green patent applications.[93] This procedure allows patent covering green technologies to be examined in a priority manner. A faster examination process has many advantages, such as, sooner licensing of technologies; reduced time to the product enter the market; and facilitation of fund-raising for start-ups companies (DECHEZLEPRÊTRE, 2013, p. 1).

Moreover, the information that it is disclosed in the patent applications provides the most up-to-date information available on new environmental technology. According to Alikhan and Mashelkar (2009, p. 60), "there is no superior source of information, since 95% of all the relevant technical information is found in these detailed documents." Hence, different stakeholders involved in the innovation process could use the information

[91] According to Gollin (2014, p. 242), environmental technologies include: (i) industrial processes which minimize resource consumption and waste production, (ii) consumer products which are environmentally benign throughout their life cycles, (iii) recycling equipment and processes, (iv) waste management technologies for solid and hazardous waste, (v) pollution control devices, and (vi) products and methods cleaning up pollution.

[92] Green patent fast-track schemes have already been implemented in the national intellectual property offices of: Australia, Brazil, Canada, China, Israel, Japan, Korea, United Kingdom (UK) and United States (DECHEZLEPRÊTRE, 2013, p. 1).

[93] On green patents, see: TRAN, Sarah. Expediting Innovation, **Harvard Environmental Law Review**, v. 16, n. 2, p. 123 – 168, Apr. 2012; KARACHALIOS, Konstatinos et al. **Patents and Clean Energy**: Bridging the Gap Between Evidence and Policy. Munich: EPO, UNEP and ICTSD, 2010; KARACHALIOS, Konstatinos. Development strategies of emerging economies in the era of climate change: Do patent statistics tell us anything? In: ABBOTT, Frederick; CORREA, Carlos; DRAHOS, Peter (Ed.). **Emerging Markets and the World Patent Order**. Cheltenham: Edward Elgar, 2013; and RIMMER, Matthew. **Intellectual Property and Climate Change**: Inventing Clean Technology. Cheltenham: Edward Elgar, 2011.

available through the patents applications to get the necessary technical details regarding a variety of inventions to further develop them (ALIKHAN; MASHELKAR, 2009, p. 60).

As observed by Gollin (2014, p. 258), the "information from the patent literature should remain readily available to innovators and those seeking licenses for compliance purposes." In this effort, countries should also adopt national regulations on patent licensing that balances "the interests of patentees and those required to use patented environmental technologies" (GOLLIN, 2014, p. 258). This could enhance research and access to environmental friendly technologies (ALIKHAN; MASHELKAR, 2009, p. 60). The continuous innovation and diffusion of improved environmental technologies is one way to achieve sustainable development[94] (DERZKO, 2014, p. 282).

In the current debates, there are two major issues regarding the interplay between intellectual property rights and environmental protection, namely: (i) natural and biological resources; (ii) and technology transfer. The first one regards the use of genetic resources of plants, animals and microorganisms as key inputs for innovative activities. Such elements are currently an essential part of the research and development in the pharmaceutical, cosmetic, agricultural and food industries. Frequently, they lead to the granting of intellectual property rights over the resulting technology (RUSE-KHAN, 2016, p. 321). The interface between intellectual property protection and the use of genetic resources has become pronounced as biotechnological innovations have progressed (KAMERI-MBOTE; OTIENO-ODEK, 2009, p. 211).

In this regard, the Convention on Biologic Diversity (CDB) constitutes the main international instrument regulating the rights over genetic resources[95] and the technologies derived from them (AMARAL JÚNIOR, 2011, p. 243). Adopted at the 1992 United Nations Conference on Environment and Development held in Rio de Janeiro, the CBD's primary objective is to conserve biological diversity.[96] Even though it recognizes this

[94] The concept of sustainable development was formally adopted in the framework of the 1992 Rio Declaration on Environment and Development. Previously, this concept was first proposed by the 1987 United Nations Report entitled Our Common Future, also known as the Brundtland Report. It defines sustainable development as development that meets the needs of the present without compromising the ability of future generations to meet their own needs (BRUNDTLAND, 1987).
[95] The CBD's Article 2, § 10 defines genetic resources as "genetic material of actual or potential value."
[96] The CBD's Article 2, § 1 defines biological diversity as "the variability among living organism from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part: this includes diversity within species, between species and of ecosystems."

conservation as a common concern of human kind,[97] the CBD establishes "the principle that states enjoy sovereign rights over biologic resources in their territories"[98] (RUSE-KHAN, 2016, p. 322). This implies that "each country has the right to control access to its genetic resources, and to determine the conditions under which this will be allowed" (GRUBB; THOMSEN, 2010, p. 52).

In this sense, the CBD "makes access to genetic resources subject to 'prior informed consent'[99], based on 'mutually agreed terms'[100] and requiring the subsequent sharing of 'benefits arising from the commercial or other utilization of genetic resources'[101]" (RUSE-KHAN, 2016, P. 322). It also addresses the need to States "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity" (Article 8(j) of the CBD). At the 10th Conference of the Parties (COP 10) in 2010, the contracting countries adopted the Nagoya Protocol. This supplementary agreement regulates the access to genetic resources and the fair and equitable sharing of benefits arising from their utilization (AMARAL JÚNIOR, 2011, p. 260).

Presently, the central problem that pervades this subject regards the lack of binding obligations and enforceable mechanisms in the international level that ensure the prior and informed consent and the sharing of the benefits arising from commercialization of IP intensive products and process based on genetic resources and traditional knowledge associated with it. Even though countries might adopt domestic measures to prevent this practice, there is no multilateral legal instrument that enables, for example, a country or an indigenous/local community to challenge a patent granted in another country that is based

[97] The CBD's preamble in its paragraph 3 affirms that: "the conservation of biological diversity is a common concern of humankind."
[98] According to CBD's Article 3: "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies […]." The CDB's preamble in its paragraph 4 also reaffirms that "States have sovereign rights over their own biological resources."
[99] According to CBD's Article 15, § 5, "access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by the Party."
[100] According to CBD's Article 15, § 4, "access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article."
[101] According to CBD's Article 15, § 7, "each Contracting Party shall take legislative, administrative or policy measures, as appropriate, […] with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."

on their genetic resource or associated traditional knowledge associated (MONT'ALVERNE, 2010, 6374).

The complexity of this issue is enhanced due to the fact that significant part of world genetic biodiversity is located within the jurisdiction of developing countries, while the great majority of R&D – pharmaceutical, biotechnological and agricultural – companies with technical capabilities to exploit them are headquartered in developed countries. Besides, only "recently have countries, mostly developing ones, started to implement domestic rules that provide access and benefit sharing. In contrast, many developed countries […] have not put in place corresponding regulations in order to ensure benefit sharing" (VIVA-EUGUI; OLIVA, 2010, p. vi).

Recurrently, developing countries complain that developed countries do not make the necessary efforts to avoid misappropriation – also known as biopiracy – of their genetic resources by these R&D companies headquartered in developed countries (AMARAL JÚNIOR, 2011, p. 250). They have long raised concerns "about the lack of response from the intellectual property system to stop [those] acts […] as well as to provide adequate intellectual property protection to traditional knowledge holders" (VIVA-EUGUI; OLIVA, 2010, p. 2).[102]

The possibility of patenting plants and animal adds another layer of complexity to this issue. As noted by Amaral Júnior (2011, p. 269), for a long time, patents were grated to protect only industrial products and processes. The advances in the field of microbiology and genetic engineering, however, favored the initiatives to patenting living organisms (AMARAL JÚNIOR, 2011, p. 269).

The TRIPS Agreement Article 27.2 (b) provides WTO Members enough room of maneuver in this regard, allowing them to exclude plants and animals from patentability in their national legislation. Specifically on plant varieties, Member can choose to protect

[102] Viva-Eugui and Oliva (2010, p. 2) cites as examples of misappropriation of genetic resources and traditional knowledge the "plant patent on the *ayahuasca* vine, sacred to the indigenous people of the Amazon; and the *enola bean*, a variety of Mexican yellow bean."

them either by patents, by an effective *sui generis* system or by any combination thereof (AMARAL JÚNIOR, 2011, p. 266).[103]

The controversy that pervades this possibility, asserts Amaral Júnior (2011, p. 266), regards cases, for example, in which a plant variety known for its therapeutic properties is patented in a country that is not the country of origin of this genetic resource. This problematic has already been raised by Brazil in the TRIPS Council, who asserted that:

> Broad Patents over microorganisms, plants and animals may result in monopoly rights for the exploitation of the patent's subject matter, thus restricting exploitation of such resources. Additionally, patents over a Member's genetic resource, but granted outside its territory raises the issue of potential conflict with the principle of the sovereignty of the Contracting Parties of the CBD over their own genetic resources (WTO, 2000, p. 5).[104]

In the opposite direction, some countries are requiring in the context of PTAs' negotiations that their counter parties renounce the TRIPS flexibilities and adopt national legislation providing for the patentability of plants and animals.[105] The risk posed by this regulatory trend lies in reproducing or even accelerating the problems already existing in the international level. Particularly, even though these rules might allow or even promote the IP protection of biodiversity and traditional knowledge and other intellectual property rights, they do it without ensuring compliance with obligations established by the CBD (VIVA-EUGUI; OLIVA, 2010, p. 1).

These provisions demand the patentability of all categories of life-forms, including plants, animals, biological processes, genes and gene sequences, without liking patentability criteria to ethical, social, economic and environmental considerations (KUANPOTH, 2007, p. 40). The patenting of biological materials, according to Kuanpoth (2007, p. 40), still has various shortcoming and flaws. This subject remains highly controversial and object to diverse legislative approaches in different jurisdictions.

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[103] In this regard, Prifti (2016, p. 309) highlights that "whereas countries such as Australia, Korea, Japan, and US grant patent on plant varieties, the European Union and other countries have chosen to exempt plant varieties from patentability." It is important to notice that, contrary to the US law, Australia, Korea and Japan allows the protection of protection of plant varieties both under the patent system as plant breeder's rights (PRIFTI, 2016, p. 309).

[104] See WTO Document IP/C/W/228 of 24 November 2000.

[105] For example, see the United States' PTAs signed with Chile (2003); Dominican Republic-Central America (2004); Morocco (2004); Peru (2006), Bahrain (2006), Colombia (2006) and Panama (2007).

It is argued that plant patenting may raise the production costs of agriculture; lead to market domination by a few commercial varieties, and result in monopolies of grain traders that may create less sustainable food supply (LIDSTROM, 2010, p. 959 – 960). Even though national legislations might provide certain patent research exemptions, "it is not clear whether such exemption extends to acts done for breeding purposes" (PRIFTI, 2016, p. 301). If they do not apply, breeders would be obliged "to ask for a license every time they need to use patented variety or related material in their breeding lines" (PRIFTI, 2016, p. 301). These are only few problematic features concerning the increase of intellectual property protection related to natural and biological resources in the framework of PTAs.

The second major issue involving the interplay between IP and environmental protection regards technology transfer. As observed by Taubman, Wager, Watal (2012, p. 219) the impact of IP, and especially the patent system, in the development, diffusion and transfer of technology relevant to climate change mitigation and adaptation[106] is in the center of the current policy discussions. The effective use of the patent system in the environmental technology context constitutes a very powerful policy tool to face the current challenges (DERZKO, 2014, p. 287).

Countries, however, have different perspectives on "how patent systems should be used in international transfers of environmental technologies" (GOLLIN, 2014, p. 261). As explained by Gollin (2014, p. 261), while developed countries favor strong protection in order to foster economic and technical progress, developing countries defend that the level of protection should correspond to the overall development and economic policies of the recipient countries.

In the multilateral trading system, the discussions regarding climate change have considered "the TRIPS provisions on the scope of patentable subject matter, flexibilities such as compulsory license, and mechanisms for technology transfer" (TAUBMAN; WAGER; WATAL, 2012, p. 219). Developing countries have, in several occasions, "raised concerns about potential barriers that intellectual property policies may pose for access to clean energy technologies" (MELÉNDEZ-ORTIZ, 2007, p. vii). It is important to stress that TRIPS Agreement "does not provide for any special treatment or flexibilities for

[106] As explained by Ruse-Khan (2016, p. 323), environmentally sound technologies (ESTs) cover both "mitigation technologies", which slow climate change by reducing greenhouse gas emissions, as well as "adaptation technologies", which help to cope with the effects of climate change.

access and dissemination of environmental sound technologies as occurs in the field of health" (MELÉNDEZ-ORTIZ, 2007, p. vii).

As explained above, the Doha Declaration on TRIPS and Public Health made significant progress in the field of pharmaceutical patents (HALL; HELMERS, 2010, p. 491). Theoretically, the same could be applied for the green technologies sector through the adoption of a TRIPS and Environmental Protection Declaration. Due to the public good character of environmental protection in the debate on climate change and technology transfer, Hall and Helmers (2010, p. 491) defend that a parallel could be drawn between the pharmaceutical and the green technologies sector. Nevertheless, due the current negotiations' stalemate, there is no political momentum for such a proposal in the WTO in the near future.

It is worth noting that the TRIPS contains a technology transfer rule in Article 66.2. It requires developed countries to provide "incentives to enterprises and institutions in their territories for the purposes of promoting and encouraging technology transfer to least-developed country Members." [107] This provision, however, encompasses only least-developed countries and it is not specifically addressed to green technologies. Besides, evidence shows that Article 66.2 has not resulted in "significant additional incentives beyond business-as-usual for transferring technology to LDC Members" (MOON, 2011, p. 12).[108]

Provisions on technology transfer are a common element in several international environmental law instruments (RUSE-KHAN, 2016, p. 323). The 1992 United Nations Framework Convention on Climate Change (UNFCCC) is the most important one aimed at stabilizing "greenhouse gas concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system" (Art. 2). The UNFCCC

[107] The mandatory nature of this provision was reaffirmed by the subparagraph 11.2 of the Ministerial Decision on Implementation-Related issues and Concerns of 20 November 2001 (WT/MIN(01)/17) (CARVALHO, 2005, p. 435).

[108] Moon (2011) analyzed 79 reports submitted from 1999 to 2010 on countries' compliance with Article 66.2 in order to assess whether this provision had resulted in an increase of technology transfer to LDCs. The study considered the following types of incentives as qualifying as technology transfer: (i) financing the purchase of technologies; (ii) incentives for foreign direct investment in technologically-oriented fields; (iii) matching businesses in developed countries with those in LDCs for skills-building purposes; (iv) training (including various scholarships and other educational opportunities in technical fields); (v) support to education systems; (vi) providing venture capital; (vii) providing insurance against the risk of doing business in LDCs for technology-related firms; (viii) building a technical training component into an aid project; and (ix) sending skilled nationals to volunteer in a technical capacity in a LDC (MOON, 2011, p. 4). The analysis found little evidence that TRIPS Article 66.2 increased the technology transfer to LDCs.

requires developed countries "to promote and help finance ITT [International Technology Transfer] and access to ESTs [Environmentally Sound Technologies] and know-how to enable [developing countries] to implement provisions of the Convention" (MASKUS; OKEDIJI, 2014, p. 392). Even though its Articles 4.3 [109] and 4.5 [110] embody these commitments, there are few significant concrete actions on the subject so far (ABBOTT, 2014, p. 168).[111]

More recently, countries adopted the 2015 Paris Climate Agreement under the UNFCCC. They committed to hold "the increase in the global average temperature to well below 2°C above pre-industrial levels and pursuing efforts to limit the temperature increase to 1.5°C above pre-industrial levels" (Art. 2.1). They recognized the importance of technology for the implementation of mitigation and adaptation actions, and committed to strengthen cooperative action on technology development and transfer (Article 10.2) (SEGGER, 2016, p. 216).[112]

In this context, a major challenge faced by countries that adopt more stringent IP rules in PTAs is to reconcile those higher standards of protection with the compliance of international and national sustainable development commitments (KAMERI-MBOTE; OTIENO-ODEK, 2009, p. 211). There is also a concern that these provisions might

[109] Article 4.3 of UNFCCC reads as: "The developed country Parties […] shall provide new and additional financial resources to meet agreed full costs incurred by developing country Parties in complying with their obligations […]. They shall also provide such financial resources, including for the transfer of technology, needed by developing country Parties to meet the agreed full incremental costs of implementing measures […]. The implementation of these commitments shall take into account the need for adequacy and predictability in the flow of funds and the importance of appropriate burden sharing among the developed country Parties."

[110] Article 4.5 of UNFCCC reads as: "The developed country Parties […] shall take all practicable steps to promote, facilitate and finance, as appropriate, the transfer of, or access to, environmentally sound technologies and know-how to other Parties, particularly developing country Parties, to enable them to implement the provisions of the Convention. In this process, the developed country Parties shall support the development and enhancement of endogenous capacities and technologies of developing country Parties. Other Parties and organizations in a position to do so may also assist in facilitating the transfer of such technologies"

[111] The Technology Mechanism (TM) aims to "enhance action on technology development and transfer in support action on mitigation and adaptation" (UNFCC, 2010, § 113). It was established at the sixteenth session of the Conference of the Parties (COP16) in Cancun (Mexico) in 2010. The TM consists of two bodies: Technology Executive Committee (TEC) and the Climate Technology Centre and Network (CTCN). While the TEC is TM's policy arm, CTCN is its implementing arm. The main TEC's activities involve a number of thematic dialogues and workshops, the production of policy briefs and signaling priority areas to the COPs (DE CONICK; SAGAR, 2015, p. 3). By its turn, the CTCN instructs national designated entities (NDEs) on submissions of requests for special technical assistance program and responding to those requests. Furthermore, the UNFCCC has supervised the development of countries' technology needs assessments (TNAs).

[112] The Technology Mechanism (TM) established under the UNFCCC also serves the Paris Agreement (Art. 10.3). The Parties established a framework to guide the operation of the TM (Art. 10.4) (SEGGER, 2016, p. 216).

deprive "developing country partners [from] the margins of flexibility allowed under the TRIPS Agreement to pursue development-friendly industrial policies" (ABBOTT, 2014, p. 169).[113]

Moreover, the adoption of higher standards of IP protection in PTAs might have effects on the costs of the patented climate change technologies, on how they are licensed and on what technological substitutes are affordably available (SARNOFF, 2011, p. 303). Although a more harmonized patent rights could induce greater inward flows of environmentally sound technologies, Maskus and Okediji (2014, p. 398) argue that: "there is a corresponding risk that licensing costs would raise the expense of mitigating [greenhouse gases]."

The overprotection of patent rights through PTAs could limit access to new environmentally sound technologies and reduce mitigation and adaptation investments in developing countries (MASKUS; OKEDIJI, 2014, p. 392-393). Even though certain PTAs[114] include soft commitments on technology transfer, they have not produced meaningful results yet (ABBOTT, 2014, p. 168). These provisions on technology transfer suffer from a lack of concrete commitments (ABBOTT, 2014, p. 169).

In the light thereof, it can be affirmed that unreasonably stringent patent provisions in PTAs might affect the countries' policy space to implement measures regarding climate change, biodiversity protection and even food security. Countries should take into consideration these implications when negotiating IP provisions in their PTAs. Through a balanced approach, States could enhance the beneficial features of patents in favor of environmental protection.

2.5 Preliminary Conclusion

The international intellectual property system is in constant expansion. It currently encompasses a wide variety of overlapping treaties and parallel institutions. The most

[113] In order to prevent such a problem, Abbott (2014, p. 169) defends that the inclusion of sustainable development as a PTA's general objective may assist countries that have implemented IP flexibilities where a conflict over textual interpretation arises.
[114] For example, see article 142 of the 2009 CARIFORUM – EU Economic Partnership Agreement (EPA).

significant rules are being set under the PTAs' framework. The recent acceleration in their adoption reflects the historical pendulous movement from multilateralism back to preferentialism. The international intellectual property rule setting is formed by a dialectical cycle of alternation in which preferentialism establish higher standards of protection and multilateralism harmonize the regulation by consolidating minimum standards (COTTIER et al, 2015, p. 474).

In this context, Brazil is isolated from this international regulatory trend. The country cannot influence the development of these new rules, since it refuses to negotiate intellectual property provisions in its PTAs. Even though it does have offensive interests in intellectual property that could be put forward, Brazil rejects to enter into this exercise that is currently shaping the international IP system. A possible way for Brazil to counterbalance regulatory trends that are being set against its interests and resist the pressure from developed countries in the multilateral forums is to build its own coalition through its PTAs network.

However, this must be cautiously undertaken, since the adoption of intellectual property obligations in the PTA's framework has important legal implications not only regarding the WTO system but also to the national implementation of these obligations. As demonstrated, any type of more extensive protection needs to be in harmony with the TRIPS Agreement. As a rule, TRIPS-Plus concessions agreed in PTAs shall be extended to all WTO Members, not only to those participating in a given PTA. The TRIPS national treatment and the MFN do not include the exception for PTAs (regional integration), such as the GATT and the GATS. However, TRIPS-Extra obligations do not need to be extended to other WTO Members. In these cases, narrow reciprocity based on national treatment is allowed under a PTA.

The simple strengthening of intellectual property rights does not have a direct positive impact on domestic innovation. Such an effect requires "sufficient scientific and technological capabilities, access to knowledge and participation in research networks, and large domestic markets and/or the ability to export" (CORIAT, ORSENIGO, 2014, p. 224). The adoption and implementation of unbalanced intellectual property obligations in PTAs has technological, economic, social and environmental implications (KAMERI-MBOTE; OTIENO-ODEK, p. 211). These problematic features should not be overlooked.

The PTA's pharma-related provisions with expansive patent and test data protection may impede access to health technologies. Rules that establish longer than normal periods of market exclusivity delay the entry of generics into the market, postponing competition and keeping the price of medicines high. Some of these provisions are specifically drafted to undermine the long fought flexibilities of the Doha Declaration on TRIPS and Public Health.

More stringent IP rules in PTAs may also hinder countries' ability to comply with international and national sustainable development commitments. The patent system plays a key role in the development, diffusion and transfer of technology in the efforts pro climate change mitigation and adaptation. Higher IP standards might result in higher costs of patented climate change technologies, hinder licensing and affect the affordability of substitute technologies. Provisions that require the patentability of plants and animals reproduce the problems already existing international level regarding compliance with the obligations on access and benefit sharing.

Due to all the above-mentioned reasons, it is important to analyze the patents provisions that are being adopted in PTAs' framework and compare them with the Brazilian legal regime. This will enable the country to adopt a pragmatic approach regarding the new rules on patent protection that are being set in the international level. In this way, Brazil could assess how it could influence the direction in which the international patent regulation is heading.

3 THE PATENT AND TEST DATA PROTECTION OBLIGATIONS IN PTAs

3.1 Introductory Remarks

The leading industrialized countries always considered the TRIPS standards to be a floor, upon which further intellectual property protection could be built on (SCHAFFER; SELL, 2014, p. 109). At the end of the TRIPS negotiations, a leading US advocate triumphantly exclaimed, "we got 95% of what we wanted" (SELL, 2011, p. 448). However, the TRIPS did not meet all the subsequent expectations of those countries and industries that were seeking more protection (DREXL, 2016, p. 61). As observed by Sell (2011, p. 448), "that 5% has always mattered, and 95% was never enough."

According to Drexl (2016, p. 61), after the 2001 Doha Development Agenda and the failure of the 2003 Ministerial Conference in Cancún, developed "countries turned away from TRIPS and started to pursue their 'TRIPS-Plus' agenda by negotiating even higher standards of IP protection as part of bilateral trade agreements." The international regulation of intellectual property rights has been dramatically expanded through the adoption of these agreements.

In this perspective, this second chapter aims to analyze the provisions on patent and test data protection accorded under PTAs, adopted from 1st January 1995 to 1st January 2017. It proceeds in three parts. First, it undertakes a literature review of studies that investigated the regulation of intellectual property provisions in PTAs. Second, it draws some methodological considerations regarding the object of analysis in the present research. At last, it assesses the selected patent and test data protection provisions in the light of the TRIPS Agreement and the Brazilian intellectual property regime.

3.2 Literature Review on IP Provisions in PTAs

There are quite a significant number of studies that have analyzed the regulation of intellectual property in PTAs. The great majority of them have: (i) investigated one particular PTA; [115] (ii) compared IP provisions across multiple PTAs and TRIPS Agreement, selecting one country or region;[116] or (iii) focused on a particular intellectual property issue, such as public health.[117] Most of them focus on the network of PTAs build up by the United States and the European Union (ELSIG; SURBECK, 2016, p. 3-4). There are, nevertheless, few studies that conduct an extensive and deep research on the regulatory trend of one single IP category.

For the purposes of the present work, it is worth recalling briefly how these studies developed their systematic research and which were their major conclusions. In this way, this work can build on the previous literature and advance knowledge in this subject.

Arbix (2009) analyzed and compared a total of 73 PTAs with TRIPS-Plus provisions adopted, since 1995, by the United States, European Union, EFTA, Switzerland, Japan, Mexico, Australia, Singapore, Chile, Canada and New Zealand.[118] This research provided a comprehensive overview of the main TRIPS-Plus provisions regarding patents,

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[115] MASKUS, Keith. Implications of Regional and Multilateral Agreements for Intellectual Property. **The World Economy**, v. 20, n. 5, p. 681-694, Aug. 1997. KANG, Peter; STONE, Clark. IP, Trade and U.S – Singapore Relations: Significant Intellectual Property Provisions of the 2003 U.S – Singapore Free Trade Agreement. **The Journal of World Intellectual Property**, v. 6, n. 5, p. 721-731, Sep. 2003. PRICE, David. The U.S – Bahrain Free Trade Agreement and Intellectual Property Protection. **The Journal of World Intellectual Property**, v. 7, n. 6, p. 829-850, Nov. 2004. ROFFE, Pedro. **Bilateral Agreements and a TRIPS-Plus World: the Chile-USA Free Trade Agreement**. Ottawa: Quaker International, 2004. SCHÄLI, Mathias. Freihandelsabkommen Schweiz – China: Zeitenwende beim Schutz des geistigen Eigenturms? In: HERREN, Jürg; MÜNCH, Peter; HOCHREUTENER, Inge (Org.). **IP-Herausforderungen in China**: Hintergrund, Entwicklungen, Lösungsansätze. Bern: Growth Publisher, 2016.

[116] FINK, Carsten; REICHENMILLER, Patrick. Tightening TRIPS: The Intellectual Property of Recent US Free Trade Agreements. **World Bank Trade Note**, n. 20, p. 1-11, Feb. 2005. ABBOTT, Frederick. Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S Federal Law. **UNCTAD – ICTSD Project on IPRS and Sustainable Development**, n. 12, p. 1 – 28, Feb. 2006. FINK, Carsten. Intellectual Property. In: CHAUFFOUR, Jean-Pierre; MAUR, Jean-Christophe (Eds.). **Preferential Trade Agreement Policies for Development**: a handbook. Washington: World Bank, 2011. MERCURIO, Bryan. TRIPS-Plus Provisions in FTAs: Recent Trend. In: BARTELS, Lorand; ORTINO, Federico (Eds.). **Regional Trade Agreements and the WTO System**. Oxford: Oxford University Press, 2006.

[117] CORREA, Carlos. **Protection of Intellectual Property and Public Health within the Framework of the Chile – US Trade Agreement**. Ottawa: Quaker International, 2004. EL-SAID, Mohammed. TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries. **American University International Law Review**, v. 31, n. 3, p. 373-444, Sep. 2016. WORLD HEALTH ORGANIZATION, WORLD INTELLECTUAL PROPERTY ORGANIZATION, WORLD TRADE ORGANIZATION. **Promoting Access to Medical Technologies and Innovation**: Intersections Between Public Health, Intellectual Property and Trade. Geneva: WTO, 2012. XIONG, Ping. Patents in TRIPS-Plus Provisions and the Approaches to Interpretation of Free Trade Agreements and TRIPS: Do They Affect Public Health? **Journal of World Trade**, 46, n.1, p. 155-186, Nov. 2012. MITCHELL, Andrew; VOON, Tania. Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law. **Journal of World Trade**, v. 43, n. 3, p. 571-601, Jun. 2015.

[118] In total, Arbix's (2009) research involves a spectrum of 48 countries.

undisclosed information, copyrights and related rights, trademarks, geographical indications, enforcement measures and accession to international IP treaties. This dissertation concluded that even though the majority of the TRIPS-Plus provisions reflect the interest of developed countries, developing countries have also been able to advance some of their own demands (ARBIX, 2009, 185-186). Besides, the proliferation of IP provisions in PTAs generates disharmony in the international intellectual property rules and poses challenges to multilateral trading system.

Lorand (2010) analyzed TRIPS-Plus provisions in 11 PTAs signed by Asia-Pacific countries and compared them to the terms found in TRIPS. This survey is based in all PTAs in force in the region until 2008. It concluded that Asia-Pacific PTAs exceed TRIPS standards in four major areas: accession to international intellectual property agreements, domestic enforcement of intellectual property terms, the expansion of the protection of pharmaceutical patents and test data, and patentability of life forms (LORAND, 2010, p. 919-920).

The WTO Secretariat has already conducted two studies (VALDÉS, TAVENGWA, 2012; VÁLDES; McCANN, 2014), which have identified the acceleration in the conclusion of PTAs with IP provisions after the WTO's creation and the entry into force of the TRIPS Agreement. The first survey assessed 194 and the second 245 PTAs notified to the WTO.[119] The most recent study demonstrated that approximately 65% of all the PTAs in force until February 2014 contained some kind of IP provision. This share increased to 90% of all PTAs that entered into force between 2010 and 2014. The commitments range widely from general clauses to explicit provisions on specific topics of IP law (VÁLDES; McCANN, 2014, p. 8). The largest systems of PTAs with high level of IP provisions are grouped around the United States, European Union (EU) and the European Free Trade Association (EFTA) (VÁLDES; McCANN, 2014, p. 1).

[119] The primary source of information used for the study was the WTO's database on Regional Trade Agreements (RTAs), which is publicly accessible at: <http://rtais.wto.org/UI/PublicMaintainRTAHome.aspx>. The study itself, however, recognizes that the database is incomplete "since only about two-thirds of the RTAs in force have been notified to the GATT/WTO" (VÁLDES; McCANN, 2014, p. 5)

Seuba (2013) analyzed the intellectual property content of 141 PTAs.[120] The author highlighted that, "for decades, intellectual property was not a relevant issue in trade negotiations, or at least it was not the object of regulation in the context of PTAs" (SEUBA, 2013, p. 240). From the 1950s to the 1980s, PTAs did not include regulation on intellectual property. This dramatically changed in the 1990s "when a new wave of PTAs anticipated, coincided and followed the adoption of the [WTO TRIPS Agreement]" (SEUBA, 2013, p. 240).[121]

The research conducted by Seuba (2013, p. 245) showed that "the majority of intellectual property provisions in PTAs are included out of the demands of developed countries, particularly when the provisions are detailed and highly demanding." The intellectual property content in PTAs is organized in three ways: (i) a general provision in the main text of the treaty remitting the specific regulation to an annex; (ii) one or a reduce number of provisions specifically related to IP; or (iii) a specific chapter on intellectual property (SEUBA, 2013, p. 252). Besides, "intellectual property obligations are not only adopted in the text of the original PTA, but are also fruit of the normative action undertaken in the context of the regime created therein" (SEUBA, 2013, p. 252).

The study developed by Roriz and Tasquetto (2013) analyzed the intellectual property provisions of 17 PTAs adopted by the main Brazilian trading partners: United States, European Union, China and India. Its aim consisted in identifying the IP regulatory trends that Brazil would face if it decided to negotiate a PTA with those countries. It concluded that the United States PTAs contain the most comprehensive and far-reaching intellectual property rules. On patent provisions, Brazil might have to build a position regarding patentable subject matter, limitation to the use of compulsory license, pharma-related provisions, patent term extension, and exclusivity of test data protection (RORIZ; TASQUETTO, 2013, p. 164).

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[120] Seuba (2013) also used the WTO Regional Trade Agreement Information-System (RTA-IS) in his research. The scholar, nevertheless, recognizes that the WTO RTA-IS "is not totally accurate when offering the list of PTAs that have been notified to the Organization and regulate intellectual property" (SEUBA, 2013, p. 252)

[121] In this regard, Fink (2001, p. 387) emphasizes that, historically, the NAFTA, which came into force in 1994, "was the first major trade agreement to include specific obligations on protection of patents, trademarks, copyright, and other forms of IPRs." However, Seuba (2013, p. 253) reminds that the 1986 US-Israel already provided for the regulation of intellectual property. Its Article 14 "granted national treatment as well as MFN and mentioned patents, copyrights, trademarks and industrial design in particular, but didn't include any specific obligations" (ELSIG; SURBECK, 2016, p. 6).

Elsig and Surbeck (2016, p. 11) mapped[122] selected IPR provisions in PTAs and discussed some descriptive statists regarding three concepts: degree of protection,[123] enforcement[124] and multilateral coherence.[125] On the first concept, the study showed that North-South Agreements present a much higher IPR protection than both North-North and South-South treaties (ELSIG; SURBECK, 2016, p. 8). On the second concept, it revealed that North-South agreements have significantly higher enforcement capacities. The study identified that the US PTAs have the strongest enforcement elements (ELSIG; SURBECK, 2016, p. 8). On the third concept, it recognized that "intercontinental and European agreements are those with the highest inclusion of WTO principles and re-affirmations of WTO and WIPO regimes (general multilateral coherence measure)" (ELSIG; SURBECK, 2016, p. 10).

Tand and Teodoro (2016) examined the IPR provisions in 5 PTAs signed between the United States and Latin American Countries.[126] They aimed to assess "the extend and variations to which those provisions achieve TRIPS-Plus goals intended by the new US trade policy" (TANG; TEODORO, 2016, p. 1063). This study evidenced a "successful use of PTAs as a strategy for promoting TRIPS-Plus standards among Latin American Countries" (TANG; TEODORO, 2016, p. 1084). The commitments undertaken have shown substantive TRIPS-Plus rules on "new technologies, copyrights and related rights, as well as on pharmaceutical and agricultural chemical products" (TANG; TEODORO, 2016, p. 1084).

The above-mentioned studies shed light in the current state of research on the regulation of intellectual property in PTAs. They provide insightful observations that guide the development of the present study. In order to build on the previous literature and advance knowledge in this subject, this research is delineated by the following structured methodological considerations.

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[122] The research developed Elsing and Surbeck (2016) were based on the Design of Trade Agreements (DESTA) Database, which contain more than 620 coded PTAs.

[123] The degree of protection's concept "captures the overall IPR content and obligations that are included in a treaty" (ELSING, SURBECK, 2016, p. 4).

[124] The concept of enforcement assesses the availability and strength of enforcement tools (ELSIG; SURBECK, 2016, p. 5).

[125] The concept of multilateral coherence measures "how much the IPR obligations are embedded in the larger network of WTO and WIP rules and regulations" (ELSIG; SURBECK, 2016, p. 5).

[126] Tand and Teodoro (2016) analyzed more precisely the US-Chile FTA (6 June 2003), US-Dominican Republic-Central America Free Trade Agreement (28 May 2004), US-Colombia Trade Promotion Agreement (22 November 2006), US-Peru Trade Promotion Agreement (12 April 2006), US-Panama Trade Promotion Agreement (28 June 2007).

3.3 Methodological Considerations

This dissertation aims to develop a comparative study between the main patent and test data protection provisions adopted in PTAs and the Brazilian regime. The aim is to identify in which direction the international patent and test data protection regulation is heading and assess how and to what extend the Brazilian regime differs from this trend. In order to achieve this goal, several methodological cuts were undertaken.

This study investigates the patent and test data provisions in bilateral and plurilateral preferential trade agreements. It understands PTAs as customs unions, free trade areas and economic integration agreements. It does not only assess the PTAs in force, but also the ones that were already signed. This is justified by the fact that, even though the signed agreements do not produce legal effects between the parties yet, their adoption already constitutes an international IP standard that influences the formation of the international intellectual property system.

The signed agreements represent an official compromise reached after long rounds of negotiations. Even if the agreement might never come into force, the rules agreed therein are used by the PTA's parties and also by third countries in their future bilateral, plurilateral and multilateral negotiations.

The patent provisions analyzed are those regarding: exhaustion of patent rights (parallel importation); criteria of patentability; patentable subject matter; disclosure requirements of genetic resources and associated traditional knowledge; compulsory license; revocation/forfeiture; and term of protection.

The test data protection provisions analyzed are those concerning: data exclusivity; market exclusivity; test data protection of "new uses"; patent-linkage; patent's holder notification; test data protection of biologics; and data exclusivity of medical and plant protection products.

The methodological reason for analyzing test data protection in conjunction with patent protection is that, as the above-mentioned provisions have already showed, TRIPS-

Plus provisions are increasingly combining both categories of intellectual property rights. Therefore, they should be analyzed jointly, even though their object of protection is different.

This study does not consider PTAs under negotiation that will probably contain specific chapters or provisions on intellectual property.[127] This intends to avoid the problem of analyzing "moving targets", since the final text of the agreement is only consolidated after it has been signed. This research also does not examine international acts that are not formally considered as an international agreement by its parties, such as side letters and memorandum of understandings (ARBIX, 2009, p. 107).

Regarding the time frame, this work assesses PTAs signed from the entry into force of TRIPS Agreement, in other words, 1st January 1995, until 1st January 2017. The TRIPS Agreement constitutes a milestone in the international intellectual property regulation and it is used by this study as a reference to assess the evolution of the international regulation on patent and test data protection.

In the literature review, scholars have frequently mentioned the WTO database (Regional Trade Agreements Information System – RTA-IS) as outdated.[128] The WTO database does not appear to be a reliable source for more detailed and fined-grained research in matters such as intellectual property. For this reason, the present study decided to use the database of the Design of Trade Agreements (DESTA) project, conducted by the World Trade Institute (University of Bern – Switzerland); University of Salzburg (Austria): and McGill University (Montreal - Canada).[129] The DESTA database contains a

[127] This work excludes from the scope of its analysis the Mega Regional Agreements under negotiation: Transatlantic Trade and Investment Partnership (TTIP), between the United States and European Union; and the Regional Comprehensive Economic Partnership (RCEP), among Australia, Brunei, Cambodia, China India, Indonesia, Japan, Laos, Malaysia, Myanmar, New Zealand, Philippines, Singapore, South Korea, Thailand and Vietnam.

[128] See: SEUBA, Xavier. Intellectual Property in Preferential Trade Agreements: What Treaties, What Content? **The Journal of World Intellectual Property**, v. 16, n. 5-6, p. 240-261, Dec. 2013; VÁLDES, Raymundo; McCANN; Maegan. **Intellectual Property Provision in Regional Trade Agreements**. WTO Staff Working Paper ERSD-2014-14. Geneva: World Trade Organization, 2014.

[129] DÜR, Andreas; BACCINI, Leonardo; ELSIG, Manfred. The Design of International Trade Agreements: Introducing a New Dataset. **The Review of International Organizations**, v. 9, n. 3, p. 353-375, Sep. 2014. DESTA won the best new dataset award of the International Political Economy Society in 2017. For more information on the DESTA project, see: <https://www.designoftradeagreements.org/>.

list of more than 620 PTAs[130] adopted between 1948 and 2017. It covers detailed data on a large set of design features, including intellectual property.

Based on the above-explained methodological frames, 68 PTAs were identified as containing substantial provisions on patents and test data protection.[131] This study examines a range of agreements that covers 93 countries and separate customs territories possessing full autonomy in the conduction of their external commercial relations.

Table 1 - List of PTAs Including Substantial Patent and Test Data Provisions signed from 1st January 1995 to 1st January 2017

No.	PTA	Year of Signature	Date Entry into Force
1	Albania EFTA	2009	01.11.2010
2	Australia Chile	2008	06.03.2009
3	Australia China	2015	20.12.2015
4	Australia Korea	2014	12.12.2014
5	Australia Malaysia	2012	01.01.2013
6	Australia US	2004	01.01.2005
7	Bahrain US	2004	01.08.2006
8	Bosnia and Herzegovina EFTA	2013	01.01.2015
9	Canada Korea	2014	01.01.2015
10	Canada EU (CETA)	2016	NA
11	CARIFORUM EU EPA	2008	29.12.2008
12	Central America EU	2012	01.12.2013
13	Central America EFTA	2013	05.09.2014
14	Central America Mexico	2011	22.11.2011
15	Central American Free Trade Agreement (CAFTA)	2004	01.11.2004
16	CAFTA Dominican Republic	2004	01.03.2006
17	Chile EFTA	2003	01.12.2004
18	Chile US	2003	01.01.2004
19	China Korea	2015	20.12.2015
20	China Switzerland	2013	01.07.2014
21	Colombia EFTA	2008	01.06.2011
22	Colombia Peru EU	2012	01.08.2013
23	Colombia US	2006	15.05.2012
24	Croatia EFTA	2001	01.01.2002
25	EU Georgia	2014	01.07.2016
26	EU Korea	2010	01.07.2011
27	EU Moldova	2014	01.09.2014
28	EU Singapore	2015	NA
29	EU Turkey	1995	01.01.1996
30	EU Ukraine	2014	NA

[130] The DESTA project collects data on three types of preferential trade agreements: customs unions, free trade agreements or partial trade agreements (or what economists often call economic integration agreements) (DESTA, 2017).

[131] In the DESTA database, one could identify 68 PTAs with substantial patent provisions adopted between 1948 and 2016. Due to the time frame set by this research, four agreements had to be excluded from the scope of analysis, since they were adopted before 1995. These agreements are the 1993 EFTA-Bulgaria; the 1994 Bolivia-Mexico; the 1992 NAFTA; and the 1992 Agreement on the European Economic Area (EEA), which brings together the European Union Member States and three EFTA States (Iceland, Liechtenstein and Norway) in a single market. It is important to note that Switzerland is not part of the EEA (EFTA, 2017).

31	EU Vietnam	2016	NA
32	EFTA Estonia	1995	01.06.1996
33	EFTA Hong Kong	2011	01.11.2012
34	EFTA Korea	2005	01.09.2006
35	EFTA Latvia	1995	01.06.1996
36	EFTA Lebanon	2004	01.07.2007
37	EFTA Lithuania	1995	01.08.1996
38	EFTA Macedonia	2000	01.05.2002
39	EFTA Montenegro	2011	01.11.2012
40	EFTA Peru	2010	01.07.2012
41	EFTA Philippines	2016	NA
42	EFTA Serbia	2009	01.10.2010
43	EFTA Services	2001	01.06.2002
44	EFTA Singapore	2002	01.01.2003
45	EFTA Tunisia	2004	01.06.2005
46	EFTA Turkey IPR Amendments	1998	19.12.2002
47	EFTA Ukraine	2010	01.06.2012
48	India Japan	2011	01.08.2011
49	Indonesia Japan	2007	01.07.2008
50	Japan Malaysia	2005	13.07.06
51	Japan Mongolia	2015	NA
52	Japan Peru	2011	01.03.2012
53	Japan Switzerland	2009	01.09.2009
54	Japan Thailand	2007	01.11.2007
55	Japan Vietnam	2008	01.10.2009
56	Jordan US	2000	17.12.2001
57	Korea US	2007	15.03.2012
58	Korea Vietnam	2015	21.12.2015
59	Mexico Northern Triangle	2000	01.06.2001
60	Mexico Uruguay	2003	15.07.2003
61	Morocco US	2004	01.01.2006
62	Nicaragua Taiwan	2006	01.01.2008
63	Oman US	2006	01.01.2009
64	Panama US	2007	31.10.2012
65	Peru US	2006	01.02.2009
66	Singapore US	2003	01.01.2004
67	Transpacific Partnership	2015	NA
68	US Vietnam	2000	10.12.2001

Source: DESTA, 2017. Table elaborated by the author.

This study considers the integration of horizontal and vertical methodologies in legal comparison. While horizontal comparison is used to compare systems belonging to the same level (e.g. comparing international agreements); vertical comparison is used to compare systems that do not belong to the same level (e.g. comparing international agreements to national laws) (MOMIROV; FOURIE, 2009, p. 295).

Vertical comparison can be top-down or bottom-up. Top-down concerns the "context of the internalization of international norms and regulations by national legal orders, whereby national law is required to incorporate international concepts into the national legal system, terminology and ideology" (MOMIROV; FOURIE, 2009, p. 295). By its

turn, bottom-up refers to “the transposition of legal concepts, or the ideas behind them, from national to international level” (MOMIROV; FOURIE, 2009, p. 296).

As observed by Scarciglia (2015, p. 46), before the 1990s, legal comparison and transpositions of legal concepts, from one legal system into another, were investigated through a horizontal methodology. However, given the increasing transnational interactions, global commerce and rapid development of web communication, the analysis of this legal phenomenon has gained greater complexity (SCARCIGLIA, 2015, p. 46). Nowadays, legal concepts move from national to international level and *vice-versa* (SCARCIGLIA, 2015, p. 46). The current dynamics involves simultaneously the imposition of international rules at the national level and “the adoption in the global sphere of principles and values of a domestic legal system” (SCARCIGLIA, 2015, p. 46).

In a similar vein, Reimann (2001, p. 1107) affirms that national legal systems are no longer alone in the legal universe, but they “coexist with regimes operating on the supra- or international level.” They are subject to, and modified by, “international treaties and conventions, trade regulations, and [regional economic integration directives]” (REIMANN, 2001, p. 1107-1108). Currently, the legal universe consists of “an extensive network of legal systems on several levels, with multiple horizontal as well as vertical connections” (REIMANN, 2001, p. 1112).

Therefore, legal pluralism and the effects of globalization demand a different approach towards comparative methodology (SCARCIGLIA, 2015, p. 46). The sole use of horizontal legal comparison ignores the existence of these “legal transplants, as well as a development of principles and rights in a global space” (SCARCIGLIA, 2015, p. 46). For these reasons, this study integrates horizontal and vertical (top-down and bottom-up) methodologies in legal comparison to investigate the complex phenomenon of the TRIPS-Plus rules in preferential trade agreements.

As explained by Momirov and Fourie (2009, p. 300), this method can be divided into four stages: (i) the formulation of a hypothesis based on the observation of *prima facie* similarities; (ii) construction and verification of a conceptual model through horizontal comparison; (iii) systematic vertical comparison (similarities and differences) between national and international systems; and (iv) synthesis of the results, providing a basis for drawing conclusions (hypotheses proved or disproved). This is undertaken through the

analysis of each of the 68 PTAs. No software nor electronic tool was used to carry out this investigation.

In the words of Jansen (2006, p. 336), "the core of comparative knowledge consists in a structured system of similarities and differences of the objects compared." Comparison is nothing more than "the construction of relations of similarity or dissimilarity between different matters of fact" (JANSEN, 2006, p. 310). This method is carried out through juxtaposing, contrasting and paralleling (ÖRÜCÜ, 2012, p. 565). A meaningful comparison, nevertheless, depends on full factual description (JANSEN, 2006, p. 312).

Therefore, this study collects and describes the PTAs provisions on patent and test data protection on the basis of carefully constructed classificatory schemes. The study discovers and describes uniformities and differences between these provisions and the TRIPS Agreement (horizontal comparison); and between these provisions and the Brazilian patent and test data regime (vertical comparison). Subsequently, it formulates interrelationships between the components of norm setting and other social phenomena raised in the literature. At last, it verifies the tentative hypotheses by empirical observations and constructs a final conclusion through various propositions (ÖRÜCÜ, 2012, p. 565).

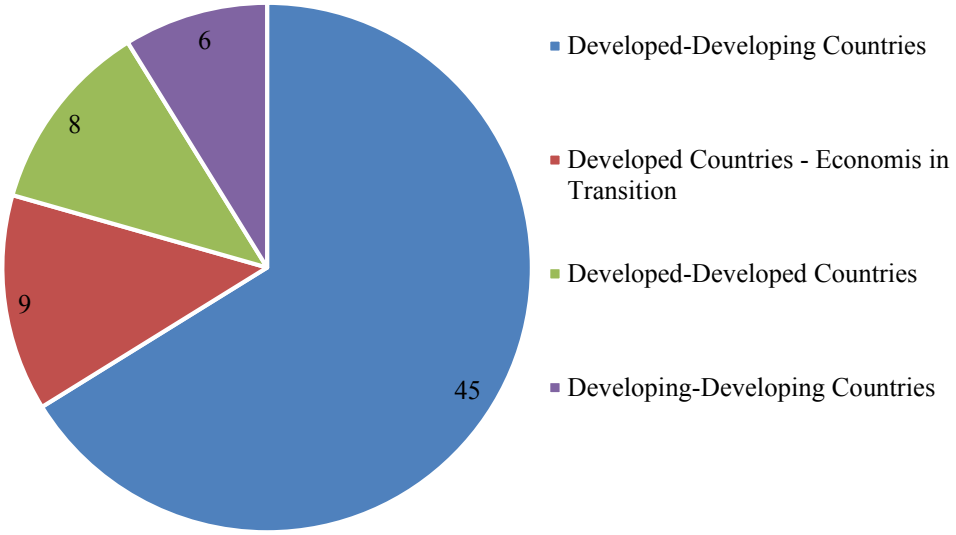
Even though there is extensive literature on TRIPS-Plus, relatively few comprehensive analyses have been carried out on the PTAs' patent and test data provisions and the Brazilian law and practice. This work aims to make a contribution towards closing this gap by undertaking a comprehensive mapping of the patent and test data provisions in PTAs and comparing them to the Brazilian patent and test data protection regimes. Although it is more complicate than the traditional approach to consider both horizontal and vertical relationships between legal systems on various levels, this technique has greater potential to fulfill critical future needs (REIMANN, 2001, p. 1117).

3.4 Analysis of The PTAs Provisions

3.4.1 General Observations

From 68 analyzed preferential trade agreements with patent provisions, 45 have been concluded between developed and developing countries, 9 between developed countries and economies in transition, 8 between developed countries and 6 between developing countries.[132]

Figure 1 - Parties Involved in PTAs with Patent Provisions - From 1st January 1995 to 1st January 2017



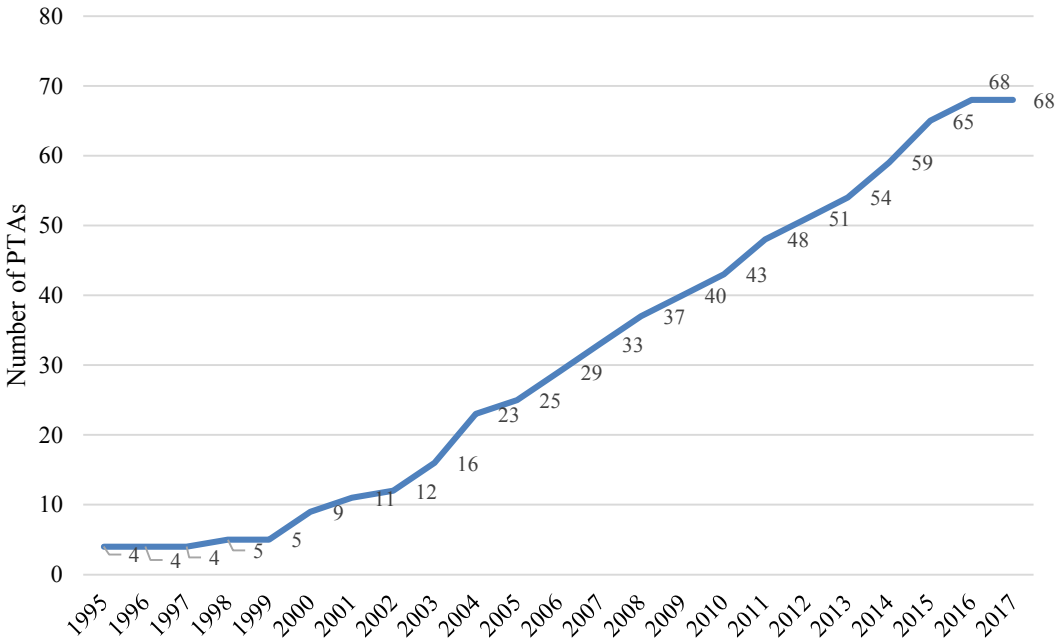
Source: DESTA, 2017. Figure elaborated by the author.

These numbers show that the great majority of PTAs regulating patent protection involves developed countries, on the one side, and developing countries or economies in transition, on the other side. They account for approximately 79% of all the analyzed PTAs adopted from 1st January 2015 to 1st January 2017.

[132] As pointed out in its official website (WTO, 2017e), there are no definitions of "developed" and "developing countries" in the WTO. Members declare themselves if they are "developed" or "developing countries." This, however, can be challenged if a Member is misusing provisions available to developing countries (WTO, 2107e). Since the WTO does not have a clear definition of which countries are developed or developing, this research adopts the concepts adopted in the United Nations 2017 World Economic Situations and Prospects (WESP). This is a UN's flagship publication on the expected trends in global economy, produced annually by the UN Department of Economic and Social Affairs (DESA), the UN Conference on Trade and Development (UNCTAD), and five UN Regional Commissions and the World Tourism Organization (UNWTO). For further details on the WESP's classifications, see Annex 1 to this Dissertation.

The number of PTAs with patent provisions has increased steadily since the entry into force of the TRIPS Agreement. In 1995, only 4 PTAs established rules on patent protection. By 2005, ten years later, this number more than tripled and reached 25. By 2015, twenty years later, the number of PTAs with patent provisions reached 65, thirteen times the initial number in 1995. Only from 2012 to 2017, 20 PTAs with patent rules were adopted, representing approximately 29.4% of all PTAs with patent provisions. This shows an acceleration in the adoption of PTAs with patent provisions in recent years.

Figure 2 - Cumulative Adoptions of Patent Provisions in PTAs per Year - From 1st January 1995 to 1st January 2017



Source: DESTA, 2017. Figure elaborated by the author.

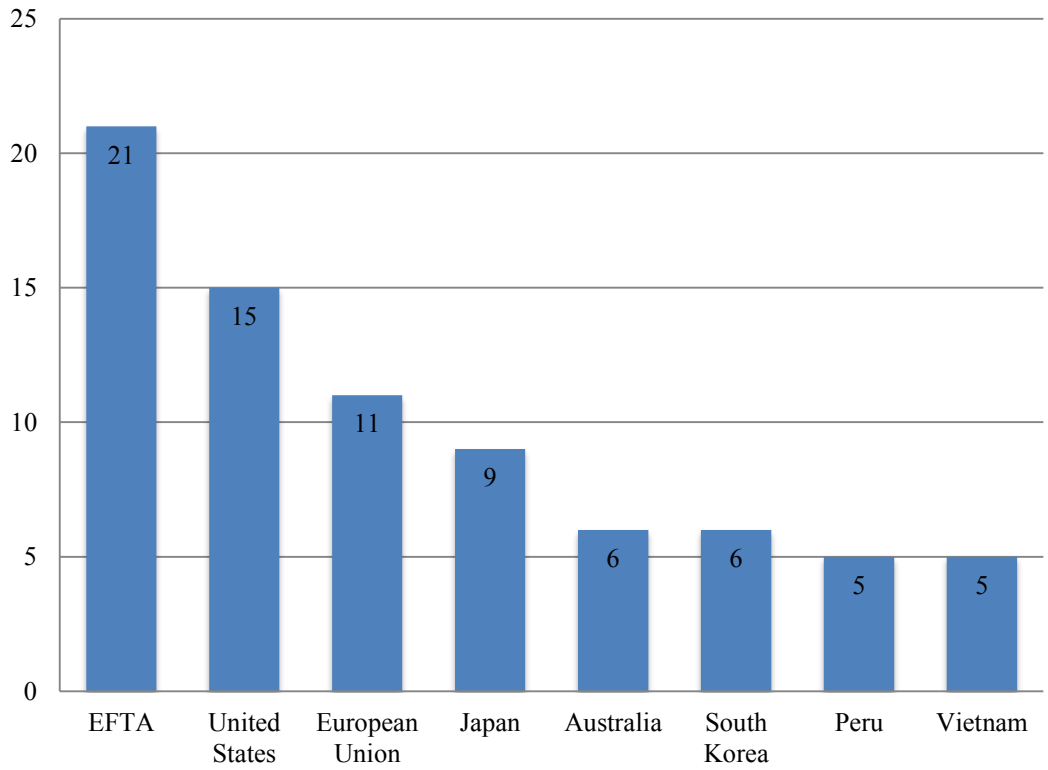
The most active player in negotiating patent provisions in PTAs is the European Free Trade Association (EFTA), formed by Iceland, Liechtenstein, Norway and Switzerland. From January 1995 to January 2017, EFTA signed 21 PTAs with patent provisions. The EFTA is followed by the United States (15), European Union (11) and Japan (8).

It is important to highlight that these most active countries pushing for deeper patent regulation through preferential trade agreements are the same that defended the inclusion of intellectual property in the Uruguay Round. Not fully satisfied with the TRIPS outcome,

they decided to shift the negotiation forum again and advance their interests and understandings of the TRIPS Agreement in the bilateral and plurilateral agreements.

Besides, it is important to notice the participation of developing countries in the adoption of patent provisions in PTAs. From January 1995 to January 2017, South Korea signed 6 PTAs with patent provision, being the most active developing country in this rule-setting dynamic. South Korea is followed by Peru (5) and Vietnam (5).

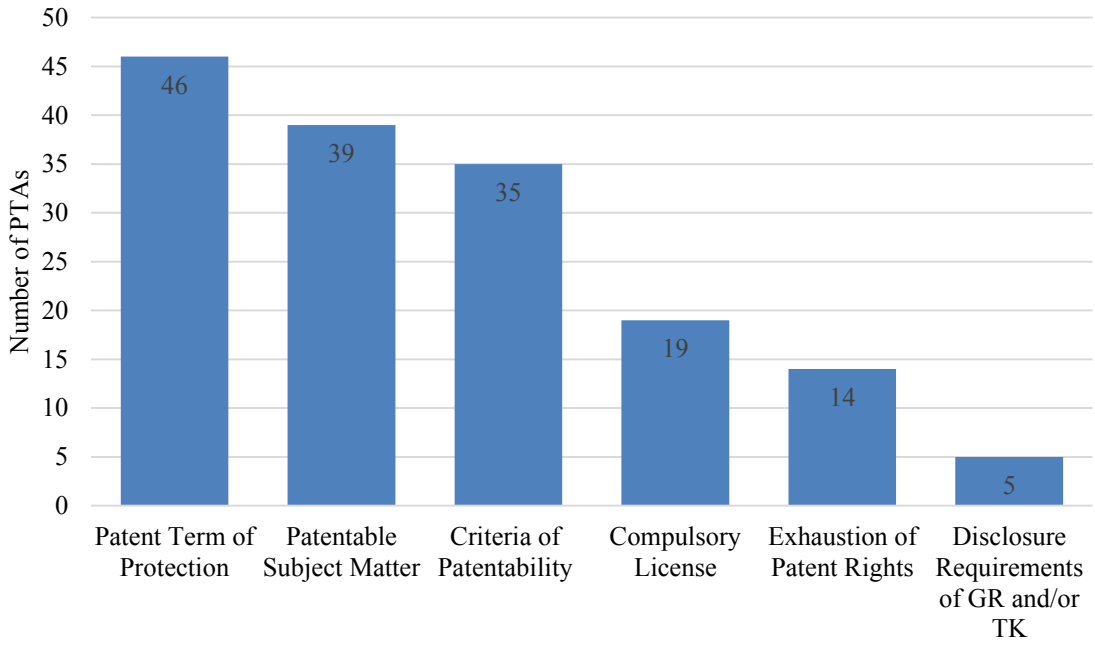
Figure 3 - Number of PTAs with Patent Provisions by Country/Trading Block, adopted from 1st January 1995 to 1st January 2017



Source: DESTA, 2017. Figure elaborated by the author.

From the analyzed patent provisions, the clause regarding aspects of patent term of protection is the most common. From the 68 analyzed PTAs, 46 have provisions on patent term of protection. Subsequently, the most frequent provisions regard: patentable subject matter (39); criteria of patentability (35); compulsory license (19); patent revocation (18); exhaustion of patent rights (14); and disclosure requirements of genetic resources and/or associated traditional knowledge (5).

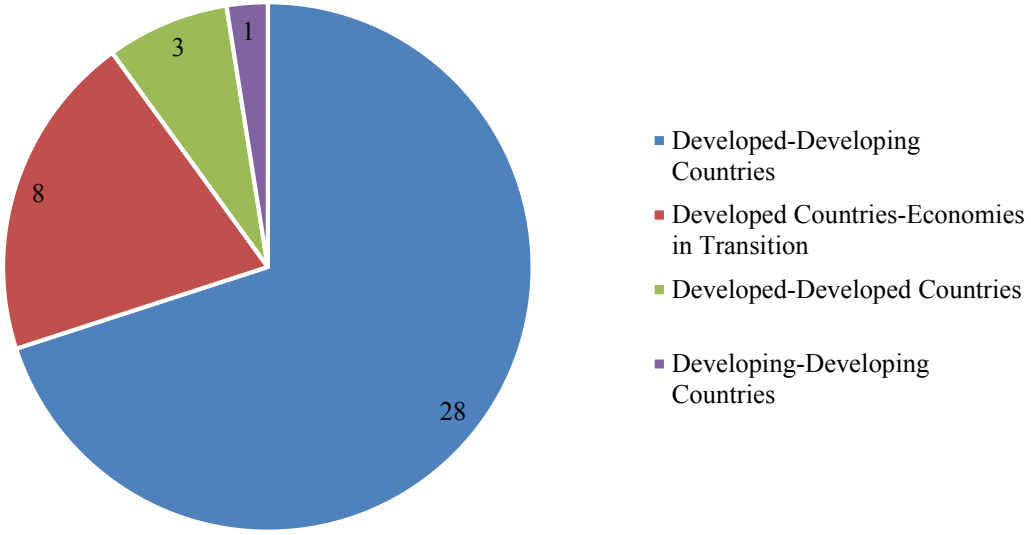
Figure 4 - Number of PTAs per Category of Patent Provision, adopted from 1st January 1995 to 1st January 2017



Source: DESTA, 2017. Figure elaborated by the author.

From 40 analyzed preferential trade agreements with test data provisions, 28 were concluded between developed and developing countries, 8 between developed countries and economies in transition, 3 between developed countries and 1 between developing countries.

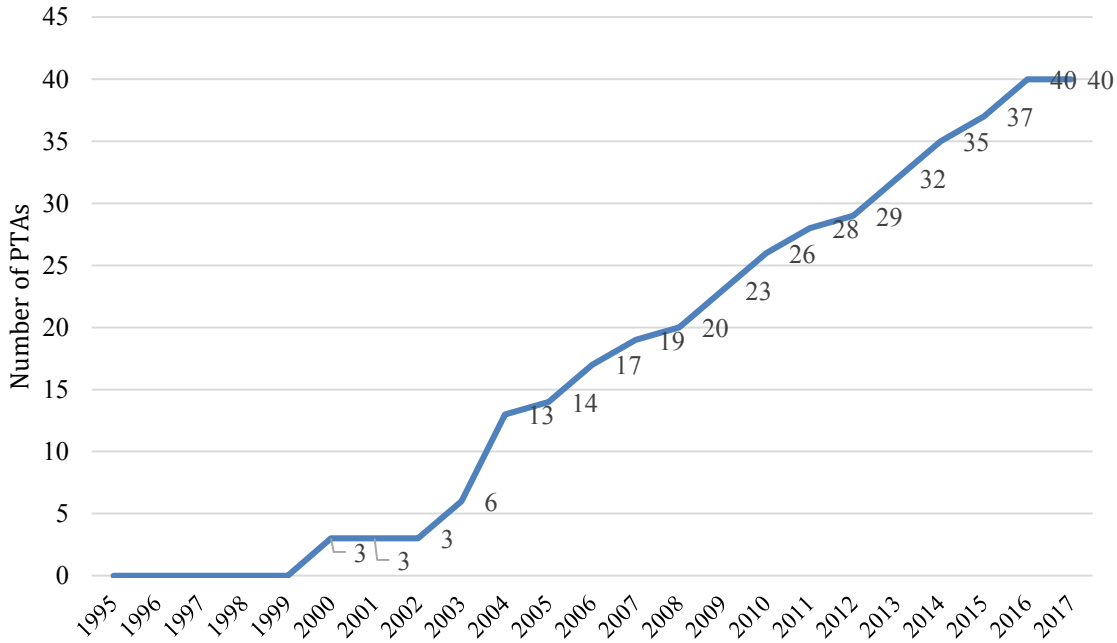
Figure 5 - Parties Involved in PTAs with Test Data Provisions, adopted from 1st January 1995 to 1st January 2017



Source: DESTA, 2017. Figure elaborated by the author.

In the period under analysis, PTAs with test data provisions started to be concluded as from 2000. Differently from patent provisions that started to be included in PTAs right after the entry into force of the TRIPS Agreement in 1995, test data provisions only started to be included in PTAs five years after the entry into force of TRIPS Agreement. As to patent provisions, there is a tendency of acceleration in the conclusion of PTAs with test data provisions. Only from 2012 to 2017, 12 PTAs with test data protection were adopted, accounting for 30% of all the PTAs with test data protection under analysis.

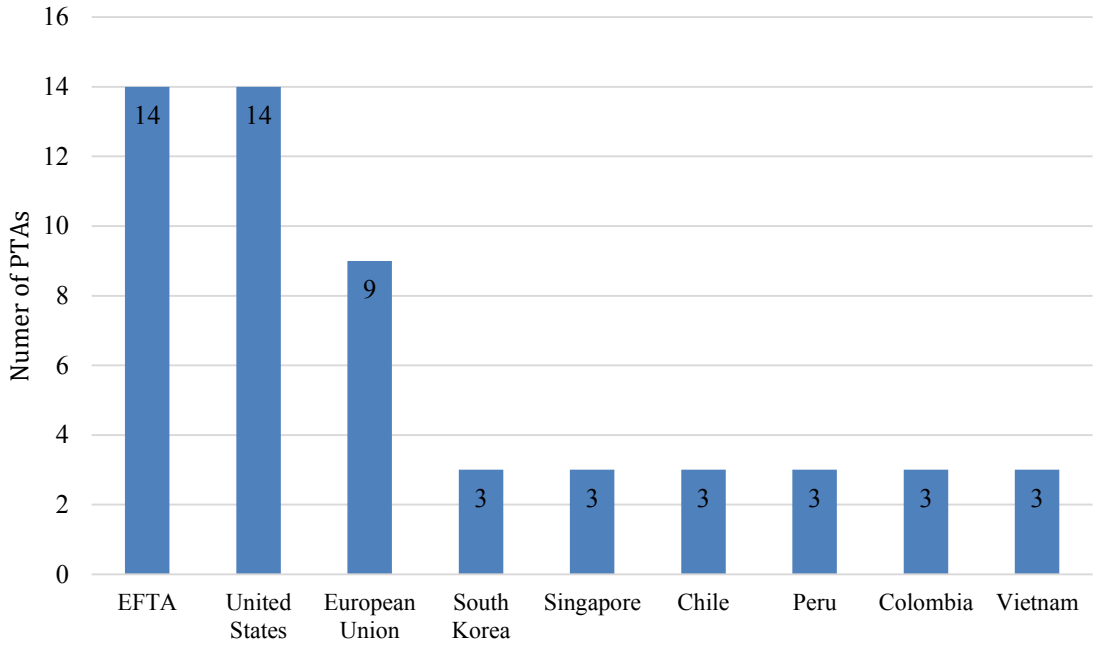
Figure 6 - Cumulative Adoptions of Test Data Provisions in PTAs per Year, from 1st January 1995 to 1st January 2017



Source: DESTA, 2017. Figure elaborated by the author.

The most active players in adopting test data protection in PTAs are EFTA and the United States. In the analyzed period, EFTA and the US were, each one, party to 14 PTAs with test data provisions. They are followed by the European Union (9), South Korea (3), Singapore (3), Chile (3), Peru (3), Colombia (3) and Vietnam (3).

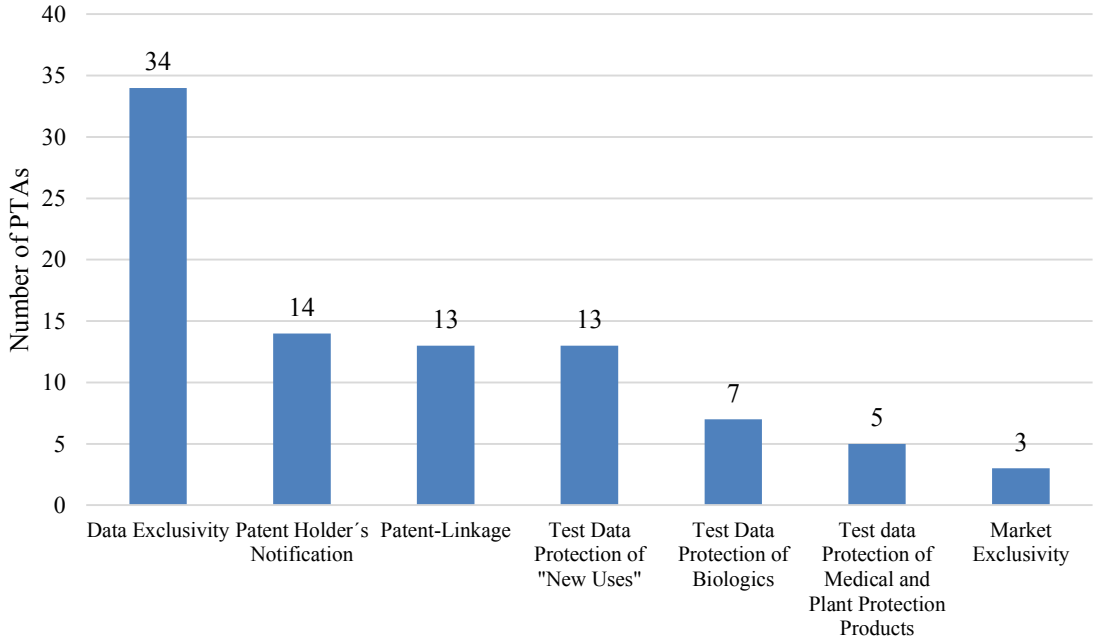
Figure 7 - Number of PTAs with Test Data Provisions by Country/Trading Block, adopted from 1st January 1995 to 1st January 2017



Source: DESTA, 2017. Figure elaborated by the author.

From the analyzed test data protection provisions, the clause requiring data exclusivity to clinical test submitted to regulatory authority for marketing approval is the most recurring one. From the 40 identified PTAs, data exclusivity is required in 34 of them. In the sequence, the most frequent provisions on test data protection regards: patent's holder notification (14); patent-linkage (13); test data protection of "new uses" (13); test data protection of biologics (7); test data protection of medical and plant protection products (5); and market exclusivity (3).

Figure 8 - Number of PTAs per Category of Test Data Provision, adopted from 1st January 1995 to 1st January 2017



Source: DESTA, 2017.

The above-mentioned preferential trade agreements and their patent and test data provisions are further analyzed in detail in the following sections.

3.4.2. Patent Provisions

3.4.2.1 Exhaustion of Patent Rights (Parallel Importation)

3.4.2.1.1 TRIPS Agreement

The doctrine of exhaustion of intellectual property rights is one of the most important topics “arising from the interface between the international IP Protection and the freedom of movement of goods and services among nations” (YUSUF, 2016, p. 23). It addresses the issue “of when the IPR holder’s control over the distribution of a specific good ceases” (ROFFE; SANTA CRUZ, 2007, p. 9).

As explained by Taubman, Wager and Watal (2012, p. 18), “the term ‘exhaustion’ refers to the generally accepted principle of IP law that a right owner’s exclusive right to control the distribution of a protection item lapses after the first distribution.” From an international trade perspective, the emphasis of the exhaustion question is “whether it operates on a national, regional or international basis” (ROFFE; SANTA CRUZ, 2007, p. 9).

National exhaustion implies that “the IP right holder’s power to control movement of the good is only extinguished upon a first sale or placing on the market within the national territory” (ABBOT; COTTIER; GURRY, 2007, p. 59). It means that, “even if the right holder’s rights are exhausted on first sale of the product in one particular national jurisdiction, this does not exhaust the rights regarding the product in other jurisdictions” (MALBON; LAWSON; DAVISON, 2014, p. 172).

This approach enables the intellectual property right holders to prevent parallel importation from third countries of IP-related products, such as books, drugs or machines (YAMANE, 2011, p. 156). In this manner, the IP-right holder is able to block the importation without its authorization of an IP-related product “streamed into the channels of commerce outside the national territory” (ROFFE; SANTA CRUZ, 2007, p. 9).

As explained by Malbon, Lawson, Davison (2014, p. 172), parallel import arises (if allowed) when “a particular type of IP-related product is sold in different countries at different prices.” In other words, parallel importation occurs when a third party buys a patented protected product in country “X”, where the product is cheaper, and import it to country “Y”, where the product is sold at a higher price (GUISE, 2007, p. 115)

Regional exhaustion means that “the IP right holder’s power to control movement of the good is only extinguished upon a first sale or placing on the market within the defined regional territory of an integration arrangement” (ABBOT; COTTIER; GURRY, 2007, p. 59). It treats the “first sale in the region as exhausting the right holder’s right within the region” (MALBON; LAWSON; DAVISON, 2014, p. 172).

For example, considering that the European Union is a region, a first sale in Germany “will be treated as a first sale in every other EU country” (MALBON; LAWSON; DAVISON, 2014, p. 172). Hence, the first sale of the IP-related product in Germany will enable the IP right holder to prevent the importation of this product into

France, an EU Member State. However, the first sale of the product in a third country will not enable the IP right holder to block the importation into any EU Member State (ABBOT; COTTIER; GURRY, 2007, p. 59).

International exhaustion entails that "the IP right holder's power to control the movement of the good is extinguished upon a first sale or placing on the market anywhere in the world" (ABBOT; COTTIER; GURRY, 2007, p. 59). It implies that "upon first sale in one jurisdiction, the IP rights are not only exhausted in that jurisdiction, they are also exhausted in every other jurisdiction" (MALBON; LAWSON; DAVISON, 2014, p. 172). This approach effectively "allows parallel importing of particular types of IP-related products" (MALBON; LAWSON; DAVISON, 2014, p. 172).

The TRIPS Agreement left entirely to the WTO Member States to regulate the exhaustion of intellectual property rights, acknowledging merely that it is a relevant topic (YUSUF, 2016, p. 23). The issue was one of the most difficult topics during the TRIPS negotiations, leading to the adoption of Article 6, "which has been described as an agreement to disagree" (MALBON; LAWSON; DAVISON, 2014, p. 173). TRIPS Article 6 merely states that, "for the purpose of dispute settlement under this Agreement, subject to the provisions of Articles 3 [National Treatment] and 4 [Most-Favored-Nation], nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

That is to say, WTO Members are entitled to adopt its own exhaustion regime without challenge, as long as they respect TRIPS Article 3 and 4 (ROFFE; SANTA CRUZ, 2007, p. 9). In other words, "national laws providing for an international exhaustions of rights and the legality of parallel imports are TRIPS-compliant as long as they do not contravene MFN and national treatment provisions" (YUSUF, 2016, p. 24). The 2001 Doha Declaration on the TRIPS Agreement and Public Health reaffirmed this understanding and recognized Article 6 as a TRIPS' flexibility (TAUBMAN; WAGER; WATAL, 2012, p. 20).[133]

[133] The paragraph 5 (d) of the 2001 Doha Declaration on the TRIPS Agreement and Public Health reads as: "accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: (d) the effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."

3.4.2.1.2 PTAs Rules

From the 68 analyzed PTAs, 14 included provisions on exhaustion of intellectual property rights and, accordingly, the possibility of the IP-right holder to block or not parallel importation of IP-related products. In order to better assess the PTAs' regulation on this topic, these provisions can be divided into 3 categories.

The first category restates the flexibility of TRIPS Article 6. It ensures that nothing in the PTA shall affect the parties' freedom to determine whether, and under what conditions, the exhaustion of intellectual property applies under their legal system.[134] From the 14 identified PTAs, 10 provided for such a provision.[135] It is worth noting that all these PTAs were concluded between at least a developing country and a developed country. This shows a developing country's strategy to maintain the room for maneuver provided by the TRIPS Agreement. The adoption of such a clause in PTAs ensures that countries are allowed to maintain an international exhaustion approach, permitting the parallel importation of IP-related products.

The second category demands, in practice, the parties to adopt a national exhaustion regime of intellectual property rights to patent-related products. This type of provision does require it expressly, but rather indirectly. It request the parties to provide that the exclusive right of the patent owner to prevent importation of a patent-related product without its authorization shall not be limited by the sale or distribution of that product outside its territory.[136] From the 14 identified PTAs, 2 provided for such a clause.[137] The United States is party in both of them, being the main supporter of this rule. Through its implementation, parties shall guarantee the intellectual property holder's right to block parallel importation.

[134] Article 18.12 of the 2015 TPP illustrates this kind of provision. It reads as: "nothing in this Agreement prevents a party from determining whether or under what conditions the exhaustion of intellectual property rights applies under its legal system."
[135] These PTAS are the 2012 Colombia-Peru-EC, 2014 EC-Korea, 2014 EC-Ukraine, 2014 Central America-EC, 2014 Canada-Korea, 2015 Australia-China, 2015 EC-Singapore, 2015 TPP and 2016 EC-Vietnam.
[136] Article 15.9.4 of the 2004 US-Morocco illustrates this type of provision. It reads as: "each party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory."
[137] These PTAS are the 2004 Australia-US and the 2004 US-Morocco.

The third category requires parties to adopt a national or regional exhaustion regime of intellectual property rights.[138] From the 14 identified PTAs, only 2 included such a provision. Not surprisingly, these two PTAs were concluded by the European Union with Georgia (2014) and with Moldova (2014).

Table 2 - Exhaustion of Patent Rights (Parallel Importation)

PTA	Year of Signature	Restatement of the TRIPS Article 6 Flexibility	Adoption of a National Regime of IPRs Exhaustion	Adoption of a National or Regional Regime of IPRs Exhaustion
Australia China	2015	Art. 11.8		
Australia US	2004		Art. 17.9.4	
Canada Korea	2014	Art. 16.7		
Canada EU (CETA)	2016	Art. 20.4		
Central America EU	2012	Art. 232		
Colombia Peru EU	2012	Art. 200		
EU Georgia	2014			Art. 152
EU Korea	2014	Art. 10.4		
EU Moldova	2014			Art. 279
EU Singapore	2015	Art. 11.3		
EU Ukraine	2014	Art. 160		
EU Vietnam	2016	Chapter 12, Art. 3		
US Morocco	2004		Art. 15.9.4	
TPP	2015	Art. 18.11		

Source: Table elaborated by the author.

3.4.2.1.3 Brazilian Regime

The Asunción Treaty, which established the Mercosur, does not provide for an explicit rule on the exhaustion of intellectual property rights (GUISE, 2007, p. 117). There is no specific protocol in the Mercosur's framework that regulates the exhaustion of patent

[138] Article 152 of the 2014 EC-Georgia PTA exemplifies this kind of provision. It reads as: "each party shall provide for a regime of domestic or regional exhaustion of intellectual property rights."

rights within the Customs Union.[139] As the general rule, Brazil adopts the national exhaustion regime of intellectual property rights (GUISE, 2007, p. 118). On the protection conferred by patent rights, Article 43, IV, of the Brazilian Industrial Property Law (Law No. 9.279)[140] reads as:

> The provisions of the previous Article [on the patent rights conferred] do not apply: to a product manufactured in accordance with a process or product patent that has been introduced into the **domestic market** directly by the patent holder or with his consent (emphasis added).

As this provision implies, parallel imports can be refrained in Brazil (GUISE, 2007, p. 118).[141] The patent owner or its licensee can exercise its right conceived by the patent granted in Brazil to prevent third parties from importing a patented product into the country without his consent (IDS, 2005, p. 96). However, when the patent owner itself or the licensee do not produce the patented product or use the process in Brazil, third parties can import it without requesting permission (DENIS B., 2010, p. 1630).

The patent owner should take into consideration two main aspects when exercising its right to prevent parallel imports. First, parallel import is not considered a criminal offense under national law,[142] if the product is put in the foreign market by the patent owner itself or under his consent (IDS, 2005, p. 96).[143] Accordingly, the legal measures to prevent the entry of the patented products into the Brazilian market are limit to civil procedures and remedies (FEKETE, 1997, p. 167). Second, third parties are authorized to parallel import when the patent owner himself is exploiting his patent through importation (IDS, 2005, p. 96; FEKETE, 1997, p. 160).

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[139] In 1995, Argentina, Brazil, Paraguay and Uruguay adopted through the Mercosur Council (CMC)'s Decision No. 8/95 the Protocol on the Harmonization of Rules on Intellectual Property, in the fields of trademarks, indications of origin and designations of origin. Its Article 13 establishes the regional exhaustion of trademarks' right (FEKETE, 1997, p. 170). This provision, however, does not bind Brazil yet, since it has not ratified the protocol until yet. At the time of writing, only Paraguay and Uruguay have ratified it.

[140] The translated version of the Brazilian Industrial Property Law (Law No. 9.279 of May 14, 1996) is available in the WIPO website at: <http://www.wipo.int/wipolex/en/text.jsp?file_id=125397>. This work uses, hereafter, this official version to conduct its analysis.

[141] The Brazilian Industrial Property Law (Law No. 9.279/1996) adopts the national exhaustion regime of intellectual property rights not only for patents (Article 43, IV), but also for industrial designs (Article 188, II) and trademarks (Article 132, III) (FEKETE, 1997, p. 164).

[142] Article 184, II, Law No. 9.279/1996.

[143] As highlighted by Fekete (1997, p. 164), the patent holder's lack of consent is the main condition for characterizing the unlawfulness of parallel importation.

Notwithstanding the incorporation of the national exhaustion regime for patent rights in Article 43, IV, of the Brazilian Industrial Property Law, some authors[144] support the legitimacy of parallel importation in the cases of compulsory license (GUISE, 2007, p. 118). This is based on Article 68 of the Brazilian Industrial Property Law, which admits the parallel importation, in the compulsory license context, when it is granted on the grounds of abuse of economic power (§ 3)[145] and in the case of importation to exploit the patent (§ 4).

3.4.2.1.4 Assessment

The exhaustion of intellectual property rights in the international trade context remains a highly controversial topic. There are both arguments pro and con the possibility of the IP-right holder to prevent parallel importation. On the one hand, national exhaustion can increase the profit making capacity of producers and provide greater returns to IP-right holders (ABBOT; COTTIER; GURRY, 2007, p. 60). It favors "market segmentation as well as differential pricing, product differentiation and differing release dates" (TAUBMAN; WAGER; WATAL, 2012, p.19). As explained by Hestermeyer (2007, p. 231), "if parallel imports are not admissible, the patent holder can separate markets – it can sell products at low prices where the market would not pay for high ones and at high prices where the market allows for such prices." However, since parallel imports are not overall prohibited, this is not what really happens.

On the other hand, international exhaustion stimulates producers to set their prices for the global market, since it precludes them from segmenting markets on the basis of intellectual property rights. This should bring those prices down, since producers will seek to maximize global demand (ABBOT; COTTIER; GURRY, 2007, p. 59). Besides, international exhaustion "facilitates parallel importation of the same product sold at lower

[144] See BARBOSA D., **Tratado da Propriedade Intellectual**. Rio de Janeiro: Lumen Juris, 210, at page 1629; FEKETE, Elisabeth. Importações Paralelas: A Implementação do Princípio da Exaustão de Direitos no Mercosul Diante do Contexto de Globalização. Anais do XVII Seminário Nacional da Propriedade Intelectual, Porto Alegre, 1997. **Proceedings…** Porto Alegre: Associação Brasileira de Propriedade Intelectual, 1997, at page 161.

[145] In this circumstance, the period in which the licensee can proceed with such parallel importation is limited to one year, counted from the granting of the compulsory license (Article 68, §3, Law No. 9.279) (FEKETE, 1997, p. 161).

prices in other countries" (TAUBMAN; WAGER; WATAL, 2012, p.19). In accordance with Abbot, Cottier and Gurry (2007, p. 59), a rule of international exhaustion is, in essence, "a tool for promoting competition and efficient allocation of resources."

The 2002 Report of the Commission on Intellectual Property Rights concluded that the most beneficial policy for developing countries is to adopt a rule of international exhaustion (CIPR, 2002, p. 42). This approach allows them to purchase essential IP-related products, such as medicines, "at the lowest price at which the manufacturer offers them anywhere in the world" (HESTERMEYER, 2007, p. 231). Therefore, developing countries "should aim to facilitate parallel imports in their legislation" (CIPR, 2002, p. 42).

In a similar vein, Sell (2011, p.454) argues that by "using parallel importation, countries can take advantage of differential pharmaceutical pricing policies in order to obtain cheaper patented goods." This flexibility, as stated in the 2001 Doha Declaration, is perfectly permissible under TRIPS (SELL, 2011, p. 454). According to Sell (2011, p. 454), this type of TRIPS-Plus provisions is designed to "limit parallel imports of patented drugs by providing the patent owner with an exclusive right to prohibit parallel importing contractually" (SELL, 2011, p. 454).

Brazil adopts, as a general rule, the national exhaustion regime of patent rights. Despite the room for maneuver provided by TRIPS Agreement (Article 6), the country decided to implement this stringent regime as regard to parallel importation. According to Guise (2007, p. 118), Brazil had no particular concern as regard to public health issues when implemented this TRIPS provision. The national exhaustion regime precludes parallel importation, which clearly limits the population's access to cheaper medicines (GUISE, 2007, p. 118). The Brazilian approach meets the high standards identified in the PTA's TRIPS-Plus clauses.

3.4.2.2 Criteria of Patentability

2.4.2.2.1 TRIPS Agreement

Criteria of patentability are the accepted parameters to define when an invention is patentable (CORREA, 2016, p. 281). In other words, the conditions, which inventions must meet to be eligible for patent protection (TAUBMAN; WAGER; WATAL, 2012, p. 98). According to TRIPS Article 27.1, "patents shall be available for any inventions […], provided that they are new, involve an inventive step and are capable of industrial application." In these terms, the TRIPS Agreement framed patentability upon the fulfillment of three criteria: novelty, inventive step and industrial applicability. They constitute the three basic steps of patentability, which were already recognized 'in many countries' laws prior to the TRIPS Agreement" (TAUBMAN; WAGER; WATAL, 2012, p. 98).

The first criterion – novelty – means that the invention "shows a new characteristic which has not already been disclosed to the public before the relevant date in the body of existing knowledge in its technical field (called 'prior art' or 'state of art')" (TAUBMAN; WAGER; WATAL, 2012, p. 98)." That is to say, "the invention has not been disclosed or described before the date of the patent application filling" (ABBOT, COTTIER, CURRY, 2007, p. 141).

The second criterion – inventive step – denotes an "advance from what has been used or described before, such that it could not be obvious to a person working in the technical field" (skilled in the art) (TAUBMAN; WAGER; WATAL, 2012, p. 98). It refers to the "conceptual distance between the prior art and invention" (ABBOT, COTTIER, CURRY, 2007, p. 146). It is a "qualitative assessment of whether the invention disclosed in the patent application is sufficient to warrant the rights […] of a patent grant" (MALBON; LAWSON; DAVISON, 2014, p. 421). This criterion is intended to "limit the grant of exclusive rights to those that have made a significant contribution to the development of […] technologies" (ABBOT, COTTIER, CURRY, 2007, p. 146).

The third criterion – industrial applicability – reflects "the possibility of making and manufacturing in practice, and that of carrying out or using in practice" (WIPO, 2004, p. 18). Hence, countries generally exclude from patentability creations that "do not aim at any direct technical result but are rather of an abstract and intellectual character" (TAUBMAN; WAGER; WATAL, 2012, p. 98).

Due to its importance, some authors (ABBOT, COTTIER, CURRY, 2007, p. 138; TAUBMAN; WAGER; WATAL, 2012, p. 98) highlight that "disclosure of the invention" might also be considered, in addition to the other three, a fourth basic criterion for patentability in some countries. The TRIPS Agreement, however, only required the three tests of patentability.

Furthermore, footnote 5 to TRIPS Article 27.1 provides that: "for the purposes of this Article, the terms 'inventive step' and 'capable of industrial application' may be deemed by a Member to be synonymous with the terms 'non-obvious' and 'useful' respectively." This provision, explains Correa (2016, p. 281), "allows member countries to interpret 'inventive step' (a concept used in Europe and in many other countries) as synonymous to 'non-obvious' (the equivalent concept applied in the United States)." According to Gervais (2003, p. 220), footnote 5 "makes clear that whatever distinction one might have found in the past, the terms "non-obvious' and "useful" correspond respectively to "inventive step" and "capable of industrial application."

In these terms, the TRIPS established the general principle of eligibility to be patented (GERVAIS, 2003, p. 220). The Agreement does not provide a precise definition of what an invention is, but it rather lays out the requirements that an invention must meet in order to be granted patent protection (CORREA, 2016, p. 276). In line with Correa (2016, p. 281), this is one of the most important flexibilities left by the TRIPS Agreement, since WTO Members are free to determine the ways in which patentability standards are nationally interpreted and applied. There is room for national policies to implement these criteria either in a vague manner, resulting in the proliferation of patents and, accordingly, undue limitations to competition; or in a strict manner, ensuring that patents are only granted when genuine technological contribution has been made (CORREA, 2016, p. 281).

3.4.2.2.2 PTAs Rules

From the 68 analyzed PTAs, 35 incorporated rules on the criteria of patentability. These provisions can be divided into 4 categories. The first category resumes the level of

protection established under the TRIPS Article 27.1.[146] It restates that patents shall be available for any inventions, provided that they are new, involve an inventive step and are capable of industrial application. Often this type of provision also reaffirms the explanation of footnote 5 to Article 27.1 by reiterating that terms "inventive step" and "capable of industrial application" may be deemed to be synonymous with the terms "non-obvious" and "useful" respectively. From the 35 identified PTAs, 33 provided for such a provision.

The second category adds to the TRIPS Article 27.1 that patents shall also be available for any "new uses"[147] or methods of using a known product.[148] From the 35 identified PTAs, 8 incorporated such a provision.[149] The TRIPS does not require patenting of all new forms, uses or methods as is established under this type of provision. According to Frankel (2012, p. 166) patenting incremental advances, without a substantive inventive step, "can have the effect of patenting the same product for much longer than the single patent term [...]". This is usually known in the literature as "ever greening" a patent.

The third category provides for a grace period for novelty and inventive step. As explained by Carvalho (2005, p. 77), "the grace period is the time span that precedes the filling of a patent application during which the disclosure of the invention under certain circumstances does not prejudice its novelty and inventiveness." The grace period assumes that novelty and inventive step are not absolute criteria and, therefore, can be relativized according to some circumstances. This legal instrument "has been incorporated since the 80s into the laws of many countries" (CARVALHO, 2005, p. 192).

This third category requires the parties to disregard information contained in public disclosures to determine if an invention is novel or has an inventive step in two situations. First, if the disclosure was made or authorized by, or derived from the patent applicant. Second, if it occurred within a certain period of time prior to the date of filling of the

[146] For instance, Article 5, Annex XII, of the EFTA Hong Kong reads as: "the Parties shall ensure in their respective domestic law at least adequate and effective patent protection for inventions in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. This means protection at a level corresponding to that in Article 27.1 of the TRIPS Agreement."
[147] As observed by Leite (2011, p. 10), new uses might occur in the medical field, in which is more common, or in other areas such as in the chemical, agricultural and biotechnological sectors. That is why the term "new use" is also commonly referred to "second use" and "new therapeutic indication" (LEITE, 2011, p. 10).
[148] For instance, Article 13.8.1 of the Australia Korea PTA read as: "Each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. In addition, each Party confirms that patents shall be available for any new uses or methods of using a known product."
[149] These PTAs are the 2004 Morocco-US, 2004 Australia-US, 2004 Bahrain-US, 2006 Oman-US, 2007 Korea-US, 2014 Australia-Korea, 2014 Canada-Korea, and 2015 TPP.

patent application.[150] This period of time varied from 6[151] to 12[152] months in the mapped provisions. From the 35 identified PTAs, 16 provided for such a provision.

The fourth category specifies how some or all of the patentability criteria (novelty, inventive step, industrial applicability), as well as the requirement of sufficient disclosure, are to be applied (WHO, WTO, WIPO, 2013, p. 186). From the 35 identified PTAs, 11 contained this type of provision. The United States is the main country to put forward this kind of provision in their PTAs.[153] From the 11 identified PTAs, the US is a party in 9 of them.[154]

On the specification of the patentability criteria, the US model requires parties to provide that an innovation is "capable of industrial application" if it has a specific, substantial and credible utility. The 2007 Japan-Thailand PTA, by its turn, sets further rules on how parties should implement the patentability criterion of novelty.[155] On the requirement of sufficient disclosure, the US PTA model demands parties to provided that a claimed invention is sufficiently supported by its disclosure.

[150] For instance, Article 18.8.8 of the Bahrain US PTA provides that: "Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure was (a) made or authorized by, or derived from, the patent applicant and (b) occurs within 12 months prior to the date of filing of the application in the Party."

[151] The Korea Vietnam PTA provided for a period of six months prior to the date of filing of the application in the territory of the Party (Art. 12.7.4).

[152] The PTAs' models of Australia and the United States, generally, provides for 12 months prior to the date of filing of the application in the Party.

[153] See, for example, the United States' PTAs with Australia (2004), Morocco (2004), Oman (2006), Colombia (2006), Peru (2006), Korea (2007) and Panama (2007).

[154] Article 18.8.10 of 2007 Korea US PTA is a good example of this kind of provision advanced by the US. It reads as: "Each Party shall provide that a claimed invention: (a) is sufficiently supported by its disclosure if the disclosure allows a person skilled in the art to extend the teaching therein to the entire scope of the claim, thereby showing that the applicant does not claim subject matter which the applicant had not recognized and described or possessed on the filing date; and (b) is industrially applicable if it has a specific, substantial, and credible utility."

[155] Article 130.2 of the 2007 Japan Thailand PTA reads as: "Each Party shall ensure that a claimed invention a claimed invention shall not be new, if it is publicly known, described in a publication distributed or made available to the public through telecommunication line in either Party or in any non-Party before the filing date of the patent application for the invention or, where priority is claimed, the priority date of the application, in accordance with its laws and regulations."

Table 3 - Provisions on Criteria of Patentability					
PTA	Year of Signature	Restatement of TRIPS Article 27.1	Patents for New Uses or Methods	Grace Period	Specification of the TRIPS Patentability Criteria + Sufficient Disclosure
Australia Chile	2008	Art. 17.19		Art. 17.22	
Australia Korea	2014	Art. 13.8.1	Art. 13.8.1	Art. 13. 8. 5	Art. 13.8.8
Australia Malaysia	2012	Art. 13.11.1		Art. 13.11.2	
Australia US	2004	Art. 17.9.1	Art. 17.9.1	Art.17.9.9	Art. 17.9.12 Art.17.9.13
Bahrain US	2004		Art. 14.8.2	Art. 14.8.8	
Canada Korea	2014	Art. 16.12.1	Art. 16.12.1		
Central America EFTA	2013	Annex XIX, Art. 4.1			
Central America Free Trade Agreement (CAFTA)	2004	Art. 15.9.1		Art. 15.9.7	Art. 15.9.10 Art.15.9.11
CAFTA Dominica Republic	2004	Art. 15.9.1		Art. 15.9.7	Art. 15.9.10 Art.15.9.11
Chile US	2003	Art. 17.9.1		Art. 17.9.7	
China Korea	2015	Art. 15.15.1			
China Switzerland	2013	Art. 11.8.1			
Colombia EFTA	2008	Art. 6.9.1			
Colombia US	2006	Art. 16.9.1		Art. 16.9.7	Art. 16.9.10 Art. 16.9.11
EFTA Hong Kong	2011	Annex XII, Art. 5			
EFTA Korea	2005	Annex XIII, Art. 2(a)			
EFTA Peru	2010	Article 6.9.1			
EFTA Philippines	2016	Annex XVIII, Art. 6.1			
EFTA Ukraine	2010	Annex XIII, Art. 4 (a).			
Japan Malaysia	2005	Article 119.1			
Japan Switzerland	2009	Art. 117.1			
Japan Thailand	2007	Art. 130.1			Art. 130.2
Jordan US	2000	Art.17			
Korea US	2007	Art. 18.8.1	Art. 18.8.1	Art. 18.8.7	Art. 18.8.10
Korea Vietnam	2015	Art. 12.7.1		Art. 12.7.4	

Table 4 - Provisions on Criteria of Patentability					
PTA	Year of Signature	Restatement of TRIPS Article 27.1	Patents for New Uses or Methods	Grace Period	Specification of the TRIPS Patentability Criteria + Sufficient Disclosure
Mexico Northern Triangle	2000	Art. 16-25.1			
Mexico Uruguay	2003	Art. 15-23.1			
Morocco US	2004		Art. 15.9.2	Art. 15.9.8	Art. 15.9.11
Nicaragua Taiwan	2006	Art. 17.13.1			
Oman US	2006	Art. 15.8.1(a)	Art. 15.8.1(b)	Art. 15.8.8	Art. 15.8.11
Panama US	2007	Art. 15.9.1		Art. 15.9.7	Art. 15.8.10 Art. 15.8.11
Peru US	2006	Art. 16.9.1		Art. 16.9.7	Art. 16.9.10 Art. 16.9. 11
Singapore US	2003	Art. 16.7.1			
Transpacific Partnership	2015	Art. 18.37.1	Art.18.37.2	Art.18.38	
US Vietnam	2000	Art. 7.1			

3.4.2.2.3 Brazilian Regime

The Brazilian Industrial Property Law incorporated the TRIPS patentability requirements in its Article 8, which reads as: "an invention is patentable if it satisfies the requirement of novelty, inventive step, and industrial application." Those concepts are further regulated under Articles 11 and 12 (novelty), 13 (inventive step) and 15 (industrial application) (IDS, 2005, p. 21).

Article 11 incorporates the principle of absolute novelty for patents.[156] It states that: "an invention [is] considered to be new if [it is] not part of the state of art." According to this principle, the technology is no longer novel and, therefore, cannot be protected if it has already entered in the state of art at any place in the world. The technology must neither be known nor used anywhere else (BARBOSA D., 2003, p. 365-366).

For the purposes of Article 11, "state of art consists of everything that became accessible to the public prior the filling data of the patent, by means of a written or oral description, by use or by any other means, in Brazil or abroad" (Article 11, §1, Law No. 9.279). For the purposes of determining novelty, the Brazilian National Institute of Industrial Property (INPI) takes into consideration the state of art from the date of the patent filling (Article 11, §2, Law No. 9.279).

The Brazilian Industrial Property Law provides for a grace period in which prior disclosure of an invention does not affect its novelty. This grace period secures the inventor that its patent application will not be harmed due to information made public prior to the patent filling (IDS, 2005, p. 30). Article 12 reads as:

> The disclosure of an invention or utility model shall not be considered to be state of the art if it occurred during the 12 (twelve) months preceding the date of filling or of priority of the patent application, if made:
>
> I. by the inventor;
> II. by the National Institute of Industrial Property - INPI, by means of official publication of the patent application filed without the consent of

[156] Alternatively, countries can adopt the principle of relative novelty, according to which novelty can be restricted to a certain geographic region or a specified period. Based on the principle of relative novelty, countries can require, for example, that the invention only needs to be unknown in its territory to be protected (BARBOSA, 2003, p. 366).

the inventor, based on information obtained from him or as a consequence of actions taken by him; or

III. by third parties, based on information obtained directly or indirectly from the inventor or as a consequence of actions taken by him (Article 12, Law No. 9.279).

Under these terms, the Brazilian Industrial Property Law grants a twelve-months grace period for the inventor to file his patent application. The disclosure must have been made by the inventor itself; the INPI; or third parties, based on the information obtained from the inventor (BARBOSA D., 2003, p. 377).

As long as the general conditions of the grace period are respected, the information published by patent offices of other countries where the inventor is also seeking patent protection does not harm the novelty requirement of a patent application in Brazil (IDS, 2005, p. 33; BARBOSA D., 2003, p. 377).[157]

The grace period is particularly important to the national small and medium size enterprises (SMEs) and individual inventors that, due to the lack of familiarity with the patent system, end up disclosing their invention before filling the patent application (IDS, 2005, p. 30). As observed by Denis Barbosa (2003, p. 370), Brazilian inventors commonly disregard the strict rule by which any disclosure not covered by the above-mentioned exceptions prevent them from patenting their invention.

By its turn, Article 13 defines the requirement of "inventive step". It states that: "an invention is endowed with inventive step provided that, to a technician versed in the subject, it is not derived in an evident or obvious way from the state of the art." Thus, the parameter to determine whether the invention is obvious or not is the technician versed in the art (BARBOSA D., 2003, p. 383).

Article 15 defines the "industrial application" requirement. In the relevant part, it reads as: "an invention [is] considered susceptible of industrial application when they can be used or produced in any kind of industry." In this context, industrial application means a change in the natural state, in contrast to simple conceptual operations (BARBOSA D., 2003, p. 381). The term "industrial" shall be interpreted in its broadest sense, covering all branches of productive activity (IDS, 2005, p. 37).

[157] This case falls under Article 12, III, of the Law No. 9.279/96.

The Brazilian Industrial Property Law does not contain any specific provisions permitting or prohibiting the patentability of "new uses" or methods. In practice, INPI applies the general patentability requirements of novelty, inventive step, and industrial application (Article 8, Law No. 9.279/96) to alleged "new uses" or methods of the already patented product other process. This includes new uses for medical products.

Accordingly, the Industrial Property Law is applied in a way that it does not limit the number of "new uses" that would be entitle to patent protection, provided that they fulfill the requirements of patentability and do no incur in any of the cases prohibited by law (Article 10, Law No. 9.279/96) (LEITE, 2011, p. 10).

The INPI's approach is the result of a series of technical discussions with different stakeholders from the civil society and industry that occurred from June to October 2007. After these consultations, INPI issued patent examinations guidelines[158] that allowed for the patentability of "new uses".[159] As a result, "new uses" are in principle subject to patent protection in Brazil (AHLERT; DESIDERIO, 2009).

3.4.2.2.4 Assessment

The Brazilian patent regime contains rules on patentability criteria that require a higher degree of protection than the one established in the TRIPS Agreement. The country adopts the strict principle of absolute novelty for patents. This principle considers that a technology is no longer novel if it has already been incorporated in the state of art in any

[158] See, for example, point 4.18 of the INPI's Resolution No. 169, July 15, 2016; and point 9.1 of the INPI's Guidelines on Patent Applications: aspects of the examinations in the chemical field, 2017.

[159] By the time INPI issued its resolution allowing for the patentability of new uses, the Brazilian Health Regulatory Agency (ANVISA) strongly opposed to the patentability of second uses of approved drugs. The crisis between the government agencies was aggravated by the Industrial Property Law's Article 229-C, which subjects the granting of patents for pharmaceutical products and processes to ANVISA's previous consent. The ANVISA officially had declared that it would not give its consent to second uses of old drugs. Aiming to solve this stalemate, in October 2009, the Federal Attorney General issued a legal opinion (Opinion No. 210/PGF/AE/2009) establishing that INPI is responsible for analyzing the patentability requirements (novelty, inventive step and industrial application); while the ANVISA's activities are restricted to prevent the production and marketing of products potentially harmful to human health (LEITE, 2011, p. 81-87). In 2012, an Inter-Ministerial Working Group (*Grupo de Trabalho Interministerial - GTI*) between INPI and ANVISA was created to coordinate the work of both governmental agencies as regard to the enforcement of Article 229-C. Currently, patent applications of pharmaceutical products and processes are initially analyzed by ANVISA, as regard to the safety of the product, and subsequently, by INPI, as regard to the patentability criteria (ALMEIDA, VASCONCELLOS, 2014, p. 507)

other country. As a general rule, this is assessed from the day the inventor files his patent application in Brazil (Art. 11, Law No. 9.279/96).

The Brazilian patent regime also sets a twelve-months grace period for the inventor to file his patent application (Art. 12, Law No. 9.279/96). During this period the disclosure of the invention will not affect its novelty. This type of rule is also found in PTAs that provide for a six to twelve-months of grace period for patents. The Brazilian Industrial Property Law presents, accordingly, one of the longest grace periods. It can be said that the longer the grace period the better for individual inventors and SMEs. Commonly, they are not used with the novelty requirement that the patent system demands and might end up disclosing their invention before filing the patent application.

The PTAs' provisions on the patentability of "new uses" is particularly used for medicines, when a second therapeutic effect is "identified for an existing medical product" (CORREA, 2016, p. 280).[160] As highlighted by Correa (2016, p. 280), "the patentability of 'second uses' has been accepted in some jurisdictions, such as the in United States and in Europe." The arguments against this practice sustain that "knowing that an existing compound can also be used to treat other diseases or symptoms is not an invention, as the pharmacological effect of such a compound is intrinsic to the compound" (CORREA, 2016, p. 280). On this view, the second use is an existing property simply discovered, often through observation during the marketing of the drug, rather than an invention (CORREA, 2016, p. 280).

In a similar vein, Abbot (2009, p. 9) explains that the practice of "ever greening" normally "involves changing the characteristics of previously developed compounds to provide a modestly improved experience for the patient-consumer." The protection of these small improvements, however, can block generic competition in the same therapeutic group, foreclosing lower prices (ABBOT, 2009, p. 9). These "ever greening" strategies usually occur when the patent expiry approximates. In this point, the innovator engages "in developing variants of the original product, trying to obtain new patents and/or extensions to further indications" (CORIAT; ORSENINGO, 2014, p. 221). As noted by Abbot (2009,

[160] According to Carvalho (2005, p. 188), second uses can be considered under three different scenarios: "(a) the composition of a known drug is modified in order to obtain a new therapeutic result; (b) the same formulation that is already in the market (or a similar one) is found to have new (and eventually unexpected) therapeutic effects; (c) the same formulation (or similar one) has new therapeutic effects if applied on patients in a certain, new manner."

p. 9), minor improvements are welcome, but to focus capital mainly on them "also means a reduced focus on developing new therapeutic classes of treatment."

The Brazilian intellectual property regime also allows for the patentability of "new uses". Even though the Industrial Property Law does not contain any provision in this regard, INPI understands that this type of invention is entitled to patent protection, provided that the patentability requirements (novelty, inventive step and industrial application) are met. The patentability of "new uses" in Brazil also includes pharmaceutical products. The INPI's approach converges with the TRIPS-Plus standards on "new uses" found in the PTAs.

3.4.2.3 Patentable Subject Matter

3.4.2.3.1 TRIPS Agreement

The TRIPS Article 27.1 obliges WTO Members to make patent available for any invention, whether products other processes, in all fields of technology. This rule is subject to optional exclusions set out in TRIPS Articles 27.2 and 27.3. They enable WTO Members to leave out from patent protection certain inventions, "even when they meet general conditions of eligibility" (TAUBMAN; WAGER; WATAL, 2012, p. 97). This exclusion can be applied on three grounds: (i) *ordre public* or morality, (ii) methods of treatment and (iii) plants and animals (TAUBMAN; WAGER; WATAL, 2012, p. 102-103).

TRIPS Article 27.2 allows WTO Members to exclude from patentability inventions that are contrary to *ordre public* or morality.[161] The TRIPS Agreement does not define the meaning of these two expressions. It leaves a certain degree of flexibility to WTO Members to decide which situations are covered, "depending upon their own conception of the protection of public values" (CORREA, 2016, p. 267). According to Taubam, Wager

[161] TRIPS Article 27.2 reads as: "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

and Watal (2012, p. 102), *ordre public* has been understood to represent ideas such as the general security and core values of society. By his turn Correa (2015, p. 267) explains that morality also refers to values prevailing in a society that differ from cultures and countries and change over time.

TRIPS Article 27.2 provides inclusive examples of *ordre public* or morality, by stating that Members may exclude from patentability inventions to "protect human, animal or plant life or health or to avoid serious prejudice to the environment." As observed by Malbon, Lawson and Davison (2014, p. 437), *ordre public* and public morality include these examples, but they are not confined to them. These concepts have a broader scope.

TRIPS Article 27.3 (a)[162] permits WTO Members to exclude from patentability (i) diagnostic, (ii) therapeutic and (iii) surgical methods for the treatment of humans and animals (TAUBMAN; WAGER; WATAL, 2012, p. 103). It applies to "specific class of inventions and to a specific way the inventions are used" (MALBON, LAWSON, DAVISON, 2014, p. 439). This exception does not apply, for example, "to any apparatus used for diagnostics or treatment or to products such as 'diagnostic kits'" (CORREA, 2016, p. 269).

TRIPS Article 27.3 (b)[163] allows WTO Members to exclude from patentability plants, animals and essentially biological process. It is important to stress that, plants may be excluded from patentability, provided that an alternative system of plant variety protection is available. The WTO Members are obliged, nevertheless, to make patent protection available to (i) micro-organisms, (ii) micro-biological processes for the production of plants and animals and (iii) non-biological processes for the production of plants and animals (CARVALHO, 2014, p. 323). It is worth noting that the TRIPS Agreement does not expressly prohibits the granting of patent protection to elements such as deoxyribonucleic acid (DNA) molecules and proteins achieved through genetic engineering (ÁGUIAR JÚNIOR, 2012, p. 59).

[162] TRIPS Article 27.3 (a) reads as: "members may also exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals."
[163] TRIPS Article 27.3 (b) read as: "Members may exclude from patentability: "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. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof […]."

Another important aspect regards the possibility to recognize computer programs (software) as patentable inventions. TRIPS Article 10.1 requires WTO Members to protect computer programs as literary work.[164] For this reason, several WTO Members excluded computer programs *per se* from patentability in their national laws, since they already have to be protected under copyrights (CARVALHO, 2014, p. 274). Nothing in the TRIPS Agreement, however, prohibits WTO Members to consider computer programs as patentable inventions. If they do, Carvalho (2014, p. 274) highlights that they must "provide for two combined mechanisms of protection, because copyright protection must be anyway available."

3.4.2.3.2 PTAs Rules

From the 68 analyzed PTAs, 39 contained rules on patentable subject matter. Due to their different characteristics, one can classify these rules into six categories.

The first category reaffirms the TRIPS Agreement's rules on patentable subject matter. That is to say, this type of provision restates that patents shall be available for any inventions, whether products or process, in all fields of technology, but parties may exclude from patentability: (i) inventions the prevention is necessary to protect *ordre public* or morality; (ii) diagnostic, therapeutic and surgical methods; and (iii) plants, animals and essentially biological process. The aim of this kind of provision is to ensure that nothing in the PTA limits the scope of the exceptions to patentability available in each Party's laws and regulations. From the 39 identified PTAs, 8 included such a provision.[165] All of these 8 PTAs have at least one contracting party that is a developing country.

The second category restates the TRIPS Article 27.2 and 27.3 rules, but it further specifies what should be understood as *ordre public* and morality and the conditions to exclude from patentability diagnostic, therapeutic and surgical methods; and plants,

[164] TRIPS Article 10.1 reads as: "computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971)."
[165] These PTAs are the 2003 Mexico-Uruguay, 2011 Central America-Mexico, 2012 Australia-Malaysia, 2013 Central America-EFTA, 2014 Canada-Korea, 2015 China-Korea, 2015 Korea-Vietnam, and 2015 TPP.

animals and essentially biological process.[166] From the 39 identified PTAs, 9 incorporated such a provision.[167] It is worth noting that 7 of them have EFTA or at least one EFTA Member State (Switzerland) as a party. These are the main actors in putting forward this kind of provision.

The third category does not provide for possible exclusions from patentability permitted under TRIPS, for example, by omitting the possibility to exclude from patentability plants, animals and essentially biological process, as well as diagnostic, therapeutic and surgical methods.[168] Hence, this provision curtails the TRIPS flexibility of optional exclusions of patentable subject matter. From the 39 identified PTAs, 8 included such a provision.[169] The United States is party to 6 of them.[170]

The fourth category requires parties to provide patent protection for plants and/or animals. Different from the other previous categories, the language adopted under this type of provision expressly demands parties to make patents available for plant and/or animal inventions. From the 39 identified PTAs, 10 incorporated such a provision.[171]

There are, however, some singularities within this category that must be highlighted. While some of these provisions require parties to make patent protection for plants and/or

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[166] Article 5 of the 2011 EFTA-Hong Kong illustrates this type of provision. It reads as: "[…] In addition to what is provided for in Article 27.2 of the TRIPS Agreement, the Parties may exclude from patentability: (a) any invention of a methods for treatment of the human or animal body by surgery or therapy or for diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods; and (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof."

[167] These PTAs are the 2000 US-Vietnam, 2004 EFTA-Tunisia, 2005 EFTA-Korea, 2009 Japan-Switzerland, 2010 EFTA-Ukraine, 2011 EFTA-Hong Kong, 2013 China-Switzerland, 2014 EC-Ukraine and 2016 EFTA-Philippines.

[168] For example, the Article 14.8.1 omits the exclusion of plants from patentability by stating that that: "each party may exclude form patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protected *ordre public* or morality, including to protect human, animal, or plant life or health or to avoid serous prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law. Each Party may also exclude from patentability animals and diagnostic, therapeutic, and surgical procedures for the treatment of humans or animals."

[169] These PTAs are the 2000 Jordan-US, 2000 Mexico Northern Triangle, 2003 Singapore-US, 2004 Australia-US, 2004 Bahrain-US, 2006 Oman-US, 2007 Korea-US and 2014 Australia-Korea.

[170] The patentability of medical methods is admitted in the United States and Australia. However, the Patent Act (35 U.S.C. section 287 (c) of the United States grants immunity to medical practitioners from liability from medical process patent infringement (CORREA, 2016, p. 268). Moreover, the US also admits the patentability of animals. After the 1980 Diamond v. Chakrabarty trial, the United States Patent and Trademark Office (USPTO) issued a notice (Animal-Patentability, 1077 Off. Gaz. Pat. Office 24, April 21, 1987) that it would consider non-naturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter, within the scope of 35 U.S.C 101 (AFONSO, 2013, p. 234).

[171] These PTAs are the: 2003 Chile-US, 2004 Morocco-US, 2004 Bahrain-US, 2004 CAFTA, 2004 CAFTA-Dominican Republic, 2006 Colombia-US, 2006 Peru-US, 2007 Panama-US, 2008 Colombia-EFTA and 2010 EFTA-Peru.

animals available without any conditionality,[172] other provisions conditioned it to the legal situation of the matter in the country before the PTA's entry into force.[173] Parties that did not provide patent protection for plants until then shall undertake reasonable efforts to make such protection available. Besides, parties that already provided patent protection for plants and animals after the PTA's entry into force shall maintain such protection.

The fifth category identified in the analyzed PTAs is the opposite of what the previous category provided. It demands parties to prohibit patent protection for plants, animals and essentially biological processes. While the TRIPS Agreement established that WTO Members may exclude these areas from patentability, this provision sets that they cannot be subject of patent protection. From 39 identified PTAs, only the 2014 EC-Ukraine presented such a provision.[174]

The sixth category requests parties to ensure that a patent application is not rejected solely on the ground that the subject matter is related to a computer program (software).[175] As already mentioned above, WTO Members are not obliged to provide patent protection to computer programs, since they have already to be protected under copyright. Hence, WTO Members have the discretion to decide whether computer programs might also be additionally protected by a patent in their national system. This PTA provision does not aim to impose the patentability of computer programs, but rather guarantee that products related to them are not rejected solely on this basis. From the 39 identified PTAs, 5 introduced such a provision.[176] Japan is a party in all of them.

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[172] Article 15.9.2 of 2004 Morocco-US PTA exemplifies this kind of provision. It reads as "each party shall make patents available for the following inventions: (a) plants, and (b) animals."

[173] Article 15.9.2 of the 2004 CAFTA-Dominican Republic exemplifies this type of provision. It states: "nothing in this Chapter shall be construed to prevent a Party from excluding inventions from patentability as set out in Articles 27.2 and 27.3 of the TRIPS Agreement. Notwithstanding the foregoing, any Party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available. Any Party that provides patent protection for plants or animals on or after the date of entry into force of this Agreement shall maintain such protection."

[174] Article 221 of the 2014 EC-Ukraine reads as: "the following shall not be patentable: (a) plant and animal varieties; (b) essentially biological processes for the production of plants or animals […]."

[175] Article 105.1 of the 2011 India-Japan PTA displays this type of provision. It reads as: "neither Party shall require the rejection of any application for patent solely on the ground that the subject matter claimed in the application includes, among other things, a computer programme. Note: This paragraph shall not prejudice the patentability or non-patentability of computer programmes per se which shall be determined in accordance with the laws and regulations of each Party."

[176] These PTAs are the: 2007 Indonesia-Japan, 2008 Japan-Vietnam, 2011 Japan-Peru, 2011 India-Japan, and 2015 Japan-Mongolia.

Table 5 - PTAs Rules on Patentable Subject Matter							
PTA	Year of Signature	Restatement of TRIPS Articles 27.2 and 27.3 (a) (b)	Specification of TRIPS Article 27.2 and 27.3 (a) (b)	Curtailment of the TRIPS Optional Exclusions of Patentable Subject Matter	Availability of Patent Protection for Plants and/or Animals	Prohibition of Patent Protection for Plants, Animals and Essentially Biologic Processes	Non-Rejection of Patent Applications Related to Computer Programs
Australia Korea	2014			Art. 13.8.2 (a) (b)			
Australia Malaysia	2012	Art. 13.11.4					
Australia US	2004			Art. 17.9.2 (a) (b)			
Bahrain US	2004			Art. 14.8.1	Art. 14.8.2		
Canada Korea	2014	Art. 16.12.2					
Central America EFTA	2013	Annex XIX, Art. 4.2 and 4.3 (a) (b).					
Central America Mexico	2011	Art. 16.14					
Central American Free Trade Agreement (CAFTA)	2004				Art. 15.9.2		
CAFTA Dominican Republic	2004				Art. 15.9.2		
Chile US	2003				Art. 17.9.2		
China Korea	2015	Art. 15.15. 2/Art. 15.15.3					
China Switzerland	2013		Art. 11.8.2				
Colombia EFTA	2008				Art. 6.9.3 (b)		
Colombia US	2006				16.9.2		
EC Ukraine	2014		Art. 221.2 Art. 221.5			Art. 221.4 (a) (b)	
EFTA Hong Kong	2011		Annex XII, Art. 5 (a) (b)				
EFTA Korea	2005		Annex XIII, Art. 2 (a) (i) (ii)				
EFTA Peru	2010				Art. 6.9.3 (b)		

Table 6 - PTAs Rules on Patentable Subject Matter							
PTA	Year of Signature	Restatement of TRIPS Articles 27.2 and 27.3 (a) (b)	Specification of TRIPS Article 27.2 and 27.3 (a) (b)	Curtailment of the TRIPS Optional Exclusions of Patentable Subject Matter	Availability of Patent Protection for Plants and/or Animals	Prohibition of Patent Protection for Plants, Animals and Essentially Biologic Processes	Non-Rejection of Patent Applications Related to Computer Programs
EFTA Philippines	2016		Annex XVIII, Art. 6.2/Art.6.3(a) (b)				
EFTA Tunisia	2004		Annex V, Art. 3(a)				
EFTA Ukraine	2010		Annex XIII, Art. 4. (a) (i) (ii)				
India Japan	2011						Art. 105.1
Indonesia Japan	2007						Art. 112.1
Japan Mongolia	2015						Art. 12.7.1
Japan Peru	2011						Art. 174
Japan Switzerland	2009		Art. 117.2/Art. 117.3 (a) (b)				
Japan Vietnam	2008						Art. 86.1/Art. 86.2
Jordan US	2000			Art. 18 (a) (b)			
Korea US	2007			Art. 18.8.2 (a) (b)			
Korea Vietnam	2015	Art. 12.7.2 (a) (b) (c)					
Mexico Northern Triangle	2000			Art. 16-25.3/Art. 16-25.4			
Mexico Uruguay	2003	Art. 15-23.3/Art. 15-23.4					
Morocco US	2004				Art. 15.9.2		
Oman US	2006			Art. 15.8.2			
Panama US	2007				Art. 15.9.2		
Peru US	2006				Art. 16.9.2		
Singapore US	2003			Art. 16.7.1			
Transpacific Partnership	2015	Art. 18.37.3/Art. 18.37.4					
US Vietnam	2000		Art. 7.2 (c)				

3.4.2.3.3 Brazilian Regime

The Brazilian Industrial Property Law does not define what an invention is. Its Article 10 only details what does not constitute an invention (BARBOSA D., 2010, p. 1110; SILVEIRA, 2014, p. 33). According to this provision, the following are not considered to be inventions:

> I. Discoveries, scientific theories, and mathematical methods;
> II. Purely abstract conceptions;
> III. Commercial, accounting, financial, educations, advertising, raffling, and inspection schemes, plans, principles or methods;
> IV. Literary, architectural, artistic and scientific works, or any aesthetic creation;
> V. Computer programs *per se*;
> VI. Presentation of information;
> VII. Rules of games;
> VIII. Surgical techniques and methods, as well as therapeutic or diagnostic methods, for application to 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 germoplasm of any natural living being, and the natural biological processes (Article 10, Law No. 9.279/96).

In line with Denis Barbosa (2010, p. 1109), the list of Article 10 can be divided into three categories: (a) things that constitutes a useful solution (I, II, IV e IX); (b) things that may constitute a useful solution, but are not "concrete" (III, V, VI, VII); and (c) things that are a useful solution and concrete, but the Law chose not to provide patent protection (VIII). All of them were expressly excluded from patent protection on the grounds that they were not considered an invention.

The Brazilian Industrial Property Law, however, makes a distinction between what cannot be object of patent protection, because it is not considered an invention; and what cannot be object of patent protection, because, even though it might constitute an invention, it is, due to political and ethical reasons, expressly prohibited by the law (IDS, 2005, p. 44). The former is enshrined in the previously referred Article 10, while the latter is embedded under Article 18. According to the Article 18 of the Industrial Property Law, it cannot be object of patent protect:

I. anything contrary to morals, standards of respectability and public security, order and health;
II. substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes for obtainment or modification, when resulting from the transformation of the atomic nucleus;[177] and
III. all part of living beings, except transgenic microorganisms that satisfy the three requirements of patentability – novelty, inventive step, and industrial application – provided for in Article 8 and which are not mere discoveries.

All the above-mentioned cases demonstrate situations in which the patent protection might not be granted, even though the object could constitute an invention and meet all the patentability requirements (IDS, 2005, p. 44).

It is important to highlight that previously to the 1996 Industrial Property Law, Brazil did not grant patent protection to chemical and pharmaceutical products (ALMEIDA; VASCONCELLOS, 2014, p. 506).[178] This changed when Brazil had to adapt its legislation to the obligations accorded under the TRIPS Agreement. Differently from other developing countries, such as India,[179] Brazil did not make use of the flexibility provided by TRIPS Article 65.4. This provision allowed WTO Members to postpone to 1st January 2005 the granting of patent protection to areas of technology not previously protected. Brazil did not benefit from this transitional period and promptly incorporated obligation to protect chemical and pharmaceutical products into the 1996 Industrial Property Law (ALMEIDA; VASCONCELLOS, 2014, p. 508).

In brief, the Industrial Property Law allows the patentability of the subject matters that do not fall within the prohibitions of Article 10, and exclusions of Article 18; and meet the requirements set forth in Articles 8 (novelty, inventive step and industrial application) (LOUREIRO, 1999, p. 44). There are, however, some nuances of Brazilian regime regarding patentable subject matters that need to be further elaborated.

[177] For example, the nuclear fusion process (IDS, 2005, p. 46). This provision of the Brazilian Industrial Property Law is also in compliance with the TRIPS Agreement, which provides for a security exception. TRIPS Article 73 (b) (i) states that "nothing in this Agreement shall be construed to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests relating to fissionable materials or the materials from which they derived."
[178] See Article 9 (b) (c) of the Law No. 5.772 of 21 December 1971.
[179] India made full use of the TRIPS Article 65.4 to consolidate its generic pharmaceutical industry. The country only started to provide patent protection for pharmaceutical products after the 10 years of transitional period had elapsed (COSTA et al, 2013, p. 12).

To begin with, it is important to reiterate that Brazilian patent regime clearly prohibits the patentability of plants and animals for not considering them inventions. The Brazilian Industrial Property Law used the flexibility established under the TRIPS Article 27.3 to exclude from patentability, in its Article 10, IX, living beings or biological materials found in nature, even if isolated, including the genome or germoplasm of any living being (AMARAL JÚNIOR, 2011, p. 266; CORREA, 2007, p. 227).[180]

In this regard, Rayol (2003, p. 30) explains that it does not constitute patentable subject matter any substance isolated from nature, be it a natural extract of plants or animals, or even an enzyme or a DNA sequence. In the light of the interpretation given to Article 10, IX, these elements constitute a part of a living being (RAYOL, 2003, p. 30).

However, it is worth noting that genetically modified microorganisms are subject of patent protection. As established under Article 18, III, transgenic modified microorganisms are subject to patent protection, provided that they satisfy the three patentability requirements (novelty, inventive step and industrial application) and are not mere discoveries. For the purposes of the Industrial Property Law, transgenic microorganisms are organisms "that express, by means of direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions."[181]

As clarified by Del Nero (2008, p. 154), the Industrial Property Law allows the patentability if the microorganism is isolated and has its genetic structured altered by the incorporation of human intellectual labor, or even if it is recombined with another biological structure. This new microscopic being constructed in laboratory is considered to be an invention.

However, Boff (2007, p. 2007) highlights that, even though the Brazilian regime does not prohibit the granting of patent protection to transgenic microorganisms and the processes obtained therefrom, it excludes from patentability microorganisms so as found in nature. As explained by Del Nero (2008, p. 153-154), microorganisms found in the nature and its process of isolation for the study of their behavior and structure are considered mere discoveries and, therefore, cannot be object of patent protection. Accordingly, Brazil excludes from patentability the non-transgenic microorganisms (IDS, 2005, p. 47).

[180] Article 10, IV, of the Law No. 9.279/96.
[181] Sole paragraph to Article 18 of the Law No. 9.279/96.

In this context, it is also useful to note that Brazil opted for a *sui generis* system to protect plant varies. In 1997, the country enacted the Plant Variety Protection Law (No. 9.456), which grants protection for plants derived from any genus or species. In order to be object of protection, the plant variety shall meet the following cumulative conditions of novelty, distinctiveness, homogeneity and stability. That is to say, it shall, respectively: (i) not have been commercially exploited yet; (ii) be distinct from other plant varieties; (iii) be all the same or similar; and (iv) keep their characteristics after repeated seed reproductions (DEL NERO, 2008, p. 51).

The protection covers any variety of plant, which had been obtained through a continuous self-pollinating process that passes on the genetic elements and characteristics of a certain species. As reinforced by Denis Barbosa (2007, p. 731), it does not comprehend any animal species or intracellular elements (BARBOSA D., 2007, p. 731).

The term of protection lasts 15 years, counted from the date of the granting of the provisional certificate; and 18 years for vines, fruit, forest and ornamental trees (SILVEIRA, 2014, p. 73).[182] The protection confers breeders the right to, during the term of protection, prevent third parties from producing for commercial purposes, offering for sale or selling without his authorization the plant variety (SILVEIRA, 2014, p. 72).[183]

As observed by Del Nero (2008, p. 51), in order to enforce the Plant Variety Protection Law, the Brazilian government created the National Service for Plant Variety Protection (*Serviço Nacional de Proteção de Cultivares - SNPC*)[184] as the competent body to analyze and grant the protection of plant varieties. Subsequently, the National Plant Variety Registry (*Registro Nacional de Cultivares* - RNC) was established[185] to grant marketing approval of seeds and seedlings of plant varieties protected in Brazil. Both governmental bodies are under the Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA).

A plant variety can only be protected under the protection certificate (*Certificado de Proteção de Cultivar*) issued by the SNPC, never by a patent issued by INPI. The protection certificate covers the material for the reproduction or vegetative propagation of

[182] Article 11 of the Law No. 9.456/97.
[183] Article 9 of the Law No. 9.456/97.
[184] Decree No. 2.366 of 5 November 1997.
[185] MAPA Ministerial Ordinance No. 527 of 31 December 1997.

the whole plant. It ensures the right of the title's holder to reproduce and market the plant variety during the term of protection (AGUIAR JÚNIOR, 2012, p. 61-62).

However, it is also important to stress that the process of genetic improvement of plants can be object of patent protection. As long as they do not derive from mere discovery of the natural reality, the genetic elements obtained through an inventive activity, with industrial application, can be object of patent protection (ÁGUIAR JÚNIOR, 2012, p. 56).

The INPI's Resolution No. 144/2015 (Guidelines for the Examination of Patent Applications in the Biotechnology Area) recognizes that DNA molecules and sequences (polynucleotides) and synthetic proteins (polypeptides) can be object of patent protection, and shall be treated as chemical compounds for examination purposes (ÁGUIAR JUNIOR, 2012, p. 56).[186] In the case of transgenic plants, there is the possibility of double protection. While the protection certificate covers the breeder's activity, the patent protection covers the mutagenic process (ÁGUIAR JUNIOR, 2012, p. 63).

As regard to diagnostic, therapeutic and surgical methods, Article 10, VIII, of the Industrial Property Law expressly exclude them from patentability. The INPI's "Guidelines for the Examination of Patent Applications in the Areas of Biotechnology and Pharmaceutical filed After December 31, 1994"[187] provides for further guidance on this matter (AFONSO, 2013, p. 186).

It clarifies, for example, that "therapeutic methods" are those that imply the cure and/or protection of a disease or malfunction of the human or animal body, or relief of their symptoms.[188] These "therapeutic methods" are not considered an invention in accordance with Article 10, VIII, of the Industrial Property Law. However, non-therapeutic methods may be subject of patent protection, as long as they are of a technical nature; not essentially biological; and not for exclusive individual use. These non-therapeutic methods include, for example, cosmetic methods that only aim at esthetic results.[189]

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[186] See points 4.2.1.2 (Natural Biologic Process) and 7.2 (Transgenic Plants) of the INPI's Resolution No. 144/2015.
[187] These Guidelines was published in the INPI's RPI No. 1648 of 6 August 2002.
[188] See point 2.36.2 of the Guidelines for the Examination of Patent Applications in the Areas of Biotechnology and Pharmaceutical filed After December 31, 1994.
[189] See point 2.36.3 of the Guidelines for the Examination of Patent Applications in the Areas of Biotechnology and Pharmaceutical filed After December 31, 1994.

By its turn, diagnostic methods are those that directly conclude on the health status of a patient as a result of an applied technique.[190] These are not object of patent protection in accordance with Article 10, VIII, of the Industrial Property Law. Nevertheless, methods of obtaining information from the human or animal body that represent only intermediate results, which are not sufficient by their own to determine the appropriate treatment, may be object of patent protection. These include, for example, methods of measuring blood pressure, blood counts and X-Rays.[191]

At last, it is worth being reminded that computer programs (software) *per se* are not subject to patent protection in Brazil. In 1998, the country adopted the Law No. 9.609,[192] which regulates the protection and commercialization of computer programs' intellectual property rights.[193] This Law considers the developer's right over the information as a form of expression and subjects it to the general rules of the Brazilian Copyright Law (Law No. 9.610/98) (SILVEIRA, 2014, p. 63).

The protection covers "information in natural language or encoded, used in automatic machines for the manipulation of data" (WTO, 2017f, p. 89).[194] This type of protection is restricted to expressions transliterated in code and to certain non-literal expressions (BARBOSA D., 2010, p. 1123). The term of software protection is 50 years, counted from 1st January of the following year of its publication or, if this information is not available, counted from its creation.[195]

3.4.2.3.4 Assessment

As a general rule, the TRIPS Agreement allows WTO Members to exclude from patent protection: (i) inventions contrary to *ordre public* or morality, (ii) methods of

[190] See point 2.37.1 of the Guidelines for the Examination of Patent Applications in the Areas of Biotechnology and Pharmaceutical filed After December 31, 1994.
[191] See point 2.37.3 of the Guidelines for the Examination of Patent Applications in the Areas of Biotechnology and Pharmaceutical filed After December 31, 1994.
[192] This new Law of Software revokes the previous Law No. 7.646/87 and, implicitly, its regulating Decree No. 96.036/88 (SILVERIA, 2014, p. 63).
[193] The INPI's Normative Instruction No. 11/2013 establishes the conditions for registering computer programs.
[194] Article 1 of the Law No. 9.609/98.
[195] Article 2, §2, of the Law No. 9.609/98.

treatment; and (iii) plants and animals. The analyzed TRIPS-Plus provisions set a stricter interpretation of those broad terms and even limit them to fewer circumstances. Some PTAs even actively demand the parties to exclude or include a category – such as plants and animals – under patent protection.

The Brazilian patent regime differs significantly from the most of these PTAs rules. The Industrial Property incorporated all optional patent exclusions set out in TRIPS Article 27.2 and 27.3. The country was able to make the most of these TRIPS' flexibilities. The Industrial Property Law excludes diagnostic, therapeutic and surgical methods from patentability. It also prohibits the patentability of plants and animals by not considering them an invention. Brazil does not grant patent protection to human and animal cells. Microorganisms so as found in nature are not object of patent protection, but genetically modified microorganisms as well as the process of genetically modifying them are object of patent protection. The country adopted a *sui generis* system for plant variety protection and no extra patent protection for natural plants is provided.

In Brazil, software is protected through copyrights rules. Computer programs cannot be object of patent protection *per se*, but automatic machines that use them can. Hence, the only identified TRIPS-Plus provision compatible with the Brazilian regime is the one promoted by Japan. This provision ensures that a patent application is not rejected solely on the ground that the subject matter is related to a computer program.

3.4.2.4 Disclosure Requirements of Genetic Resources and Associated Traditional Knowledge

3.4.2.4.1 TRIPS Agreement

The TRIPS Agreement does not require the disclosure of origin of genetic resources and associated traditional knowledge in patent applications. Its Article 29 only demands Members to require patent applicants to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art (TABUMAN; WAGER; WATAL, 2012, p. 100).

However, this issue has already been brought to the WTO, when Member States discussed the relationship between the TRIPS Agreement and the CBD.[196] Some WTO Members defended that the disclosure requirement of genetic resources could constitute an important mechanism to ensure that these two international agreements are applied in a non-conflicting and mutually supportive manner (TABUMAN; WAGER; WATAL, 2012, p. 207).

Therefore, Latin American countries, notably Brazil, Peru and Ecuador raised the "initiative to amend the TRIPS Agreement in order to introduce an obligation to disclose the origin of biological resources in patent applications" (CORREA, 2007, p. 238). Other WTO Members, such as China, Colombia, India, Indonesia, Kenya (on behalf of the African Group), Mauritius (on behalf of African, Caribbean and Pacific – ACP Group), Peru and Thailand further supported the proposal to insert a new Article 29*bis* (ALEMAN, 2014, p. 75).[197]

The proposal, in brief, required WTO Members to oblige "a patent application for an invention relating to genetic or biological materials or to traditional knowledge to provide information on source and origin, prior informed consent and equitable benefit sharing" (TABUMAN; WAGER; WATAL, 2012, p. 209). This revived the debate whether patents could be revoked for not complying with these disclosure requirements. That is, if failure to disclose the source and/or origin, evidence of prior informed consent and evidence of equitable benefit sharing could be a possible ground for patent revocation (MALBON; LAWSON; DAVISON, 2014, p. 522).

The European Union and its Member States, for example, expressed their willingness to discuss the introduction of a multilateral system for disclosure within the TRIPS Council, but were against the possibility to revoke a patent due to failure to meet those requirements. In their view, these requirements should not constitute an obstacle for the granting and the validity of the patents. For them, sanctions should fall outside of the patent law (ALEMAN, 2014, p. 75).

Due to these and other reasons, the proposal has been resisted by other WTO Members. The discussions on this topic have not yet led to any compromise in the context

[196] In its paragraph 19, the 2001 Doha Ministerial Declaration, which set the mandate for negotiations, instructed the TRIPS Council to examine the relationship between the TRIPS Agreement and the CBD.
[197] See WTO Document TN/C/W/59 of 19 April 2011.

of the Doha negotiations (FINK, 2011, p. 401). The issue has also been discussed under other forums, such as in the WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) and the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD). There have also been proposals to amend the Patent Cooperation Treaty (PCT) [198] (HENNINGER, 2010, p. 258).

Currently, there is no multilateral agreement that requires the disclosure of the source or origin of biological resources and associated traditional knowledge in patent applications (YU, 2015, p. 118). As observed by Amaral Júnior (2011, p. 261), the Nagoya Protocol provided its signatories countries broad regulatory space to establish the appropriate domestic procedures in this matter. Each country is responsible for taking the effective national measures to address non-compliance as well as establish checkpoints for the use of the genetic resources (AMARAL JÚNIOR, 2011, p. 261).

3.4.2.4.2 PTA Rules

From the 68 analyzed PTAs, only 5 PTAs provided for the disclosure of the origin of biological resources and/or associated traditional knowledge in patent applications.[199] Even though 14 of the analyzed PTAs provided for some kind of regulation regarding genetic resources, traditional knowledge and even folklore,[200] only 5 of them specifically regulated the disclosure requirements on patent applications.

It is worth noting that all of the 14 PTAs that regulated some aspect of genetic resources and traditional knowledge were concluded between developed and developing countries; or between two developing countries/autonomous customs territory. It can be asserted that this type of provision is particularly found when at least one of the parties is a developing country.

[198] See Swiss proposal to amend the PCT: WIPO/PCT/RWG/4/13, PCT/R/WG/5/11 Rev; PCT/R/W/6/11; and PCT/R/WG/7/7; and in the WIPO IGC: WIPO/GRTKF/IC/11/10.
[199] These PTAs are the 2008 CARIFORUM-EU-EPA, 2008 EFTA-Colombia, 2012 Colombia-Peru-EU, 2010 EFTA-Peru and 2016 EFTA-Philippines.
[200] The others PTAs contain general rules on genetic resources, traditional knowledge an even folklore are the: 2006 Nicaragua-Taiwan, 2010 EU-Korea, 2012 Central America-EU, 2013 Central America-EFTA, 2015 China-Korea, 2013 China-Switzerland, 2014 EU-Ukraine, 2015 Australia-China and 2015 TPP.

Colombia, Peru, EFTA and European Union, are the main actors putting forward provisions on disclosure requirements. As a general rule, the 5 identified PTAs demand the parties involved to require the disclosure of the origin or of source of the genetic resource and/or associated traditional knowledge used in the invention in patent applications.[201] The 5 PTAs differ from each other mainly in relation to their scope. The 2008 CARIFORUM-EU is the only PTA that restricts the disclosure obligation to genetic resources. All the other 4 PTAs extend this obligation to genetic resources and associated traditional knowledge.

All the EFTA Agreements with Colombia (2008), Peru (2010) and Philippines (2016), require the fulfillment of the prior and informed consent (PIC) in addition to the disclosure of the origin or source of the genetic resource and associated traditional knowledge in patent applications. The disclosure, thus, includes a statement that PIC was obtained to access the referred genetic resource and traditional knowledge. The European Union Agreements with CARIFORUM (2008); and Colombia and Peru (2012) does not provide for the fulfillment of the PIC in patent applications.

In the EFTA Agreements with Colombia (2008) and Peru (2010), the parties even agreed to provide for administrative, civil or criminal sanctions if the inventor or the patent applicant willfully makes a wrongful or misleading declaration of the origin or source of the genetic resource.[202] The 2012 Colombia-Peru-EU, by its turn, provides for cooperation activities to train patent examiners to analyze patent applications related to genetic resources and associated traditional knowledge.[203]

[201] The Article 6.5.5 of the 2010 EFTA-Peru illustrates this type of provision. It reads as: "according to their national law, the Parties shall require that patent applications contain a declaration of the origin or source of a genetic resource, to which the inventor or the patent applicant has had access. As far as provided in their national legislation, the Parties will also require the fulfillment of prior informed consent and they will apply the provisions set out in this Article to traditional knowledge as applicable."
[202] See Article 6.5.6 of the 2008 EFTA-Colombia and Article 6.5.6 of the 2010 EFTA-Peru.
[203] See Article 201.8 of the 2012 Colombia-Peru-EU.

Table 7 - PTAs Rules on Disclosure Requirements			
PTA	Year of Signature	Disclosure Requirements of Genetic Resources	Disclosure Requirements of Genetic Resources and Traditional Knowledge
CARIFORUM EU	2008	Art. 150.4	
EFTA Colombia	2008		Art. 6.5.5
Colombia Peru EU	2012		Art. 201.7
EFTA Peru	2010		Art. 6.5.5
EFTA Philippines	2016		Annex XVIII, Art. 10.3

Source: Table elaborated by the author.

3.4.2.4.3 Brazilian Regime

Brazil has recently adopted a new legislation on biodiversity. The Law No. 13.123/2015 and the Decree No. 8.772/2016 regulate the access to genetic resources and traditional knowledge in Brazil. The subject was previously regulated by the Provisional Measure No. 186-16-2001,[204] which was revoked with the entry into force of the new legislation.

The Genetic Heritage Management Council (*Conselho de Gestão do Patrimônio Genético - CGen*) is the competent body, under the Ministry of Environment, to enforce Law No. 13.123/2015.[205] That is to say, CGen is responsible for coordinating the development and implementation of policies for the access to genetic resources and associated traditional knowledge as well as benefit sharing in Brazil (BOFF, 2015, p. 119).[206]

The CGen also manages the National System for the Management of Genetic Heritage and Associated Traditional Knowledge (*Sistema Nacional de Gestão do Patrimônio Genético e do Conhecimento Tradicional Associado - SisGen*) created by the

[204] Under the Provisional Measure No. 186-16-2001, the disclosure requirement of genetic resources and associated traditional knowledge was regulated under Article 31.
[205] Article 6 of the Law No. 13.123/2015.
[206] The CGen is composed by representatives of the federal administration (60%) and representatives of the civil society (40%), which include, in equal terms, representatives of business sector, academics, indigenous populations, local communities and traditional farmers (Article 6 of Law No. 13.123/2015).

Decree No. 8.722/2016. This is an electronic platform designed to, among other functions, registry the access to genetic resources or associated traditional knowledge.[207]

The new Brazilian framework on biodiversity touches industrial intellectual property mainly in two points. First, before applying to any kind of intellectual property protection, studies/researches that use national genetic resources or associated traditional knowledge shall be registered in the SisGen. The registry shall be undertaken previously to the request for any type of intellectual property right protection in Brazil.[208] Second, the granting of an intellectual property right is subject to the authorization of use or the registration of the final product or the reproductive material in the SisGen (INPI, 2017). [209] Those requirements have a direct effect in the patent applications in Brazil.

At the time of writing, the Brazilian Patent Office (INPI) has not yet defined how it will operationalize these procedures (INPI, 2017). Currently, the INPI applies its Resolution No. 134/2006, which requires that patent applications related to national biodiversity products shall inform the origin of the genetic resource or the associated traditional knowledge. The patent applicant shall submit the number and the date of the CGen's authorization to access the genetic resource or associated traditional knowledge (SACCARO JÚNIOR, 2013, p. 38). This ensures that the patent application is in compliance with the law of access, including the access and benefit sharing (VÉLEZ, 2010, p. 237).

According to the INPI's Resolutions No. 207/2009 and No. 208/2009, this information can be provided until the patent examination, not necessarily in the filling of the patent application (SACCARO JÚNIOR, 2013, p. 38). Moreover, INPI may request the applicant to send the CGen's documents, if the patent examiner finds any evidence of use of genetic resources during the patent examination (VÉLEZ, 2010, p. 238). Accordingly, the burden is shared between the patent applicant and patent examiner, "with the latter being in charge of formally requesting the completion of documentation under penalty of suspension of the proceedings" (VÉLEZ, 2010, p. 238). The failure to disclose the genetic

[207] See Article 20 of the Decree No. 8.772/2016.
[208] Article 20, §1, II, of the Decree No. 8.772/2016.
[209] Article 38, §4, Law No. 13.123/2015.

resource and associated traditional knowledge constitutes a ground to revoke the patent after it has been granted (INPI, 2017).[210]

It is important to stress that the disclosure requirements above mentioned only apply to patent applications based on Brazilian genetic resources and traditional knowledge. That is to say, genetic resources and associated traditional knowledge obtained in the Brazilian territory (VÉLEZ, 2010, 237-238). The patent applications based on third countries genetic resources and traditional knowledge are not bound to these disclosure requirements. For example, if an invention is based on a genetic resource from India, there is no obligation to disclose its origin to INPI, since it is not a national genetic resource.

On the author's view, the implementation of this type of provision in way that it does not discriminate between national and foreign genetic resources would be a greater boost in the transparency of patent applications, not only for Brazil, but also for other countries. Therefore, the Brazilian Patent Office should also require the disclosure of genetic resources and associated traditional knowledge accessed in other countries.

3.4.2.4.4 Assessment

The obligation to disclose the origin of the genetic resource or the associated traditional knowledge in patent applications constitutes a relevant mechanism, particularly for mega diverse countries, such as Brazil. Although it does not solve all the problems associated to misappropriation, it does constitute a transparency tool that enables other rights related to the exploitation of genetic resources and associated traditional knowledge to be enforced.

In order to provide effectiveness to the rules on access and benefit sharing, numerous countries and regions have adopted laws providing for disclosure requirements of genetic resources and associated traditional knowledge, particularly in the patent law

[210] As stated in Article 50, IV, of the Law No. 9.279/96, "nullity of a patent shall be administratively declared when: any of the essential formalities that are indispensable for granting has been omitted during the processing thereof."

field (HENNINGER, 2010, p. 293). In accordance with Henninger (2010, p. 293), such requirements can be found in:

> the Andean Community,[211] Belgium,[212] Bolivia,[213] […] China,[214] Colombia,[215] Costa Rica,[216] Denmark,[217] Ecuador,[218] Egypt,[219] the European Community (EC),[220] Germany,[221] India,[222] the Kyrgyz Republic,[223] New Zealand,[224] Norway,[225] Panama,[226] Peru,[227] the Philippines, Portugal, Romania,[228] South Africa,[229] Sweden,[230] Switzerland,[231] Thailand[232] and Venezuela,[233] among other countries.

This obligation is not imposed by the TRIPS Agreement or any other multilateral agreement. All the proposals to amend the TRIPS Article 29 in this sense have failed so far. The countries that perceive this requirement as an important mechanism to ensure the mutual supportiveness between the patent system and the protection of genetic resources have advanced their positions in the PTAs.

As noted by Fink, (2011, p. 401), this shows that the rules set in intellectual property chapters can also advance the interests of developing countries. Peru, Colombia and the Philippines, for example, have persuaded developed countries to insert such a clause in

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[211] Andean Community: Decision No. 486 (Common Intellectual Property Regime) December 2000, Article 26(h); Andean Community Decision 391.
[212] Belgium: Patent Law; Project Law No. 2005-04028/33.
[213] Bolivia: Supreme Decree No. 24676, Article 2, Final Provisions VII.
[214] China: Patent Law Amendment 2008, Article 5(2), 26(5).
[215] Colombia: Executive Decree 720.
[216] Costa Rica: Biodiversity Law 7788, Article 80, Rules on Access (2003), Article 25; amendments made in 2009.
[217] Denmark: Act 412, 31 May 2000 amending Danish Patent Act, paragraph 3; Danish order on Patents and Supplementary Protection Certificates, Order N. 93, Danish Penal Code 163.
[218] Ecuador: Constitution (2008), IP Law.
[219] Egyptian Law No. 82 of 2002 on the Protection of Intellectual Property Rights Article 13.
[220] EC Directive 98/44, Recital 27.
[221] Germany: Patent Act §34a PatG.
[222] India: Patent Law Amendment 2002 Section 10, 25.
[223] Kyrgyz Republic: On Protection of Traditional Knowledge (26 June 2007), Article 8.
[224] New Zealand: Patent Bill 2009 and Section 17 Patent Act (1953).
[225] Norway: Patent Law Amendment 2004, Section 8b.
[226] Panama: Executive Decree No. 25 (28 April 2009), Article 19.
[227] Peru: Biodiversity Law (10 August 2002) Article 4c.
[228] Romania: Implementation of Regulations of Patent Law 64/1991, Rule 14(1)(c).
[229] South Africa: Patent Law Amendment (7 December 2005).
[230] Swedish Patent Decree, Sect. 5a.
[231] Switzerland: Amendment of Patent Law of 22 June 2007, RO 2008 2551, Article 49a.
[232] Thailand: Act on Protection and Promotion of Traditional Thai Medical Intelligence B.E 2542.
[233] Venezuela: Biodiversity Law 2009.

their PTAs. According to Vivas-Eugui and Oliva (2010, p. ix), this is also possible because these developed countries, such as Switzerland and Norway, already have a history of progressive legislation on intellectual property and biodiversity. By any means, the accorded PTA rules are of great relevance to patent law, affecting national examination and granting of patents (VIVAS-EUGUI; OLIVA, 2010, p. ix).

The Brazilian patent system converges with the rules on disclosure requirements that are being established under PTAs. The Law No. 13.123/2015 subjects the granting of any intellectual property rights derived from access to genetic resources and associated traditional knowledge to the previous registration or authorization.[234] INPI already requires that patent applications related to national biodiversity products shall inform the origin of the national genetic resource or the associated traditional knowledge. The Brazilian Industrial Property Law [235] even determines that the omission to provide essential information, such as the origin of the genetic resource and associated traditional knowledge, might revoke the granted patent.

3.4.2.5 Compulsory License

3.4.2.5.1 TRIPS Agreement

The TRIPS Agreement does not use the term "compulsory license",[236] but rather the expression "other use without the authorization of the right holder" (TAUBMAN; WAGER; WATAL, 2012, p. 109). The "other use" refers to use other than that allowed under Article 30 on the exceptions to the patent rights conferred (MALBON; LAWSON; DAVISON, 2014, p. 493). Under this expression, the TRIPS Article 31 provides for the minimum standards that WTO Members shall comply when adopting regulation or issuing a compulsory license.

[234] See Article 47 of the Law No. 13.123/2015.
[235] Article 50, IV, of the Law No. 9.279/96.
[236] In other legal instruments, compulsory license may also be referred as non-voluntary licenses or licenses of right (GERVAIS, 2003, p. 250).

Taubman, Wager and Watal (2012, p. 109) defines this legal mechanism as "a license given by a government authority to a person other than the patent owner that authorizes the production, importation, sale or use of the patent-protected product without the consent of the patent owner." It may be granted "by and administrative authority (e.g., a patent office) or by the courts" (CORREA, 2016, p. 294). Its purpose is to "mitigate the monopolistic rights conferred by a patent and, therefore, […] promote competition by third parties without denying the patent holder's right to receive a remuneration for the use of his invention" (CORREA, 2007, p. 235). Compulsory licenses are, in brief, government authorizations that permit competing companies "to produce a particular product and sell it in completion with the patent holder, on the payment of a license fee" (FINK, 2011, p. 391).

As explained by Yamane (2001, p. 170), TRIPS Article 31 provides for three very different types of case-by-case use without authorization of the right holder: "government use, authorization to use the patented technologies by the third party in the market, and state intervention to rectify anti-competitive behavior, based on national competition laws."

WTO Members are free to determine the grounds on which compulsory license are granted.[237] As highlighted by Hestermeyer (2007, p. 241), "the TRIPS Agreement does not contain any explicit limitations for the grounds on which a compulsory license may be granted." Article 31 does not enumerate all the permissible reasons for the grant of compulsory license. It only provides for some examples (HESTERMEYER, 2007, p. 244). The grounds specifically referred to in the TRIPS Agreement are: (i) emergency and extreme urgency; (ii) anti-competitive practices; (iii) non-commercial use; (iv) dependent patents; (v) and other grounds determined by national law (CORREA, 2016, p. 294).

It is important to stress that there is nothing in the TRIPS Agreement that prohibits WTO Members to grant compulsory licenses on the grounds of non-working of a patent. The obligation to work the patent, explains Carvalho (2014, p. 292-293), "means that patentees have the general obligation to supply the market with the patented articles or the articles manufactured with the patented process." It does not matter if the patented product is imported or locally manufactured.

[237] In this regard, Yamene (2011) highlights that, exceptionally, TRIPS "Article 31(c) limits the grounds for compulsory license of semi-conductor technology only for public non-commercial use, or to remedy a practice determined by judicial or administrative process to be anti-competitive."

In this regard, TRIPS Article 27.1 states that patent rights shall be enjoyable without discrimination as whether products are imported or locally produced. [238] Nevertheless, Correa (2016, p. 297) emphasizes that Art. 27.1 "should not be interpreted as a prohibition of compulsory licenses grounded on the lack of insufficient industrial exploitation of the invention in the country of grant." Accordingly, WTO Members are allowed to adopt the non-working of a patent as a ground to grant a compulsory license in their national legislation.

While TRIPS Article 31 does not exhaust all the reasons for granting a compulsory license, it does impose "conditions and procedures on the circumstances in which compulsory license may be allowed" (MALBON; LAWSON; DAVISON, 2014, p. 495-496). Put another way, "Members may determine the grounds for an award of compulsory license, but must accord with the conditions and procedures required by the TRIPS" (MALBON; LAWSON; DAVISON, 2014, p. 496). The main conditions for granting compulsory licenses include the following:

(i) **Individual Merit**. Decisions on compulsory license shall be considered on its individual merits. They cannot be based on general measures, encompassing, for example, all patents relating to certain kind of technology (Art. 31 (a)) (CORREA, 2016, p. 297).

(ii) **Prior Request**: Except in cases of national emergency, extreme urgency, public non-commercial use and when necessary to remedy anti-competitive practices, the proposed user must have made reasonable efforts to obtain authorization from the right holder within a reasonable period of time (Art. 31 (b)) (GERVAIS, 2003, p. 250; CORREA, 2016, p. 298). The 2001 Doha Declaration on the TRIPS Agreement and Public Health[239] makes clear that each WTO Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency. These include health crises relating to HIV/AIDS, tuberculosis and malaria (TAUBMAN; WAGER; WATAL, 2012, p. 112).

(iii) **Scope and Duration**. The scope and duration of the compulsory license "shall be limited to the purpose for which it was authorized" (Art. 31 (c)). A compulsory license does not have necessarily to run until the end of the patent term. It should be liable to termination as soon as the purposes for which it was granted no longer justify the license (GERVAIS, 2003, p. 251; TAUBMAN; WAGER; WATAL, 2012, p. 113).

[238] Carvalho highlights that while working requirement is not prohibited under the TRIPS, local-working requirement it is. Local working requirement implies the "obligation to carry out the exploitation exclusively in the territory of the country where the patent has been granted" (CARVALHO, 2014, p. 293). According to the author, local working requirement is against the very international idea of free international trade, the WTO and the TRIPS Agreement, because it indeed denies free trade (CARVALHO, 2014, p. 296-297).

[239] See § 5.c of the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

(iv) **Non-exclusivity**. The license holder does not have the right "to prevent the grant of other licenses or the use of the invention by the patent owner" (Art. 31(d)) (TAUBMAN; WAGER; WATAL, 2012, p. 113).

(v) **Predominantly for Domestic Market Supply**. Compulsory licenses "shall be authorized predominately for the supply of the domestic market of the Member authorizing such use" (Art. 31 (f)). The TRIPS Agreement does not completely ban exports of products covered under compulsory license (CORREA, 2016, p. 298). It allows it to remedy anti-competitive practices (Art. 31 (k)) and to permit the export of generic pharmaceuticals to countries lacking sufficient domestic manufacturing capacities (Paragraph 6 System) (TAUBMAN; WAGER; WATAL, 2012, p. 113).

(vi) **Adequate Remuneration**. The patent owner shall be paid "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization" (Art. 31(h)). Special criteria may be applied "in cases of licenses to remedy anti-competitive practices" (Art. 31 (k)) (CORREA, 2016, p. 299).

(vii) **Judicial or Similar Review**. The patent owner shall be entitled to judicial or other higher authority review regarding "the legal validity of any decision relating to the granting of a license as well as [the] determined remuneration [Art. 31 (i) (g)]" (CORREA, 2016, p. 300).

(viii) **Dependent Patents**. Where the use of patent requires the authorization to use a prior patent (dependent patents), a compulsory license my only be issued on the earlier patent "if the invention in the later patent involves an important technical advance and the owner of the earlier patent has a right to obtain a cross-license for the later patent" (Art. 31 (l)) (TAUBMAN; WAGER; WATAL, 2012, p. 113).

According to these conditions, the TRIPS Agreement explicitly allows WTO Members to provide for different forms of compulsory licenses (CORREA, 2007, p. 235). It is also remarkable how TRIPS Art. 31 includes terms that are open to widely different interpretations.[240] As noted by Malbon, Lawson and Davison (2014, p. 497), this loose text allows "interpretations that accommodate the very broad array of existing Member practices expectations, rather than a strict minimum series of standards."

3.4.2.5.2 PTAs Rules

From the 68 analyzed PTAs, 19 contained provisions on compulsory license. According to their peculiarities, these clauses can be divided into six categories. The first category reaffirms the level of flexibility and the conditions that WTO Members shall

[240] For example, Malbon, Lawson and Davison (2014, p. 497) cites the expressions: "reasonable commercial terms and conditions", "national emergency or other circumstances of national emergency", "predominantly for the supply of the domestic market", "adequate protection of legitimate interests", "adequate remuneration", and so on.

respect when allowing for the issuance of compulsory license, so as established under TRIPS Article 31.[241] From the 19 identified PTAs, 6 incorporated such a provision.[242] It is important to stress that all of them were signed between developing countries or between developing and developed countries. PTAs between developed countries did not provide for such a clause.

The second category restricts the issuance of compulsory licenses to the grounds set in the TRIPS Agreement. That is to say, parties shall only allow the issuance of a compulsory license in the case of: (i) emergency and extreme urgency; (ii) anti-competitive practices; (iii) non-commercial use; and (iv) dependent patents.[243] They are prohibited to determine other grounds for compulsory license in their national law. The TRIPS Agreement does not provide for any such limitation, "merely requiring that compulsory licenses be considered on their individual merits" (FINK, 2011, p. 391). From the 19 identified PTAs, 6 incorporated such a clause.[244] The EFTA is a party in all of them.

The third category restricts the issuance of compulsory licenses to fewer grounds than those set in the TRIPS Agreement. It reduces the grounds under which a party may grant a compulsory license to: (i) anti-competitive practices; (ii) emergency and extreme urgency; and (iii) non-commercial use. The parties are then prohibited to issue a compulsory license due to any other grounds, including patent's dependency as provided in the TRIPS Agreement (Art. 31(l)). From the 19 identified PTAs, 3 included such a provision.[245] The United States is a party in all of them.

The fourth category establishes new requirements for compulsory licenses granted on the grounds of non-working of the patent. It determines that compulsory licenses granted due to the failure to work the patent shall only be used to satisfy the domestic market on

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[241] Article 18.41 of the 2015 illustrates this kind of provision. It reads "the parties understand that nothing in this chapter limits a party's rights and obligations under Article 31 of the TRIPS Agreement, any waiver or any amendment to that Article that the parties accept."

[242] These PTAs are the 1995 EC-Turkey, 2000 Mexico-Northern Triangle, 2003 Mexico-Uruguay, 2004 EFTA-Lebanon, 2005 EFTA-Korea and 2015 TPP.

[243] Art. 3, § 8 (Annex V) of the EFTA-Lithuania exemplifies this type of provision. It reads as: "the State Parties to this Agreement shall ensure in their national laws at least […]: compulsory license of patents is only possible under the conditions of Article 31 of the TRIPS Agreement."

[244] These PTAs are the 1995 EFTA-Lithuania, 1998 EFTA-Turkey, 2000 EFTA-Macedonia, 2001 Croatia-EFTA, 2003 Chile-EFTA, and 2004 EFTA-Tunisia.

[245] These PTAs are the 2000 US-Jordan, 2003 Singapore-US and 2004 Australia-US.

reasonable commercial terms.[246] It also provides that importation shall constitute working of the patent. Accordingly, if a patented product is imported, no compulsory license on the ground of non-working of the patent can be issued.

As explained above, the TRIPS Agreement does not provide for further criteria regarding compulsory license granted on non-working's grounds. The Agreement leaves the WTO Members free to determine the reasons that justify the granting of a compulsory license, not even mentioning non-working as a possible reason. This clearly demonstrates the TRIPS-Plus nature of this category. From the 19 identified PTAs, 6 included such a provision.[247] From these 6 PTAs, EFTA is a party to 5.

The fifth category was identified in the 2000 US-Vietnam PTA. It prohibits the parties to grant compulsory licenses of dependent patents (compulsory cross-licensing), except to remedy anti-competitive practices.[248] This provision significantly restricts the TRIPS Art. 31(l), which allows WTO Members to provide for cross-licensing of dependent patents.

The sixth and last category of PTAs' provision on compulsory license was found in the 2014 EU-Ukraine PTA. This clause requires parties to provide for compulsory license of dependent patents in cases where the patent owner cannot exploit a plant variety or a biotechnological invention without infringing a prior plant variety patent. As already alluded above, WTO Members are not obliged to provide for protection of plant varieties through patents. They can choose between patents, an effective *sui generis* system or combination thereof (TRIPS Art. 27.3(b)).

The EU-Ukraine provision does not really contravene the TRIPS rules in terms of compulsory license in the case of dependent patents (Art. 31(l)). It actually applies the TRIPS standards to the situations where the parties provide for plant variety protection under patents rights. While the TRIPS provision in this regard is generally drafted, the EU-

[246] Art. 3, §6, of Annex XV of the 2000 EFTA-Macedonia exemplifies this type of provision. It reads as: "the parties to this Agreement shall ensure in their national laws at least […]: Licenses granted on the grounds of non-working shall be used only to the extent necessary to satisfy the domestic market on reasonable commercial terms."

[247] These PTAs are the 1995 EFTA-Estonia, 1995 EFTA-Latvia, 1998 EFTA-Turkey, 2000 EFTA-Macedonia, 2000 US-Jordan and 2001 Croatia-EFTA.

[248] Ar. 7.8(l) of Chapter II of the 2000 US-Vietnam PTA reads as: "the party shall not authorize the use of the subject matter of a patent to permit the exploitation of another patent, except as a remedy for an adjudicated violation of domestic laws regarding anticompetitive practices."

Ukraine provision specifies the field of application. Hence, the EU-Ukraine PTA deepens the TRIPS regulation, including a TRIPS-Plus provision.

Table 8 - PTAs Rules on Compulsory License							
PTA	Year of Signature	Restatement of TRIPS Art. 31	Restriction of Compulsory License to the grounds of TRIPS Art. 31	Restriction of Compulsory License to fewer grounds than the TRIPS Art. 31	Restrictions of Compulsory License for Non-Working of the Patent	Prohibition of Compulsory License of Dependent Patents, except to Remedy Anti-Competitive Practices	Compulsory License for Plant Dependent Patents
Australia US	2004			Art. 17.9.7			
Chile EFTA	2003		Annex XII, Art. 3 (c)				
Croatia EFTA	2001		Annex VII, Art. 3, §6		Annex VII, Art. 3, §6		
EU Turkey	1995	Art. 4. 2, § 1					
EU Ukraine	2014						Art. 221.11 Art.221.12
EFTA Korea	2005	Annex XIII, Art. 2(c)					
EFTA Lebanon	2004	Annex V, Art. 3(b)					
EFTA Lithuania	1995		Annex V, Art. 3, § 8				
EFTA Estonia	1995				Annex IV, Art. 3, §8		
EFTA Latvia	1995				Annex V, Art. 3, § 8		
EFTA Macedonia	2000		Annex V, Art. 3, § 6		Annex V, Art. 3, § 6		
EFTA Tunisia	2004		Annex V, Art. 3 (b)				
EFTA Turkey IPR Amendments	1998		Art. 3.1, §5		Art. 3.1, §5		
Mexico Northern Triangle	2000	Art. 16-29					
Mexico Uruguay	2003	Chapter XV, Art. 15-26					
Singapore US	2003			Art. 16.7.6			
TPP	2015	Art. 18.41					
US Jordan	2000			Art. 4.20	Art. 4.20 (c)		
US Vietnam	2000					Chapter II, Art. 7.8 (l)	

3.4.2.5.3 Brazilian Regime

The compulsory license under the Brazilian intellectual property regime shall be applied in the light of the Article 5, XXIX, of the 1988 Federal Constitution. This provision states that the "law shall ensure the authors of industrial inventions a temporary privilege for their use […], taking into consideration **the social interest** and **technological and economic development** of the country" (emphasis added). This constitutional provision, as observed by Sichel (2010, p. 152), sets the limits of patent rights, by emphasizing that they shall be in accordance with the principle of the social function of the property and serve for the country's technological and economic development.

The Brazilian Industrial Property Law (No. 9.279/96) regulates the granting of compulsory licenses in its articles 68 to 74. Under the Brazilian regime, compulsory licenses shall always be granted on a non-exclusive basis, and sublicensing shall not be permitted.[249] As this implies, compulsory license cannot exclude the title's holder himself from exploiting his patent or from licensing it to other interested parties (IDS, 2005, p. 147). Besides, the prohibition to sublicense the compulsory license demonstrates the *intuitu personae* nature of this legal act (BARBOSA D., 2010, p. 1636).

Another important characteristic of the Brazilian regime is that "the third party requesting the license must have the economic capacity to use the patented subject matter" (MESIDOR, 2014, p. 26).[250] As a general rule, the licensee shall begin the exploitation of the patent within one year, from the granting of the compulsory license.[251] The patent owner may require the cancellation of the compulsory license if the licensee does not fulfill this obligation.[252]

The Industrial Property Law provides for five situations in which compulsory licenses might be granted, namely: (i) if the patent owner exercises his rights in an abusive manner;[253] (ii) if the patent owner engages in abuse of economic power;[254] (iii) when the

[249] Article 72 of the Law No. 9.279/96.
[250] Article 68, §2, of the Law No. 9.279/96.
[251] Article 74 of the Law No. 9.279/96.
[252] Article 74, §1, of the Law No. 9.279/96.
[253] Article 68 of the Law No. 9.279/96.
[254] Article 68 of the Law No. 9.279/96.

employee who is co-patent owner grants *ex legis* a license to his employer;[255] (iv) in the cases of dependent patents;[256] and (v) national emergency or public interest[257] (BARBOSA D., 2010, p. 1635).

The **abuse of patent rights** occurs when the patent owner exceeds the limits of his exclusive rights or misuses them. It includes, for example, tie-in licenses or sales, discriminatory royalties and territorial and quantitative restrictions (BARBOSA D., 2010, 1641).

The Industrial Property Law expressly states that the non-working of the patent is also a reason for granting a compulsory license.[258] This happens when the patent owner fails to manufacture or incomplete manufacture the object of the patent; or to make full use of the patented process within the Brazilian territory. The patent owner might be excluded from this obligation if he can prove that the working of the patent in Brazil is not economically feasible. In this case, the product can be manufactured abroad and imported to Brazil (GUISE, 2007, p. 134).[259] In addition to those situations, it also constitutes non-working of the patent the commercialization that does not satisfy the needs of the national market.[260]

In 2000, under the WTO Dispute Settlement System, the United States requested consultations with Brazil in respect to its patent local working requirements.[261] The US perceived Article 68 of the Brazilian Industrial Property Law as inconsistent with Brazil's obligations under Articles 27[262] and 28[263] of the TRIPS Agreement and Article III of the GATT 1994 (WTO, 2017g).[264] The United States argued that the Brazilian working

[255] Article 91, §2, of the Law No. 9.279/96.
[256] Article 70, I of the Law No. 9.279/96.
[257] Article 71 of the Law No. 9.279/96.
[258] The Brazilian legislative approach is based on Article 5 (A) (2) of the Paris Convention, which states that: "each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work." It important to highlight that the TRIPS Agreement in its Article 2 incorporate the Articles 1 through 12, and Article 19, of the 1967 Paris Convention (IDS, 2005, p. 137).
[259] Article 68, §1, I, of the Law No. 9.279/96.
[260] Article 68, §1, II, of the Law No. 9.279/96.
[261] Brazil – Measures Affecting Patent Protection (DS199).
[262] In the relevant part, TRIPS Article 27.1 reads as "patents shall be available and patent rights enjoyable without discrimination as to the place of inventions, the field of technology and whether products are imported or locally produced."
[263] TRIPS Article 28 establishes the rights conferred by a patent.
[264] The Article III of the 1994 GATT deals with national treatment on internal taxation and regulation.

requirements discriminated patent owners whose products were imported, but not produced in Brazil (GUISE, 2007, p. 133).

In the consultations, Brazil indicated that its patent regime had the similar type of working requirement provisions as in the United States' regime, more precisely, in the Sections 204[265] and 209[266] of the US Patent Law (GUISE, 2007, p. 133-134). In response, Brazil counter attacked and demanded further consultations on the compatibility of those US provisions with TRIPS Agreement (GUISE, 2007, p. 134).

In July 2001, the United States and Brazil notified the Dispute Settlement Body (DSB) that a mutually satisfactory solution on this matter had been found (WTO, 2017g). The United States agreed to withdraw the WTO panel against Brazil under the following circumstances: (i) Brazil would held prior talks with the US government if it deemed necessary to apply Article 68 to grant compulsory license on patents held by US companies; and (ii) Brazil would not proceed with further dispute settlement action regarding the provisions of the US patent law.[267]

Turning back to the analysis of the Brazilian regime. The compulsory license granted on the grounds of **abuse of economic power** counts on an analysis of the market situation and market power (BARBOSA D., 2010, p. 1643). The Industrial Property Law does not define the grounds and practices for granting this type of compulsory license (MESIDOR, 2014, p. 27). The subject is regulated under the Brazilian Competition Law (Law No. 12.529 of November 30, 2011), which sets, among the actions that constitute a violation to the economic order, the exercise in an abusive manner of a dominant position.[268] As a general rule, a dominant position materialized "when a company or a group of companies is able to unilaterally or jointly change market conditions or when it controls 20% or more of the relevant market."[269]

Law No. 12.529/2011 provides for two circumstances in which compulsory licenses can be granted due to abuse of economic power. First, it can be issued as a penalty for a

[265] The Section 204 of US Patent Law requires that small business firms or nonprofit organizations that have received federal funding to develop an invention shall manufacture it substantially in the United States.
[266] The Section 209 of the US Patent Law requires that inventions derived from federally owned patents to be manufactured substantially in the United States.
[267] See Brazil – Measures Affecting Patent Protection: Notification of Mutually Agreed Solution (Document WT/DS199/4/L/454/IP/D/23/Add.1).
[268] Article 36, IV, of the Law No. 12.529/2011.
[269] Article 36, § 2, of the Law No. 12.529/2011.

violation of economic dominance.[270] This violation must be related to the use of the patent right. Second, it can be issued to prevent occasional negative effects of an act of economic concentration over the affected market[271] (MESIDOR, 2014, p. 26).

As for the **patent co-ownership between employee and employer**, if the employee wants to license the patent, he shall give preference to the employer. The same applies the other way around. If the employer wants to license the patent, he shall give preference to the employee (IDS, 2005, p. 168). In Denis Barbosa's (2010, p. 1635) perspective, this also constitutes a modality of compulsory license, since the patent owners are not completely free to license the patent to whomever they want.

By its turn, the compulsory license granted on the grounds of **dependent patent** relies on an assessment whether the subsequent patent can be exploited without infringing the earlier patent. If it can, there is no dependency relation. If it cannot, there is a dependency relation (IDS, 2005, p. 143). The possibility of granting compulsory license of a dependent patent is regulated under Article 70 of Brazilian Industrial Property Law.[272]

For its purpose, a dependent patent is considered to be a "patent whose exploitation necessarily depends on the use of the object of an earlier patent."[273] The compulsory license shall be granted when: there is a situation of dependency of patent with regard to another; the object of the dependent patent constitutes a substantial technical progress with regard to the earlier patent; and title holder fails to reach an agreement with the patent holder of the dependent patent on the exploitation of the earlier patent (BARBOSA D., 2010, p. 1680).[274]

At last, the compulsory license issued on the grounds of **national emergency** or **public interes**t has specificities that need to be highlighted. The main difference that distinguishes this type of compulsory license from the above discussed situations is that the prevailing interest is not the licensee's interest, but the public interest (BARBOSA D., 2010, p. 1660). On this view, Guise (2007, p. 135) stresses that in this case there is no remedy against abuse or misuse of patent rights, but a prevalence of public over private

[270] Article 37, 38, IV, a, of the Law No. 12.529/2011.
[271] Article 61, § 2, V, of the Law No. 12.529/2011.
[272] The TRIPS Article 31(l) regulates the possibility of granting compulsory license of dependent patents.
[273] Article 70, § 1, of the Law No. 9.279/96.
[274] Article 70, of the Law No. 9.279/96.

interests. Accordingly, the compulsory license for exploiting the patent is granted *ex officio*, not as a result of an interested party's request (BARBOSA D., 2010, p. 1670).

It is also important to stress that the emergency must have national coverage. Local emergencies do not fall within the scope of this type of compulsory license. The public interest, by its turn, pervades all the spheres of the Brazilian State, be it local, regional or federal (BARBOSA D., 2010, p. 1666). However, the compulsory license shall not be issued if the patent holder or his licensee is willing to respond to the national emergency or public interest (BARBOSA D., 2010, p. 1668). If granted, the license must have a limited duration, which can be extended under the necessary circumstances (IDS, 2005, p. 146-147).[275]

The Federal Executive Power is responsible for enacting the declaration of national emergency or public interest.[276] The President has the exclusive competence in this declaratory process (BARBOSA D., 2010, p. 1668). The State's competent authority to meet the public need in question is accountable for assessing the national emergency or public interest. For example, the Ministry of Health is competent for assessing the national emergency and or public interest in situations involving public health (BARBOSA D., 2010, p. 1675). By its turn, the INPI is in charge of implementing the administrative decision, both for arbitrating the remuneration to be paid to the title's holder as well as for registering the compulsory license (BARBOSA D., 2010, p. 1676).

In 2007, Brazil issued the first compulsory license on public interest grounds based on the 1996 Industrial Property Law.[277] This happed after unsuccessful negotiations with the pharmaceutical company Merck to reduce the price of Efavirenz (Sustiva),[278] an

[275] Article 70, §1, of the Law No. 9.279/96.
[276] The Decree No. 3.201, 6 October, 1999, regulates the granting, *ex office*, of compulsory license in cases of national emergency and public interest. This Decree was updates by the Decree No. 4.830, 4 September 2003, which incorporated the flexibilities provided by the TRIPS Agreement and the 2001 Doha Declaration on TRIPS and Public Health (GUISE, 2007, p. 136).
[277] Under the 1971 Brazilian Industrial Property Code (Law No. 5.772, 21 December, 1971), three compulsory licenses were granted in Brazil. It was the first time this legal mechanism was applied since its incorporation into Brazilian intellectual property regime. The first two compulsory licensed were granted on public interest grounds and referred to a vaccine; while the third was granted on insufficient exploitation grounds (GUISE, 2007, p. 127).
[278] Previously, in November 2006, Thailand also granted a compulsory license for Efavirenz and, two months later, for Lopinavir, another antiretroviral (ARV). They were issued for government use and based on the flexibility of TRIPS Agreement. The Brazilian approach was drawn on the Thailand's experience (CORIAT; ORSENIGO, 2014, p. 234).

essential drug for treating HIV/Aids patients (MESIDOR, 2014, p. 26).[279] The measure was justified by the fact that "the short-term impact of Efavirenz on the federal budget would severely compromise the sustainability of Brazil's free and universal HIV/AIDS program" (D'ALMEIDA et. al., 2008, p. 43).

Therefore, the president of Brazil signed the compulsory license order for government use (REICHMAN, 2009, p. 250). The official pharmaceutical laboratory of the Brazilian Ministry of Health, *Farmanguinhos*, was entrusted to produce the generic versions of Efavirenz. While *Farmanguinhos* was preparing to enter into full production, the generics were to be imported from India (CORIAT, ORSENIGO, 2014, p. 234).

For the most part, compulsory license is used as a threat mechanism by Brazilian government to reduce the price of medicines. In other occasions, the Ministry of Health had already threated to issue a compulsory license, but it ended up not really doing it, since the prices of the target patented medicines were substantially reduced (CORREA, 2007, p. 236; GUISE, 2007, p. 137). Accordingly, Brazil uses this mechanism as a bargaining chip in its national policy for setting the prices of medicines. Often, the mere existence of the governmental power to grant a compulsory license is enough to persuade patent holders to lower their prices (HESTERMEYER, 2007, p. 241).

3.4.2.5.4 Assessment

For the most part, the rules identified in the PTAs restrict compulsory license to a very limited set of circumstances (SELL, 2011, p. 454). Differently from the TRIPS Agreement that allows WTO Members to determine the grounds on which compulsory licenses are granted, the PTAs rules fixed those grounds to the ones mentioned in the TRIPS Agreement or even reduced them to fewer circumstances. Besides, even though the TRIPS Agreement does not prohibit WTO Members to grant compulsory licenses on the grounds of non-working of the patent nor expressly regulates the matter, some PTAs have

[279] Brazil is not the country that has granted compulsory licenses after the adoption of the TRIPS Agreement to ensure access to drugs (mainly to HIV/AIDS) at reduced prices. As pointed out by Correa (2016, p. 293), other developing countries, such as Ecuador Eritrea, Ghana, India, Indonesia, Malaysia, Mozambique, Thailand, Zambia and Zimbabwe, have also acted so.

set requirements on this regard. Those provisions are a significant curtailment of the flexibility provided by the TRIPS Agreement, already recognized by all WTO Members in the paragraph 5(b) of the Doha Declaration on TRIPS and Public Health.[280]

The TRIPS-Plus provisions on compulsory license are the ones that differ the most from the Brazilian patent law and practice. The Brazilian Industrial Property Law provides for other circumstances – such as abuse of patent rights, non-working of the patent, public interest – that goes beyond the examples cited by the TRIPS Agreement. Besides, Brazil has already used the TRIPS flexibility to grant a compulsory, on public interest grounds, to provide access to the antiretroviral drug Efavirenz at a lower cost. Moreover, the Industrial Property Law does not limit the compulsory license of dependent patents to remedy anti-competitive practices. It also does not provide for compulsory license of dependent plant patents, since plat varieties are protected under a *sui generis* system in Brazil, not under patent law.

Accordingly, the Brazilian regime differs significantly from the rules on compulsory license that are being set under PTAs. Although stricter rules in this matter do not necessarily results in a better innovation system, it is also important to mention that compulsory licenses shall only be used as a last resort. This mechanism is a clear exception to the patent rights and shall only be used when necessary. The process of issuing a compulsory license is long, expensive and very politically sensitive (D'ALMEIDA et. al., 2008, p. 45). It also sends a wrong message to the industry that spends a lot of time and money to develop, for example, new treatments for existing diseases.

3.4.2.6 Revocation/Forfeiture

3.4.2.6.1 TRIPS Agreement

Revocation and forfeiture are legal instruments that answer the questions of when and on what grounds a patent can be terminated before its expiry date (TAUBMAN,

[280] The paragraph 5(e) of the Doha Declaration reads as: "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."

WAGER, WATAL, 2012, p. 115). The TRIPS Agreement does not provide detailed rules on this issue. Article 32 simply establishes that "an opportunity for judicial review of any decision to revoke or forfeit a patent shall be available."

A WTO Member does not contravene this obligation "if the review is provided by an appellate body within the patent office or other administrative body" (CARVALHO, 2014, p. 481). Gervais (2003, p. 254) clarifies that "the term 'judicial' implies that where the authority in question is not a court of law, it must follow the formal legal procedure of a court."

As observed by Carvalho (2014, p. 417), "what is remarkable in Article 32 […] is not what it says but rather what it does not say." This provision does not define the terms revocation and forfeiture neither list the grounds on which patents can be revoked or forfeited (CARVALHO, 2014, p. 417).[281] Malbon, Lawson and Davison (2014, p. 520) explain that during the negotiations attempts were made to limit the grounds of revocation, but no consensus was achieved. Accordingly, the final agreed text left open the grounds for revocation and forfeiture (MALBON; LAWSON; DAVISON, 2014, p. 520).

However, one may not forget that the TRIPS Agreement, through its Article 2.1, incorporated rules of the 1967 Paris Convention that also relates to the subject (YOMANE, 2011, p. 168). These rules set some binding limits on the grounds of revocation and forfeiture. They include:

> (i) a grace period of at least six months to pay outstanding fees;[282]
> (ii) the prohibition of forfeiture on working-requirement's grounds, when the patent holder imports patent-protected products manufactured in another country;[283] and
> (iii) the prohibition of forfeiture to prevent abuse of exclusive rights, except in cases where the grant of compulsory license would not have been sufficient to prevent such abuses [284] (MALBON; LAWSON;

[281] The expression revocation means "the result of an act repealing, annulling, withdrawing, rescinding, or cancelling a right"; while forfeiture "takes place when a right is lost as penalty of crime, neglect, etc." (UNCTAD-ICTSD, 2005, p. 414). According to Malbon, Lawson and Davison (2014, p. 519), the distinction between this two words is that "'revoke' deals with granted patents which should not have been granted (such as an application which should have failed as it did not satisfy a threshold requirement of, say, novelty), while 'forfeit' deals with taking away a valid grant (such as taking away the rights conferred because of a failure to work the invention."

[282] Article 5bis (1) of the 1967 Paris Convention.

[283] Article 5A (1) of the 1967 Paris Convention.

[284] Article 5A (2) and (3) of the 1967 Paris Convention.

DAVISON, 2014, p. 520; TAUBMAN; WAGER; WATAL, 2012, p. 115).[285]

Hence, WTO Members shall not only observe their TRIPS obligations, but also take into consideration the other rules incorporated from the 1967 Paris Convention. In sum, TRIPS Article 32 does not set out all possible cases or other substantive conditions or requirements for revocation or forfeiture, leaving considerable flexibility to WTO Members to determine their grounds (MALBON; LAWSON; DAVISON, 2014, p. 523).

3.4.2.6.2 PTAs Rules

From the 68 analyzed PTAs, 18 incorporated provisions on revocation.[286] It is important to stress that no agreement used the term "forfeiture", in the sense of taking away a valid patent. All the identified PTAs only addressed the subject using the term "revocation". It is also important to highlight that no PTA restated the TRIPS standard on revocation/forfeiture. Except for the 2015 Australia-China PTA,[287] all identified PTAs departed from a stricter standards of patent revocation than the one established under the TRIPS Agreement. In general, these provisions limited the grounds on which one can revoke a patent. They differ from each other on the situations in which the parties may allow patent revocation. From their analysis, one can classify them into 5 categories.

[285] In addition to those, Carvalho (2014, P. 480-481) defends the interpretation that the TRIPS Agreement has other implicit grounds on which governments may revoke patents. These include the invalidity of the patent because: (i) its subject does not qualify as an invention (Art. 27.1); (ii) its specification do not comply with the mandatory formal requirement of full disclosure (Art. 29.1); and (ii) because the invention falls under one of the exclusions from patentability (Art. 27.2 and 27.3).

[286] These PTAs are the 2000 US-Vietnam, 2000 Mexico Northern Triangle, 2003 US-Singapore, 2003 Chile-US, 2004 Morocco-US, 2004 Australia-US, 2004 Bahrain-US, 2004 CAFTA, 2004 CAFTA-Dominica Republic, 2006 Oman-US, 2006 Peru-US, 2006 Colombia-US, 2007 Panama-US, 2007 Korea-US, 2008 Australia-Chile, 2014 Australia-Korea, 2015 Australia-China and 2015 TPP.

[287] The 2015 Australia-China PTA is the only identified agreement that includes a provision on patent revocation, which does not limit the grounds on which one may apply it. Its Article 11.9 (c) and (d) merely state that each party shall provide an opportunity for interested parties to seek revocation and that the decisions in this regard shall be reasoned and in writing.

The first category demands the parties to allow for patent revocation only when the grounds that would have justified a refusal to grant the patent exist.[288] From the 18 identified PTAs, 2 included such a provision.[289] This is the most stringent type of clause, since it restricts to this sole premise the situations in which one may revoke a patent. Surprisingly, this provision was not only found in a PTA between a developing and a developed country (US-Vietnam), but also in a PTA among developing countries, the 2000 Mexico-Northern Triangle PTA, which, in addition to Mexico, comprehends Guatemala, El Salvador and Honduras.

The second category requests the parties to limit the grounds on which one can revoke a patent to two situations, namely: (i) on the grounds that would have justified a refusal to grant the patent, or (ii) on the basis of fraud. From the 18 identified PTAs, only the 2003 Chile-US PTA contained such a provision.[290]

The third category limits the grounds on which one can revoke a patent to three situations, namely: (i) on the grounds that would have justified a refusal to grant the patent, (ii) on basis of fraud, or (iii) if the patent is used in a manner determined to be anticompetitive. From the 18 identified PTAs, only the 2008 Australia-Chile PTA incorporated such a provision.[291]

The fourth category limits the grounds on which one can revoke a patent to four situations, namely: (i) on the grounds that would have justified a refusal to grant the patent, (ii) on basis of fraud, (iii) misrepresentation, or (iv) inequitable conduct. From the 18 identified PTAs, 6 contained such a provision.[292]

The fifth category limits the grounds on which one can revoke a patent to five situations. This provision states that a patent may only be revoked: (i) on the grounds that

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[288] Art. 16.30 of the 2000 Mexico-Northern Triangle PTA illustrates this type of provision. It reads as: "[…] each party may revoke or cancel a patent only when there are reasons that would have justified the refusal to grant it."

[289] These PTAs are the 2000 Mexico-Northern Triangle and the 2000 US-Vietnam.

[290] Art. 15.9.5 and footnote 24 to Art. 15.9.5 of the 2003 Chile-US PTA reads as: "a party may revoke or cancel a patent only when the grounds exists that would have justified a refusal to grant the patent. Fraud in obtaining a patent may constitute grounds for revocation or cancellation."

[291] The 2008 Australia-Chile PTA, in its Article 17.21.2, provides that: "each party shall provide that a patent may only be revoked or cancelled on grounds that would have justified a refusal to grant the patent." In the sequence, Article 17.21.3 states that: "notwithstanding paragraph 2, a party may also provide that a patent may be revoked or cancelled on the basis of fraud, or that the patent is used in a manner determined to be anticompetitive in a judicial proceeding."

[292] These PTAs are the 2004 Australia-US, 2004 Morocco-US, 2004 Bahrain-US, 2006 Oman-US, 2007 Korea-US and 2014 Australia-Korea.

would have justified a refusal to grant the patent, (ii) on basis of fraud, (iii) misrepresentation, (iv) inequitable conduct, or (v) when the grant of a compulsory license would not have been sufficient to prevent abuses (Article 5.A (3) of the 1967 Paris Convention).[293] From the 18 identified PTAs, 6 provided for such a provision.[294] It is worth noting that the US is a party in all of these 6 PTAs.

The sixth category limits the grounds on which one can revoke a patent to five situations. This provision establishes that a patent may only be revoked: (i) on the grounds that would have justified a refusal to grant the patent, (ii) insufficient or unauthorized amendments to patent specifications; (iii) non-disclosure of prescribed materials; (iv) fraud; and (v) misrepresentation. This type of provision was only identified in the 2003 US-Singapore PTA.[295]

In comparison with the previous provisions on revocation, the fifth and sixth categories provide the greater degree of flexibility, since they explicitly list five cases in which a patent may be revoked.

[293] The Article 16.9 of the 2006 US-Colombia illustrates this type of provision. It reads as: "without prejudice to Article 5.A(3) of the Paris Conventions, each Party shall provide that a patent may be revoked or nullified only on grounds that would have justified a refusal to grant the patent according to its laws. However, a Party may also provide that fraud, misrepresentation, or inequitable conduct may be the basis for revoking, nullifying, or holding a patent unenforceable."

[294] These PTAs are the 2004 CAFTA, 2004 CAFTA-Dominican Republic, 2006 Peru-US, 2006 Colombia-US, 2007 Panama-US and 2015 TPP.

[295] The Article 16.7.4 of the 2003 US-Singapore reads as, in the relevant part: "each party shall provide that a patent may only be revoked on grounds that would have justified a refusal to grant the patent, or that pertain to the insufficiency of or unauthorized amendments to that patent specification, non-disclosure or misrepresentation of prescribed material particulars, fraud, and misrepresentation."

Table 9 - PTAs Rules on Revocation					
PTA	Year of Signature	Right to seek revocation and need to the decisions be reasoned and in writing.	Revocation only on grounds that would have justified a refusal to grant the patent	Revocation only on grounds that would have justified a refusal to grant the patent or on basis of fraud	Revocation only on grounds that would have justified a refusal to grant the patent, on basis of fraud or anti-competitive use
Australia Chile	2008				Art. 17.21
Australia China	2015	Art. 11.9(c)(d)			
Chile US	2003			Art. 15.9.5	
Mexico Northern Triangle	2000		Art. 16-30		
US Vietnam	2000		Art. 7.6		

Table 10 - PTAs Rules on Revocation				
PTA	Year of Signature	Revocation only on grounds that would have justified a refusal to grant the patent, on basis of fraud, misrepresentation or inequitable conduct	Revocation only on grounds that would have justified a refusal to grant the patent, on basis of fraud, misrepresentation or inequitable conduct, without prejudice to Article 5.A(3) of the Paris Convention	Revocation only on grounds that would have justified a refusal to grant the patent; insufficient or unauthorized amendments to patent specifications; non-disclosure of prescribed materials; fraud; and misrepresentation
Australia Korea	2014	Art. 13.8.4		
Australia US	2004	Art. 17.9.5		
Bahrain US	2004	Art. 14.8.4		
Central American Free Trade Agreement (CAFTA)	2004		Art. 15.9.4	
CAFTA Dominican Republic	2004		Art. 15.9.4	
Colombia US	2006		Art. 16.9.4	
Korea US	2007	Art. 18.8.4		
Morocco US	2004	Art. 15.9.5		
Oman US	2006	Art. 15.8.4		
Panama US	2007		Art. 15.9.4	
Peru US	2006		Art. 16.9.4	
US Singapore	2003			Art. 16.7.4
Transpacific Partnership	2015		Art. 18.39	

3.4.2.6.3 Brazilian Regime

The Brazilian regime provides for both patent forfeiture and revocation. A patent can be revoked if it is granted in contrary to the provisions of the Industrial Property Law.[296] This is a broad rule, which covers cases in which a patent can be revoked due to substantive flaws (such as, not meeting the patentability criteria of novelty, inventive step and industrial application) and formal flaws (such as, the omission of any essential formalities indispensable for the patent granting) (IDS, 2005, p. 115-116).

The patent can be totally revoked, when it concerns all the claims; or partially, when it concerns only some of the claims (RAMOS; GUTERRES, 2016, p. 108).[297] The condition for the partial revocation is that "the subsisting claims themselves constitute patentable subject matter."[298] This norm ensures that patents are not entirely invalidated as long as they constitute a patentable invention (IDS, 2005, p. 116).

A patent can be revoked through administrative or judicial procedures. Even though the Industrial Property Law does provide for an exhaustive list of grounds on which a patent can be revoked, it does set the situations in which a patent can be administratively revoked. Its Article 50 subjects the administrative revocation to the situations in which: (i) any of the legal requirements were not satisfied; (ii) the specifications are not clearly and sufficiently described[299] and the claims do not clearly and precisely defines the subject matter of protection;[300] (iii) the object of patent protection extends beyond the application originally filed; and (iv) any of the essential formalities that are indispensable to the patent granting has been omitted (BARBOSA D., 2010, p. 1712).

The effects of the administrative patent revocation retroact to the date of the filing of the patent application (RAMOS; GUTERRES, 2016, p. 108). In other words, the revocation has *ex tunc* effects (IDS, 2005, p. 116). The patent produces all its effects while the decision on its revocation has not yet been issued. Patents enjoys a presumption (*juris tantum*) of validity (BARBOSA D., 2010, p. 1712).

[296] Article 46 of the Law No. 9.279/96.
[297] Article 47 of the Law No. 9.279/96.
[298] Article 47 of the Law No. 9.279/96.
[299] Article 24 of the Law No. 9.279/96.
[300] Article 25 of the Law No. 9.279/96.

In the cases in which a patent is revoked due to an infringement regarding the patent authorship, the real inventor can take legal action to demand the adjudication of the patent (BARBOSA D., 2010, p. 1712).[301] That is, the real inventor can request in court the transfer of the ownership of the patent award issued by INPI to him (RAMOS; GUTERRES, 2016, p. 108).

With regard forfeiture, the Industrial Property Law provides that it shall be applied if, after two years from the granting of first the compulsory license, this period has not been sufficient to prevent or remedy abuse or disuse of the patent.[302] As such, a patent can only be forfeited if it is cumulatively: (i) based on the lack of use or abuse; and (ii) already object of a compulsory license; which (iii) has not been able to prevent or remedy these conducts after two years from its granting. The forfeiture shall not apply if there are justifiable reasons, such as effective arrangements to start working the patent. This rule is substantially in accordance with Article 5.A(3) of the Paris Convention. (IDS, 2005, p. 161)

A patent can only be forfeited through an administrative process before the INPI. This lawsuit shall be instituted *ex officio* by INPI itself or at the request of any party having a legitimate interest in the case. In the proceedings instituted upon request, INPI may proceed with the lawsuit if the legitimate interested party abandons it (RAMOS, GUTERRES, 2016, p. 129).[303] The INPI may perceive that the continuation of the lawsuit is necessary to defend a public interest (IDS, 2005, p. 161). The decision on a patent's forfeiture has effects from the date of the request or from the date of the publication of the *ex officio* institution of the proceedings (RAMOS, GUTERRES, 2016, p. 129).[304]

3.4.2.6.4 Assessment

The TRIPS Agreement does not provide for detailed rules on patent revocation and forfeiture. The Agreement does not set the grounds on which a patent can be object of

[301] Article 49 of the Law No. 9.279/96.
[302] Article 80 of the Law No. 9.279/96.
[303] Article 80, §2, of the Law No. 9.279/96.
[304] Article 83 of the Law No. 9.279/96.

revocation or forfeiture. It simply requires a chance for judicial review on any decision on this regard.

The analyzed PTA's rules, in contrast, establish the grounds on which a patent can be revoked. The level of flexibility of these provisions varies in accordance with the number of situations in which this can occur. The greater the number of situations, the more flexible the provision is. The identified basis for revoking a patent include: (i) the grounds that would have justified a refusal to grant the patent; (ii) insufficient or unauthorized amendments to patent specifications; (iii) non-disclosure of prescribed materials; (iv) fraud; (v) misrepresentation; (vi) inequitable conduct; and (vii) when the grant of a compulsory license would not have been sufficient to prevent abuses (Article 5.A (3) of the 1967 Paris Convention).

In Brazil, as a general rule, a patent can be revoked if it is granted in contradiction to the provisions of the Industrial Property Law. Due to the broad scope of Article 46, the Brazilian patent regime covers virtually all the above-mentioned grounds for patent revocation. More specifically, Article 50, I, of the Industrial Property Law provides that a patent can be administratively revoked if any of the legal requirements were not satisfied. This provision allows for the revocation on the grounds that would have justified a refusal to grant the patent.

Moreover, Article 50, IV, states that a patent can also be administratively revoked if any of the essential formalities that are indispensable for granting have been omitted. In this case, the non-disclosure of prescribed materials could also constitute a cause for patent revocation.

By its turn, Article 32 states that "in order better clarify or define a patent application, the applicant may make changes until the time of the request for examination, provided these are limited to the subject matter initially disclosed in the application." As such, any insufficient or unauthorized amendments to patent specifications that contravene this Industrial Property Law provision could also constitute a ground for patent revocation.

Furthermore, Article 216 states that the acts set forth in the Industrial Property Law shall be taken by the parties or by their duly qualified attorneys in fact. As it stands, the infringement of this rule through misrepresentation could also constitute a reason for patent revocation.

It is also useful to note that, while some PTAs allows a patent to be revoked on the grounds that the grant of a compulsory license has not been sufficient to prevent abuses; the Brazilian regime considers this situation as a premise for patent forfeiture. Although Article 5.A(3) of the 1967 Paris Convention[305] uses exactly the term "forfeiture" to describe this situation, the identified PTAs do not seem to make a difference between both legal institutes.

In brief, under the Brazilian regime, the revocation of a patent depends on a specific reasoning of each individual case. There must be a case-by-case analysis to assess how and to what extent an action violates a provision of the Industrial Property Law. Given the broad coverage of situations in which a paten can be revoked, the Brazilian patent regime differs significantly from the PTAs rules that set a limited number of them.

3.4.2.7 Term of Protection

3.4.2.7.1 TRIPS Agreement

According to TRIPS Article 33, "the term of protection available shall not end before the expiration of the period of twenty years counted from the filling date." The filling date is the date of the patent application (TAUBMAN; WAGER; WATAL, 2012, p. 114). As highlighted by Correa (2016, p. 300), "there is no obligation to extend patent rights beyond this term, even if the patent holder has not been able to exploit the invention during a long period after the application." In the same line, Taubman, Wager and Watal (2012, p. 115) reiterate that the "TRIPS Agreement does not require the grant of patent term extension, and thus a minimum obligatory standard the available term need only run to twenty years from the filing date."

[305] The Article 5 (A) 3 of the 1967 Paris Convention reads as: "forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license."

For better understanding the TRIPS-Plus provisions on patent term of protection, it is also important to highlight the meaning of footnote 8 to Article 33.[306] This provision makes clear that the patent offices of WTO Members are not obliged to undertake substantive examination of patent applications. As explained by Carvalho (2014, p. 493), nothing in the TRIPS Agreement prohibits its Members to undertake this task by adhering to a regional patent office or by relying on the work done by a patent office of another country. Hence, WTO Members are allowed to simply re-register a patent granted in another country (CARVALHO, 2014, p. 493).

The TRIPS Article 33 must be read in conjunction with Article 62.2, which states that procedures for granting patents may not be unreasonably delayed in a manner that significantly curtails the period of protection (CARVALHO, p. 491, 2014).[307] This provision, however, does not require WTO Member States to provide for an extension of the patent term of protection to compensate delays in the examination of patent applications (CORREA, 2007, p. 228). As highlighted by Carvalho (2014, p. 671), Article 62.2 does not call for measures that may "compensate" for unreasonable delays, but it calls for measures that "avoid" unreasonable delays. Besides, TRIPS Article 62.2 refers to unreasonable delays in the granting of patents, not in the issuance of administrative marketing authorizations of patented products (CARVALHO, 2014, p. 674).

3.4.2.7.2 PTAs Rules

From the 68 analyzed PTAs, 46 incorporated rules related to the term of patent protection. It is important to highlight that any agreement directly increased the TRIPS term of protection of 20 years. That is to say, none of the PTAs expressly required parties to grant a 25 or 30 years of patent protection. The extension of the patent term of protection is carried out through provisions that demand countries to compensate for

[306] Footnote 8 to TRIPS Article 33 reads as: "it is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filling date in the system of original grant."

[307] In its integrity, TRIPS Article 62.2 reads as: "where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection."

unreasonable delays in the granting process, marketing approval, as well as through supplementary protection certificates for certain products. The identified PTAs provisions on patent term extension can be divided into 10 main categories.

The first category reaffirms the TRIPS level of patent term of protection. In other words, it only restates that parties shall provide a term of protection for patents that shall not end before the period of 20 years, counted from the date of filling. In this category, no further language on term adjustment is provided. From the 46 identified PTAs, 8 included this type of provision.

It is interesting to note that this type of provision is mainly found in the PTAs signed just before the entry into force of the TRIPS Agreement (1st January 1995). No such provision is found in PTAs signed after 2003. From the 8 PTAs, 6 of them were signed between developed countries and developing countries/economies in transition in the period from 1995 to 2000.[308] Only two of them were signed between developing countries.[309]

One may not forget that the TRIPS Agreement (Articles 65.2 and 65.3) established a transition period of 5 years for developing countries and economies in transition to implement the TRIPS obligations until 1st January 2000. The Agreement (Article 65.4) also allowed developing countries that before the entry into force of TRIPS did not grant patent protection for a particular field of technology to delay the implementation of this obligation until 1st January 2005. That is to say, developing countries had a 10 years of transition period to provide patent protection for areas of technology that they previously did not provide, such as for pharmaceutical and agrochemical products.

The language found in at least 2 of these PTAs is clearly aimed at curtailing this TRIPS flexibility. The PTAs signed by Turkey with the European Union (1995)[310] and with the EFTA (1998)[311] required the parties to ensure the patentability of pharmaceutical products and processes before 1st January 1999. In these terms, Turkey compromised to provide patent protection for pharmaceuticals before the time limit established under the TRIPS Agreement.

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[308] These PTAs are the 1995 EC Turkey, 1995 EFTA Estonia, 1995 EFTA Latvia, 1995 EFTA Lithuania, 1998 EFTA Turkey and 2000 US Vietnam.
[309] The 2000 Mexico Northern Triangle PTAs and the 2003 Mexico Uruguay.
[310] Article 6 of the 1995 EC-Turkey PTA
[311] Article 3.2 of the 1998 EFTA-Turkey PTA.

The second category requires parties to provide the means to, at the request of the patent owner, adjust the term of the patent to compensate for unreasonable delays occurred during the patent granting. This is a general rule that does not specify the field of technology nor the product. From the 46 identified PTAs, 13 incorporated this kind of provision.[312] The United States is a party in all of these 13 PTAs. The language adopted is practically the same in all of them. For that reason, it can be asserted that this category reflects an US model of patent term extension.[313]

For the purposes of this provision, an unreasonable delay includes a downtime in the issuance of the patent of more than 4 or 5 years from the date of filling of the application, or 2 or 3 years after a request for examination of the application has been made, whichever is later. These periods of 4 or 5 years,[314] or 2 or 3 years[315] vary in accordance with the US PTA's partner(s). Delays in the granting process caused by patent applicant or any opposing third party are not included in the determination of this period.

The third category demands parties to extend the patent term of protection to compensate unreasonable delays in the patent issuance in another territory. This provision applies when a country permits the grant of a patent on the basis of a patent granted in another country. As explained above, footnote 8 to TRIPS Article 33 allows WTO

[312] Under this second category, it is important to highlight a specific feature of the US PTAs with Colombia (2006), Peru (2016) and Panama (2007). These agreements provide for a compensation for unreasonable delays in the issuance of patents in all fields of technology, except for pharmaceuticals products. In other words, Colombia, Peru and Panama safeguarded themselves from having to extend this obligation to pharmaceuticals products. Both PTAs used the term "may" – not "shall" – to indicate the not binding commitment to provide the means to compensate for unreasonable delay in the issuance of a patent for pharmaceutical product. For all the other fields of technology, this provision is binding.

[313] Article 17.9.8 (a) of the 2004 Australia US PTA is a good example of this US model of patent term extension provision. It reads as follows: "If there are unreasonable delays in a Party's issuance of patents, that Party shall provide the means to, and at the request of a patent owner, shall, adjust the term of the patent to compensate for such delays. An unreasonable delay shall at least include a delay in the issuance of a patent of more than four years from the date of filing of the application in the Party, or two years after a request for examination of the application has been made, whichever is later. For the purposes of this paragraph, any delays that occur in the issuance of a patent due to periods attributable to actions of the patent applicant or any opposing third person need not be included in the determination of such delay."

[314] The US PTAs with Singapore (2003), Australia (2004), Bahrain (2004), Morocco (2004), Korea (2007) and Oman (2006) establish a more than 4 years period from the filling date; while the US PTAs with/within Chile (2003), CAFTA (2004), CAFTA-Dominican Republic (2004), Colombia (2006), Peru (2006), Panama (2007) and TPP (2015) establish a more than 5 years period from the filling date.

[315] The US PTAs with Singapore (2003), Australia (2004), Bahrain (2004), Morocco (2004) and Oman (2006) provide for a two years period after a request for examination of the application, while the US PTAs with/within Chile (2003), CAFTA (2004), CAFTA-Dominican Republic (2004), Colombia (2006), Korea (2007), Peru (2006), Panama (2007) and TPP (2015) provide for a three years period after a request for examination of the application.

Members to rely on another Member's system to issue a patent. From the 46 identified PTAs, 3 incorporated such a provision.[316] All 3 of them have the US as a party.[317]

The fourth category requires parties to provide the means to compensate the patent owner for unreasonable delays occurred during the marketing authorization. This is a general rule that does not specify the field of technology nor the product subject to the marketing approval. From the 46 identified PTAs, only the 2003 EFTA-Chile PTA included such a rule.[318]

The fifth category compels the parties to provide additional protection of up to five years for pharmaceutical and plant protection products. It does not subject this extension of the patent term of protection to any delay in the granting of the patent or in the marketing approval process. This type of provision was found in the PTAs signed by EFTA with Macedonia (2000) and Croatia (2001).

The sixth category demands the parties to make available an adjustment of the patent term of pharmaceutical products to compensate the curtailment of the effective patent term as a result of the marketing approval procedures. Differently from the other previous categories, this type of provision applies specifically to pharmaceutical products subjected to patent protection. Hence, this adjustment does not affect all fields of technology, but only the pharmaceutical branch.[319] From the 46 identified PTAs, 18 incorporated this category of provision.[320] From them, only 2 specified the time limit that this extension might not exceed. The 2015 EC-Singapore and the 2016 EC-Vietnam set, respectively, a 5 years (Art. 11.31) and a 2 years limit (Art. 8.3.1) of compensation period.

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[316] These PTAs are the 2003 US-Singapore, 2004 Bahrain-US and 2006 Oman-US.

[317] The 2003 US-Singapore was the only of them that provided for a maximum period of compensation. Under this PTA the patent term of protection may be extended up to five years (Art. 16.7.8).

[318] Article 3 (a) of the Annex XII of the 2003 EFTA-Chile PTA read as: "each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval or sanitary permit process."

[319] Article 6.9.5 of the 2008 Colombia-EFTA PTA illustrates this fourth category of provision. It reads as: "With respect to any pharmaceutical product that is covered by a patent, each Party may make available a restoration/compensation of the patent term or patent rights to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in the territory of that Party."

[320] These PTAs are the 2000 Jordan-US, 2004 Bahrain-US, 2003 Singapore-US, 2004 Australia-US, 2004 CAFTA, 2004 CAFTA-Dominican Republic, 2006 Peru-US, 2006 Colombia-US, 2006 Oman-US, 2007 Panama-US, 2007 Korea-US, 2008 Colombia-EFTA, 2011, EFTA-Peru, 2012 Colombia-Peru-EC, 2013 Central America-EFTA, 2015 EC-Singapore, 2016 EC-Vietnam and 2015 TPP.

The seventh category requires parties to provide an extension of the patent term to compensate the owner for unreasonable curtailment of the effective pharmaceuticals' patent term as a result of the marketing approval process in another territory. This provision applies if the party accepts in its national marketing authorization procedures evidence of previous marketing approval of the same or similar product issued in another country. That is to say, the party shall make available this extension of the patent term, whenever it approves the marketing of a new pharmaceutical product based on the information on the safety and efficiency of the pharmaceutical accredited in another country. From the 46 identified PTAs, 2 incorporated such a provision.[321] The US is a party in both of them.

The eighth category requests parties to provide an adjustment of the patent term of pharmaceutical and plant products to compensate the curtailment of the effective patent term as a result of marketing approval procedures. This type of provision applies only to pharmaceutical and plant products under patent protection. From the 46 identified PTAs, 10 incorporated this category of provision.[322] The EFTA is a party in 8 of them, being the greatest promoter of this kind of rule.[323] This compensatory period covers a maximum period of five years.[324]

The ninth category is found in the 2016 Comprehensive Economic and Trade Agreement (CETA), between Canada and European Union. This PTA establishes a *sui generis* protection for pharmaceuticals. It demands the parties to provide an extra period of protection for pharmaceuticals under patent protection that have to pass through marketing authorization procedures. This *sui generis* protection takes effect at the end of the lawful

[321] These PTAs are the 2004 Bahrain-US and 2006 Oman-US.
[322] These PTAs are the 2001 EFTA Service, 2002 EFTA-Singapore, 2005 EFTA-Korea, 2009 Japan-Switzerland, 2009 Albania-EFTA, 2009 EFTA-Serbia, 2010 EU-Korea, 2010 EFTA-Ukraine, 2011 EFTA-Montenegro and 2013 Bosnia and Herzegovina-EFTA.
[323] Article 4 (b) of Annex V of the 2009 Albania-EFTA PTA illustrates this kind of provision. It reads as "The Parties shall ensure in their national laws at least the following: (b) a compensatory term of protection for pharmaceuticals and plant protection products, which shall be calculated from the expiry of the maximum term of patent of 20 years for a period equal to the period, which elapsed between the filing date of the patent application and the date of the market authorisation of the product, reduced by a period of five years. Such compensatory protection shall cover a period of five years at the most and shall be granted under the following conditions: (i) the product is protected by a patent in force; (ii) there has been an official marketing authorisation for the medicinal or plant protection product; (iii) the right conferred by the patent has been postponed by administrative procedures regarding authorisation of market access, so that the effective use of the patent amounts to less than 15 years; and (iv) the effective protection conferred by the patent and the compensatory protection shall together not exceed 15 years."
[324] The 2009 EFTA-Serbia PTA established that parties may also confer, according to their national law, a six-month extension of the compensatory term of protection for pharmaceuticals (Annex VI, Art. 4(c)).

term of that patent.[325] That is to say, pharmaceutical products enjoy a 20 years-term of protection plus the period of this *sui generis* protection. Such extra period of protection may not exceed a period of two to five years.[326]

It is important to stress that this *sui generis* protection confers the same rights as conferred by the patent and is subject to the same limitations and obligations.[327] Besides, its granting does not depend on unreasonable delays in the marketing approval process. This extra period of protection shall be available for all pharmaceuticals products under patent protection that have to pass through marketing approval to be commercialized.

The tenth category embodies the supplementary protection certificate (SPC) mechanism.[328] This legal instrument, so as it is formulated, was established by the European Union[329] to "offset the loss of patent protection for pharmaceuticals and plant protection products that occurs due to the compulsory lengthy testing and clinical trials this products require prior to obtaining marketing approval" (EUROPEAN COMMISION, 2017a).[330]

Even though other countries[331] also provide for rules on the extensions of protection for certain products that are subject to regulatory approval before they can be marked, the terminology SPC is used to designate the EU regulation that are directly applicable to the Member States of the European Economic Area – EEA (28 EU + 3 EFTA Countries)[332] (ACOSTA et al, 2016, p. 7).

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[325] See Article 20.27.4 of the 2016 CETA.
[326] See Article 20.27.6 of the 2016 CETA.
[327] See Article 20.27.8 of the 2016 CETA.
[328] The WIPO Handbook on Industrial Property Information and Documentation, in its Part 8, page 23, defines supplementary protection certificate as: "an industrial property right which is granted for a product which has obtained authorization to be placed on the market as a medical product or plant protection. The certificate takes effect at the end of the term of a patent which protects the product as such, a process to obtain the product or an application of the product."
[329] The SCP was instituted by Council Regulation (EEC) No. 1768/1992, which was later repealed by the Regulation (EC) No. 469/2009, concerning the supplementary protection certification for medical products. The SCP was further elaborated by the Regulation (EC) No. 1610/1996, concerning the creation of a SCP for plant protection products; and the Regulation (EC) No. 1901/2006, concerning medical products for pediatric use (ROS, 2015, p. 19).
[330] Similar rights can be obtained in other jurisdictions outside the European Union. In the United States, for example, the 1984 Drug Price Competition and Patent Term Restoration Act (known as the Hatch-Waxman Act) "increased the effective patent term of protection by an additional maximum period of five years" (PUGATCH, 2006, p. 118).
[331] These other countries include Australia, Israel, Japan, South Korea and the United States.
[332] Even though Switzerland is not part of the EEA, it also introduced the SPC (IGE, 2017).

The SPC provides, in addition to the patent term, an extra period of protection "to compensate for the period during which regulatory approval for a [pharmaceutical or plant products] covered by the patent was sought" (ABBOT; COTTIER; GURRY, 2007, p. 604). In practical terms, this mechanism adds an extra period to the effective patent term of protection (ABBOT; COTTIER; GURRY, 2007, p. 604).

It demands a further period of protection of up to five years for patented medical and plant products subjected to marketing authorization procedures. Besides, this period can be extended by an additional six months for medical products for which pediatric studies have been conducted.[333] Under this term, from the 42 identified PTAs, 3 included such a provision. Not surprisingly, the European Union is a party in all of them.[334]

At last, it is important to stress that, legally speaking, the SPC does not "extend" the patent term of protection, since it is applied, exactly, after the patent term of protection has expired (WIPO, 2013, p. 23). The SPC constitutes, in fact, a complement to the patent term of protection. The practical consequences of this mechanism are the continuation of the protection conferred by the said patent, but only in respect to the specific product covered by this certificate (WIPO, 2013, p. 23).

In brief, while the patent covers the exclusivity over an invention; the SPC covers only the product authorized for commercialization (BARBOSA D., 2014, p. 142). It is worth being reminded that period of protection is not the same as term of protection. As explained by Carvalho (2014, p. 673), "period of protection is the period during which patent rights can still be enforced, even if, in some cases, the term may have already expired." The SPC, thus, grants a longer period of protection to certain products.

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[333] Article 186 of the 2014 EC-Georgia PTA illustrates this category of provision. It reads as: "Supplementary Protection Certificate. 1. The Parties recognise that medicinal and plant protection products protected by a patent on their respective territory may be subject to an administrative authorisation procedure before being put on their market. They recognise that the period that elapses between the filing of the application for a patent and the first authorisation to place the product on their respective market, as defined for that purpose by domestic law, may shorten the period of effective protection under the patent. 2. Each Party shall provide for a further period of protection for a medicinal or plant protection product which is protected by a patent and which has been subject to an administrative authorisation procedure, that period being equal to the period referred to in the second sentence of paragraph 1, reduced by a period of five years. 3. Notwithstanding paragraph 2, the duration of the further period of protection may not exceed five years. 4. In the case of medicinal products for which pediatric studies have been carried out, and provided that the results of those studies are reflected in the product information, the Parties shall provide for a further six months' extension of the period of protection referred to in paragraph 2."

[334] This type of provision is found in the PTAs signed by the European Union with Ukraine (2014), Moldova (2014) and Georgia (2014).

Table 11 - PTAs Rules Related to Patent Term of Protection						
PTA	Year of Signature	TRIPS 20 Years of Protection	Adjustment to Compensate Unreasonable Delays in Granting Process	Adjustment to Compensate Unreasonable Delays in the Granting Process in Another Territory	Adjustment to Compensate Curtailment of the Patent Term due to the Marketing Approval	Additional Protection of up to 5 years for Pharmaceutical and Plant Protection Products
Australia US	2004		Art. 17.9.8 (a)			
Bahrain US	2004		Art. 14.8.6 (a)	Art. 14.8.7		
CAFTA	2004		Art. 15.9.6 (a)			
CAFTA Dominican Republic	2004		Art. 15.9.6 (a)			
EFTA Chile	2003				Annex XII, Art. 3 (b)	
Chile US	2003		Art. 17.9.6			
Colombia US	2006		Art. 16.9.6 (b)			
EU Turkey	1995	Art. 4. 2, § 3				
EFTA Estonia	1995	Art. 3, § 5				
EFTA Latvia	1995	Art. 3, § 5				
EFTA Lithuania	1995	Art. 3, § 5				
EFTA Turkey IPR Amendments	1998	Annex, XII, Art. 3.1, § 6				
EFTA Macedonia	2000					Annex V, Art. 3, § 4
Croatia EFTA	2001					Annex VII, Art. 3, § 4
Korea US	2007		Art. 18.8.6 (a)			
Mexico Northern Triangle	2000	Art.16-32				
Mexico Uruguay	2003	Art. 15-29				
Morocco US	2004		Art. 15.9.7			
Oman US	2006		Art. 15.8.6 (a)	Art. 15.8.7		
Panama US	2007		15.9.6 (b)			
Peru US	2006		Art. 16.9.6 (b)			
Singapore US	2003		Art. 16.7.7	Art. 16.7.8		
TPP	2015		18.46.3/18.46.4			
US Vietnam	2000	Art. 7.10				

Table 12 - PTAs Rules Related to Patent Term of Protection					
PTA	Year of Signature	Adjustment to Compensate Curtailment of Pharmaceuticals' Patent Term due to Marketing Approval	Adjustment to Compensate Curtailment of Pharmaceuticals' Patent Term due to Marketing Approval in Another Country	Adjustment to Compensate Curtailment of the Patent Term of Pharmaceuticals and Plant Products due to Marketing Approval	SPC
Albania EFTA	2009			Annex V, Art. 4 (b)	
Australia US	2004	Art. 17.9.8 (b)			
Bahrain US	2004	Art. 14.8.6 (b) (i)	Art. 14.8.6 (b) (ii)		
Bosnia and Herzegovina EFTA	2013			Annex VII, Art. 5 (b)	
Central America EFTA	2013	Annex XIX, Art. 4.5			
CAFTA	2004	Art. 15.9.6 (b)			
CAFTA Dominican Republic	2004	Art. 15.9.6 (b)			
Colombia EFTA	2008	Art. 6.9.5			
Colombia Peru EU	2012	Art. 230. 4			
Colombia US	2006	Art. 16.9.6 (c)			
EU Georgia	2014				Art. 186
EU Korea	2010			Art. 10.35.1/Art. 10.35.2	
EU Moldova	2010				Art. 314
EU Singapore	2015	Art. 11.31			
EU Ukraine	2014				Art. 220
EU Vietnam	2016	Art. 8.3.1/Art. 8.3.2			
EFTA Korea	2005			Annex XIII, Art. 2 (b)	
EFTA Montenegro	2011			Annex VI, Art. 5 (b)	
EFTA Peru	2011	Art. 6.9.5			
EFTA Serbia	2009			Annex VI, Art. 4 (b) (c)	
EFTA Services	2001			Art. 3 (b)	
EFTA Singapore	2002			Annex XII, Art. 3 (b) (i)	

Table 13 - PTAs Rules Related to Patent Term of Protection					
PTA	Year of Signature	Adjustment to Compensate Curtailment of Pharmaceuticals' Patent Term due to Marketing Approval	Adjustment to Compensate Curtailment of Pharmaceuticals' Patent Term due to Marketing Approval in Another Country	Adjustment to Compensate Curtailment of the Patent Term of Pharmaceuticals and Plant Products due to Marketing Approval	*Sui Generis* Protection for Pharmaceuticals
CETA	2016				Art. 20.27
EFTA Ukraine	2010			Annex XIII, Art. 4 (b)	
Japan Switzerland	2009			Art. 117.5/Art. 117.6	
Jordan US	2000	Art. 4.23 (a)			
Korea US	2007	Art. 18.8.6 (b)			
Oman US	2006	Art. 15.8.6 (b) (i)	Art. 15.8.6 (b) (ii)		
Panama US	2007	15.9.6 (c)			
Peru US	2006	Art. 16.9.6 (c)			
Singapore US	2003	16.8.4 (a)			
TPP	2015	18.48.2			

3.4.2.7.3 Brazilian Regime

The Brazilian Industrial Property Law (Article 40) provides for a period of 20 years of patent protection, counted from the date of filling of the patent application.[335] This term of protection is available for any inventions, whether products or processes, in all fields of technology.

The Brazilian patent regime includes patent term adjustment for excessive delays incurred by the patent office. Article 40, §1, of the Industrial Property Law ensures a minimum period of 10 years of patent protection, counted from the date of the patent granting. This provision aims to guarantee that the title's holder will not be harmed by undue delays in the INPI patent's examination (IDS, 2005, p. 78).[336]

That is to say, if there is a difference of more than 10 years between the filling date and the granting date, the patent term of protection will be, to the extent of that difference, extended for more than 20 years (LIMA et al, 2013, p. 88). In practical terms, Article 40, §1, enables the extension of the 20 years of protection required under the TRIPS Agreement (ALMEIDA; VASCONCELLOS, 2014, p. 509).[337]

However, it is worth noting that Article 40, §1, does not apply when INPI is prevented from examining the patent application due to pending judicial dispute or for reasons of *force majeure* (IDS, 2005, p. 79). As observed by Denis Barbosa (2014, p. 159), the minimum term of protection will only be applied in cases in which INPI, by its own and exclusive delay, grants a patent when the remaining time of protection is less than ten years (BARBOSA D., 2014, p. 159). The lack of infrastructure and staff are no excuses for the delay in patent examinations (BARBOSA D., 2010, p. 1508).

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[335] Under the previously Brazilian 1971 Industrial Property Code, the term of patent protection was of 15 years, from the date of the filling of the patent application.

[336] It is useful to note that, in 2013, the Brazilian Fine Chemicals, Biotechnology and Specialty Industries Association (ABIFINA) moved a Direct Unconstitutionality Action (ADIN) before the Federal Supreme Court (STF), questioning the constitutionality of Article 40, §1, of Law No. 9.279. The ADI No. 5061 claims that this Industrial Property Law's provision violates the constitutional rules and principles of Articles 1, IV; 3, II; 5, XXIX, XXXIV, XXVI, LXXVIII, 37, *caput* and § 6; 170, *caput,* III, IV, V, sole paragraph; 173, § 5; and 219. In brief, the ADIN No. 5061 alleges violations to principles such as free enterprise; free market; morality and administrative efficiency; and civil liability for acts of the State (ALMEIDA; VASCONCELLOS, 2014, p. 512). At the time of writing, no ruling on the ADI 5061 has been issued yet.

[337] There are currently two proposals under the Brazilian Congress to revoke Article 40, §1, of the Law No. 9.279/96. These are the Draft Bill (*Projeto de Lei*) No. 5.402/2013 and the Draft Bill (*Projeto de Lei*) No. 3944/2012.

In sum, Almeida (2014, p. 31) explains that the Brazilian Industrial Property sets two parameters to count the patent term of protection. First, if the patent is granted before the tenth anniversary of the filling of the patent application; the patent term of protection shall be twenty years, counted from the filling date (Article 40, *caput*). Second, if INPI, due to exclusive internal reasons, delays the decision on the patent application until the tenth anniversary of its filling; the patent term of protection shall be at least ten years, counted form the day of the patent's granting (ALMEIDA, 2014, p. 31).

In order to secure the right of the population to accessible medicines, and to diminish the adverse effects of Article 40, §1; the INPI issued the Resolution No. 68 in 2013. This legal binding instrument provides that patent applications regarding medicines that are regularly purchased by the Brazilian Health System (*Sistema Único de Saúde - SUS*) will be given priority under the request of the Ministry of Health (ALMEIDA; VASCONCELLOS, 2014, p. 511).[338] Notwithstanding this measure, the extension of Article 40, §1, has already been granted to at least 14[339] medical related patents, delaying the entry of generic drugs into the Brazilian market (LIMA et al, 2013, p. 92).

3.4.2.7.4 Assessment

Although the TRIPS Agreement (Article 33) requires a minimum term of protection of 20 years, counted from the filing date; the identified PTAs are incorporating provisions that in practical terms prolongs this period of protection (CORREA, 2007, p. 228; SELL, 2011, p. 454). This is undertaken through different types of provisions that extends or adds up to the patent's term of protection.

In this context, it is important to note that among the biggest patent offices in the world, such as State Intellectual Property Office of the People's Republic of China (SIPO),

[338] See Article 4 of the INPI's Resolution No. 68/2013.

[339] These medicines are the Altabax (P19814747), extended 26 months; Brilinta (P19810802), extended 27 months; Caprelsa (P197711302), extended 43 months; Chantix (P19814592), extended 19 months; Cialis (P19506559), extended 2 months; Firmagon (P19808523), extended 22 months; Humira (P19707379 and P19715219), extended 36 months; Levitra (P19816155), extended 21 months; Mycamine (P19504791), extended 60 months; Myrbetriq (P19804500), extended 21 months; Pradaxa (P19807843), extended 28 months; Tarceva (P19601200), extended 57 months; Tykerb (P19906904), extended 28 months; and Xarelto (P10017050), extended 18 months.

the European Patent Office (EPO) and the Japan Patent Office (JPO),340 the Unites States Patent Office (USPTO) is the only that grants a patent term extension due to unreasonable delays in the granting process (BARBOSA D., 2014, p. 137). This practice is based on the US Patent Law, which allows extensions of the patent term not only due to the patent office's inefficiency, but also due to interference in the proceedings, secrecy or appellate reviews. This term of patent extension cannot exceed 5 years under the US Law (BARBOSA D., 2014, p. 137).341

Not surprisingly, the United States is party to all the 13 identified PTAs requesting adjustment to compensate unreasonable delays in the patent's granting process. Under these PTAs, the US trading-partners will have to adapt their national legislation to comply with this obligation. Even though these PTAs provide for pre-determined periods of delays, 342 it is still difficulty to quantify reasonableness in the granting process (CARVALHO, 2014, p. 672).

Remarkably, in this regard, the Brazilian patent regime has stricter rules than the ones identified in these PTAs or even than in the US legislation. For the cases in which INPI's delays the patent examination by its own fault, the Brazilian Industrial Property Law (Article 40, §1) ensures a minimum period of 10 years of protection, counted from the date of the patent granting. The Brazilian standard is significantly higher than any other identified in this survey.

By their turn, the PTAs provisions that grant an extension of patent terms so as to compensate for delays in obtaining marketing approval aim to avoid the reduction of the real period of patent exclusivity (CARVALHO, 2014, p. 622). Pharmaceutical and agro-chemical companies, for example, file for patent applications as soon as they identify a new molecule (CARVALHO, 2014, p. 622). Firms compete by trying to discover and develop a new molecule first (CORIAT, ORSENIGO, 2014, p. 221).

However, they cannot start selling their product right after filling their patent application in the patent office. As explained by Malbon, Lawson and Davison (2014, p.

340 According to the 2016 WIPO World Intellectual Property Indicators, SIPO became, in 2015, the first office to receive more than a million applications in a single year. The Chinese Patent Office was followed by the USPTO, Japan Patent Office (JPO) the Korean Intellectual Property Office (KIPO) and the European Patent Office (EPO) (WIPO, 2016, p. 21).

341 See Section 154 (b) of USC 35.

342 When the granting takes more than 4 or 5 years from the filling date; or 2 or 3 years from which examination was requested.

518-519), “a drug compound for human treatment may be patented, but this does not entitle the patent owner to sell the drug unless the owner satisfies other human treatment requirements, such as efficacy and safety.”

Accordingly, firms still have to pass through the lengthy and expensive process of gathering all the necessary data to file for marketing approval in the sanitary authorities. These marketing authorization procedures can take considerable time and the authorization to commercialize the product in question may only be obtained late in the life of the patent (CARVALHO, 2014, p. 622). As observed by Coriat and Orsenigo (2014, p. 221), “the ‘real’ life of a patent is thus much shorter than the statutory duration.” For these reasons, particularly, pharmaceutical and agro-chemical companies allege that this long marketing approval process reduces their period of patent exclusivity in practice.

Contrariwise, Brazil does not provide for any adjustments to compensate curtailment of the patent term due to the marketing approval. The country also does not have any kind of legal mechanism, such as the European Supplementary Protection Certificate (SPC), that compensates for the period during which regulatory approval of pharmaceutical, plant protection and medical pediatric products were sought (BARBOSA D., 2014, p. 140).

As observed by Carvalho (2014, p. 622), the problem with the provisions requiring the adjustment to compensate the curtailment of the patent term of pharmaceuticals and plant products due to marketing approval (category eight) is that “it does not link the delay in obtaining the marketing approval to unreasonableness (thus, to government’s fault) nor does it exclude delays caused by the originator.” Accordingly, even if the delay in obtaining the approval is exclusively attributable to that originator, not to the government, the originator would still be entitled to an extension limited to a maximum of five years. The aim of this type of provision (category eight) is to guarantee a minimum period of 15 years of “patent exclusive use” (CARVALHO, 2014, p. 622).

With regard to the analyzed TRIPS-Plus provisions on term of protection, Correa (2007, p. 230) calls attention to those PTAs that provide for compensation due to delays both in the granting and in the marketing approval. Since the grounds for the extensions are independent, nothing prevents them from being applied cumulatively. This can result in an extension several of years beyond the twenty years required under the TRIPS Agreement (CORREA, 2007, p. 230).

In accordance with Carvalho (2014, p. 493), countries should take cautiously the extension of patent term of protection as compensation for unreasonable delays in its granting or marketing approval. Such compensations impose a burden on the entire society due to an error or negligence of the administration (CARVALHO, 2014, p. 493). It is easier and more effective to improve the work of patent offices and sanitary agencies "in a way that makes them act expeditiously" (CARVALHO, 2014, p. 493).

For Brazil, it is crucial to provide INPI the necessary staff and infrastructure to fulfill its tasks in reasonable timeframes. This would prevent the extension of patent terms of protection due to INPI's current incapacity to examine all the patent applications in a timely manner (LIMA et al, 2013, p. 90).

3.4.3 Test Data Provisions

3.4.3.1 TRIPS Agreement

The protection of undisclosed information[343] covers both trade secrets (Art. 39.2) and test data submitted to government agencies (Art. 39.3) (TAUBMAN; WAGER; WATAL, 2012, p. 126). Due to the scope of this research, this section does not analyze the regulation on trade secrets,[344] since it is an intellectual property category interchangeable with patents. That is to say, trade secrets may be available for the same subject matter of

[343] Dessemontet (2016, p. 337) explains that the expression undisclosed information was retained "because other terms did not have the same meaning in different legal systems."

[344] Also known as confidential commercial information, trade secrets are "traditionally protected in civil and common law countries against misappropriation through dishonest practices" (ABBOT; COTTIER; GURRY, 2007, p. 591). As explained by Dessemontet (2016, p. 339), "unlike the patents for invention that are delineated in statutory enactments in precise and detailed manner, trade secrets are usually protected either under common law rules that were laid down by courts of law [in common law countries], or under unfair competition statutes [in civil law countries] that lack uniformity and are therefore difficult to compare to each other." The TRIPS Agreement is the first multilateral instrument addressing protection of trade secrets (GERVAIS, 2003, p. 274).

protection as patents. It is up to the inventor to choose the best desirable form of protection in a case-by-case assessment (ABBOT; COTTIER; GURRY, 2007, p. 591).[345]

To the contrary, the correlation between test data protection and patent protection is increasingly intertwined. This relationship differs according to the product and depends on the institutional environment of each country (YAMANE, 2011, p. 478). Generally, governments require those seeking marketing approval to submit undisclosed test and other data that detail a product's efficacy and safety to human, animal and plant life and health (UNCTAD; ICTSD, 2005, p. 530; TAUBMAN; WAGER; WATAL, 2012, p. 128). In order to obtain marketing authorization, standards attesting that a product is clinically proven to be safe and effective have to be met (SANDERS, 2007, p. 15). Exactly these tests submitted to government agencies are protected under this category of undisclosed information (MALBON; LAWSON, DAVISON, 2014, p. 582).

Before the TRIPS Agreement, there was "no multilaterally agreed norms on the protection of data submitted to governments for regulatory purposes" (ABBOT; COTTIER; GURRY, 2007, p. 596). The TRIPS is the first international agreement to establish rules in this regard, setting the minimum standards that WTO Members shall observe in their national legislation.[346]

It is important to stress that the scope of TRIPS Article 39.3 is confined to test data referring pharmaceutical and agricultural chemical products (CARVALHO, 2014, p. 578). In the words of Carvalho (2014, p. 578), these two fields were mainly chosen due to the concerns of the industry "with the losses occurred in view of the high costs of obtaining test data as well as with restrictions on patentability of some pharmaceutical-related inventions." On the grounds of lack of sufficiently inventive level, the TRIPS Article 27.1 (Patentable Subject Matter) allows WTO Members to exclude from patentability objects that might be protected under test data protection, such as "second uses of known

[345] According to Abbot, Cottier and Gurry (2007, p. 591), trade secrets have two principal advantages compared with patents. While there is no limitation on the term of trade secret protection, the term of patent protection is (generally) 20 years from the date of application. While the holder of a trade secret is not required to disclose that information to the public; the patent holder is obliged to disclose the invention (ABBOT; COTTIER; GURRY, 2007, p. 591).

[346] TRIPS Article 39.3 reads as: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall be protected such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that data are protected against unfair commercial use."

substances, new formulations, new administration routes, therapeutic methods, etc." (CARVALHO, 2014, p. 578-579).

The TRIPS Article 39.3 provides for two forms of protection to be accorded to such undisclosed information.[347] It requires WTO Members to protect them (i) against unfair commercial use and (ii) against disclosure of the relevant protected information (UNCTAD; ICTSD, 2005, p. 531; TAUBMAN; WAGER; WATAL, 2012, p. 129). These two modalities of test data protection are cumulative (CARVALHO, 2014, p. 581).

Even though Article 39.9 does not state how this is to be achieved, it provides for exceptions to this obligation where disclosure is necessary: (i) to protect the public[348] and (ii) where steps are taken to ensure that the data are protected against unfair commercial use (TAUBMAN; WAGER; WATAL, 2012, p. 129; MALBON; LAWSON, DAVISON, 2014, p. 591). According to the UNCTAD-ICTSD Resource Book on TRIPS and Development (2005, p. 532), these exceptions allow disclosure to enable, for example, "a compulsory license to obtain a marketing approval, particularly when the license is aimed at remedying anti-competitive practices or at satisfying public health measures."

In this regard, Dessemontet (2016, p. 357) affirms that these exceptions acknowledge, in a figurative way, that: "the public Administration is not the owner of the confidential information necessary to control the marketing of drugs and agrochemicals, but only the trustee of that information, the public being the ultimate beneficiaries, but only for very limited purposes." These exceptions, however, must be strictly confined to necessity and to the purpose, since its "disclosure destroys the economic value of the data" (CARVALHO, 2014, p. 615).

In order to be object of protection, these tests and other data have to fulfill the requirements established under Article 39.3. In consonance with Taubman, Wager and Watal (2012, p. 128-129), these conditions are that:

[347] TRIPS Article 39.3 does not really specify what such test and other date could be. According to Malbon, Lawson and Davison (2014, p. 584), they could include "both the results of clinical trials as well as the experimental design for those clinical trials, the proposed labels, risk assessment conclusions, and so on."
[348] In the words of Carvalho (2014, p. 615), "this generally refers to information of secondary effects and risks that certain drugs cause when combined with other substances."

(i) data have not be disclosed;[349]
(ii) their submission is required as a condition of approving the marketing of pharmaceutical or agricultural chemical products;[350]
(iii) the products utilize new chemical entities;[351] and
(iv) the origination of the test or other data has required a considerable effort.

The obligation to protect test data arises "from the cumulative combination of all the requirements, and not from one of those requirements only" (CARVALHO, 2014, p. 611). If all these conditions are met, the owner of this information must, under national law, "have the possibility of preventing such information from being disclosed to, acquired by or used by others without their consent in a manner contrary to honest commercial practices" (GERVAIS, 2003, p. 275).[352]

It is worth noting that TRIPS Article 39.3 does not define the meaning of the term "unfair commercial use." As explained by Malbon, Lawson and Davison (2014, p. 587), this expression was a compromise, which leaves it open to WTO Members to further interpret it. They can, therefore, "adopt different systems for the protection of test data submitted to regulatory authorities as long as relevant TRIPS provisions are […] respected" (YAMANE, 2011, p. 47).

The TRIPS Article 39.3 leaves enough room for each WTO Member determine how to protect test data submitted to government agencies against unfair commercial use.

[349] As observed by Carvalho (2014, p. 610), "test data lose protection as soon as they are disclosed." This means that the tests and other data must not have previously been in the public domain. Nevertheless, as observed by Malbon, Lawson and Davison (2014, p. 584), WTO Members still have the flexibility to decide where prior disclosure may take in consideration or ignored. For example, "an application for marketing approval of the same chemical entity in another jurisdiction could be considered to be disclosure" (Malbon; Lawson; Davison, 2014, p. 584).

[350] Malbon, Lawson and Davison (2014, p. 582) clarify that WTO Members are not obliged to protect undisclosed test and other date "unless such information is required as a condition of marketing approval." Therefore, "protection is not obligatory for voluntary or excess information provided as part of the application" (MALBON; LAWSON; DAVISON, 2014, p. 582). Besides, Carvalho (2014, p. 602) highlights that "test data protection must be protected only in those countries the governments of which maintain a pre-marketing approval system." In other words, there is no obligation to protect test data if pharmaceuticals and agrochemical products are not subject to pre-marketing approval or where approval is based on manufacturers' warranties (CARVALHO, 2014, p. 602).

[351] TRIPS Article 39.3 does not define what should be meant by "new chemical entity". According to the UNCTAD-ICTSD Resource Book on TRIPS and Development (2005, p. 530), WTO Members "may apply a concept similar to the one applied under patent law, or consider that a chemical entity is 'new' if there were no prior application for approval of the same drug." Article 39.9 also does not specify "whether newness should be absolute (universal) or relative (local)" (UNCTAD; ICTSD, 2005, p. 530). In the absence of a definition of "new chemical entity", Carvalho (2014, p. 604-605) asserts that WTO Members "may adopt whatever concept of novelty that fits their legal systems and practices."

[352] Since Article 39.3 does not expressly limit the term of protection, Yamane (2011, p. 741) affirms that it is possible to interpret that "authorities are required to protect regulatory data for "as long as a possibility of unfair commercial use of this data exits."

This flexibility resulted in a broad variety of approaches that differs significantly from jurisdiction to jurisdiction (MUSUNGU, 2016, p. 507). WTO Members have different perspectives on how to best implement this obligation in their national legislations.

On the one hand, some countries understand that the most effective method for complying with the obligation to protect against "unfair commercial use" is grant the originator of the tests and other data a period of exclusive use (UNCTAD; ICTSD, 2005, p. 531).[353] On this view, test data shall be protected not only against disclosure, but also against their use by generic manufactures in marketing authorization procedures (CARVALHO, 2014, p. 573). Hence, government agencies are prohibited, "during the exclusivity period, to rely on data they have received in order to assess subsequent applications for the registration of similar products" (UNCTAD; ICTSD, 2005, p. 531).[354]

These countries interpret as "unfair commercial use" the possibility of a competitor to rely on the tests and other data produced by other company to receive marketing approval. This is seen as a "springboard" to shortcut the expensive and time-consuming efforts to develop its own tests on the safety and efficacy of a product (GERVAIS, 2003, p. 277).

As explained by Carvalho (2014, p. 569), these countries understand that "not to impose an identical burden on the originator's competitors is a negatively discriminatory practice that puts the originator in disadvantage." Obtaining such information is a very long and costly exercise, which has to be surpassed by the originator to meet regulatory requirements (CARVALHO, 2014, p. 569). Medical trials, for example, are costly and demand substantial technical skill and expertise (SANDERS, 2007, p. 15). Authorizing the commercialization of the competitor's product by simply proving its similarity to the originator's product is seen as allowing competitors to free ride on the originator's efforts (CARVALHO, 2014, p. 569).

[353] As noted by Yamane (2011, p. 471), during the Uruguay round, the United States have already supported the understanding that protection against "unfair commercial use" should include the "regulators not relying (non-reliance) on the originator's data for examining the second and subsequent applicants for drug approval, for a fixed period of time (market-exclusivity)."

[354] During the review conducted by the TRIPS Council, some WTO Members expressed their view that protection of test data required under TRIPS Article 39.3 is more than simple preservation of confidentiality (CARVALHO, 2014, p. 592). These countries include: Egypt (IP/Q3/EGY/1), China (IP/Q3/CHN/1) and Antigua (IP/Q3/ATG/1).

After all, they do not incur in the expenses of obtaining and in the time of collecting the required test data (MALBON; LAWSON; DAVISON, 2014, p. 586). The protection of such information from use or reliance by second and subsequent applicants would, according to this perspective, constitute a way to avoid competitors to gain this unfair commercial advantage (MALBON; LAWSON, DAVISON, 2014, p. 586).

On the other hand, some countries argue that Article 39.3 requires the protection of tests and other data in the framework of unfair competition rules.[355] On this view, TRIPS Article 39,3 does not constrain WTO Members to recognize exclusive rights on test data (UNCTAD; ICTSD, 2005, p. 531). The essential (or, rather only) governments' obligation regarding their protection is to keep them secret (CARVALHO, 2014, p. 573)

These countries usually defend that there are other ways – other than through periods of data exclusivity – to protect such information against "unfair commercial use". On their view, only if the test data undertaken by the originator had been acquired through dishonest commercial practices, the subsequent applicants could be prevented from using these results as basis for an independent submission of marketing approval (UNCTAD; ICTSD, 2005, p. 531). The mere marketing approval of a generic product based on the already submitted test data would not constitute fraud or dishonesty (CARVALHO, 2014, p. 572).

In this perspective, governmental agencies are allowed to rely, as long as they are not dishonestly obtained, on the data presented by one company to assess the submissions made by other companies relating to similar products (UNCTAD; ICTSD, 2005, p. 531). In these jurisdictions, generic companies can benefit from a "me too" registration from the time the data is submitted by its originator (CARVALHO, 2014; MUSUNGU, 2016, p. 507). The countries that advocate this position commonly assert that prohibiting the regulatory body to rely on the information that it already possesses would result in a great deal of repetitive toxicological and clinical investigations (UNCTAD; ICTSD, 2005, p. 531).

[355] In the same exercise of the above footnote, some WTO Members stated their understanding that "Article 39.3 did not require more than the preservation of secrecy over the data by the authority to which they were submitted" (CARVALHO, 2014, p. 591). Accordingly, governments are allowed to rely on those data to authorize the marketing of generic products with the same new chemical entity previously approved (CARVALHO, 2014, p. 591). These countries include: India (IP/Q3/IND/1), Sri Lanka (IP/Q3/LKA/1), Canada (IP/Q3/CAN/1), Japan (IP/Q3/JPN/1), Italy (IP/Q3/ITA/1), the Netherlands (IP/Q3/NDL/1), Slovak Republic (IP/Q3/SVK/1), Sweden (IP/Q3/SWE/1), Slovenia (IP/Q3/SVN/1), Argentina (IP/Q3/ARG/1) and Bolivia (IP/Q3/BOL/1) (CARVALHO, 2014, p. 591).

This would be a waste of funds and ethically questionable, since it imposes additional costs that are passed on to the consumer, making, for example, generic medicines more expensive. Besides, this would also imply subjecting human beings and animals to clinical trials for each version of pharmaceutical or agrochemical product when its safety, quality and efficacy are already known (MUSUNGU, 2016, p. 507). Such a requirement is seen as socially inefficient and unethical (MUSUNGU, 2016, p. 507; CARVALHO, 2014, p. 570). The repetition of these tests "put in risk the lives and cause the suffering of animals and humans" (CARVALHO, 2014, p. 570).

In sum, the TRIPS Article 39.3 protects only the tests and other data submitted by the private industry to get the official marketing approval of pharmaceutical and agricultural products that utilize new chemical entities (DESSEMONTET, 2016, p. 357). In concrete terms, Yamane explains that it requires WTO Members to "prevent leakage to competitors of data submitted to the regulatory authorities" (YAMANE, 2011, p. 471).

TRIPS Article 39.3 does not oblige WTO Members to grant data exclusivity, so as implemented in some developed countries (YAMANE, 2011, p. 471). No exclusive rights on test data are mandated (CORREA, 2007, p. 247). WTO Members are free to choose whether their regulatory authorities can rely on bioequivalence tests to grant marketing approval. This enables companies seeking registration of generic versions of the original product to rely on the studies undertaken by the originating company (MUSUNGU, 2016, p. 506-507).

It is also important to stress that the protection of tests and other data under TRIPS Article 39.3 is available independently of other intellectual property rights, including patents. As noted by Taubman, Wager and Watal (2012, p. 128), WTO Members "have to provide for test data protection irrespective of whether or not the products are covered by patents."

Notwithstanding the compromise reflected in the language adopted under TRIPS Art. 39.3, considerable controversy still exists about the national implementation of the obligation to protect test data against "unfair commercial use" (UNCTAD; ICTSD, 2005, p. 531). Essentially, this controversy is "an issue of whether or not such use or reliance [on the test data submitted by the first applicant] is 'unfair'" (MALBON; LAWSON; DAVISON, 2014, p. 586).

More than twenty years after the entry into force of the TRIPS Agreement, there is still a significant "lack of harmonization as to how WTO Members view protection of test data" (CARVALHO, 2014, p. 573). Whether there is, in addition to secrecy, a non-reliance obligation; this is not harmonized by the TRIPS Agreement; and the standards and procedures vary from jurisdiction to jurisdiction (SANDERS, 2007, p. 15). Countries try to promote their approach on this issue through their preferential trade agreements (MUSUNGU, 2016, p. 507).

3.4.3.2 PTAs Rules

From the 68 analyzed PTAs, 40 incorporated provisions on the protection of test data submitted to government agencies. The great majority of them considerably advance the TRIPS' regulation in this regard. From the 40 identified PTAs, only 2 adopted the same level of test data protection required in the TRIPS Agreement.[356] The others increased the multilateral standard by requiring the parties to provide data exclusivity, market exclusivity, test data protection of "new uses", patent-linkage, patent holder's notification, test data protection of biologics, test data protection of medical and plant protection products.

3.4.3.2.1 Data Exclusivity

This type of provision requires the parties to prevent applicants seeking marketing approval of pharmaceutical and agricultural chemical products from relying on the undisclosed test or other data submitted to the competent authority by the first applicant for

[356] These Agreements are the 2000 Mexico Northern Triangle and the 2016 EFTA-Philippines. In this regard, it is important to highlight the case of 2006 Nicaragua-Taiwan PTA. In this Agreement, there is neither direct reference to the TRIPS standards of protection, nor to higher levels of protection. Its Article 17.1 only states that: "a Party shall observe and respect the national legislations and international treaties adopted by the other Party relating to the manufacturing, marketing and distribution of pharmaceutical and agrochemical goods." Hence, whether Nicaragua and Taiwan will have to provide the same or a higher level of test data protection as in the TRIPS Agreement will depend on their national legislations and adopted international treaties.

a certain period of time. This minimum term of protection varies according to the agreement and whether it is a pharmaceutical or agricultural chemical product.

The minimum term of data exclusivity granted to pharmaceutical products ranges from 5 to 8 years, while to agricultural chemical products from 5 to 10 years.[357] This period is counted from the date of the first marketing authorization in the party's territory. No matter what level of exclusivity is established, it is important to stress that it "refers to the data, not to the product" (CARVALHO, 2014, p. 599). It is also worth being reminded that this data exclusivity covers the submission of data in regulatory approval process of both patented and non-patented products (ABBOTT, 2005, p. 89-90).

During this exclusivity period, the second applicant can only rely on the first applicant's test data with his consent. During this time, the second applicant is obliged either to develop its own test data or to seek permission of the test data's originator (CARVALHO, 2014, 637). These provisions are designated to force generic producers to produce their own clinical data independently and at their own expenses, rather than rely on the safety and efficacy findings of the test data's originator (SANDERS, 2007, p. 15; SELL, 2011, p. 453).

From the 40 identified PTAs, 34 incorporated such a provision. The United States[358] is the main supporter of this type of clause, being a party to 14 PTAs with such a rule. Subsequently, there are EFTA, with 13 PTAs, and the European Union, with 5.[359]

It is also important to stress that this type of provision does not mean market exclusivity or product exclusivity. As noted by Carvalho (2014, p. 599), "competitors may

[357] Article 5.2 of Annex XIII of the EFTA illustrates this kind of provision. It reads as: "the Parties shall prevent applicants for marketing authorisation for pharmaceuticals and agricultural chemical products from relying on, or referring to, undisclosed test data or other data submitted to the competent authority by the first applicant for a period, counted from the date of marketing authorisation, of at least five years for pharmaceuticals and at least ten years for agrochemical products."

[358] Although the methodological framework of this research has excluded NAFTA from its analysis, it is interesting to know how this important regional trade agreement regulates test data protection. Its article 1711.6 provides for a data exclusivity period of 5 years for pharmaceutical and agricultural chemical products' test data. Even before the entering into force of the TRIPS Agreement, the NAFTA already provided this kind of TRIPS-plus provisions (UNCTAD; ICTSD, 2005, p. 535).

[359] Remarkably, Japan only has one PTA – the 2009 Japan-Switzerland – that provides for test data exclusivity. In its domestic legislation, Japan prohibits for eight years the reliance on the test data by competitive products. It argues that: "the regulatory authorities should, after marketing the original product, re-examine [their] efficacy, safety and side-effects" (YAMAN, 2011, p. 472-473). After this period, the regulatory authorities can rely on such information to examine the application of generic products, but it cannot authorize their marketing for another year. The Japanese regime grants one-year market exclusivity after the eight-year data exclusivity period is over. Japan justifies the delayed entry of generic products in the market based on these post-marketing surveillance arguments (YAMAN, 2011, p. 473).

introduce generic products in the market provided that their approval by the government is not based on the originator's data (during the term of protection)." Hence, competitors can market generic products as long as they provide information on safety and efficacy as a result of their own efforts.

This type of provision also does not require originality as to the submitted information, since the exclusivity does not concern the information *per se* (CARVALHO, 2014, p. 599). The obligation lies on the competitor's bearing the costs of producing its own test data to be submitted to the regulatory authorities during the term of protection (CARVALHO, 2014, p. 599). So as regulated, "test data protection […] is conceived of not only as a confidentiality rule, but also as a non-reliance obligation on the part of regulatory authorities" (YAMANE, 2011, p. 477).

For the most part, this type of provision drops the requirement of "substantial efforts" established under the TRIPS Article 39.3. [360] Accordingly, any test data, "no matter how simple and costless their acquisition is, must be protected, provided they were submitted by the originator as a condition for obtaining marketing approval" (CARVALHO, 2014, p. 637). WTO Members are not obliged under Article 39.3 to extend the scope of protection to such a degree (YAMANE, 2011, p. 477).

Certain PTAs, however, ensure some room for maneuver in the implementation of such provision. They restate one or both TRIPS Art. 39.3 exceptions, regarding the protection of the public and against unfair commercial use;[361] and secure the parties right to adopt abbreviated approval procedures on the basis of bioequivalence or bioavailability studies.[362]

Furthermore, the 2004 EFTA-Tunisia PTA, 2004 EFTA Lebanon and 2005 EFTA-Korea allow the parties to adopt a right-to-remuneration system, as opposed to a data exclusivity system. That is to say, test data protection of pharmaceutical and agricultural

[360] Some PTAs, on the contrary, expressly provide for the requirements of "substantial efforts." See, for example, the following agreements: 2000 US-Vietnam (Art. 9.5), 2003 Chile-EFTA (Annex XII, Art. 4.2), 2006 Colombia-US (Art. 16.10.2(b)), 2006 Peru-US (Art. 16.10.2(a)), 2007 Korea-US (Art. 18.9.1(a)), 2007 Panama-US (Art. 15.10.2(a)), 2008 Colombia-EFTA (Art. 6.11.2), 2010 EFTA-Peru (Art. 6.11.2), 2011 EFTA-Montenegro (Annex VI, Art. 6.1) and 2016 EC-Vietnam (Art. 9.1(a)).
[361] See, for example, the agreements: 2003 Chile-US (Art. 17.10.1), 2006 Colombia-US (Art. 16.10.1(a)), 2016 EC-Vietnam (Art. 9.1. (a)), 2004 EFTA-Tunisia (Annex V, Art. 4), 2006 Peru-US (Art. 16.10.2(a)) and 2007 Panama-US (Art. 15.10.2(a)).
[362] See, for example, the agreements: 2006 Colombia-US (Art. 16.10.2(b)), 2006 Peru-US (Art. 16.10.2(b)), 2007 Panama-US (Art. 15.10.2 (b)), 2008 Colombia-EFTA (Art. 6.11.2) and 2010 EFTA-Peru (Art. 6.11.2).

chemical products can be secured by the right of the originator to receive an adequate remuneration for the reliance on its test date (right-to-remuneration), instead of granting a minimum term in which third parties cannot rely on test data submitted by the first applicant (data exclusivity).

Another variant of the data exclusivity clause regards situations in which a country accepts to market pharmaceutical and agricultural chemical products based on test data submitted in another country. That is, when a country admits the submission of evidence regarding the safety and efficacy of a product that was previously approved in another territory. In these cases, the parties shall also prevent subsequent applicants from relying on this information for a certain period of time. This type of provision has an "extraterritorial effect of protection of data submitted in another country" (CARVALHO, 2014, p. 637). As such, the data exclusivity is based not only on data submitted in the country where regulatory approval is sought, but is also based on data submitted in foreign countries, and on the marketing approval derived therefrom (ABBOTT, 2005, p. 89-90).

From the 40 identified PTAs, 12 incorporated such a provision (extraterritorial data exclusivity). From the 12 PTAs, 9 of them provide for a protection for pharmaceutical and agricultural chemical products, while 3 of them establish this protection exclusively for agricultural chemical products. The minimum term of extraterritorial data exclusivity granted in all of these PTAs is the same: 5 years for pharmaceutical chemical products and 10 years for agricultural chemical products. This term of protection starts counting from the date of registration in that other country. It is important to highlight that the United States is a party in all of these 12 PTAs.

3.4.3.2.2 Market Exclusivity

This category of clause demands the parties to prevent the second applicant from marketing a similar product during a certain period of time, even if he submits his own test data to the governmental agencies. In fact, this exclusivity does not refer to the data itself, but to the product. As explained by Carvalho (2014, p. 600), it "stands for the protection of

the product the marketing of which has been obtained with the support of protected test data."

In these terms, the first applicant to have his product authorized for commerce gains the exclusivity to explore the market for a predefined term, during which he may prevent generic manufactures from entering into it.[363] For these reasons, Carvalho (2014, p. 600) understands that this type of market exclusivity is closer "to patent protection than to test data protection [as such]" (CARVALHO, 2014, p. 600).

From the 40 identified PTAs, only 3 presented such a provision. They were put forward by EFTA and they covered pharmaceutical products. The 2010 EFTA-Ukraine provided for a 5 years of marketing exclusivity; while the 2011 EFTA-Montenegro and 2013 EFTA-Bosnia and Herzegovina, 10 years,[364] counted from the initial authorization of the reference product. It is worth noting that, in both cases, this protection appears to complement the already established data exclusivity protection. In practical terms, this provision blocks the marketing approval of a generic drug during the period of market exclusivity (CORIAT, ORSENIGO, 2014, p. 230).

3.4.3.2.3 Test Data Protection of "New Uses"

This provision extends the protection of test data to new information submitted in support of an old product (CARVALHO, 2104, p. 637). Commonly, pharmaceutical and agrochemical manufactures discover "new uses" of a product that has already been authorized for commercialization. Sometimes, even old drugs for which patents have expired "prove to be effective cures for diseases other than the ones they were originally developed to fight" (BRANSTETTER, 2016, p. 22).

This "new use" involves, for example, new indications, new formulations or a new methods of administration. This type of test data protection concerns exactly this information that validates the new therapeutic indications of a pharmaceutical products and the "new uses" of agrochemicals products already in the market.

[363] In this regard, Abbott (2004, p. 6) reminds that, during the Uruguay Round, the United States and certain other developed country Members had argued for a five-year data exclusivity, but this was not accepted.
[364] According to Art. 6.3 of the EFTA-Montenegro, this 10 year-period shall be extended to a minim of eleven years, if the marketing authorization holder obtains an approval for one or more new therapeutic indications, which are held to bring significant clinical benefit.

From the 40 identified PTAs, 13 provided for such a provision.[365] The main promoters of this kind of clause are the United States (7), European Union (3), EFTA (3) and Australia (2). Depending on the agreement, the protection covers test date concerning "new uses" of chemical pharmaceutical products, chemical agricultural products or both of them. From the 13 selected PTAs, 7 covered only test data concerning "new uses" of pharmaceutical products,[366] 4 covered both pharmaceutical and agricultural products;[367] and 2 covered only agricultural products.[368]

In all the agreements, the type of test date protection granted to the information on "new uses" is the same as the protection granted to the undisclosed information of the previously approved new chemical entity. That is to say, in the agreements where test data protection of a new chemical entity is conceived as date exclusivity, the same is provided for the test data of "new uses".[369] This same logic applies to market exclusivity. In the agreements where test data protection is considered as market exclusivity, this same type of protection is extended to test date concerning "new uses".[370]

The period of data exclusivity or market exclusivity differs from agreement to agreement and in accordance with the product. For test date regarding "new uses" of pharmaceutical products, the United States' model requires three years of protection for this new clinical information; while the EU's and EFTA's model adds at least one year to the period of data exclusivity or market exclusivity for one or more new therapeutic indications. For test data regarding "new uses" of agricultural products, the periods of protection are 3 or 10 years.

The United States' model also provides for extraterritorial protection of test data regarding "new uses". This applies when a country accepts to market the "new uses" of a product based on test data submitted in another country. That is, when a country admits the

[365] These agreements are the: 2000 US-Jordan, 2004 Australia-US, 2004 US-Morocco, 2004 Bahrain-US, 2006 US-Oman, 2007 US-Korea, 2010 EFTA-Ukraine, 2011 EFTA-Montenegro, 2013 Bosnia and Herzegovina, 2014 EC-Georgia, 2014 EC-Moldova, 2015 TPP and 2016 CETA.
[366] These agreements are the 2004 US-Morocco, 2010 EFTA-Ukraine, 2011 EFTA-Montenegro, 2013 Bosnia and Herzegovina-EFTA, 2014 EC-Georgia, 2014 EC-Moldova and 2015 TPP.
[367] These agreements are the 2000 US-Jordan, 2004 Bahrain-US, 2006 US-Oman and 2007 US-Korea.
[368] The 2004 Australia-US and the 2016 CETA.
[369] See, for example, Articles 14.9.2(a) and 14.9.2(b) of the 2000 US-Jordan, and Articles 18.9.2 (a) and 18.9.2 (c) of the 2007 US-Korea.
[370] See, for example, Article 6.3, Annex VI, of the 2011 EFTA-Montenegro and Article 5.5, Annex XIII, of the 2010 EFTA-Ukraine.

submission of evidence regarding the efficacy and safety of "new uses" of a product that was previously approved in another territory.[371]

3.4.3.2.4 Patent-Linkage

This provision establishes a link "between the exclusive patent right and the marketing approval process by subjecting marketing approval for competing generic products to the consent or acquiescence of the patent holder" (UNCTAD; ICTSD, 2005, p. 536). In other words, government agencies "are required to refuse to provide marketing approval to a generic [product] if a patent on the [product is] in force, unless the patent owner consents to such approval" (SELL, 2011, p. 454). That is to say, patents are linked to the marketing approval process, in such a way that the regulatory authority is precluded from giving effect to marketing approval "prior to the expiration of the patent term without the 'consent or acquiescence' of the patent holder" (ABBOTT, 2005, p. 89-90).

Patent protection and marketing approval are not linked in the TRIPS Agreement (SELL, 2011, p. 454). There is no requirement that a WTO Member shall refrain from granting marketing approval to a generic producer based on term of patent protection. This is an additional restriction of great importance (ABBOTT, 2004, p. 7). According to Shadlen et al (2011, p. 20), after the conclusion of the Uruguay Round, the transnational pharmaceutical industry has advocated for this linkage, "whereby health authorities consult with IP authorities and deny registration to drugs when patents are in force."

From the 40 identified PTAs, 13 included a patent-linkage provision. All of them restricted this nexus between patent protection and marketing approval to pharmaceutical products. It is also important to stress that the US is a party in all these 13 PTAs, being the main supporter of this type of provision. To make it even more stringent, some US PTAs even prohibit the parties to alter the duration of the market exclusivity granted as test data protection in the cases where patent protection terminates earlier than this data exclusivity period.[372] As observed by Shadlen et al (2011, p. 20), even though patent-linkage is not

[371] See, for example, Articles 18.9.2(b) and 18.9.2 (d) of the 2007 US-Korea and Articles 15.9.2(b) and 15.9.2(d) of the 2006 US-Oman.
[372] See, for example, Article 16.8.3 of the 2003 Singapore-US, and Article 18.9.4 of the 2007 Korea-US.

demanded by the TRIPS, "it has become an obligation for many countries that have negotiated trade agreements with the US […]."

It is also worth pointing out that the 2016 Comprehensive Economic and Trade Agreement (CETA), between Canada and European Union, also provides for some regulation regarding patent-linkage. The CETA does not require its parties to link the grating of marketing authorization of pharmaceutical products to the existence of patent protection. However, it does demand the parties that rely on such mechanism to ensure that all litigants have the means for equivalent and effective rights of appeal.[373]

3.4.3.2.5 Notification of the Patent Holder

This type of provision requires government agencies to notify the patent owner "of any applications for generic product approval" (SELL, 2011, p. 454). Accordingly, the parties shall put in place a system that informs the patent owner that another person is seeking marketing approval of a product during the term of an applicable patent. To a certain degree, this provision also relates patent protection to marketing approval.

From the 40 identified PTAs, 14 provided for such a provision. This obligation is established either as complement to patent-linkage or as an alternative to patent-linkage. It only covers pharmaceutical products. The United States is again a party in all of the 14 identified PTAs.

3.4.3.2.6 Test Data Protection for Biologics

This provision demands the parties to provide test data protection for biological medicines. These are drugs based on biotechnology and derived from genetic material, cells, or other biological sources (BRANSTTER, 2016, p. 20). They include, for example,

[373] See Article 20.28 of the 2016 CETA.

"vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins" (FDA, 2107).

The TRIPS Agreement in its Article 39.3 requires only the protection of test data related to chemically synthesized drugs, not to biologics. This category of TRIPS-Plus provision expands the TRIPS' scope by adding to the protection of test data of pharmaceutical and agricultural chemical products, the test data of biological drugs.

From the 40 identified PTAs, 7 incorporated provisions on test data protection of biologics. The parties of these agreements understand that the best way to protect them is to grant a data exclusivity by which the second applicant cannot rely on the test data submitted to the competent authority by the first applicant for a certain period of time. The term of data exclusivity among these PTAs varies from 5 to 8 years.

3.4.3.2.7 Data Exclusivity of Medical and Plant Protection Products

In comparison with the TRIPS Article 39.3, some of the EU PTAs significantly expand the scope of test data protection by changing the terms "pharmaceutical" and "agricultural chemical products" by respectively "medical" and "plant protection products." These are broader terms that go beyond the strict protection of test data regarding pharmaceutical and agricultural products made of chemical compounds.

In the EU PTAs, medical products include, for example: chemical drugs, biologics (vaccines, (anti)toxins, blood, blood components, blood-derived products), herbal drugs, radiopharmaceuticals, gene therapy products, cell therapy products and tissue engineered products.[374] By its turn, plant protection products might consist of or contain active

[374] See, for example, Art. 6.1 of the Annex 2-D of the 2010 EC-Korea PTA; and Footnote 1 to Art. 315.1 of the 2010 EC-Moldova PTA.

substances, safeners or synergists.[375] From the 40 identified PTAs, 5 presented such broad terms.[376]

The protection of test data regarding products other than pharmaceutical and agricultural chemical products against unfair commercial use constitutes a more extensive protection than that required by the TRIPS Agreement. The substantive protection required by the TRIPS Article 39.3 is only mandatory with respect to pharmaceutical and agricultural chemical products. As long as this type of PTA clause does not violate other TRIPS Agreement's provisions, WTO Member are free to adopt it (CARVALHO, 2014, p. 581).

[375] For example, see footnote 65 to Art.10.35 of the 2010 EU-Korea PTA.

[376] These are the European Union's PTAs with Korea (2010), Georgia (2014), Moldova (2014) and Ukraine (2014). It is important to stress that, even though the 2010 EC-Korea PTA do not use the term "medical products" in heading of its Article 10.36, the footnote to this provisions specify that they cover the pharmaceutical products as defined in its Annex 2-D. This annex defines "pharmaceutical products" as described as "medical products" in the other EU PTAs. It is also worth pointing out that the 2016 Comprehensive Economic and Trade Agreement (CETA), between the European Union and Canada, uses term plant protection products to refer to this kind of test data protection. As to pharmaceutical products, the CETA explains in its Article 20.6 that this term covers chemical drugs, biological drugs, vaccine or radiopharmaceuticals.

Table 14 - PTAs Rules on Test Data Submitted to Governmental Agencies						
PTA	Year of Signature	Data Exclusivity of Pharmaceutical Chemical Products	Data Exclusivity of Pharmaceutical and Agricultural Chemical Products	Extraterritorial Data Exclusivity of Agricultural Chemical Products	Extraterritorial Data Exclusivity of Pharmaceutical and Agricultural Chemical Products	Market Exclusivity for Pharmaceutical Chemical Products
Albania EFTA	2009		Annex V, Art. 5.2.			
Australia US	2004		Art. 17.10.1(a) Art. 17.10.1(b)		Art. 17.10 (c)	
Bahrain US	2004		Art. 14.9.1(a)		Art. 14.9.1(b)	
Bosnia and Herzegovina EFTA	2013		Annex VII, Art. 6.2			Annex VII, Art. 6.2
Central America EFTA	2013		Annex XIX, Art. 5(c)			
Central American Free Trade Agreement (CAFTA)	2004		Art. 15.10.1(a)		Art. 15.10.1(b)	
CAFTA Dominican Republic	2004		Art. 15.10.1(a)		Art. 15.10.1(b)	
CETA	2016	Art. 20.29.2				
Chile EFTA	2003		Annex XII, Art. 4.2			
Chile US	2003		Art. 17.10.1			
China Switzerland	2013		Art. 11.11.2			
Colombia EFTA	2008		Art. 6.11.2			
Colombia Peru EU	2012		Art. 231.2			
Colombia US	2006		Art. 16.10.1(a) Art.16.10.2 (b)	Art. 16.10.1 (a)		
EU Singapore	2015		Art. 11.33 Art. 11.34			
EU Vietnam	2016		Art. 9.1 (a) (b)			
EFTA Hong Kong	2011		Annex XII, Art. 4.2			
EFTA Korea	2005		Annex XIII, Art. 3			
EFTA Lebanon	2004		Annex V, Art. 4.			

Table 15 - PTAs Rules on Test Data Submitted to Governmental Agencies						
PTA	Year of Signature	TRIPS Art. 39.3 Level of Protection	Data Exclusivity of Pharmaceutical and Agricultural Chemical Products	Extraterritorial Data Exclusivity of Agricultural Chemical Products	Extraterritorial Data Exclusivity of Pharmaceutical and Agricultural Chemical Products	Market Exclusivity for Pharmaceutical Chemical Products
EFTA Montenegro	2011		Annex VI, Art. 6.1/Art. 6.2			Annex VI, Art. 6.2
EFTA Peru	2010		Art. 6.11.2			
EFTA Philippines	2016	Annex XVIII, Art. 8.1				
EFTA Serbia	2009		Annex VI, Art. 5.2			
EFTA Tunisia	2004		Annex V, Art. 4			
EFTA Ukraine	2010		Annex XIII, Art. 5.2			Annex XIII, Art. 5.4
Japan Switzerland	2009		Art. 121.1			
Korea US	2007		Art. 18.9.1 (a)		Art. 18.9.1(b)	
Mexico Northern Triangle	2000	Art. 16.37				
Morocco US	2004		Art. 15.10.1		Art. 15.10.1	
Oman US	2006		Art. 15.9.1(a)		Art. 15.9.1(b)	
Panama US	2007		Art. 15.10.1(a) Art. 15.10.2(a) Art. 15.10.2(b)	Art. 15.10.1(b)		
Peru US	2006		Art. 16.10.1(a) Art. 16.10.2(a) Art. 16.10.2(b)	Art. 16.10.1(b)		
Singapore US	2003		Art. 16.8.1		Art. 16.8.2	
Transpacific Partnership	2015		Art. 18.47.1 Art. 18.50.1 (a)		Art. 18.47.2 Art. 18.50.1(b)	
US Vietnam	2000		Art. 9.5 Art. 9.6			

Table 16 - PTAs Rules on Test Data Submitted to Governmental Agencies							
PTA	Year of Signature	Test Data Protection for New Uses	Patent-Linkage	Notification of marketing approval requests of products covered by a patent	Biologics	Data Exclusivity of Plant Protection Products	Data Exclusivity of Medical and Plant Protection Products
Australia US	2004	Art. 17.10.1(b)	Art. 17.10.4 (a)	Art. 17.10.4 (b)			
Bahrain US	2004	Art. 14.9.2 (a) Art. 14.9.2 (b)	Art. 14.9. 4 (a)	Art. 14.9.4 (b)			
Bosnia and Herzegovina EFTA	2013	Annex VII, Art. 6.3					
Central America EFTA	2013						
Central American Free Trade Agreement (CAFTA)	2004		Art. 15.10.2 (a)	Art. 15.10.2 (b)			
CAFTA Dominican Republic	2004		Art. 15.10.2 (a)	Art. 15.10.2(b)			
CETA	2016	Art.20.30.4			Footnote 30 to Art. 20.29.1	Art. 20.30	
Chile EFTA	2003						
Chile US	2003		Art. 17.10.1 (c)	Art. 17.10.1 (b)			
China Switzerland	2013				Art. 11.11.2		
Colombia Peru EU	2012				Footnote 72 to Art. 231.1 Art. 231.2		
Colombia US	2006		Art. 16.10.4 (a)	Art. 16.10.4 (b)			
EU Georgia	2014	Art. 187.4					Art. 187.3 Art. 187.4 Art. 188.2 Art. 188.4

Table 17 - PTAs Rules on Test Data Submitted to Governmental Agencies						
PTA	Year of Signature	Test Data Protection for New Uses	Patent-Linkage	Notification of marketing approval requests of products covered by a patent	Biologics	Data Exclusivity of Medical and Plant Protection Products
EU Korea	2010				Footnote 67 to Art. 10.36 Art 6.1 of Annex 2-D	Art. 10.36.1 Art. 10.36.2 Art. 10.36.3 Art. 10.37.2 Art. 10.37.3
EU Moldova	2014	Art. 315.3			Footnote 1 to Art. 315.1	Art. 315.1 Art. 315.2(a) Art. 316.2 Art. 316.4
EU Ukraine	2014					Art. 222.2 Art. 223.2 Art. 223.4
EFTA Hong Kong	2011				Annex XII, Art. 4.2	
EFTA Montenegro	2011	Annex VI, Art. 6.3				
EFTA Ukraine	2010	Annex XIII, Art. 5.5				
Jordan US	2000	Footnote 10 to Art. 4.22		Art. 4.23 (b)		
Korea US	2007	Art. 18.9.2 (a) Art. 18.9.2 (c)	Art. 18.9.4 Art. 18.9.5 (b)	Art. 18.9.5 (a)		
Morocco US	2004	Art. 15.10.2	Art. 15.10.4 (a)	Art. 15.10.4 (b)		
Oman US	2006	Art. 15.9.2 (a) Art. 15.9.2 (c)	Art. 15.9.4 (a)	Art. 15.9.4 (b)		
Panama US	2007		Art. 15.10.4 (a)	Art. 15.10.3 (b) Art. 15.10.4 (b)		
Peru US	2006		Art. 16.10.4 (a)	Art. 16.10.3 (b) Art. 16.10.4 (b)		
Singapore US	2003		Art. 16.8.3 Art. 16.8.4 (c)	Art. 16.8.4 (b)		
Transpacific Partnership	2015	Art. 18.50.2 (a)	18.53.2	Art. 18.53.1(a)	Art. 18.51.1 Art. 18.51.2	

3.4.3.3 Brazilian Regime

No other international instrument required test data protection in Brazil until the adoption of the TRIPS Agreement. The country also did not have any national legislation specifically addressing test data of pharmaceutical and agricultural chemical products submitted to government agencies for marketing approval (BARBOSA, D., 2003, p. 688).

This changed in 1996 with the adoption of the Industrial Property Law (No. 9.279), which regulated the matter under its Article 195, XIV. This provision reads as:

> A crime of unfair competition is perpetrated by anyone who: divulges, exploits, or utilizes, without authorization, results of tests or other undisclosed data whose preparation involves considerable effort and that were submitted to government agencies as condition for obtaining approval to commercialize products.

In these terms, Article 195, XIV, of the Industrial Property Law incorporated the TRIPS Article 39.3 into the Brazilian legal order (BASSO; RODRIGES JÚNIOR, 2010, p. 179). The protection provided by Article 195 does not cover information publicly known or "evident" for technical person on the matter. As in the TRIPS Article 39.3, only test data whose production "involved a considerable effort" are protected against disclosure (CORREA, 2007, p. 249). When necessary to protect the public, the test data can be disclosed by the government agency empowered to authorize the commercialization of the product.[377]

The Brazilian Industrial Property Law punishes the unauthorized disclosure or use of confidential information with a penalty of imprisonment, for three months to one year, or a fine (CORREA, 2007, p. 249). It provides for a more extensive protection than the one required under the TRIPS Agreement by extending test data protection to information on safety and efficacy of products other than pharmaceutical and agricultural chemical products. Moreover, there are some specificities concerning test data protection of pharmaceutical and agricultural products that need to be further clarified.

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[377] Art. 195, § 2, Law No. 9.279/96.

The Brazilian Health Regulatory Agency (ANIVSA) is the governmental body responsible for the marketing approval of pharmaceutical products for human use.[378] Pharmaceutical companies have first to be granted a marketing authorization by ANVISA in order to sell their products in Brazil.

Currently, there is no legal instrument in the Brazilian intellectual property regime that prevents ANVISA from relying on the test it has already received to assess subsequent applications for the marketing approval of similar pharmaceutical products. The Brazilian intellectual property regime does not provide for any kind of data or market exclusivity period for the marketing approval of pharmaceutical products for human use. The marketing procedures of generic pharmaceutical products are not subject to any form of exclusivity period (CORREA, 2007, p. 249)

In practice, ANVISA permits national and foreign pharmaceutical companies to register medicines (whether chemical or biological) based on the results of clinical tests of other identical previously registered medicines (BASSO; RODRIGUES JÚNIOR, 2010, p. 179-180). In other words, ANVISA authorizes the introduction of competing pharmaceutical products into the Brazilian market by companies that do not incur in the costs of administering tests and gathering information that guarantee the security and efficacy of their products (BASSO; RODRIGUES JÚNIOR, 2010, p. 180).

In contrast, the Brazilian approach towards the protection of test data of agricultural chemical products is significantly stricter. The Ministry of Agriculture, Livestock and Food Supply (MAPA) is the competent authority in charge of granting marketing approval for agricultural chemical products. In this process, ANVISA is only responsible for the toxicological evaluation of the product (ANVISA, 2017).

In this regard, it is important to stress that MAPA, ANVISA and the Ministry of the Environment (MMA), through the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA), are responsible for establishing the guidelines and requirements regarding the submission of test data of agricultural chemical products for

[378] The Decree No. 3.029, of April 16, 1999, approves the ANVISA's regulation. Its Article 30 states that the Agency shall provide confidential treatment to the technical, operational, economic, financial and accounting information it requests from companies and individuals that produce or commercialize products. The disclosure of such information is only possible when necessary to avoid discrimination of the consumer, producer, service provider or trader; or in circumstances of risk to the population's health.

marketing approval (ANVISA, 2017).[379] It is also useful to note that MAPA is accountable for the marketing approval of pharmaceutical products for veterinary use (MAPA, 2017).

The Law No. 10.603/2002 "introduced data exclusivity in Brazil but limited to [agricultural][380] and veterinary products" (CORREA, 2007, p. 249). It prohibits, for a certain period of time, the reliance on test data regarding pharmaceutical products for veterinary use, fertilizers, agro-toxics (pesticides) and their components and related products submitted to marketing approval. This protection falls on the information whose elaboration involves considerable efforts and that has commercial value while not disclosed[381] (BARBOSA D., 2010, p. 2116).

It is important to reiterate that Law No. 10.603/2002 excludes from its scope test data regarding pharmaceutical products for human use (BARBOSA, P., 2009, p. 256-246; IDS, 2005, p. 409). As observed by Silva and Vallini (2005, p. 344-345), the Brazilian option to restrict the application of such TRIPS-Plus provision to agricultural and veterinary sectors was, to a great extent, influenced by NGOs that advocated for the exclusion of pharmaceutical products for human use from its scope.[382] For this reason, Article 195, XIV, of the Industrial Property Law remains the main provision to regulate test data protection of pharmaceuticals for human use in Brazil (BARBOSA D., 2010, p. 2113).

Turning to Law No. 10.603/2002, the obligation of the competent authorities is twofold. They are prevented from disclosing the test data submitted to them (secrecy), except when necessary to protect public health;[383] and from using this information in favor of subsequent applicants (non-reliance) (KUNG; MACHADO, 2003, p. 64).[384] The period of data exclusivity differs according to whether the product uses or not new chemical or biological entities.

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[379] See Article 2, I, of the Decree No. 3.029, of April 16, 1999.
[380] In this regard, Carvalho (2014, p. 597) stresses that, given the weight of the agricultural sector in their economies, test data for agricultural chemical products may be more economically relevant for certain developing countries that test data for pharmaceutical products. Therefore, they should carefully assess the economic risks of a long data exclusivity protection entails.
[381] Sole paragraph of Article 1 of Law No. 10.603/2002.
[382] In this regard, Denis Barbosa (2010, p. 2113) highlights that the Provisional Measure No. 69 of 2002 covered test data of pharmaceutical products for human use, but they were excluded when this Provisional Measure was transformed into the Law No. 10.603/2002.
[383] Test data concerning agricultural and pharmaceuticals products for veterinary use might be disclosed when necessary to protect public health. According to Silva and Vallini (2005, p. 344), this exception could be used, for example, in cases of poisoning by pesticides or for the existence of cross-resistance between veterinary products and medicines for human use.
[384] Article 3 of Law No. 10.603/2002.

For products using new chemical or biological entities, the competent authority shall grant 10 years of data exclusivity. This period is counted from the date of marketing approval in Brazil; or it endures until the first permission to rely on such data is issued in any other country, whichever occurs first. By any means, at least one year of data exclusivity is secured.[385]

For products that do not use new chemical or biological entities, the competent authority shall grant 5 years of data exclusivity. This period is counted from the date of marketing approval in Brazil; or it endures until the first permission to rely on such data is issued in any other country, whichever occurs first. In any case, at least one year of data exclusivity is guaranteed.[386] Conforming to Barbosa P. (2009, p. 247), this second option covers the most often cases, since the great majority of the recent products launched in the market are not based on new chemical and biological entities. In fact, they are a result of "new uses", based in the improvement of an already known chemical or biological entity (BARBOSA, P., 2009, p. 247).

For further test data requested by the competent authority after the marketing authorization, the remaining term of protection of the reference product, or, at least one year of protection, whichever occurs last, shall be granted to this new information.[387] As follows, no additional period of data exclusivity is granted to this new requested information, except if the remaining data exclusivity period of the referenced product lasts less than one year by the time this new test data is submitted. Accordingly, this provision ensures at least one year of data exclusivity to the requested new information (BARBOSA D., 2010, p. 2132).

During the above-mentioned terms, only upon the prior authorization of the test data's originator, the competent authority can use the submitted undisclosed information to justify the marketing approval of a similar product.[388] After these terms have elapsed, the competent authorities shall permit the reliance on such test data by subsequent applicants.[389]

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[385] Article 4, I, of Law No. 10.603/2002.
[386] Article 4, II, of Law No. 10.603/2002.
[387] Article 4, III, of Law No. 10.603/2002.
[388] Articles 5 and 6 of Law No. 10.603/2002.
[389] Article 3, § 2, of Law No. 10.603/2002.

It is worth noting that the data exclusivity granted by Law No. 10.603/2002 does not prevent the marketing authorization of similar product. It only prevents the competent authority from using the submitted data to grant marketing authorization to third parties during the exclusivity period (BARBOSA, D., 2010, p. 2130). The Law recognizes the economic value and availability of test data, allowing the test data's originator to license this information during this exclusivity period (BARBOSA D., 2010, p. 2118).

Moreover, Law No. 10.603/2002 regulates compulsory license of test data concerning agricultural and veterinary products. It establishes three situations in which the competent authority can use the submitted test data without the originator's consent (KUNG; MACHADO, 2003, p. 64). According to these rules, the State can issue a license: (i) if, after two years of the marketing approval, the product has not been commercialized in Brazil; [390] in case of (ii) violation of the economic order (infringement of the Antitrust Law No. 8.884/94);[391] and in case (iii) of public interest and/or emergency [392] (BARBOSA, P., 2009, p. 248; BARBOSA D., 2010, p. 2119).[393]

Only in the second situation, if the test data originator has engaged in anticompetitive practices, there will be no payment of remuneration (KUNG; MACHADO, 2003, p. 64). On the other two situations, the unauthorized use of the test data by the competent authority is permitted upon the payment of remuneration, which shall take into account the data's economic value (CORREA, 2007). If there is no agreement between the parties on the remuneration's amount, a commission formed by representatives of the agricultural, health, environment, intellectual property, industrial policy and anti-trust areas will arbitrate the due value (KUNG; MACHADO, 2003, p. 64).[394]

The Law No. 10.603/2002 clearly states that, notwithstanding the granting of the marketing approval by the competent authority, the intellectual property's holder is the exclusive responsible for monitoring the compliance of any intellectual property right protected in Brazil.[395] As such, the competent authority is not obliged to inform the patent holder, for example, that a competing company is seeking marketing approval for a generic

[390] Article 7 of the Law No. 10.603/2002.
[391] Article 8, I, of Law No. 10.603/2002.
[392] Article 8, II, of the Law No. 10.603/2002.
[393] Although TRIPS Article 39.3 does not prohibit compulsory license of test data, Carvalho (2014, p. 628) points out that only few WTO Members, such as Brazil and Saudi Arabia, provide for this mechanism in their national legislation.
[394] Article 7, § 4, of the Law No. 10.603/2002.
[395] Article 13 of the Law No. 10.603/2002.

product nor to check if the product in question still has a patent in force. The right holder itself shall raise any alleged violations of its intellectual property right (BARBOSA, P., 2009, p. 247).

In sum, it can be asserted that Brazil has a peculiar regime regarding the protection of undisclosed test data. On the one hand, test data of pharmaceutical products (whether chemical or biological) for human use submitted to ANVISA for marketing approval do not have an exclusivity period of protection. On the other hand, the test data of pharmaceutical products for veterinary use and agricultural products (whether chemical or biological) submitted to marketing approval have an exclusivity period of protection of 5 years (for old entities) or 10 years (for new entities).

3.4.3.4 Assessment

The TRIPS Agreement leaves WTO Members significant leeway with regard to how they should protect test data submitted to government agencies for marketing approval purposes. Its article 39.3 adopts vague terms such as “considerable efforts” and “unfair commercial use” that provide them a wide degree of flexibility in this regard. Whether regulatory authorities can, without disclosing the data, rely on the test data submitted by one firm to approve the marketing of others competing products is a matter of national policy (SHADLEN et al, 2011, p. 20-21).

The analyzed PTAs contain language that provides for protection that is more extensive than is required by TRIPS Article 39.3 (CARVALHO, 2014, p. 635). In essence, they require the parties to implement in their domestic legislations exclusive rights to test data submitted for marketing approval (UNCTAD; ICTSD, 2005, p. 536). It does not come as surprise that exactly the United States, the European Union and EFTA are the most active players in obtaining concessions in test data protection from their trading partners (CARVALHO, 2014, p. 635).

As highlighted by Carvalho (2014, p. 568), already during the Uruguay Round, developing countries did not have a decisive role in the final formulation of the provision on test data protection. The TRIPS Article 39.3 was, in fact, drafted by the United States,

the European Union and Switzerland (an EFTA Member State) with a "strong interest in the protection of the research-based pharmaceutical industry they host" (CARVALHO, 2014, p. 568). Not fully satisfied with the room for maneuver provided by Article 39.3, these countries started to promote their view on how this provision should be implemented through their PTAs. Their positions in bilateral and plurilateral realms reflect their national and regional legislation on the matter.

The 28 European Countries plus 3 EFTA Countries (Norway, Iceland and Liechtenstein),[396] which together form the European Economic Area (EEA), adopt a common standard of data exclusivity for pharmaceutical referred to as the 8+2+1 system.[397] The European Medicines Agency is responsible for the marketing authorization of pharmaceuticals products for human and veterinary use throughout these countries (ABBOT, COTTIER, GURRY, 2007, p. 603).

As explained by Abbott, Cottier and Gurry (2007, p. 603), the 8+2+1 system functions as follows. For a period of eight years, subsequent applicants are prohibited from relying on the undisclosed information submitted by the test data's originator to obtain marketing approval. After this period, subsequent applicants might even rely on this information, but they have to wait two years from the end of the data exclusivity's period to put their products in the market.

Accordingly, the test data's originator enjoys in practice at least a ten-year period of market exclusivity. This term can be extended with an additional year if, during the first eight years of that period, the holder of the firs first marketing authorization obtains an approval for one or more new therapeutic indications that are considered to bring a substantial clinical benefit (ABBOT, COTTIER, GURRY, 2007, p. 604).

In these terms, the EU provides for an eight-year period of data exclusivity and a ten-year (or eventually, eleven-year) period of test data market exclusivity (CARVALHO,

[396] Switzerland has its own system of pharmaceuticals and agrochemicals test data protection. In the pharmaceutical's field, Switzerland grants a ten-year period of data exclusivity (Art. 12 of the Therapeutic Products Act – TPA). The Swiss Agency for Therapeutic Products (SWISSMEDIC) is the Swiss registration authority for pharmaceuticals products for human and veterinary use. For agrochemicals, Switzerland provides for a ten-year period of data exclusivity (Art. 13 of the Regulation on Fertilizers; and Art. 14 of the Regulation on Plant Protection Products) (MEITIGER, 2005, p. 129). The Federal Office for Agriculture (FOAG) is the Swiss registration authority for plant protection products.

[397] Article 13.1 of Directive 2001/82/EC on the Community Code relating to veterinary medical products, as amended by Directive 2004/28/EC; and Article 10.1 of Directive 2004/27/EC on the Community Code relating to medical products from human use, as amended by Directive 2004/27/EC (MEITIGER, 2005, p. 129).

2014, p. 600). This implies that, "after the initial eight-year period, the European sanitary authorities may rely on the data submitted by originator in order to approve bioequivalent products" (CARVALHO, 2014, p. 600). However, these products can only be commercialized after the end of the ten or eleven-year period of market exclusivity (CARVALHO, 2014, p. 660). This protection covers test data of both chemical and biological pharmaceutical products (YAMANE, 2011, p. 473).

For agrochemicals products, as a general rule, the European Economic Community (28 EU + 3 EFTA Countries) provides for a 10 year-period of data exclusivity for agrochemicals products (MEITIGER, 2005, p. 129).[398] The competent authorities of the EEC Member States are in charge for granting marketing approval of food and plant protection products. They, nevertheless, have to respect the requirements, procedure and timeframes of the European regulation.[399] Eventually, the European Commission and the European Food Safety Authority can be involved in the authorization process (EUROPEAN COMISSION, 2017b).

In the United States, the Federal Food, Drug and Cosmetic (FD&C) Act establishes a five-year term of data exclusivity for test data regarding pharmaceutical chemical products (YAMANE, 2011,p. 472).[400] The Biologics Price Competition and Innovation (BPCI) Act[401] sets a twelve-year period[402] of data exclusivity for drugs based on biotechnology (YAMANE, 2011, p. 473).[403] It also grants the first four years of this term as market exclusivity, preventing the entry of follow-on biologics in the American market[404] (YAMANE, 2011, p. 473).[405] The Food and Drug Administration (FDA) is the competent authority for granting marketing authorization for chemical and biological medicines in the United States (BRANSTETTER, 2016, p. 22).

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[398] Article 13.3 of the Directive 91/414/EEC concerning the placing of plant protection products on the market; and Article 12 of the Directive 98/8/EC regarding the placing of biocidal products on the market (MEITIGER, 2005, p. 129).
[399] The Regulation (EC) No. 1107/2009 sets the rules and procedures for authorization of plant protection products.
[400] FD&C Act Act, Section 505, 21 U.S.C 355, §355(c)(3)(D)(ii) and §355(j)(5)(D)(ii).
[401] The BPCI Act was enacted as part of the Affordable Care Act in 2010 (BRANSTETTER, 2016, p. 23).
[402] The American biotechnology sought a fourteen-year period of data exclusivity, but, at last, the BPCI Act granted a twelve-year period of data exclusivity for biologics' test data (CARVALHO, 2014, p. 640)."
[403] BPCI Act, 42 U.S.C, §262(a)(7)(A).
[404] As explained by Carvalho (2014, p. 639), this means that: "a biological entity that is identical or similar to the entity of reference shall not be registered even if the subsequent applicant submits independently obtained data proving their efficacy and non-toxicity."
[405] BPCI Act, 42 U.S.C, §262(a)(7)(B).

The Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act,[406] links test data protection of chemical pharmaceutical products to patent protection (CARVALHO, 2014, p. 619-620). It requires the FDA to notify patent holders of any request to market a generic drug that may infringe their patent; and it provides legal tools for the patent holder to prevent the entry of a generic chemically synthetized drug while the patent that protect that chemical entity still in force (BRANSTETTER, 2016, p. 23). For biologics, the BPCI Act also requires the notification to the patent holder of generic entrants; and provides for the legal tools to prevent the entry of biosimilar products while the patent of the biological drug still in force (BRANSTETTER, 2016, p. 23).

For test data regarding agricultural chemical products, the Federal Insecticide, Fungicide and Rodenticide (FIFRA) Act grants a ten-year period of data exclusivity.[407] It also establishes "an obligation for competitors to contribute to the costs of test data if they wish to rely on such data during the five years following this ten-year term of exclusivity"[408] (MEITIGER, 2005, p. 130). This means that, only after fifteen years after the first marketing approval, the test data may be referred to without any obligation towards its originator (MEITIGER, 2005, p. 130). The Environmental Protection Agency (EPA) is the competent authority for granting marketing authorization for plant protection products in the United States (DINCA, 2005, p. 548).

The protection of test data exemplifies the complex relationship among the intellectual property systems, innovation and access to medicines (WTO, WIPO, WHO, 2013, p. 13). On the one hand, protecting such information is important given the "considerable efforts made to generate these data and thus bring new medicines to the market" (WTO, WIPO, WHO, 2013, p. 13). It provides a strong incentive for pharmaceutical companies to undertake the necessary investments to launch a new pharmaceutical product in the market (DINCA, 2005, p. 536). At least in the field of

[406] The Hatch-Waxman Act (Public Law 98-417) amended the Federal Food, Drug and Cosmetic (FD&C) Act, being codified in Titles 15, 21, 28 and 35 of the US Code.
[407] FIFRA Act, 7 U.S.C, §136a(c)(1)(F)(i).
[408] FIFRA Act, 7 U.S.C, §136a(c)(1)(F)(iii).

orphan drugs,[409] certain empirical findings[410] have shown that the market exclusivity system has resulted in a serious increase in its numbers in countries that have implemented such a system (DINCA, 2005, p. 536).

The majority of the pharmaceutical companies also back this position. As noted by Yamane (2011, p. 477), they "seem to prefer data exclusivity to patents in those countries without well-functioning judicial systems, because administrative protection is pre-emptory and more reliable than courts". According to Sell (2011, p. 453), they also favor such provisions, "because they offer new rights and opportunities to maximize returns on their products by delaying competition."

On the other hand, certain types of test data protection delay the entry of generic products in the market (WTO, WIPO, WHO, 2013, p. 13). They establish a system of exclusive rights based on priority "first-come, first-served" through which subsequent applicants are prevented from relying on data that the competent governmental authorities already have (CARVALHO, 2014, p. 640). The collection of comparable test data by competing manufacturers may be prohibitively expensive and take several years (FINK, 2011, p. 391-392). These exclusive rights create in effect a "huge barrier to entry of generic suppliers (who should generate their own test data) and [confers] market exclusivity even if a patent has not been granted in a particular country" (CORIAT, ORSENIGO, 2014, p. 230).

This is particularly problematic for essential products, such as medicines. As observed by Musungu (2016, p. 507), since the necessary resources are allocated to produce test data whose efficacy and safety have already been proven, data exclusivity not only imposes additional costs, which are passed on to the consumer, but also affects research and development of new delivery methods, new manufacturing process, etc.

In this sense, data exclusivity serves as an extra protection mechanism to patent protection (SANDERS, 2007, p. 15). Even in certain cases where the product is already off

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[409] Orphan drugs are "drugs meant to treat rare diseases" (DINCA, 2005, p. 533). The pharmaceutical industry would be unwilling to develop drugs under normal market conditions to such diseases, since, due their rarity, it is harder to recoup the investments made to develop them. Therefore, the United States grants a seven-year period of market exclusivity to orphan drugs (Orphan Drug Act, 1984, codified at 21 U.S.C and 42 U.S.C); while the European Union provides for a ten-year period of market exclusivity for orphan drugs (Council Regulation on Orphan Medical Products 141/2000) (DINCA, 2005, p. 534).

[410] See SKILLINGTON, G.; SOLOVY, Eric. The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement. **Northwestern Journal of International Law and Business**, v. 24, n. 1, p. 1-52, 2003, at page 12.

patent, the necessary resources to gather the data are usually too high for generic manufacturers to enter the market. The stakeholders who defend the pro-competitive effects of low entry barriers for pharmaceutical products oppose to the enactment of laws on data exclusivity. They argue that the "early entry of generic competition is likely to increase the affordability of medicines at the lowest possible price" (UNTCAD; ICTSD, 2005, p. 531-532).

In addition, the data exclusivity provisions in PTAs have been interpreted "as possibly precluding governments' possibilities to use compulsory licensing as a means of making available low-price pharmaceutical products" (UNCTAD; ICTSD, 2005, p. 537). There is limited importance in holding a compulsory license if the licensee still has to spend time and money producing its own clinical trial to obtain marketing approval (SANDERS, 2007, p. 15). Arguably, the third party authorized to produce a patent product under compulsory license would depend on the patent's holder consent for relying on its test data to market the product (UNCTAD; ICTSD, 2005, p. 537). Generic producers need to be able to obtain marketing approval to effectively make use of a compulsory license (FINK, 2011, p. 391).

According to Carvalho (2014, p. 570), there are mainly three arguments that speak against the prohibition to rely on the test data submitted to regulatory agencies. First, this exclusive protection leads to waste of scarce resources, since it demands competitors to repeat the same tests on a product's safety and efficacy that is known. Instead of spending time and money in duplicating the same information, companies could use these scarce resources to create new products and uses (CARVALHO, 2014, p. 570).

Second, differently from the subject matter of patent protection, test data only in part constitutes new knowledge. They are in fact purely factual information on the security and efficacy's results of a chemical entity (CARVALHO, 2014, p. 571). They lack the creative/innovative aspect of the patent's subject matter.

Third, test data is not of purely private nature (as trade secrets are), because they conceal information that is of special public relevance, such as safety, efficacy, toxicity, etc. (CARVALHO, 2014, p. 571). These three arguments demonstrate that the protection of test data and patents operate in different ways (CARVALHO, 2014, p. 572).

Nevertheless, this study identified numerous PTAs with provisions linking marketing approval to patent law. In addition to data exclusivity, these patent-linkage provisions contribute to delay "the entry of generic drugs to market and may deter generic competition" (SELL, 2011, p. 454).

In accordance with Carvalho (2014, P. 619), test data protection should have no relationship with patent protection. While test data refer to the safety and efficacy of the chemical entity, patents cover the chemical entity itself (CARVALHO, 2014, p. 622). Test data protection might exist even when there is no patentable invention. As explained by the author (CARVALHO, 2014, P. 619), "test data are undisclosed information that is submitted to governments in support of applications for marketing approval of products containing new chemical entities, regardless of whether those entities are inventions for the purposes of patent law." Therefore, test data protection should not "depend on the expiry of the patent on the chemical entity concerned" (CARVALHO, 2014, p. 622).

Besides, patent-linkage provisions transfer the burden of defending patents from the right holder to the government regulatory agency (SHADLEN et al, 2011, p. 20; CARVALHO, 2014, p. 621).[411] These provisions create an extra obligation for the regulatory authorities to determine the validity of the patents (UNCTAD; ICTSD, 2005, p. 537). Through this provision, the governmental authority responsible for approving the product replaces the patent holder in ensuring the exclusivity of patent rights (CARVALHO, 2014, p. 621). As noted by Abbott (2005, p. 89-90), patent-linkage "adds a complex layer to the typical medicines approval process, requiring the medicines regulatory authority to become involved in determining patent status." Besides, Abbott (2005, p. 90) calls attention to the fact that patent-linkage could also prevent the effective use of compulsory licensing, since the patent holder is entitled to block marketing approval by the medicines regulatory authority.

The Brazilian regime on test data protection advances in significant aspects as to the TRIPS rules. It does not reflect all the TRIPS-Plus provisions identified in the analyzed PTAs, but it has a higher level of protection than required in the multilateral level. The Brazilian Industrial Property Law (No. 9.279/96), in its Article 195, XIV, extends test data protection against unfair commercial use to products other than pharmaceutical and

[411] As highlighted by Carvalho (2014, p. 621), intellectual property rights are private rights whose primary responsibility to raise their violation lies on the intellectual property owner.

agricultural chemical products. Under the TRIPS Agreement, only the protection of test data regarding those products is mandatory.

The Law No. 10.603/2002 provides for a higher degree of protection than the TRIPS Agreement by granting a data exclusivity period of 5 years (for old entities) or 10 years (for new entities) for test data regarding agricultural products and pharmaceutical products for veterinary use.[412] It is also important to emphasize that, differently from the TRIPS Agreement, Law No. 10.603/2002 requires protection of test data of both new and old entities. Besides, while the TRIPS Agreement only requires this protection for test data protection of chemical products, the Brazilian Law provides for the protection of both chemical and biological agricultural products and pharmaceutical products for veterinary use.

As stressed, pharmaceutical products for human use (whether chemical or biological) do not benefit from data exclusivity protection and are regulated under the general rules of Article195, XIV of the Industrial Property Law. The Brazilian regime also does not provide for any kind of market exclusivity due to test data protection. That is to say, provided that competitors submit their own test data, even regarding veterinary and agricultural products, they can always be granted marketing approval.

Moreover, there is no legal instrument in the Brazilian regime that provides for the patent-linkage or the obligation of the competent governmental body to inform the patent holder of a marketing approval request of an entity that still under patent protection. The Brazilian regime provides for the protection of test data submitted to competent authorities for marketing approval regardless if such information is the object of a patent application or of a granted patent in Brazil (KUNG; MACHADO, 2003, p. 64).

3.5 Preliminary Conclusion

[412] In effect, the Law No. 10.603/2002 constitutes a market barrier to generic agrochemicals and pharmaceuticals products for veterinary use, since it prevents the MAPA from using the information it already has to favor greater competition in the intern market (BARBOSA D., 2010, p. 2125).

After more than 20 years since the entry into force of the TRIPS Agreement, the rights and obligations agreed therein never looked so balanced. The TRIPS is full of flexibilities, exceptions and broad and ambiguous terms that enable WTO Members to interpret and implement the Agreement in accordance with their national interests. Looking back to 1995, the initial critics to the TRIPS Agreement looks almost irrelevant in comparison to the current intellectual property governance and norm setting (SELL, 2011, p. 448).

In recent years, the forum for adding additional standards of increased intellectual property rights protection shifted towards preferential trade agreements (COTTIER, 2015, p. 80). As demonstrated in the present study, the rules on patent and test data accorded under preferential trade agreements require stronger and broader standards of protection and eliminates much of the legally permitted flexibility under the TRIPS (SELL, 2011, p. 448).

On patent protection, these new rules: (i) prevent parallel importation by requiring the parties to adopt a national or regional exhaustion regime of intellectual property rights; (ii) specify how the patentability criteria (novelty, inventive step and industrial application) shall be applied; (iii) require the grant of patents for "new uses" of known compounds; (iv) limit potential exclusions from patentability; (v) limit the grounds under which a compulsory license may be granted; (vi) limit the grounds under which a patent may be revoked; (vii) demand the disclosure of the origin of the genetic resource and/or associated traditional knowledge; (viii) require patent term extension under certain conditions, such as for unreasonable delays in the grating process and for the curtailment of the patent term of protection due to marketing approval (ABBOT, 2005, p. 89; SELL, 2011, p. 453; CORIAT; ORSENIGO, 2014, p. 230; WHO; WTO; WIPO; 2013, p. 186).

On test data, these new rules: (i) extend the protection to information on safety and efficacy of products other than pharmaceutical and agricultural chemical products, such as biologics; (ii) prevent second applicants from relying on test data submitted to the competent authority by the first applicant (data exclusivity); (iii) prevent the entry into the market of generic products even if the generic manufacturer submits his own test data to the competent authority (market exclusivity); (iv) provide for the protection of test data regarding "new uses" of known compounds; (v) link patent protection to the marketing authorization of pharmaceutical products; and (vi) demand the competent authority to

notify the patent owner of any application for marketing a generic pharmaceutical product (SELL, 2011, p. 453).

The above undertaken analysis has shown that the Brazilian intellectual property regime does not dramatically differ from the patent and test date protection rules that are being established under Preferential Trade Agreements. Brazil already has legislation that even exceeds the level of protection required under the TRIPS Agreement. The country promptly internalized the TRIPS Agreement's obligations and even renounced the transition periods allowed to developing countries.

On the one hand, Brazil used extensively the policy space provided under the TRIPS Agreement. The country adopts a strict interpretation of the patentability criteria (novelty, inventive step and industrial application); and excludes methods of treatment, plants and animals from patentability. Brazil has even already used the flexibility of the TRIPS Article 31 to issue a compulsory license of an antiretroviral drug. The measure enabled the national health system to expand the treatment for the people with HIV/AIDS in the country. The Industrial Property Law also provides for several grounds upon which a patent may be revoked. The national legislation also permits the reliance on the information submitted to ANVISA for the marketing approval of pharmaceutical products for human use.

On the other hand, Brazil has stricter rules than the ones accorded under the TRIPS Agreement or even the ones that are being adopted under PTAs. The country prohibits parallel importation of patented products; allows the grant of patents for "new uses" of known compounds; and ensures a minimum term of ten years of patent protection for cases in which INPI, by its own fault, delays the granting of the patent in over ten years. Given its immense biodiversity, the Brazil also requires the disclosure of the origin of national genetic resources and associated traditional knowledge. On test data protection, the Brazilian regime grants data exclusivity to information concerning the safety and efficacy of plant protection and veterinary products. This exclusivity covers test data referring to products using both new and old chemical or biological entities.

The analysis undertaken by this study made clear that there is a strong correlation between the intellectual property rules established under PTAs and the national legislation of the parties. The research evidenced that great part of the intellectual property rules

pushed through PTAs reflected a national rule on a particular subject matter. Through this approach, countries transplant national intellectual property norms into an international agreement. Such norms are internalized in the intellectual property regime of the other PTA's contracting parties. After they are widely dispersed, it is easier to "multilateralize" them through amendments to existing multilateral trade and/or intellectual property agreements or even through the adoption of a new multilateral agreement. This phenomenon can be explained by the theory of the diffusion of norms, the subject of the next chapter.

Table 18 - TRIPS-Plus Norms in the Brazilian Intellectual Property Regime		
Subject	Legal Instrument	Observation
National Exhaustion Regime of Patent Rights	Art. 43, IV, Industrial Property Law	Parallel Importation can be refrained in Brazil
Patentability of New Uses	INPI Resolution No. 169/2016	The patentability of new uses is allowed as long as it meets the patentability requirements of novelty, inventive step and industrial application, established under Article 8 of the Industrial Property Law.
Disclosure Requirements of Genetic Resources and Associated Traditional Knowledge.	INPI Resolution No. 134/2006.	Patent applications related to national biodiversity products shall inform the origin of the genetic resource or the associated traditional knowledge.
Extension of the Patent Term of Protection due to Delays in the Granting Process	Art. 40, §1, Industrial Property Law.	The patent term of patent protection shall not be less than 10 years, counted from the date of the grating; except if INPI has been prevented from examining the merits of the application due to judicial dispute or for reasons of *force majeure*.
Test Data Protection regarding products other than pharmaceutical and agricultural chemical products.	Art. 195, XIV, Industrial Property Law.	The protection of test data is not restricted to pharmaceutical and agricultural chemical products, but covers test data of any other product submitted as a condition for obtaining marketing approval.
Test Data Protection for both new and old chemical entities of agricultural chemical products.	Art. 4, I, II, Law No. 10.603/2002	In contrast to the TRIPS Agreement, which only requires this protection to new chemical entities, the Brazilian regime provides for the protection of both new and old chemical entities.
Data Exclusivity to information regarding pharmaceutical products for veterinary use, fertilizers, pesticides, and their components.	Art. 4, I, II, Law No. 10.603/2002	The competent authority shall grant 10 years of data exclusivity for products that use new chemical or biological entities, and 5 years for products that do not use new chemical or biological entities.
Data exclusivity for new requested data regarding veterinary and agricultural products.	Article 4, III, of Law No. 10.603/2002	At least one year of protection of new information.

Source: Table elaborated by the author.

4 DIFFUSION OF INTELLECTUAL PROPERTY NORMS

4.1 Introductory Remarks

The world is interconnected as never before. These connections structure the freedoms and constraints that countries face when implementing policies at international, regional, national and local levels. Understanding how norms diffuse across these spheres is key to comprehend how policies change over time (SHIPAN; VOLDEN, 2012, p. 788).

In today's interconnected world with low barriers to communication and travel, ideas, norms and policies are transnationally diffused (SHIPA; VOLDEN, 2012, p. 789; GILARDI, 2012). Different geographical levels of legal phenomenon cut across each other, overlap and interact in many complex ways. They are no longer precisely enclosed or hermetically sealed in a single hierarchical legal regime (TWINING, 2000, p. 253).

Preferential Trade Agreements, in this context, serve as important channels of diffusion of intellectual property policies and norms across the globe. This diffusion occurs when decisions on innovation policy in a given country are systematically conditioned by prior policy choices made in other countries. These prior choices are reflected in the intellectual property obligations accorded under their PTAs.

The proliferation of intellectual property rules in PTAs, however, deepens the fragmentation of the international intellectual property system. This fragmentation even puts in question the coherence of international law as a whole (ILC, 2006, p. 248). Therefore, it is necessary to rethink how to implement and interpret these new rules in a way to ensure the predictability and legal security that systemic coherence can provide.

In this perspective, this third chapter aims to demonstrate the diffusion of intellectual property norms through preferential trade agreements. Therefore, this chapter proceeds in three parts. First, it explains how intellectual property policies and norms diffuse across different legal leves. Second, it shows some evidences of diffusion of intellectual property norms on patent and test data protection through PTAs. At last, it addresses the issue of the fragmentation of international law, which is aggravated by the proliferation of preferential

trade agreements. It aims to delineate possible mechanisms to provide greater coherence between these new intellectual property rules accorded under PTAs, the WTO regime and other international law subsystems.

4.2 Diffusion of Intellectual Property Policies and Norms

Intellectual property policies and norms diffuse through diverse channels and are backed by different stakeholders. This phenomenon influences national innovation systems across the world, imposing new balances between the private and public interests. According to Simmons, Dobbin and Garrett (2006, p. 787), "international policy diffusion occurs when government policy decisions in a given country are systematically conditioned by prior policy choices made in other countries." States, international organizations, or even private actors can mediate this process (SIMMONS; DOBBIN; GARRETT, 2006, p. 787). In the words of Strang (1991, p. 325), diffusion is a process whereby "prior adoption of a trait or practice in a population alters the probability of adoption for remaining non-adopters."[413]

It is important to stress that diffusion is a process, as opposed to an outcome. That is to say, "diffusion is the interdependent process that is conducive to the spread of policies" (GILARDI, 2012, p. 454). A clear separation of diffusion from convergence is of key importance. As explained by Thorstensen and Kotzias (2015, p. 25), regulatory convergence indicates the higher degree of approximation and commitment among States in the standardization and adoption of common regulation (THORSTENSEN; KOTZIAS, 2015, p. 25).[414] Hence, while the diffusion describes the nature of the process itself, convergence characterizes the result of the process. Convergence is the outcome, that is to

[413] Drawing on the Elkins and Simmons' (2005, p. 34) observation, diffusion research "is motivated by the observation that nation-states, or some other jurisdictional unit, choose similar institutions within a fairly circumscribed period of time."

[414] For a deeper analysis on the regulatory coherence and convergence in the international trade see: THORSTENSEN, Vera; BADIN, Michelle (Coords.). **Coerência e Convergência Regulatória no Comércio Exterior**: o Caso do Brasil Frente a União Europeia e Estados Unidos com ênfase na Experiência do Reino Unidos. São Paulo: CCGI/FGV, 2017; THORSTENSEN, Vera; KOTZIAS, Fernanda. Barreiras Regulatórias: Um Novo Desafio para Governança da OMC. **Política Externa**, São Paulo, v. 24, n. 1, p. 81-92, Jul./Dec. 2015.

say, a significant increase in similarity of policies and norms among countries. As noted by Gilardi (2012, p. 454), convergence can, but does not need to follow from diffusion.

There are many ways in which policies diffuse. As noted by Gilardi (2012, p. 460), the list of diffusion mechanisms is almost as long as that of scholars that have written on the subject. However, the literature recognizes four main mechanisms of diffusion, namely (i) coercion, (ii) competition, (iii) learning; and (iv) emulation (GILARDI, 2012, p. 461).

Coercion implies that "international organizations and powerful countries can pressure states to adopt certain policies" (GILARDI, 2012, p. 561). Coercive diffusion involves asymmetries where the stronger party imposes its policy preferences on the weaker one. As noted by Simmons, Dobbin and Garrett (2006, p. 790), given its essentially hierarchical nature, coercion is a form of "vertical diffusion." Its main mechanism is conditionality. That is, "in order to access certain resources, national governments must comply with given policy requirements" (GILARDI, 2012, p. 461).

In this regard, Gilardi (2012 p. 461) provides two examples of coercive policy diffusion. First, the fiscal austerity and other economic reforms imposed by international financial institutions, such as the International Monetary Fund (IMF) and the World Bank to provide financial help. Second, the national transposition of the *acquis communautaire* (i.e., the corpus of EU legislation) and the restructuring of domestic political institutions and practices to approve the accession of a new EU Member State.

Competition describes "the process whereby policy makers anticipate or react to the behavior of other countries in order to attract or retain economic resources" (GILARDI, 2012, p. 462). Countries compete with each other to enhance their attractiveness as to international mobile capital and export-market share (SOLÍS; KATADA, 2009, p. 14; SIMMONS; DOBBIN; GARRETT, 2006, p. 792) In this setting, the most important relationships in the diffusion process are horizontal (SIMMONS; DOBBIN; GARRETT, 2006, p. 793). Examples of competitive policy diffusion include the adoption of measures to attract "foreign capital, direct loans, a contract to host the Olympics, or any investment or honor" (ELKINS; SIMMONS, 2005, p. 42)

Learning designates "the process whereby policy makers use the experience of other countries to estimate the likely consequences of policy changes" (GILARDI, 2012, p. 463). It assumes that countries assess the benefits and drawbacks of a certain policy by

comparing the countries that have adopted it and those that have not (GIRALDI, 2012, p. 464). In this setting, policies diffuse "because policy makers intentionally and systematically study other states when considering status quo changes" (GLICK; FRIEDLAND, 2014, p. 981).

Emulation indicates "the process whereby policies diffuse because of their normative and socially constructed properties instead of their objective characteristics" (GIRALDI, 2012, p. 466). Emulation is also often referred to as imitation (SHIPAN; VOLDEN, 2008, p. 843). It depicts the process whereby "countries adopt policies that they deem appropriate, frequently following the lead of strong countries or socio-cultural peers" (SOLÍS; KATADA, 2009, p. 14). As explained by Solís and Katada (2009, p. 13), policies diffuse "not because of an objective examination of their effectiveness, but rather because of the meaning they hold for policy makers and by notions of their appropriateness."

In a similar vein, Shipan and Volden (2008, p. 842) observe that emulation is better understood in contrast to learning. Whereas in learning, policy makers focus on the policy itself – what were its political consequences, how was it adopted, was it effective; in emulation, policy makers focus on the other government – what did that government do and how can we appear the same (SHIPAN; VOLDEN, 2008, p. 842). As such, emulation does not involve concerns about the effects of policies, but rather a desire to do whatever the leader (the strongest party) has done (SHIPAN; VOLDEN, 2008, p. 844).

It is important to stress that policy diffusion is not always beneficial. As observed by Volden and Schipan (2012, p. 790), "while it is important to recognize the favorable aspects of [it], it would be wrong to declare interrelated policy decisions across governments as always beneficial." How diffusion affects policy choices depend on "the capacity of policy makers, political circumstances surrounding policy change, and the characteristics of the policies themselves" (VOLDEN; SCHIPAN, 2012, p. 793).

The diffusion of policies does not exist in a vacuum. They are usually implemented based on some kind of normative act. The diffusion of policies is, therefore, intrinsically related with the dissemination of laws and norms across different jurisdictions (FARRAN; RAUTENBACH, 2015, p. 2). Although they are not the only, or even the main object; legal rules, concepts and ideas can also be object of diffusion (TWINING, 2006, p. 260).

According to Twining (2006, p. 246), diffusion of law[415] "is generally considered to take place when one legal order, system or tradition influences another in some significant way." This phenomenon "creates networks and shared legal approaches" (FARRAN; RAUTENBACH, 2015, p. 5).

In this respect, Watson uses the concept of "legal transplant" to describe the "moving of a rule or system law from one country to another, or from one people to another" (WATSON, 1974, p. 21). The author emphasizes that his phenomenon is not restricted to the modern world, but has been common since the earliest history of antiquity (WATSON, 1974, p. 22). Now and then, the receptions and transplants of norms come in all shapes and sizes (WATSON, 1974, p. 30).

According to Acharya (2004, p. 247), the forces that create the demand for new norms include: (i) major security or economic crisis (war or depression), since they call into question the "existing rules of the game"; (ii) shifts in the distribution of power or the great powers' interest and interactions (e.g. the end of the Cold War); (iii) domestic political changes in the norm-taker; and (iv) the international or regional demonstration of the effectiveness of a norm.

In analyzing the complexities of norm diffusion, Twining draws important considerations that shall be taken in account when studying this phenomenon. To begin, the relations between the norm-exporter and norm-importer are not necessarily bipolar, "involving only one exporter and one importer" (TWINING, 2006, p. 260). Since the sources of importation are often diverse, "the simple binary interaction between legal order and traditions cannot be [always] assumed" (TWINING, 2006, p. 249).

Moreover, the diffusion of norms derives from vertical and horizontal cross-level interactions. It takes place across different levels of ordering, such as local-local, sub-state, national-international or regional-regional, not just between national legal systems (TWINING, 2006, p. 249). Besides, although the most noticeable agents of norm import and export are governments, there are many other agents of diffusion (TWINING, 2006, p.

[415] Twining (2006, p. 239) explains that, "since 1959, the study of diffusion of law has proceeded under many labels including reception, transplants, spread, expansion, transfer, exports and imports, imposition, circulation, transmigration, transposition, and transfrontier mobility of law." This work uses the term "diffusion" to cover all of these terms.

251). States are not the only, and may be not the main, agents in this process (TWINING, 2006, p. 260).

The pathways through which norms diffuse "may be complex and indirect and influences may be reciprocal" (TWINING, 2006, p. 260). Although the paradigmatic example of a norm-reception involves a formal act of adoption or enactment, much of the norms diffused are informally received (TWINING, 2006, p. 251). As such, diffusion may occur through "information interaction without involving formal adoption or enactment" (TWINING, 2006, p. 260).

In this regard, it is also useful to note that the reception of norms often involves a lengthy process that, "even if there were some critical moments, cannot be understood without reference to events prior and subsequent to such moments" (TWINING, 2006, p. 252). For these reasons, it is sometimes difficult to determine one or more specific reception dates (TWINING, 2006, p. 260).

Despite the tendency to assume that most diffusion involves a movement from imperial or other powerful center to a colonial, dependent or less developed periphery, it is important to remind that other patters also exist (TWINING, 2006, p. 260). Norm creation and diffusion may also derive from weaker actors challenging and influencing the global normative process (ACHARYA, 2011, p. 96). In this regard, Acharya (2011, p. 95) develops the concept of "norm subsidiarity", which describes the "process whereby local actors create rules with a view to preserve their autonomy from dominance, neglect, violation, or abuse by more powerful central actors."

The norm diffused from one legal order to another does not retain its identity without significant change (TWINING, 2006, p. 260). As observed by Twining (2006, p. 253), "how and to what extent any particular 'import' retains its identity or is accepted, ignored, used, assimilated, adapted, rooted, resisted, rejected, interpreted, enforced selectively, and so on, depends largely on local conditions." In a similar vein, Acharya (2004, p. 239) affirms that local agents "reconstruct foreign norms to ensure the norms fit the agent's cognitive priors and identities." One may also not forget that often the resistance to foreign legal ideas, laws and institutions constitutes part of some broader political struggle (TWINING, 2006, p. 254). It is also wrong to presume that imported law always fills a vacuum or wholly replaces prior local law (TWINING, 2006, p. 260).

Some researchers have already addressed the diffusion of intellectual property norms. The study developed by Firth (2015, p. 186) demonstrates how important EU trademark norms have found their way into New Zealand law by way of the TRIPS Agreement. This example involves three actors: the United Kingdom, the EU and New Zealand and plays out as follows.

The United Kingdom embraced the EU trademarks norms as a result of its membership in the European Union (FIRTH, 2015, p. 171). In 1994, the UK enacted the Trademarks Act to comply with the Directive No. 89/104/EEC. By its turn, New Zealand, when implementing the TRIPS Agreement, followed other Commonwealth jurisdictions and adopted text from the 1994 UK Trademarks Act (FIRTH, 2015, p. 172). Accordingly, New Zealand adopted through diffusion "many features of EU law as reflected in the UK's 1994 Trademark Act" (FIRTH, 2015, p. 186).

Besides, Firth (2015) calls attention to the fact that, by the time the EU was negotiating the TRIPS Agreement, the Community Trademark Regulation 40/94 was under preparation. Not surprisingly, "much of the trademarks section of the TRIPS draft offered by the EC negotiators closely resembled contemporaneous EC legislation" (2015, p. 172). The final version of the TRIPS Agreement signed in 1994 in Marrakesh is substantially based on the Dunkel draft, which contains many of the EU proposals on trademarks. For these reasons, by the time TRIPS Agreement entered into force, the UK was already TRIPS-compliant in trademarks terms, given its 1994 Trademarks Act enacted in compliance with the EU Directive 89/104/EEC (FIRTH, 2015, p. 172). This case illustrates Twining's (2006, p. 250) observation that "the pathways of diffusion may be complex and indirect."

The research developed by Michael (2016, p. 2) finds evidence that the "global diffusion of regulatory data protection can be directly traced to international coercion from the United States and the European Union." The central question that Michael tries to answer is why countries without significant originator pharmaceutical industries – "that is, virtually every country outside the United States, United Kingdom, Switzerland, Germany and France" – are adopting TRIPS-Plus provisions on test data protection (MICHAEL, 2016, p. 5).

Through quantitative and qualitative analysis, the author demonstrates this is done through the coercive mechanism of norm diffusion. The US coerces weaker trading patterns in adopting regulatory data protection by requiring such protection as a condition for concluding trade or bilateral intellectual property agreements (MICHAEL, 2016, p. 2). By its turn, the EU "coerces applicants by demanding that they adopt such rights during the EU accession negotiations" (MICHAEL, 2016, p. 2).

4.3 The Diffusion of Intellectual Property Norms Through PTAs

The analysis developed by this study found some evidence of diffusion of intellectual property norms through PTAs. On the whole, the analysis of the intellectual property provisions on patent and test data protection has shown three main models pushed forward by the United States, EFTA and European Union. Certainly, these models were adjusted according to the other party involved. Their main characteristics, however, remained the same.

This practice is also recognized in the literature. As noted by Baccini, Dür and Haftel (2015, p. 168), "states that form or reform trade agreements do not start from scratch but rather look for an existing institutional model to follow." In this manner, the PTA's design is not done in isolation, "but rather is influenced by interdependence among countries and by the preferences of the more powerful players in the international economic system" (BACCINI; DÜR; HAFTERL, 2015, p. 169).

It is possible to track the diffusion of intellectual property norms between international trade agreements (horizontal) and from national to international realm (vertical) by considering the date of their adoption in each of these respective regimes. Even though the relations between-norm exporter and norm-importer are not necessarily bipolar and norms might be informally received; these parameters provide some indications on how intellectual property norms are diffusing. Without claiming to be comprehensive, the present study finds evidence of the dissemination of intellectual property norms in the following arrangements.

On a horizontal setting, it is remarkable the diffusion of TRIPS norms across the 68 analyzed PTAs. In order to reaffirm the level of commitment and flexibilities agreed under the WTO Agreement, countries engaging in PTAs often directly or indirectly transplant intellectual property rules from the TRIPS Agreement into their bilateral or plurilateral trade agreements. This study found evidence of legal transplants from TRIPS to PTAs in matters related to exhaustion of intellectual property rights, patentability criteria, exclusions from patentability, compulsory license, patent term of protection, and protection of test data submitted to governmental agencies.

Moreover, it is noticeable the diffusion of the 2001 Doha Declaration on the TRIPS Agreement and Public Health through the analyzed PTAs. From the 68 PTAs under investigation, 26 reaffirmed their commitment to the Doha Declaration.[416] They account for 44.8% of all PTAs signed after November 2001, date of the Doha Declaration's adoption. Although the great majority of PTAs referring to the Doha Declaration were adopted between developing and developed countries, this reference could also be found in PTAs between developed countries. States make use of this multilateral declaration to ensure that the obligations agreed under the PTA do not prevent the effective use of the TRIPS' understanding regarding public health.

Through this linkage, the parties are entitled to rely upon the Doha Declaration when interpreting and implementing the rights and obligations agreed under the preferential trade agreement. They are also required to ensure consistency between the PTA's provisions and the Doha Declaration, in a way that the PTA's provisions are implemented without prejudice to the Doha Declaration. These provisions set boundaries on how and to what extend the intellectual property commitments under a certain PTA shall be construed in the face of the adoption or maintenance of public health measures.

Even though the references to the Doha declaration in PTAs might appear significant, Flynn et al (2013, p. 180) highlight that they normally lack further specific

[416] These PTAs are the 2003 Chile-US (Preamble); 2005 EFTA-Korea (Art. 2c); 2006 US-Colombia (Art. 16.13.2b); 2006 US-Peru (Art. 16.13); 2007 US-Korea (Art. 18.11); 2007 US-Panama (Art. 15.12); 2008 EFTA-Colombia (Art. 6.2.5); 2008 CARIFORUM-EU (Art. Art.147b); 2010 EFTA-Peru (Art. 6.2.5); 2010 EU-Korea (Art. 10.34); 2010 EU-Moldova (Art. 313); 2012 Central America-EU (Art. 229.2a); 2012 Colombia-Peru-EU (Art. 197.2); 2013 Central America-EFTA (Art. 2.5); 2013 Switzerland-China (Art. 11.5.1); 2014 EU-Georgia (Art. 185); 2014 EU-Ukraine (Art. 219); 2014 Canada-Korea (Art. 16.5.1); 2014 Australia-Korea (Art. 13.10.1); 2015 China-Korea (Art. 15.5.2); 2015 Australia-China (Art. 11.7.1); 2015 TPP (Art. 18.6); 2015 EU-Singapore (Art. 11.30); 2016 EU-Vietnam (Art. 8.2); 2016 EFTA-Philippines (Art. 2.6); and 2016 CETA (Art. 20.3).

commitments clarifying how countries can operationalize it in the view of other provisions that exceed the TRIPS' level of protection. Usually, PTAs have numerous TRIPS-Plus provisions that predictably lead to higher prices and lower availability of pharmaceutical products (FLYNN et al, 2013, p. 181). The challenge in this regard resides in harmonizing the apparently conflicting provisions within a certain PTA.

Table 19 – Horizontal Diffusion of Intellectual Property Norms from the TRIPS Agreement to PTAs

Norm	TRIPS Agreement	PTAs		
		Year of Signature	PTA	Provision
Exhaustion of Intellectual Property Rights	Article 6	2012	Central America-EU	Art. 232
		2012	Colombia-Peru-EU	Art. 200
		2014	EU-Ukraine	Art. 160
		2014	Canada-Korea	Art. 16.7
		2014	EU-Korea	Art. 10.4
		2015	Australia-China	Art. 11.8
		2015	EU-Singapore	Art. 11.3
		2015	TPP	Art. 18.11
		2016	EU-Vietnam	Chapter 12, Art.3
Patentability Criteria	Article 27.1	2000	Mexico-Northern Triangle	Art. 16-25.1
		2000	US-Vietnam	Art. 7.1
		2003	Singapore-US	Art. 16.7.1
		2003	Mexico-Uruguay	Art. 15-23.1
		2005	Japan-Malaysia	Art. 119.1
		2005	EFTA-Korea	Annex XIII, Art. 2(a)
		2008	Colombia-EFTA	Art. 6.9.1
		2009	Japan-Switzerland	Art. 117.1
		2010	EFTA-Ukraine	Annex XIII, Art. 4(a)
		2010	EFTA-Peru	Art. 6.9.1
		2011	EFTA-Hong Kong	Annex XII, Art. 5
		2013	China-Switzerland	Art. 11.8.1
		2013	Central America-EFTA	Annex XIX, Art. 41
		2015	China-Korea	Art. 15.15.1
		2016	EFTA-Philippines	Annex XVIII, Art. 6.1
Patentable Subject Matter (Exclusions from Patentability)	Articles 27.2 and 27.3	2003	Mexico-Uruguay	Art. 15-23.3/Art. 15-23.4
		2011	Central America-Mexico	Art. 16.14
		2012	Australia-Malaysia	Art. 13.11.4
		2013	Central America-EFTA	Annex XIX, Art. 4.2, 4.3(a) (b)
		2014	Canada-Korea	Art. 16.12.2
		2015	China-Korea	Art. 15.15.2/Art. 15.15.3
		2015	Korea-Vietnam	Art. 12.7.2 (a)(b)(c)
		2015	TPP	Art.18.37.3/Art.18.37.4

Source: Table elaborated by the author.

Table 20 - Horizontal Diffusion of Intellectual Property Norms from the TRIPS Agreement to PTAs				
Norm	TRIPS Agreement	PTAs		
		Year of Signature	PTA	Provision
Compulsory License	Article 31	1995	EU-Turkey	Art. 4.2, §1
		2000	Mexico-Northern Triangle	Art. 16-29
		2003	Mexico-Uruguay	Chapter XV, Art. 15-26
		2004	EFTA-Lebanon	Annex V, Art. 3b
		2005	EFTA-Korea	Annex XVIII, Art. 2c
		2015	TPP	Art. 18.41
Patent term of protection of 20 years counted from the filing date	Article 33	1995	EU-Turkey	Art.4.2.§3
		1995	EFTA-Estonia	Art. 3, §5
		1995	EFTA-Latvia	Art. 3, §51
		1995	EFTA-Lithuania	Art. 3, §5
		1998	EFTA-Turkey IPR Amendments	Annex X, Art. 3.1, §6.
		2000	Mexico-Northern Triangle	Art. 16-32
		2000	US-Vietnam	Art. 7.10
		2003	Mexico-Uruguay	Art.15.29
Protection of Data Submitted to Governmental Agencies	Article 39.3	2016	EFTA-Philippines	Art. 8.1
		2000	Mexico-Northern Triangle	16.37

Source: Table elaborated by the author.

Still on the horizontal setting, it is noticeable the diffusion of intellectual property norms from one PTA to another. Commonly, intellectual property provisions established in a first PTA are simply replicated *ipsis litteris* in the following agreements. It is virtually a "copy and paste exercise" of norm diffusion. Normally, at least one party of the primary agreement is responsible for disseminating the established intellectual property rule. However, it is possible to notice the diffusion of norms between parties that are not directly or indirectly linked to the first originating PTA in which the norm was first established. The relations between the norm-importer and norm-exporter are, thus, multipolar and they do not always occur in a linear basis.

For example, the norm accorded by Japan[417] and Indonesia in their 2007 PTA, on the non-rejection of patent applications on the sole ground that the subject matter is related to a computer program (software), is subsequently identically replicated in the following Japan's PTAs with Vietnam (2008), Peru (2011), India (2011) and Mongolia (2015). The

[417] Article 2(1) of the Japan Patent Act (Act No. 121 of 13 April 1959, as amended up to 2006) "ensures that computer related inventions may be patentable subject matter as long as there is a 'creation of technical ideas utilizing laws of nature'" (See WIPO Document SCP/15/3, Annex II, page 89).

diffusion of this provision through the Japan's PTAs demonstrates the country's interest in ensuring that software-related patent applications from Japanese companies will not be denied abroad.

In 2001, EFTA amended its Constitutive Agreement[418] and established, among other subjects, new rules on intellectual property protection. The EFTA countries agreed to provide additional term of protection for pharmaceutical and plant protection products object of marketing approval procedures. This compensatory period covers a maximum period of five years. After that this understanding has been established among the EFTA parties, they started to diffuse this norm in their preferential trade agreements.

The same type of provision can found in the PTAs signed by EFTA with Singapore (2002), Korea (2005), Albania (2009), Serbia (2009), Ukraine (2010), Montenegro (2011) and Bosnia and Herzegovina (2013). The same standard already adopted by Korea in its PTA with EFTA, was then replicated in its PTA with the European Union (2010). Switzerland, an EFTA Member State, also disseminated the same type of provision in its PTA with Japan (2009).

The diffusion of this provision through the EFTA's PTAs shows the interest of EFTA Members States in ensuring the effective use of the patent. Lengthy marketing approval processes might prevent patent-holders from effectively benefiting from the monopolistic rights conferred by patents. This is particular important for Switzerland, which has an important pharmaceutical industry that heavily invest in research and development of new medicines.

The 2010 PTA between the EU and Moldova[419] demands the parties to provide for a supplementary protection certificate (SPC). This legal instrument, so as it is formulated, has been designed by the European Union since 1992.[420] It establishes a further period of protection of up to five years for patented plant and medical products subject to marketing approval as well as an additional six months if the medical product is for pediatric use. The

[418] The Vaduz Agreement of June, 2001, revised the Convention Establishing the European Free Trade Association.
[419] By the time Moldova signed the PTA with the EU, its national patent law enacted in 2008 already provided for SPCs. See Articles 69 to 72 of Law No. 50-XVI of March 7, 2008, on the Protection of Inventions.
[420] See footnote 329.

European Union[421] replicated this provision in its PTAs with Georgia (2014)[422] and Ukraine (2014).[423] The willingness of Georgia and Ukraine to adopt this rule also express their desire to become a member of the EU in the future. The incorporation of certain rules of the of EU legislation will certainly be taking into account when considering any candidate for future enlargement of the trading block.

The United States is also diffusing intellectual property norms of their interest. Since the signing of the PTA with Singapore in 2003, the US has diffused the patent-linkage provisions in its PTAs with/within Chile (2003), CAFTA (2004), CAFTA-Dominican Republic (2004), Bahrain (2004), Australia (2004), Morocco (2004), Peru (2006), Colombia (2006), Oman (2006), Korea (2007) and TPP (2015).

By linking the exclusive patent right to the marketing approval process, the United States aims to subject the marketing approval of competing generic firms to the consent or acquiescence of US patent holders. As such, the regulatory authorities of the US PTA's partners shall, unless the patent owner consent to such approval, deny the marketing approval of products whose patent term has not yet expired.

Under the US Law, the Hatch-Waxman Act[424] links test data protection of chemical pharmaceutical products to patent protection (CARVALHO, 2014, p. 619-620). As observed by Carvalho (2014, p. 620), through its trade-related negotiations, the United States succeeded to transpose the Hatch-Waxman's patent-linkage provision to the national law of a number of developing countries. This leads us to another setting of diffusion of intellectual property norms.

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[421] By analyzing how EU norms are diffused, Manners (2002, p. 244) identifies six factors that shape this process. According to the author (MANNERS, 2002, p. 244-245), the EU norms are diffused through: (i) Contagion, when there is an unintentional diffusion of ideas from the EU to other political actors; (ii) Information, by disseminating strategic communications, such as new policies initiatives and declaratory communications; (iii) Procedures, by institutionalizing the relationship of the EU and a third party, such as cooperation agreements, membership of an international organization or enlargement of the EU itself; (iv) transference, when the EU exchange goods, trade or aid or technical assistance with third parties through largely substantive or financial means; (v) *Overt diffusion*, as a result of the physical presence of the EU in third states and international organizations; (vi) and Cultural filter, based on the interplay between the construction of knowledge and the creation of social and political identity by the subjects of norm diffusion.

[422] According to the 2016 Trade Policy Review conducted by the WTO, Georgia already introduced the concept of SCP in 2010, with the purpose of harmonizing with the EU Regulation 1768/92. This was undertaken through the amendments to its Patent Law (WTO, 2016, p. 73).

[423] At the time of writing, Ukraine has not yet internalized the legal institute of the SCP, so as formulated by the EU, into its intellectual property regime.

[424] The Hatch-Waxman Act (Public Law 98-417) amended the Federal Food, Drug and Cosmetic (FD&C) Act, being codified in Titles 15, 21, 28 and 35 of the US Code.

Table 21 - Examples of Horizontal Diffusion of Intellectual Property Norms Between PTAs		
Norm	PTA-Diffuser	PTA-Receiver
A claimed invention is capable of industrial application if it has a specific, substantial and credible utility.	2004 CAFTA (Art. 15.9.11)	2004 CAFTA-DR (Art. 15.9.11)
		2006 US-Peru (Art. 16.9.11)
		2006 US-Colombia (Art. 16.9.11)
		2006 US-Oman (Art. 15.8.11b)
		2007 US-Panama (Art. 15.9.11)
		2007 US-Korea (18.7.10b)
		2014 Australia Korea (13.8.8b)
Disclosure of the origin of a genetic resource and traditional knowledge; and proof of prior and informed consent in patent applications.	2008 EFTA-Colombia (Art. 6.5.5)	2010 EFTA-Peru (Art. 6.5.5)
Non-Rejection of Patent Applications Related to Computer Programs	2007 Indonesia-Japan (Art. 112.1)	2008 Japan-Vietnam (Art. 86.1/Art. 86.2)
		2011 Japan-Peru (Art. 174)
		2011 India-Japan (Art. 105.1)
		2015 Japan-Mongolia (Art.12.7.1)
Revocation only on grounds that would have justified a refusal to grant the patent, on basis of fraud, misrepresentation or inequitable conduct, without prejudice to Article 5.A(3) of the Paris Convention.	2004 CAFTA (Art. 15.9.4)	2004 CAFTA-DR (Art. 15.9.4)
		2006 Peru-US (Art. 16.9.4)
		2006 Colombia-US (Art. 16.9.4)
		2007 Panama-US (Art. 15.9.4)
		2015 TPP (Art. 18.30)
Adjustment to Compensate Curtailment of the Patent Term of Pharmaceuticals and Plant Products due to Marketing Approval.	2001 EFTA Service (Art. 3.b)	2002 EFTA-Singapore (Annex XII, Art. 3.b.i)
		2005 EFTA-Korea (Annex XIII, Art. 2b)
		2009 Japan-Switzerland (Art. 117.5/Art. 117.6)
		2009 Albania-EFTA (Annex V, Art. 4b)
		2009 EFTA-Serbia (Annex VI, Art.4.b.c)
		2010 EU-Korea (Art. 10.35.1/Art. 10.35.2)
		2010 EFTA-Ukraine (Annex XIII, Art. 4.b)
		2011 EFTA-Montenegro (Annex VI, Art. 5b)
		2013 Bosnia&Herzegovina-EFTA (Annex VII, Art. 5b)
Patent-Linkage	2003 US-Singapore (Art.16.8.4c)	2003 Chile-US (Art. 17.10.1b)
		2004 CAFTA (Art. 15.10.2a)
		2004 CAFTA-DR (Art. 15.10.2a)
		2004 Bahrain-US (Art. 14.9.4a)
		2004 Australia-US (Art.17.10.4a)
		2004 Morocco-US (Art.15.10.4a)
		2006 Peru-US (Art. 16.10.4a)
		2006Colombia-US(Art. 16.10.4b)
		2006 Oman-US (Art. 15.9.4a)
		2007 Korea-US (Art. 18.9.5b)
		2007 Panama-US (Art. 15.10.4a)
		2015 TPP (Art. 18.53.2)

Source: Elaborated by the author.

On a vertical setting, intellectual property norms diffuse from national to international regime (bottom-up) as well as from international to national regime (top-down).[425] In this dynamic, PTAs are used as the main vector to export national intellectual property norms and practices to the international realm and to compel the contracting parties to import them into their national intellectual property system. The evidences of vertical bottom-up and top-down diffusion of intellectual property norms can be perceived in several of the analyzed PTAs.

The 2004 US-Morocco PTA prohibited parallel importation of patent products. This was a significant departure from the 2000 Morocco's Industrial Property Act,[426] which adopted an international regime of exhaustion for patent rights (ALOUI, 2009, p. 153; KONGOLO, 2002, p. 189). In 2006, Morocco enacted a decree [427] amending and supplementing its Industrial Property Act, prohibiting parallel importation of patented products (LLANOS, 2015). Currently, with exception to patents, parallel imports are authorized in Morocco (WTO, 2016, p. 82). In the United States, the case law that determines the national exhaustion of patent rights prevails since its development in the late 19th Century (WIPO, 2014, p. 4).[428]

Moreover, on the patentability criteria, the 2004 US-Morocco PTA requested the parties to provide that a claimed invention is industrially applicable if it has a "specific, substantial and credible utility."[429] This is a concept embedded in the 2001 United States' patent examiners guidelines.[430] It departures significantly from the concept adopted by the 2000 Moroccan Industrial Property Act.[431] Through the above-mentioned amendments,

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[425] This concept of vertical diffusion could also be applied to the WTO TRIPS Agreement. As observed by Reich (2004, p. 323), since its creation, the WTO is becoming "a major player in the field of global harmonization of national laws." The subject matter of the TRIPS Agreement, for example, covers domestic laws and policies on standards related to the availability, scope, use of intellectual property rights and the means of their enforcement. In effect, the TRIPS Agreement, from a top-down approach, harmonized previously divergent national intellectual property laws (REICH, 2004, p. 339).

[426] Article 55(d) of 2000 Morocco Industrial Property Act (Law No. 17-97 on the Protection of Industrial Property Law).

[427] Decree No. 2-05-1485 of 20 February 2006 amending and supplementing Decree No. 2-00-368 7 June 2004 for the implementation of the Law No. 17.97 on the protection of industrial property.

[428] See the Supreme Court decision on Adams v. Burke, 84 U.S, 453 (1873).

[429] Article 15.9.11(b) of the 2004 US-Morocco PTA.

[430] See USPTO Utility Examination Guidelines, Federal Register Volume 66, Number 4, Friday January 5, 2001.

[431] Article 27 of the Moroccan 2000 Industrial Property Act defined the patentability criterion of capable of industrial application as follows: "an invention shall be considered industrially applicable if it can be made or used in any kind of industry, including agriculture."

Morocco inserted, in 2006,[432] the concept of industrial applicability[433] in its Industrial Property Act so as under the United States practice. This same standard of industrial applicability is required by the US in at least other 7 PTAs.[434]

The 2004 Bahrain-US PTA demanded the parties to make patents available for any "new uses" or methods using a known product, including products for particular medical conditions.[435] The 2004 Bahraini Law on Patents and Utility Models[436] did not extend patent protection for "new uses" or methods of a known product. This changed in 2006, when Bahrain amended its Law on Patents and Utility[437] and expressly added a provision extending patent protection for "new uses" and methods using a known product, including medical products.[438]

The United States, by its turn, makes patent protection available for "new uses" of known products based on a provision inserted in the US Patent Law in 1952.[439] The § 101 of the 35 U.S.C states that "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, **or any new and useful improvement thereof**, may obtain a patent therefor, subject to the conditions and requirements of this title" (emphasis added). It is, thus, evident that the United States' law and practice on patent for "new uses" precede and influenced that of Bahrain.

The 2014 EU-Georgia PTA required the parties to provide for a regime of domestic or regional exhaustion of intellectual property rights. The European Union adopts a regional exhaustion regime of intellectual property rights, "under which parallel imports from third countries are not allowed without authorization by the right holder, while parallel imports within the EU are permitted" (WTO, 2013b, p. 91). As interpreted by the EU Court of Justice, the regime is enshrined in Article 34 and 36 of the Treaty on the

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[432] Decree No. 2-05-1485 of 20 February 2006 amending and supplementing Decree No. 2-00-368 7 June 2004 for the implementation of the Law No. 17.97 on the protection of industrial property.
[433] See Article 29 of the Law No. 23-13 amending and supplementing Law No. 17-97 on the Protection of Industrial Property, November 21, 2014.
[434] 2006 US-Oman (Art. 15.8.11.b), 2006 US-Colombia (Art. 16.9.11), 2006 US-Peru (Art. 16.9.11), 2007 US-Korea (Art. 18.7.10b), 2007 US-Panama (Art. 15.9.11), 2004 CAFTA (Art. 15.9.11); and 2004 CAFTA-Dominican Republic (Art. 15.9.11).
[435] Article 14.8.2 of the 2004 Bahrain-US PTA.
[436] Law No (1) for the Year 2004 on Patents and Utility Models.
[437] Law No. 14 of 2006 amending some Provisions of Law No. 1 of 2004 in Respect of Patents and Utility Models.
[438] Article 3.3(b) of the Bahraini Patent and Utility Models Law No. 14 of 2006 reads as: "[…] the Patent may be granted for any use or method of use of a known product, including the product used in certain medical cases."
[439] The United States Patent Law is codified in Title 35 of the United States Code (35 U.S.C).

Function of the European Union (TFEU), as an expression of the fundamental freedom of goods within the single market (WIPO, 2014, p. 6; BONADIO, 2011, p. 159).

In the survey undertaken by the WIPO's Standing Committee on the Law of Patents (SCP) on exceptions and limitations to patent rights, Georgia clarified that the 2014 EU-Georgia PTA obliged the country to introduce a national exhaustion regime for intellectual property objects.[440] However, when implementing this provision, Georgia excluded patented products from this obligation. For this category of intellectual property, the country applies the international exhaustion, which allows parallel imports. This example illustrates the Acharya's (2011, p. 95) concept of norm subsidiary, whereby local actors create rules as a view to preserve their autonomy from dominance of more powerful actors.

The 2004 Bahrain US-PTA requested the parties to provide patent protection for plants.[441] At that time, the 2004 Bahraini Law on Patents and Utility Models excluded plants from patentability.[442] This changed in 2006, when Bahrain amended its law[443] and removed plants from the list of items excluded from patentability (CALLAGHAN; MENDOCA, 2014). As such, plant varieties may be object of patent protection in accordance with the present Bahraini Patent Law.

The United States, by its turn, makes plant protection available through patents, utility patents and protection certificates (AFONSO, 2013, p. 229). The US government grants patents to who "has invented or discovered and asexually reproduced a distinct and new variety of plant, other than a tuber propagated plant or a plant found in an uncultivated state" (USPTO, 2017). The term of patent protection of plants is 20 years, counted from the filling date. The US practice is based on the § 161 of the 35 U.S.C, inserted in the US Patent Law since 1952.[444] As it stands, it is possible to affirm that the legal approach to protect plant creations through patents was diffused from the United States to Bahrain through their PTA.

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[440] See the WIPO's Document SCP/21/7.
[441] Article 14.8.2 of the 2004 Bahrain-US PTA.
[442] Article 3 (c) of the Law No (1) for the Year 2004 on Patents and Utility Models reads as: "none of the following may be granted a patent: plants, animals – excluding microorganisms – and methods with biological bases for the production of plantations and animals."
[443] Law No. 14 of 2006 amending some Provisions of Law No. 1 of 2004 in Respect of Patents and Utility Models. See Article 3 of the Law No. 14 of 2006.
[444] The § 161 of the 35 U.S.C reads as: "whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title."

The Peruvian Law No. 29.316, of January 13, 2009, constitutes a great example of internalization of international intellectual property commitments into national legislation. It amends, incorporates and regulates several provisions of the PTA signed between Peru and the United States in 2006. It implements the PTA's obligations regarding copyrights and related rights, trademarks, patents, test data and enforcement of intellectual property and related laws.

On patents, the changes incorporated into the Peruvian IP regime include adjustment in the patent term of protection to compensate unreasonable delays in the granting process[445] and limitation on the grounds for patent revocation.[446] On test data protection, the changes incorporated into the Peruvian IP regime comprehend, for example, data exclusivity of five years for information regarding the safety and efficacy of pharmaceutical products submitted to governmental agencies for marketing approval[447] and the non-limitation to implement abbreviated marketing approval procedures on the basis of bioequivalence or bioavailability studies.[448]

The diffusion of these norms through the 2006 PTA creates a greater alignment of the Peruvian IP regime to the United States IP laws and practices. The US provides for the extension of the patent term of protection due to delays in the granting process based on the § 154 of the 35 U.S.C. The patent term adjustment under the US Patent Law takes into consideration the different deadlines for each step of the examination of the patent application. As a general rule, it adds a day for each day of unreasonable delay to the normal twenty-years term of patent protection.

Moreover, the already mentioned 1984 Hatch-Waxman Act introduced in the US intellectual property regime a five-year term of test data exclusivity for pharmaceutical chemical products and allowed for the submission of bioequivalence or bioavailability studies in marketing approval applications. In light thereof, it is possible to assert that the

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[445] The Law N. 29316 modifies Article 32 of the Legislative Decree N. 1075, Complementary Provisions to the Andean Community Decision 486. It implements the obligation under Article 6(b) of the 2006 US-Peru PTA.

[446] The Law N. 29316 incorporates Article 8-A into the Legislative Decree N. 1075, Complementary Provisions to the Andean Community Decision 486. It implements the obligation under Article 16.9.4 of the 2006 US-Peru PTA.

[447] The Law N. 29316 modifies Article 3 of the Legislative Decree N. 1072, on the Protection of Test Data or Other Non-Disclosed Information of Pharmaceutical Products. It implements Article 16.10.2(b) of the 2006 US-Peru.

[448] The Law N. 29316 modifies Article 5 of the Legislative Decree N. 1072, on the Protection of Test Data or Other Non-Disclosed Information of Pharmaceutical Products. It implements Article 16.10.2(b) of the 2006 US-Peru.

2006 PTA was an important vector to diffuse US intellectual property norms into the Peruvian intellectual property regime.

Table 22 - Examples of Vertical Diffusion of Intellectual Property Norms From International to National Level		
Norm	Norm-Maker	Norm-Taker
National Exhaustion of Patent Rights	US	Morocco
National Exhaustion Regime of IPRs	EU	Georgia
An invention is deemed to be industrially applicable if it has a "specific, substantial and credible utility."	US	Morocco
Patent for New (Second) Uses and Methods	US	Bahrain
Patent protection for plants	US	Bahrain
Patent Term Adjustment to Compensate Unreasonable Delays in Granting Process	US	Peru
Five-year term of test data exclusivity for pharmaceutical chemical products	US	Peru

Source: Table elaborated by the author.

Turning to the provisions requiring the disclosure of the genetic resources and associated traditional knowledge in patent applications, the present study did not find direct evidence of top down vertical diffusion of them. There were no legal transplants from PTAs to national intellectual property regimes through PTAs. By the time this provision was established in the identified PTAs,[449] the involved parties already provided this obligation in their national/regional legislation. They pretty much intended to reinforce a national/regional approach in the international realm. This, however, did not prevent this type of provision from having been diffused horizontally.

4.4 Mechanisms for Solving Conflicts of International Law Norms

[449] These PTAs are 2008 EFTA-Colombia (Art. 6.5.5), 2010 EFTA-Peru (Art. 6.5.5), 2012 Colombia-Peru-EU (Art. 201.7) and 2016 EFTA-Philippines (Art. 10.3).

Notwithstanding the different opinions in favor or against the proliferation of intellectual property provisions in preferential trade agreements, the different groups in this discussion may agree on one thing. The multiplication of PTAs hinders the communication of these agreements between themselves, with the WTO rules and with the general rules of international law. This problematic reflects the phenomenon of the fragmentation of international law occasioned by the increasing normalization of the international relations.

Drawing on Celli Júnior's (2014, p. 584) observation, the fragmentation of trade rules in PTAs leads to the uncoordinated creation of special treaty regimes that are often incompatible with each other. The significant number of PTAs transforms the international trade regulation into an intricate system of overlapping agreements. This is a potential source of conflict between PTAs, the multilateral trading system and other international law subsystems (CELLI JÚNIOR, 2014, p. 584).

As explained by Amaral Júnior (2008, p. 17), international treaties have multiplied in a vertiginous scale in the most different domains from the second half of the 20th Century. Progressively, international rules have been accorded to regulate the most diverse fields such as non-proliferation of nuclear weapons, environmental protection, human rights and trade (AMARAL JÚNIOR, 2008, p. 13). This resulted in the creation of several normative subsystems with their own logic and specific principles. Their coexistence increases the chances of conflict of norms and intensifies the trend of international law's fragmentation (AMARAL JÚNIOR, 2008, p. 12).

The International Law Commission (ILC) [450] has already developed important study addressing this problematic. The 2006 Report on "Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law" compiles the main conclusions of the ILC's study group. According to its findings, the normative conflict is endemic to international law because of the spontaneous, decentralized and non-hierarchical nature of its law-making process (ILC, 2006, p. 246).

In analyzing this issue, Pauwelyn (2003, p. 12) lists eight reasons that make the conflict of international law norms an inevitable occurrence. The first three reasons refer to

[450] In 1947, the United Nations General Assembly created the International Law Commission (ILC) to implement the Assembly's mandate, under article 13 (1) (a) of the United Nations' Charter to "initiate studies and make recommendations for the purpose of […] encouraging the progressive development of international law and codification" (ILC, 2017).

the law-making process of international norms, the fourth relates to their enforcement and the remaining four reasons regards the recent development of modern international law. The reasons are the following:

(i) "International law does not have one central legislator, nor one central executive" (PAUWELYN, 2003, p. 13). The law-making process is decentralized. There are as many law-makers as there are states;
(ii) Time is an even more important variable in international law, since all its norms have essentially the same binding value. In principle, any later norm can overrule an earlier one (*lex posterior derogat legi priori*) (PAUWELYN, 2003, p. 14);
(iii) The law-making process also comprehends a multitude of domestic actors. Even though States are considered to constitute one single entity under international law, in practice, they are represented by a multitude of domestic actors (e.g., members of parliament, diplomats, industry associations, NGOs and academics) in the international law-making process (PAUWELYN, 2003, p. 15);
(iv) International law does not have "a centralized court system with general and compulsory jurisdiction" (PAUWELYN, 2003, p. 16);
(v) The shift from an international law on "co-existence" – dealing with issues such as territorial sovereignty, diplomatic relations, war and peace treaties – to an international law on "co-operation" – addressing, for example, the states' pursuit of common goals in the fields of human rights, environment and trade (PAUWELYN, 2003, p. 17). The increasing number of specific treaties enhances the potential conflict between their norms (PAUWELYN, 2003, p. 18);
(vi) The globalization, reflected in the ever-increasing interdependence between States, "has resulted in a proportional boost to the potential for conflict between norms of international law in different sectors" (PAUWELYN, 2003, p. 20);
(vii) The move from all norms of international law being equal towards "the recognition that some norms, based on their substantive content, are more important than others" (PAUWELYN, 2003, p. 22). The emergence of the concept of *jus cogens* reflects an awareness that "not all norms of international law should have the same status" (PAUWELYN, 2003, p. 21);
(viii) There is an increase in the judicial settlement of disputes. International courts or tribunals are more frequently asked to solve matters of international law. This implies that "issues of conflict between norms are more likely to arise *in concreto*" (PAUWELYN, 2003, p. 22).

In this context, the "presumption against conflict" constitutes an important mechanism to eliminate certain potential conflicts. As elaborated by Jenks, over more than sixty years ago (1953, p. 451), "where the interpretation of a treaty provision is doubtful, there is a presumption that the provision was not intended to be in conflict with the provisions of another law-making treaty of a general character." This mechanism assumes

that the new norm is in harmony with the international law in force before its creation (AMARAL JÚNIOR, 2008, p. 18).

Another basis for solving conflicts of international law norms is the 1969 Vienna Convention on the Law of Treaties (VCLT). As highlighted by International Law Commission (2006, p. 250), the VCLT "provides the normative basis – the 'tool-box' – for dealing with fragmentation." Its Article 30, for example, regulates the application of the successive treaties relating to the same subject matter, that is, an earlier and later treaty both of which are in force.[451] In such cases, later law overrides prior law (*lex posterior derogate legi priori*).

Moreover, Article 31 (3) (c) of the VCLT enshrines the "principle of systematic integration", according to which "international obligations are interpreted by reference to their normative environment" (ILC, 2006, p. 2008). Article 31 (3) (c) provides that, for the purposes of interpretation, any relevant rules of international law applicable in the relations between the parties shall be taken into account. In these terms, the rights and obligations accorded between the parties under a certain agreement can be used for interpretive purposes to solve a conflict of international norms involving the same parties.

Furthermore, the VCLT recognizes in its Articles 53[452] and 64[453] the superiority of *jus cogens* norms over other norms of the international law system.[454] The term *jus cogens* designates the category of norms "that are so fundamental that derogation from them can never be allowed" (ILC, 2006, p. 182). The concept of *jus cogens* "presupposes the consensus around essential values for international coexistence" (AMARAL JÚNIOR, 213, p. 129). In the case of conflict between treaties and *jus cogens*, "the former shall not only be non-applicable, but wholly void, giving rise to no legal consequences whatsoever" (ILC, 2006, p. 184).

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[451] As a general rule, when all the parties to the earlier treaty are parties also to the later treaty, the earlier treaty applies only to the extent that its provisions are compatible with those of the later treaty (Art. 30.3. VCLT). When the parties to the later treaty do not include all the parties to the earlier one, the treaty to which both States are parties governs their mutual rights and obligations (Art. 30.4(b)).

[452] Article 53 of the VCLT reads as: "a treaty is void if, at the time of its conclusion, it conflicts with a peremptory norm of general international law. For the purposes of the present Convention, a peremptory norm of general international law is a norm accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character."

[453] Article 64 of the VCLT reads as: "if a peremptory norm of general international law emerges, any existing treaty which is in conflict with that norm becomes void and terminates."

[454] However, "there is no hierarchy between the *jus cogens* norms *inter se"* (ILC, 2006, p. 185).

The VCLT, however, did not exactly determinate which norms have the status of *jus cogens*. According to Amaral Júnior (2013, p. 125-126), the candidates include: the prohibition of aggressive use of force, the prohibition of piracy, the prohibition of genocide, the prohibition of slavery, crimes against humanity and basic rules of international humanitarian law. The content of *jus cogens* is determined, *de facto*, by State practice and in the jurisprudence of international tribunals (ILC, 2006, p. 190).

It is also important to stress that, when analyzing the problematic of the fragmentation of international law, one of the main ILC's conclusions is that special treaty regimes are not "self-contained regimes"[455] (ILC, 2006, p. 248). That is to say, the international law subsystems are not hermetically isolated from the general international law. According to the ILC (2006, p. 100), no regime is self-contained and isolated from the general international law.

In order to attenuate the problems that fragmentation puts to the coherence of international law, Amaral Júnior (2008, p. 18) supports the use of the dialogue between the sources of international law.[456] This interpretive tool facilitates the communication of the subsystems between themselves and with the general rules of international law. Without pretending to exhaust all the possibilities by which this dialogue may occur, Amaral Júnior (2008, p. 21) distinguishes three kinds of them.

First, the systematic coherence dialogue applies in the situations in which a treaty of general nature provides the basic concepts for the implementation of a specific treaty. This specific treaty is part of a subsystem of rules that are not materially complete. The use of the Vienna Convention on the Law of the Treaties in the settlement of disputes involving the breach of the WTO Agreements is an example of systemic coherence dialogue (AMARAL JÚNIOR, 2008, p. 21).

Second, the coordination and adaptation dialogue stems from the need to coordinate isolated treaties and normative subsystems, so that they can constitute a whole full of meaning (AMARAL JÚNIOR, 2008, p. 22). This can be undertaken through mutual

[455] Simma and Pulkowski (2006, p. 492) reminds that, in its original meaning, the concept of "self-contained regime" denoted a set of treaty provisions that cannot be complemented through the application of other rules by way of analogy."

[456] The Article 38 of the Statute of the International Court of Justices recognizes as sources of international law: (i) international conventions; (ii) international custom, and (iii) the general principles of law. Judicial decisions and the teachings of the most highly qualified publicists are considered subsidiary means for the determination of the rules of law (AMARAL JÚNIOR, 2013, p. 47).

consultations between the parties; collaboration initiatives between international organizations concerned; and compatibility statements aimed at making a new agreement compatible with previous or future agreements dealing with the same subject matter (AMARAL JÚNIOR, 2008, p. 22-24). The WHO, WIPO and WTO's trilateral cooperation on the interface between intellectual property and public health is an example of the coordination and adaptation dialogue.

Third, the systematic dialogue of complementarity applies to situations in which norms and principles are used to complement the meaning of the obligations under a certain treaty (AMARAL JÚNIOR, 2008, p. 25). The 2001 Doha Declaration on TRIPS and Public Health is an example of the systemic dialogue of complementarity. It ensures that the TRIPS Agreement's norms and principles can and should be interpreted and implemented in a manner supportive of WTO Member's right to protect public health and promote access to medicines for all.[457]

At last, Amaral Júnior (2008, p. 18) emphasizes that the dialogue of sources only happens between horizontal norms, which are at the same hierarchical level. In the case of *jus cogens* norms, there is not really a dialog, but rather a monologue. Given its superiority, the *jus cogens* norms prevail over the norms of a particular subsystem (AMARAL JÚNIOR, 2008, p. 18).

The rising number of PTAs with intellectual property provisions increases the chance of conflict between the international law norms. According to Arbix (2009, p. 175), the TRIPS-Plus obligations accorded within the PTAs' framework suggest that the conflicts might not only arise between different subsystems, such as trade, environmental protection and human rights, but also within the own international trade regime. As observed by Arbix (2009, p. 175), the interaction between the TRIPS Agreement with other bilateral, regional and multilateral agreements might be extremely conflicting, since they reproduce the disputes over markets, technologies and development.

In this regard, the present work is on the view that the conflict of norms, although aggravated by the increasing fragmentation, is innate to international law. They have to be solved through the above-mentioned techniques of legal reasoning. The dialogue of sources proposed by Amaral Júnior is an important technique that could be applied to these

[457] See paragraph 4 of the 2001 Doha Declaration on TRIPS Agreement and Public Health.

TRIPS-Plus provisions in case of conflict. This would provide greater coherence, predictability and legal security to the international system.

At the same time, it is also useful to note that the internal international property rules have historically been constructed through the pendulum's movement between preferential and multilateral agreements. The great part of the intellectual property norms accorded at the international level reflects in a way or another an already recognized practice in a certain country or group of countries. The intellectual property policies are diffused across the world through these vertical and horizontal movements of norms.

4.5 Preliminary Conclusion

The increasing normalization of the international relations aggravates the fragmentation of international law. The proliferation of preferential trade agreements increases the chances of normative conflicts not only between PTAs and the WTO regime, but also between PTAs and other international law subsystems. Nevertheless, the conflict of international norms shall be perceived as a natural occurrence, given the spontaneous, decentralized and non-hierarchical essence of its law-making process.

These are very important notions that shall be taken into consideration when analyzing the new intellectual property rules established under preferential trade agreements. There are useful tools, such as the presumption against conflict and the Vienna Convention on the Law of Treaties, to hinder or solve possible conflicts between these norms and the WTO regime and other international law subsystems.

The promotion of the dialogue of sources also constitutes an important tool to attenuate the problems that the multiplication of intellectual property norms in different forums and instruments puts to the coherence of the international law. In this perspective, countries should apply the systematic coherence, coordination and adaptation, and complementarity dialogues, when complying with the intellectual property obligations under PTAs. This would provide greater coherence, predictability and legal security to the international intellectual property system.

One may also not forget that the international intellectual property system has been built up through the currents and crosscurrents of preferentialism and multilateralism. Historically, intellectual property rights have been first bilaterally recognized for then to be subsequently "multilateralized". The dissemination of intellectual property norms through PTAs should be understood as normal phenomenon of the international intellectual property system law-making process. The consensus on a specific intellectual property policy or norm is influenced by their diffusion in the national and international realms.

Diffusion is the process whereby intellectual property policies and norms are disseminated across countries. It may occur through coercion, competition, learning and emulation. Each of these mechanisms has influenced the intellectual property regimes of different countries worldwide. The diffusion of TRIPS-Plus norms on patent and test-data protection, however, is not always advantageous. Their benefits will depend on the particular innovation environment of each receiver-country.

Intellectual property rules are diffused in different directions. In a horizontal setting, these norms are diffused from the TRIPS Agreement to the PTAs and from a PTA to another PTA. In a vertical setting, these norms are diffused from specific countries' law and practice to PTAs (bottom-up); and from PTAs to a particular country's law and practice (top-down).

The United States, EFTA and European Union[458] are main diffusers of intellectual property norms on patent and test data protection. They use their distinct PTA programs to disseminate their favored regulatory frameworks (BACCINI; DÜR; HAFTERL, 2015, p. 178). They have an active role in changing norms in the international system and diffusing them into the legal system of other countries (MANNER, 2002, p. 252). Preferentialism is mainly used by developed countries to "make their own domestic IP concepts the internationally dominant concept in competition with other developed countries" (DREXL, 2016, p. 64-65)

From the analysis undertaken by this study, it is also possible to note that, usually, the parties involved in a PTA with TRIPS-Plus provisions merely reaffirm an already established national norm or practice. That is to say, they normally do not commit to standards that provide a higher level of intellectual property protection than they already

[458] On Manners' view, in addition to the military conceptions, the EU should also be considered a normative power (MANNER, 2002, p. 253).

provide nationally. By analyzing the implementation of the PTAs patent and test data protection obligations, a significant number of countries simply accorded to provide the same standard of protection that they already provided nationally.

Besides, even though certain countries do agree to adopt higher levels of intellectual property protection than they already provide in a PTA's framework, this does not mean that they will implement them nationally.[459] The vertical (top-down) diffusion of these norms does not always occur. Some countries never come to internalize these TRIPS-Plus provisions and give effect to them. The lack of enforceable dispute settlement mechanisms or their toothless in the great majority of PTAs might explain why several provisions accorded within their scope are not nationally implemented. Comparatively, the possibility to challenge non-compliance with the TRIPS Agreement before the WTO dispute settlement mechanism and to suffer commercial retaliation constitute a greater incentive for WTO Members to nationally implement their TRIPS obligations.

[459] For example, the 2004 US-Morocco (Art. 15.9.2) provision demands the parties to make patents available for plants and animal inventions. The Moroccan Law passed through several amendments but never incorporated such provision. In fact, the last version of the Moroccan Industrial Protection Law (Law No. 17-97), in its Article 24 (c), excludes plants and animals from patentability.

5 CONCLUSION

Preferential Trade Agreements have increased in number and importance and cover a significant proportion of the world trade today. They constitute the legal framework that enables the creation of the most advanced regional and global value chains. The presence of intellectual property provisions in PTAs only tends to increase as the world transits from a labor-intensive-economy to a knowledge-based economy. The recent years have been marked by the proliferation of these rules in preferential trade agreements that, through cross-pollination and much of borrowing of national intellectual property norms, influence other States' innovation system.

Historically, the currents and crosscurrents of preferentialism and multilateralism have shaped the adoption of intellectual property rules in the international level. While preferentialism establishes higher standards of protection, multilateralism harmonizes the regulation by consolidating minimum standards. This dialectical cycle of alternation can be perceived in the bilateral IP agreements adopted throughout the nineteenth century that culminated with the adoption of the 1883 Paris Convention and 1886 Bern Convention, as well as the bilateral and regional IP agreements adopted throughout the twentieth century that preceded the adoption of the 1994 TRIPS Agreement. The term "plus" used to characterize the TRIPS as a Bern and Paris-Plus agreement is now being used to refer to the PTAs provisions that exceeds the TRIPS' standards of IP protection (TRIPS-Plus).

In light thereof, the TRIPS Agreement should not be seen as the end point in the development of the international intellectual property regime, nor PTAs be perceived as drastic deviations from the traditional path of regime development. The TRIPS Agreement and these PTAs simply represent, respectively, the systole and diastole movements that characterize the building of the international intellectual property regime. In recent years, the pendulum of the development of intellectual property rules has moved back to preferentialism.

This last wave of preferentialism happens in a context of increasing normalization of the international relations. The multiplication of intellectual property norms in different forums and instruments aggravates the fragmentation of international law. The proliferation of intellectual property rules through PTAs enhances the chances of

normative conflicts between PTAs themselves, between PTAs and the WTO regime and between PTAs and other international law subsystems. The conflict of international norms, however, shall be seen as natural phenomenon due to the spontaneous, decentralized and non-hierarchical essence of its law-making process. The presumption against conflict, the Vienna Convention on the Law of Treaties and the promotion of a dialogue of sources of international law constitute useful tools to prevent or even solve possible conflicts. This would confer greater coherence, predictability and legal security to the international intellectual property system.

The advancement of intellectual property provisions within the PTAs' framework is, by itself, neither good nor bad. The impact that these norms have depends on the context in which they apply. Their possible beneficial or harmful effects rely upon how they are designed, the country's level of economic and industrial development, the size of the country's domestic market and/or its ability to export, and how and to what extend these rules proceeds in line with the WTO and other multilateral regimes. There is no conclusive evidence that the adoption of stringent intellectual property rights within PTAs leads to a direct and automatic increase in trade, foreign investment and technology transfer. There are other factors – such as macroeconomic stability, efficiency of the judicial system, scientific and technological capabilities, participation in research networks, and other business regulations – that determine the net benefit and impact of a particular intellectual property norm.

Nevertheless, when entering into such commitments, countries should be aware that the adoption of intellectual property provisions in a PTA's framework has significant legal implications regarding not only the WTO system, but also to the national implementation of these obligations. Since the TRIPS Agreement does not provide for a regional integration exception as to the most-favored-nation principle, such as provided in the GATT (Article XXIV) and in the GATS (Article V), any TRIPS-Plus advantage shall be extended to all WTO Members, not only to the PTA's parties. This also has important bargain implications in a PTA's negotiation, since the benefits of an intellectual property concession cannot be offered more than once.

Based on the TRIPS non-discrimination clauses, other WTO Members can even bring complaints before the WTO Dispute Settlement System due to the non-extension of this TRIPS-Plus advantage contained in a PTA. This applies even though this complaining

WTO Member does not belong to the PTA's contracting parties. Thereby, the TRIPS-Plus concessions made in PTAs indirectly become subject to the WTO Dispute Settlement System. In contrast, the few existing TRIPS-Extra obligations do not need to be extended to other WTO Members, since they do not fall within the TRIPS Agreement's scope. In such cases, PTAs allow for narrow reciprocity based on national treatment.

Furthermore, although TRIPS Article 1:1 allows WTO Members to recognize higher standards of intellectual property protection in international agreements and in their domestic legislation; this shall be undertaken in a manner that it does not contravene the TRIPS Agreement provisions. This non-contravention obligation functions as a coherence mechanism, affecting the States' ability to introduce additional intellectual property protection. As such, any form of more extensive protection needs to be in accordance with the TRIPS Agreement.

Countries should not underestimate the problematic consequences that the implementation of unbalanced TRIPS-Plus provisions might have in their economic, technological, health and environmental policies. By agreeing to more stringent intellectual property rules, countries run the risks of "importing" intellectual property norms that do not reflect their national efficiency trade-off between access to new technologies and incentives for innovation.

The mere strengthening of intellectual property rights does not have a direct positive impact on domestic innovation. It is too simplistic to imply that more intellectual property protection will definitively always lead to more innovation. A balanced intellectual property regime is only one factor among many others – such as institutions, human capital and research, infrastructure, business and market sophistication – that helps to improve a country's innovative environment.

In this context, absorption and imitation are also important approaches to enhance technological catch-up. Certain developed countries, such as the Netherlands, Switzerland and Japan, have already adopted, during a certain period of time, lower standards of intellectual property protection to facilitate the development of their own competitive industrial branches. More recently, this strategy has also been implemented by developing countries, such as China, India and South Korea. The adoption of overprotective IP rules in

PTAs could harm countries that have not yet achieved a high level of domestic innovation capacity.

The PTAs' pharma-related provisions with higher levels of patent and test data protection may hinder access to affordable health technologies when nationally implemented. Intellectual property rules that provide for longer than normal periods of market exclusivity delay the entry of generic products into the market, postponing competition and maintaining prices high. Besides, the mere adoption of stronger intellectual property rules based on developed countries' law and practice will not necessarily be translated into more investment in research and development of drugs to fight endemic diseases in developing countries, such as malaria, dengue or zika.

Some of these pharma-related provisions are clearly drafted to erode the TRIPS Agreement's room for maneuver that allows WTO Members to design their intellectual property policies in accordance with public health goals. They undermine the long fought and recognized flexibilities enshrined in the 2001 Doha Declaration on the TRIPS Agreement and Public Health. Developing countries should consider that, when committing to these rules within a PTA's framework, their exchange in intellectual property provisions for gains in the agricultural and textile sectors are not automatically converted into higher public or private health expenditures. Further national measures should be put in place to counterbalance the resulting pressure that these norms might have on the national health systems.

More stringent IP rules in PTAs may also restrict countries' capability to meet international and national sustainable development commitments. Higher IP standards might result in higher costs of patented climate change technologies, hinder licensing and affect the affordability of substitute technologies. The rules that form a country's patent regime should be designed to enhance the development, transfer and dissemination of environmentally sound technologies. This constitutes a key strategy to mitigate and adapt to the harmful effects of climate change.

Moreover, PTAs' provisions that require the patentability of plants and animals reproduce and even accelerate the problems already existing in the international level regarding compliance with the obligations on access and benefit sharing. The mere

availability of patent protection for plants and animals also does not contribute to fight misappropriation of genetic resources worldwide.

On the contrary, PTAs' provisions that require the disclosure of the origin of genetic resources and associated traditional knowledge in patent applications constitute an important mechanism to enhance the mutual-supportiveness between the patent system and the protection of biodiversity. Although they do not solve all the problems related to misappropriation, they do constitute a transparency tool that enables other rights related to the use of biodiversity and traditional knowledge to be enforced. The disclosure provisions demonstrate that intellectual property rules set in PTAs can also advance interests that are primarily linked to developing countries.

The analysis undertaken by this study demonstrated that 79,4% of the PTAs with patent provisions and 90% of the PTAs with test data provisions, signed from 1st January 1995 to 1st January 2017, were adopted between developed countries and developing countries/economies in transition. These numbers show that the great majority of PTAs regulating these IP categories have as their normative background a developed-developing country relationship. In this scenario, the PTAs between developed countries or between developing countries are a minority. This study also evidenced the accelerating trend in the conclusion of PTAs with patent and test data protection in the last years. The EFTA, United States and European Union are the most active players in adopting PTAs with patent and test data provisions; while South Korea, Peru and Vietnam are the most active developing countries in this this process.

On patent protection, the identified TRIPS-Plus provisions: (i) prevent parallel importation of patented-products by demanding the institution of national or regional exhaustion regimes of intellectual property rights; (ii) stipulates how the patentability criteria (novelty, inventive, step and industrial application) shall be applied; (iii) demand the grant of patents for "new uses" or methods of using a known product; (iv) restrict potential exclusions from patentability; (v) reduce the circumstances under which compulsory licenses may be issued; (vi) limit the grounds under which a patent may be revoked; (vii) require the disclosure of the origin of genetic resources and associated traditional knowledge in patent applications; (viii) request patent term extension, such as for unreasonable delays in the grating process and for the curtailment of the patent term of protection due to marketing approval.

On test data protection, the identified TRIPS-Plus provisions: (i) extend the protection to information on safety and efficacy of products other than pharmaceutical and agricultural chemical products, such as biologics; (ii) prevent second applicants from relying on test data submitted to the competent authority by the first applicant (data exclusivity); (iii) prevent the entry into the market of generic products even if the generic manufacturer submits his own test data to the competent authority (market exclusivity); (iv) provide for the protection of test data regarding "new uses" of known compounds; (v) link patent protection to the marketing authorization of pharmaceutical products; and (vi) demand the competent authority to notify the patent holder of any application for marketing a generic pharmaceutical product.

The systematic investigation carried out by this research demonstrated that there is a strong connection between the IP norms accorded under PTAs and the national legislation of the contracting parties. Usually, countries use PTAs as a means to export and import national intellectual property laws and practices. A significant part of the analyzed IP rules pushed through PTAs reflected a national rule on particular subject matter. The term "diffusion" describes this process whereby intellectual property policies and norms are disseminated across different regulatory levels. It occurs through coercion, competition, learning and emulation among countries.

The present study demonstrated that intellectual property rules diffuse in different directions. In a horizontal context, these norms are diffused from the TRIPS Agreement to PTAs as well as from one PTA to another PTA. In a vertical context, these norms are diffused from specific countries' laws and practices to PTAs (bottom-up); and from PTAs to a particular country's laws and practices (top-down).

Developed countries are the main diffusers of intellectual property norms on patent and test data protection. They use their PTAs to disseminate their favored regulatory approaches and their understandings on how the TRIPS flexibilities, exceptions and broad and ambiguous terms should be interpreted and implemented. They play an active role in creating and changing international intellectual property rules and diffusing them into others intellectual property regimes worldwide.

Frequently, a national intellectual property norm from one contracting party is transplanted into the PTA's text to then be internalized into the intellectual property regime

of the other contracting party. After this norm is widely diffused, it is easier to "multilateralize" it through amendments to the existing multilateral agreements or even through the adoption of a new multilateral agreement. The consensus on a specific intellectual property norm is influenced by its diffusion in the international and national realms.

However, this study calls attention to the fact that, frequently, the parties involved in PTAs with TRIPS-Plus provision simply acknowledge an intellectual property norm or practice already established in their national legislation. In other words, the contracting parties do not always commit to higher standards of IP protection than they already provide internally. By analyzing the implementation of the PTAs patent and test data protection obligations, a significant number of countries merely accorded to provide the same standard of intellectual property protection that they already provided nationally.

Besides, although some countries do commit to adopt higher levels of intellectual property protection than they already provide internally, this does not mean that they will implement them. Some countries never come to internalize their TRIPS-Plus obligations on patent and test data protection accorded within their PTAs. The vertical (top-down) diffusion of these norms does not always occur. This might be explained by the lack of efficient enforceable dispute settlement mechanisms in the great part of PTAs.

At the present moment, Brazil is apart from this preferentialism wave of adopting intellectual property provisions in PTAs. The country cannot influence the development of these new rules, since it rejects to adopt intellectual property commitments in the few and shallow PTAs that it negotiates as a Mercosur State Party or with other LAIA countries. Although it does have offensive interests in the intellectual property field that could be diffused through its PTAs, Brazil rejects to enter into this law-making process that is currently shaping the international intellectual property system. A possible way for Brazil to counterbalance regulatory trends that are being set against its interests and resist the pressure from developed countries in the multilateral forums is to build its own coalition through its PTAs' network.

The analysis undertaken by this study demonstrated that the Brazilian intellectual property regime does not radically differ from the TRIPS-Plus provisions on patent and test data protection that are being adopted under PTAs. Brazil already has intellectual

property laws that exceed the level of protection required under the TRIPS Agreement. The country promptly incorporated the TRIPS Agreement's obligations and even renounced the transition periods to developing countries. The differences between the Brazilian intellectual property regime and the analyzed TRIPS-Plus obligations vary in accordance to each specific category of provision.

On the one hand, it is remarkable how Brazil extensively used the policy space provided under the TRIPS Agreement to build its intellectual property regime. The country was able to benefit from various exceptions and constructive ambiguities provided by the text of the TRIPS Agreement. The country adopts a strict interpretation of the patentability criteria and excludes methods of treatment, plants and animals from patentability.

Brazil has even already used the flexibility of the TRIPS Article 31 to issue a compulsory license of the antiretroviral drug Efavirenz. The measure enabled the national health system to expand the access to treatment for the people with HIV/AIDS in the country. The Brazilian regime provides for other grounds – such as abuse of patent rights, non-working of the patent, public interest – for the granting of a compulsory license than the grounds exemplified by TRIPS Agreement. Differently from what is being negotiated under the PTAs, the Brazilian Industrial Property Law also provides for a several grounds upon which a patent may be revoked.

On test data protection, the national legislation permits the reliance on the information submitted to ANVISA for the marketing approval of pharmaceutical products for human use. The Brazilian intellectual property regime does not provide for patent-linkage nor the obligation of the competent regulatory authority to inform the patent holder of any marketing approval request for a product that still under patent protection. It also does not provide for the adjustment of the patent term of protection due to delays in a product's marketing approval. The marketing approval in Brazil is granted regardless of the product is under patent protection or not.

On the other hand, Brazil has stricter rules than the ones accorded under the TRIPS Agreement or even than the TRIPS-Plus provisions that are being adopted under PTAs. The country prohibits parallel importation of patented products, since it adopts, as a general rule, the national exhaustion regime of intellectual property rights. This doctrine blocks, for example, the parallel importation of cheaper medicines into the country. The

doctrine of international exhaustion, in contrast, is usually recommended to developing countries that want to reduce the weight of the medicines' costs in their national health budgets.

Moreover, Brazil allows for the grant of patents for "new uses" of known compounds, provided that they meet the patentability requirements. If this analysis is not diligently undertaken, the INPI runs the risk of patenting the same product for much longer than a single period. That is to say, patents for "new uses" can have an "ever greening" effect, unduly postponing competition in the national market.

The Brazilian regime ensures a minimum term of ten years of patent protection for cases in which INPI, by its own fault, delays the granting of the patent in over ten years. The problem of this kind of rule is that it imposes a burden on the society due to negligence or error of the public administration. It would be easier and more effective to improve INPI's work in a way that makes it acts expeditiously than to postpone the access to cheaper technological goods to the Brazilian society. Therefore, it is crucial to provide INPI the necessary infrastructure and staff to examine all the patent applications in a timely manner.

Given its immense biodiversity, Brazil also requires the disclosure of the origin of national genetic resources and associated traditional knowledge in patent applications. However, these disclosure requirements only apply to patent applications based on Brazilian genetic resources and associated traditional knowledge. This obligation does not bind patent applications based on third countries genetic resources and associated traditional knowledge. Hence, the Brazilian approach does little in the global efforts to implement transparency tools that help to combat the misappropriation of genetic resources. The implementation of this obligation in a way that it does not differentiate between national and foreign genetic resources could enhance the transparency of patent applications not only for Brazil, but also for other countries.

On test data protection, the Brazilian regime grants data exclusivity to information concerning the safety and efficacy of plant protection and veterinary products. This obligation prevents the competent regulatory authorities from disclosing the test data submitted to them (secrecy) and from using this information in favor of subsequent applicants (non-reliance). The period of data exclusivity lasts 5 years, for old entities, or 10

years for new entities, whether chemical or biological. However, it is worth mentioning that as long as competitors submit their own test data, even regarding veterinary and plant protection products, they can always be granted marketing approval. There is no "market exclusivity" for test data under the Brazilian regime.

The analysis undertaken by this research allows us to partially reject the initial hypothesis proposed by this dissertation. The results demonstrated that Brazilian intellectual property regime does not always have a lower level of patent and test data protection than the ones required under the TRIPS-Plus provisions in PTAs. As evidenced, in certain aspects, the Brazilian intellectual property regime on patent and test data protection has even higher standards the ones found in the analyzed PTAs.

In the future, Brazil should use intellectual property commitments in its PTAs to limit the adoption of particularly harmful unilateral strategies. This can be undertaken by safeguarding the TRIPS flexibilities and by reinforcing the letter and spirit of the 2001 Doha Declaration on the TRIPS Agreement and Public Health. The country should use to the fullest extend the room for maneuver left by the TRIPS Agreement to design a pro-competitive PTA. Brazil could design a model of IP chapter that addresses the issues that it perceives as problematic under the TRIPS Agreement. The country could, thus, advance its understandings on how the TRIPS provisions should be better interpreted and implemented.

This process demands a better organization of the Brazilian internal IP interests. This is a key component to ensure that future international IP commitments faithfully reflect the country's demands. This includes consultations not only with Brazilian IP right holders, but also with Brazilian IP users and consumers. The different stakeholders should be equally able to express their respective interests in this process. Brazil should not diffuse IP standards that only serve the interests of few economically powerful right holders. The interests of few should not harm the welfare of the country as a whole. This exercise of internal consensus building before the adoption of IP provisions facilitates the point in which the PTA is subject to democratic control and put on the table of parliamentarians to be ratified.

Brazil does not need to abandon the multilateral level of intellectual property norm setting, but it can combine it with others bilateral, plurilateral and regional spheres. The

country should promote an open regionalism, aimed at improving its innovative environment in a non-discriminatory manner. Therefore, Brazil should ensure that possible IP provisions in its future PTAs are sufficiently flexible to take into account the socio-economic situations and needs of its contracting parties. This can be built on through the permission of countries to adopt exceptions and limitations necessary for pursuit of legit public policy goals. These IP provisions should also be designed to respect other international obligations, particularly those relating to the protection of the environment, biological diversity, food security and public health.

REFERENCES

ABBOTT, Frederick. Trade Costs and Shadow Benefits: EU Economic Partnership Agreements as Models for Progressive Development of International IP Law. In: DREXL, Josef; RUSE-KHAN, Henning; NADDE-PHLIX, Souheir (Ed.). **EU Bilateral Trade Agreements and Intellectual Property**: for Better or Worse? Berlin: Springer, 2014.

_____. Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health. **ICTSD's Programme on IPRs and Sustainable Development**, Geneva, n. 24, p. 1-38, Jun. 2009.

_____. Intellectual Property Rights in the World Trade. In: GUZMAN, Andrew; SYKES, Alan (Ed.). **Research Handbook in International Economic Law.** Cheltenham: Edward Elgar, 2007.

_____. The Cycle of Action and Reaction: Developments and Trends in Intellectual Property Health. In: ROFFE, Pedro; TANSEY, Geoff; VIVAS-EUGUI, David (Ed.). **Negotiating Health**: Intellectual Property and Access to Medicines. London: Earthscan, 2006.

_____. Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S Federal Law. **UNCTAD – ICTSD Project on IPRS and Sustainable Development**, Geneva, n. 12, p. 1 – 28, Feb. 2006.

_____. The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health. **The American Journal of International Law**, Washington, v. 99, n. 2, p. 317 – 358, Apr. 2005.

_____. Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism. **Journal of International Economic Law**, v. 8, n. 1, p. 77-100, Jan. 2005.

_____. The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements. **Quaker United Nations Office**, Geneva, Ocassional Paper 14, Apr. 2004.

ABBOTT, Frederick; COTTIER, Thomas; GURRY, Francis. **International Intellectual Property in an Integrated World Economy**. New York: Aspen Publishers, 2007.

ACHARYA, Amitav. Norm Subsidiarity and Regional Orders: Sovereignty, Regionalism, and Rule-Making in the Third World. **International Studies Quarterly**, v. 55, n. 1, p. 95-123, Mar. 2011.

_____. How Ideas Spread: Whose Norms Matter? Norm Localization and Institutional Change in Asian Regionalism. **International Organization**, v. 58, n. 2, p. 239-275, Apr. 2004.

ACOSTA, Luis et al. **Patent Term Extensions and Adjustments**: Australia, Canada, European Union, France, Germany, Israel, Japan, South Korea, United Kingdom. Washington: The Law Library of the Congress, 2016. Available at: <https://www.loc.gov/>. Accessed on: 18 Oct. 2017.

AFONSO, Larissa. **Exclusões e Exceções ao Direito de Patentes**. 2013. 371 f. Dissertação (Mestrado em Direito) – Universidade de São Paulo, São Paulo, 2013.

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA. **Regularização de Produtos Agrotóxicos**. Available at: <http://portal.anvisa.gov.br/registros-e-autorizacoes/agrotoxicos/produtos/registro>. Accessed on: 26 Sep. 2017.

AGUIAR JÚNIOR, Ruy. Direito de Patente e Transgenia. **Revista da Associação Brasileira da Propriedade Intelectual**, v. 120, p. 54-67, Sep./Oct. 2012.

AHLERT, Ivan; DESIDERIO, Teixeira. A Patenteabilidade dos Novos Usos de Substâncias Conhecidas. **Revista da Associação Brasileira da Propriedade Intelectual**, v. 100, p. 23-31, May/Jun. 2009.

ALEMAN, Marco. Impact of TRIPS-Plus Obligations in Economic Partnership- and Free Trade Agreements on International IP Law. In: DREXL, Josef; RUSE-KHAN, Henning; NADDE-PHLIX, Souheir (Ed.). **EU Bilateral Trade Agreements and Intellectual Property**: for Better or Worse? Heidelberg, Springer, 2014.

ALIKHAN, Shahid; MASHELKAR, Raghunath. **Intellectual Property and Competitive Strategies in the 21st Century**. The Hague: Kluwer Law International, 2004.

ALMEIDA, Renata; VASCONCELLOS, Alexandre. Sobre a Extensão das Patentes Farmacêuticas no Brasil: Existe Remédio à Luz dos Poderes do Estado? **Cadernos de Prospecção**, v. 7, n. 4, p. 504-515, Oct./Dec. 2014.

ALMEIDA, Liliane. A Validade do Prazo Fixado pelo INPI para a Patente Mailbox. **Revista da Associação Brasileira da Propriedade Intelectual**, v. 130, p. 24-41, May./Jun. 2014.

ALOUI, Omar. Intellectual Property. In: HUFBAUER, Gary; BRUNEL, Claire (Ed.). **Capitalizing on the Morocco-US Free Trade Agreement**: a Road Map for Success. Washington: Peterson Institute, 2009.

AMARAL JÚNIOR, Alberto do. **Curso de Direito Internacional Público**. 4 ed. São Paulo: Atlas, 2013.

_____. **Comércio Internacional e a Proteção do Meio Ambiente**. São Paulo: Atlas, 2011.

_____. O Diálogo das Fontes: Fragmentação e Coerência no Direito Internacional Contemporâneo. **Anuário Brasileiro de Direito Internacional**, v. 2, p. 11-33, Jul. 2008.

ARBIX, Daniel do Amaral. **Tratados TRIPS Plus e o Sistema Multilateral do Comércio**. 2009. 203 f. Dissertação (Mestrado em Direito) – Universidade de São Paulo, São Paulo, 2009.

BACCINI, Leonardo; DÜR, Andreas. The New Regionalism and Policy Interdependence. **British Journal of Political Science**, Cambridge, v. 42, n. 1, p. 57-79, Jun. 2011.

BACCINI, Leonardo; DÜR, Andreas; HAFTEL, Yoram. Imitation and Innovation in International Governance. In: DÜR, Andreas; ELSIG, Manfred (Ed.). **Trade Cooperation**: The Purpose, Design and Effects of Preferential Trade Agreements. Cambridge: Cambridge University Press, 2015.

BALDWIN, Richard. 21st Century Regionalism: Filling the Gap Between the 21st Century Trade and 20th Century Trade Rules. **World Trade Organization – Economic Research and Statistic Division**, Geneva, Staff Working Paper ERSD-2011-08, p. 1-18, May 2011.

BARBOSA, Denis. **Uma Introdução à Propriedade Intelectual**. 2 ed. Rio de Janeiro: Lumen Juris, 2003.

_____. **Tratado da Propriedade Intelectual**. Rio de Janeiro: Lumen Juris, 2010.

_____. A Inexplicável Política Pública por Trás do Parágrafo Único do Art. 40 da Lei de Propriedade Industrial. **Revista da Escola de Magistratura Regional Federal**, v. 19, n. 1, p. 127-186, Nov./Apr. 2014.

BARBOSA, Pedro. A Proteção dos Dados de Testes Sigilosos Submetidos à Regulação Estatal. **Revista da Escola da Magistratura Federal 2ª Região**, v. 12, n. 1, p. 234-285, Aug. 2009.

BARTELT, Sandra. Compulsory Licenses Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health. **The Journal of World Intellectual Property**, v. 6, n. 2, p. 283-310, Mar. 2003.

BASSO, Maristela; RODRIGUES JÚNIOR, Edson. **Intellectual Property in Brazil**. New York: Wolters Kluwer, 2010.

BIRKBECK, Carolyn; BOTWRIGHT, Kimberley. **The Future of the Global Trade and Investment Architecture**: Pursuing Sustainable Development in the Global Economy – Overview of Issues, Challenges and Debates. E15initiative. Geneva: International Centre for Trade and Sustainable Development (ICTSD) and World Economic Forum, 2015. Available at: <http://e15initiative.org/publications/the-future-of-the-global-trade-and-investment-architecture/> Accessed on: 16 Jun. 2016.

BIRKBECK, Carolyn; MARCHANT, Ron. Implementation of the Technical Assistance of the WIPO Development Agenda. **The Journal of Intellectual Property**, v. 14, n. 2, p. 103-132, Mar. 2011.

BOFF, Salete Oro. Acesso aos Conhecimentos Tradicionais: Repartição de Benefícios pelo Novo Marco Regulatório. **Revista Direito Ambiental e Sociedade**, v. 5, n. 2, p. 110-127, 2015.

_____. Patentes na Biotecnologia e Desenvolvimento. In: BARRAL, Welber; PIMENTEL, Luiz Otávio (Org.). **Propriedade Intelectual e Desenvolvimento**. Florianópolis: Fundação Boiteux, 2007.

BONADIO, Enrico. Parallel Imports in a Global Market: Should a Generalized International Exhaustion be the Next Step? **European Intellectual Property Review**, v. 33, p. 153-161, Feb. 2011.

BRAGA, Carlos; FINK, Carsten; SEPULVEDA, Claudia. Intellectual Property Rights and Economic Development. **World Bank Discussion Paper**, n. 412, p. 1 - 57, Mar. 2000.

BRANSTETTER, Lee. TPP and the Conflict over Drugs: incentives for innovation versus access to medicines. In: SCHOTT; Jeffrey, CIMINO-ISAACS, Cathleen. **Assessing the Trans-Pacific Partnership**. Volume 2: innovations in trading rules. Washington: Peterson Institute for International Economics, 2016.

BRUNDTLAND, Harlem. **Report of the World Commission on Environment and Development**: Our Common Future. New York: United Nations, 1987.

CALLAGHAN, Dayle; MENDOCA, Sarah. Gulf Co-operation Council Countries: the emerging IP landscape. **Thomas Reuters Practical Law**, 17 Sep. 2014. Available at: <https://www.rouse.com/magazine/articles/news-and-articles/gulf-co-operation-council-countries-the-emerging-ip-landscape/>. Accessed on: 22 Nov. 2017.

CARVALHO, Nuno. **The TRIPS Regime of Patent and Test Data**. 4 ed. Kluwer: Alphen aan den Rijn, 2014.

_____. **The TRIPS Regime of Patent Rights**. 2 ed. Kluwer: The Hague, 2005.

CELLI JÚNIOR, Umberto; ELEOTERIO, Belisa. O Brasil, o Mercosul e os Acordos Preferenciais de Comércio: alternativas e perspectivas. In: IGLESIAS, Enrique; DAMIANI, Gerson; GARCÉ, Adolfo; ZIBETTI, Fabíola (Org.). **Os Desafios da América Latina no Século XXI**. São Paulo: EDUSP, 2015.

CELLI JÚNIOR, Umberto; SALLES, Marcus; TUSSIE, Diana; PEIXOTO, Juliana. **Mercosur in South-South Agreements**: in the Middle of Two Models of Regionalism. Geneva: UNCTAD, 2010. Available at: <https://vi.unctad.org/resources-mainmenu-64/digital-library?view=search>. Accessed on: 30 Nov. 2017.

CELLI JÚNIOR, Umberto. A OMC e a Fragmentação das Regras do Sistema de Comércio Internacional nos Acordos Preferenciais de Comércio. In: BAPTISTA, Luiz Olavo; RAMINA, Larissa; FRIEDRICH, Tatyana (Coord.). **Direito Internacional Contemporâneo**. Curitiba: Juruá, 2014.

COMMISSION ON INTELLECTUAL PROPERTY RIGHTS. **Integrating Intellectual Property and Development Policy**. London: CIPR, 2002.

CORIAT, Benjamin; ORSENIGO, Luigi. IPRs, Public Health and the Pharmaceutical Industry: Issues in the Post-2005 TRIPS Agenda. In: CIMOLI, Mario; DOSI, Giovanni;

MASKUS, Keith; OKEDIJI, Ruth; REICHMAN, Jerome; STIGLITZ, Joseph (Ed.). **Intellectual Property Rights**: Legal and Economic Challenges for Development. Oxford: Oxford University Press, 2014.

CORREA, Carlos. Patent Rights. In: CORREA, Carlos; YUSUF, Abdulqawi (Ed.). **Intellectual Property and International Trade**: the TRIPS Agreement. 3ed. Alphen aan den Rijn: Wolters Kluwer, 2016.

_____. TRIPS and TRIPS-Plus Protection and Impacts in Latin America. In: GERVAIS, Daniel. **Intellectual Property, Trade and Development**: strategies to optimize economic development in a TRIPS-Plus era. Oxford: Oxford University Press, 2007.

_____. Bilateral Investment Agreements: agents of new global standards for the protection of intellectual property rights? **Transnational Dispute Management**, v. 1, n. 4, p. 1- 31, Aug. 2004.

COSTA, Cíntia; PARANHOS, Julia; VASCONCELLOS, Alexandre. Brasil, Índia e China: o Marco Legal da Biodiversidade e a Proteção Patentária no Âmbito do Sistema Farmacêutico de Inovação. XV Congresso Latino-Iberoamericana de Gestão de Tecnologia. 2013, Porto. **Proceedings…** Porto: ALTEC, 2013. Available at: <http://www.altec2013.org/programme_pdf/655.pdf>. Accessed on: 17 Oct. 2017.

COTTIER, Thomas; SIEBER-GASSER, Charlotte; WERMELINGER, Gabriela. The Dialectical Relationship of Preferential and Multilateral Trade Agreements. In: DÜR, Andreas; ELSIG, Manfred (Ed.). **Trade Cooperation**: the Purpose, Design and Effects of Preferential Trade Agreement. Cambridge: Cambridge University Press, 2015.

COTTIER, Thomas. Working Together Towards TRIPS. In: WATAL, Jayashree; TAUBMAN, Antony (Ed.). **The Making of the TRIPS Agreement**: Personal Insights from the Uruguay Round Negotiations. Geneva: WTO, 2015.

CURTIS, John. **Trade and Innovation**: Policy Options for a New Innovation Landscape. Geneva: International Centre for Trade and Sustainable Development and World Economic Forum, 2016.

D'ALMEIDA, Cristina et. al. New Antiretroviral Treatments and Post-2005 TRIPS Constraints: First Moves Towards IP Flexibilization in Developing Countries. In: CORIAT, Benjamin (Ed.). **The Political Economy of HIV/AIDS in Developing Countries**: TRIPS, Public Health Systems and Free Access. Cheltenham: Edward Elgar, 2008.

DE CONINCK, Heleen; SAGAR, Ambuj. **Technology in the 2015 Paris Climate Agreement and Beyond**. Geneva: ICTSD, 2015.

DECHEZLEPRÊTRE, Antoine. **Fast-Tracking Green Patent Applications**: An Empirical Analysis. Geneva: ICTSD, 2013.

DEL NERO, Patrícia. **Biotecnologia**: Análise Crítica do Marco Jurídico Regulatório. São Paulo: Editora Revista dos Tribunais, 2008.

DERZKO, Natalie. Using Intellectual Property Law and Regulatory Processes to Foster the Innovation and Diffusion of Environmental Technologies. In: MENELL, Peter; TRAN, Sarah (Ed.). **Intellectual Property, Innovation and the Environment**. Cheltenham: Edward Elgar, 2014.

DESIGN OF TRADE AGREEMENTS DATABASE - DESTA. **Project Description**. Available at: <https://www.designoftradeagreements.org/project-description/>. Accessed on: 11 Jul. 2017.

DESSEMONTET, François. Protection of Undisclosed Information. CORREA, Carlos; YUSUF, Abdulqawi (Ed.). **Intellectual Property and International Trade**: the TRIPS Agreement. 3ed. Alphen aan den Rijn: Wolters Kluwer, 2016.

DINCA, Razvan. The "Bermuda Triangle" of Pharmaceutical Law: Is Data Protection a Lost Ship? **Journal of World Intellectual Property**, v. 8, n. 4, p. 517-563, Jul. 2005.

DINWOODIE, Graeme B. The Architecture of the International Intellectual Property System. **Chicago-Kent Law Review**, v. 77, p. 993-1014, Jan. 2002.

DRAHOS, Peter. BITS and BIPS: Bilateralism in Intellectual Property. **The Journal of World Intellectual Property**, v. 4, n. 6, p. 791-808, Nov. 2001.

_____. The Universality of Intellectual Property Rights: Origins and Development. In: WORLD INTELLECTUAL PROPERTY ORGANIZATION (Org.). **Intellectual Property and Human Rights**. Geneva: WIPO, 1999.

DREXL, Josef. The Concept of Trade-Relatedness of Intellectual Property Rights in Times of Post-TRIPS Bilateralism. In: In: ULLRICH; Hans; HILTY, Reto; LAMPING, Matthias; DREXL, Josef (Ed.). **TRIPS plus 20**: from Trade Rules to Market Principles. Heidelberg: Springer, 2016.

DÜR, Andreas; BACCINI, Leonardo; ELSIG, Manfred. The Design of International Trade Agreements: Introducing a New Dataset. **The Review of International Organizations**, v. 9, n. 3, p. 353-375, Sep. 2014.

ELEOTERIO, Belisa; MESQUITA, Alebe. The Twenty-First Century Regionalism: Brazil and Mercosur in the New International Scenario. In: ADINOLFI, Giovanna; BAETENS, Freya; CAIDO, José; LUPONE, Angela; MICARA, Anna (Ed.). **International Economic Law**: Contemporary Issues. Cham: Springer, 2016.

ELKINS, Zachary; SIMMONS, Beth. On Waves, Clusters and Diffusion. The Annals of the American Academy of Political and Social Science. **The Annals of the American Academy of Political and Social Science**, v. 598, n. 1, p. 33-51, Mar. 2005.

EL-SAID, Mohammed. TRIPS-Plus, Public Health and Performance-Based Rewards Schemes Options and Supplements for Policy Formation in Developing and Least Developed Countries. **American University International Law Review**, v. 31, n. 3, p. 373-444, Sep. 2016.

ELSING, Manfred; SURBECK, Jenny. Intellectual Property Rights and Preferential Trade Agreements: Data, Concepts and Research Avenues. **NCCR Trade Working Paper**, Working-Paper No. 2016/2, p. 1-17, Apr. 2016.

EUROPEAN FREE TRADE ASSOCIATION – EFTA. **The Agreement on the European Economic Area**. Available at: <http://www.efta.int/eea/eea-agreement>. Accessed on: 26 Jul. 2017.

EUROPEAN COMISSION – EC. **Supplementary Protection Certificates for Pharmaceutical and Plant Protection Products**. Available at: <https://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates_en >. Accessed on: 9 Aug. 2017a.

_____. **Procedure to apply for authorization of a PPP**. Available at: < https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/application_procedure_en >. Accessed on: 30 Sep. 2017b.

FARRAN, Sue; RAUTENBACH, Christa. Introduction. In: FARRAN, Sue; GALLEN, James; HENDRY, Jennifer; RAUTENBACH, Christa (Ed.). **The Diffusion of Law**: the Movement of Laws and Norms Around the World. New York: Routledge, 2015.

FEKETE, Elisabeth. Importações Paralelas: A Implementação do Princípio da Exaustão de Direitos no Mercosul Diante do Contexto de Globalização. Anais do XVII Seminário Nacional da Propriedade Intelectual, Porto Alegre, 1997. **Proceedings…** Porto Alegre: Associação Brasileira de Propriedade Intelectual, 1997.

FINK, Carsten. Intellectual Property. In: CHAUFFOUR, Jean-Pierre; MAUR, Jean-Christophe (Ed.). **Preferential Trade Agreement Policies for Development**: a handbook. Washington: World Bank, 2011.

_____. Regime Shifting in the International Intellectual Property System. **Perspective on Politics**, v. 7, n. 01, p. 39-44, Mar. 2009.

FINK, Carsten; MASKUS, Keith. Why We Study Intellectual Property Rights and What We Have Learned. In: FINK, Carsten; MASKUS, Keith (Ed.). **Intellectual Property and Development**: Lessons from Recent Economic Research. Washington: World Bank, 2005.

FINK, Carsten; REICHENMILLER, Patrick. Tightening TRIPS: The Intellectual Property of Recent US Free Trade Agreements. **World Bank Trade Note**, n. 20, p. 1-11, Feb. 2005.

FIRTH, Alison. Reception of EU Trade Mark Law in New Zealand. In: BJÖRKDAHL, Annika; CHABAN, Natalia; LESLIE, John; MASSELOT, Annick (Ed.). **Importing EU Norms**: Conceptual Framework and Empirical Findings. Heidelberg: Springer, 2015.

FLYNN, Sean et al. The US Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement. **American University Law Review**, v. 28, n.1, p. 105-202, 2013.

FRANKEL, Susy. The Intellectual Property Chapter in the TPP. In: LIM, C. L; ELMS, Deborah; LOW, Patrick (Ed.). **The Trans-Pacific Partnership:** a quest for a twenty-first-century trade agreement. Cambridge: Cambridge University Press, 2012.

GERVAIS, Daniel. **The TRIPS Agreement**: Drafting History and Analysis. 2 ed. London: Sweet & Maxwell, 2003.

GILARDI, Fabrizio. Transnational Diffusion: Norms, Ideas and Policies. In: CARLSNAES, Walter; RISSE, Thomas; SIMMONS, Beth (Ed.). **Handbook of International Relations**. 2 ed. London: Sage Publications, 2012.

GLICK, David; FRIEDLAND, Zoe. How Often do States Study Each Other? Evidence of Policy Knowledge Diffusion. **American Politics Research**, v. 42, n. 6, p. 956-985, Mar. 2014.

GOLLIN, Michael. Using Intellectual Property to Improve Environmental Protection. In: MENELL, Peter; TRAN, Sarah (Ed.). **Intellectual Property, Innovation and the Environment**. Cheltenham: Edward Elgar, 2014.

GRUBB, Philip; THOMSEN, Peter. **Patents for Chemicals, Pharmaceuticals, and Biotechnology**: Fundamentals of Global Law, Practice and Strategy. 5 ed. Oxford: Oxford University Press, 2010.

GUISE, Mônica. **Comércio Internacional, Patentes e Saúde Pública**. Curitiba: Juruá, 2007.

HALL, Bronwyn; HELMERS, Christian. The Role of Patent Protection in (Clean/Green) Technology Transfer. **Santa Clara Computer and High Technology Law Journal**, v. 26, n. 4, p. 487 – 532, Aug. 2010.

HELFER, Laurence R. Regime Shifting in the International Intellectual Property System. **Perspective on Politics**, v. 7, n. 01, p. 39-44, Mar. 2009.

_____. Toward a Human Rights Framework for Intellectual Property. **UC Davis Law Review**, Davis, v. 40, n. 3, p. 971-1020, Mar. 2007.

_____. Regime Shifting: the TRIPS Agreement and New Dynamics of Intellectual Property Lawmaking. **Yale Journal of International Law**, v. 29, n. 1, p. 1-84, Winter 2004.

_____. **Intellectual Property Rights in Plant Varieties**: International Legal Regimes and Policy Options for National Governments. Rome: FAO, 2004.

HENNINGER, Thomas. Disclosure Requirements in Patent Law and Related Measures: a Comparative Overview of Existing National and Regional Legislation on IP and Biodiversity. In: WERTH, Alexander; REYES-KNOCHE, Susanne (Ed.). **Triggering the Synergies Between Intellectual Property Rights and Biodiversity**. Eschborn: GTZ, 2010.

HESTERMEYER, Holger. **Human Rights and the WTO**: the Case of Patents and Access to Medicines. Oxford: Oxford University Press, 2007.

HILTY, Reto. The Proportionality Principle in the TRIPS Agreement. In: ULLRICH; Hans; HILTY, Reto; LAMPING, Matthias; DREXL, Josef (Ed.). **TRIPS plus 20**: from Trade Rules to Market Principles. Heidelberg: Springer, 2016.

INTERNATIONAL LAW COMMISSION – ILC. Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law. Geneva: United Nations, 2006.

_____. Draft Articles on Most-Favoured-Nations Clauses. **Yearbook of the International Law Commission**, v. 2, p. 16-73, 1978.

_____. **Home**. Available at: <http://legal.un.org/ilc/>. Accessed on: 12 Nov. 2017.

INTERNATIONAL UNION FOR THE PROTECTION OF NEW PLANT VARIEITES. **About UPOV**. Available at: <http://www.upov.int/portal/index.html.en>. Accessed on: 2 Apr. 2017.

INSTITUTO DANNEMANN SIEMSEN DE ESTUDOS DE PROPRIEDADE INTELECTUAL – IDS. **Comentários à Lei de Propriedade Industrial**. Rio de Janeiro: Renovar, 2005.

INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL – INPI. **Marco Legal da Biodiversidasde Cria Novas Exigências para o Exame de Patentes**. Available at: <http://www.inpi.gov.br/noticias/marco-legal-da-biodiversidade-cria-novas-exigencias-para-o-exame-de-patentes>. Accessed on: 10 Oct. 2017.

JANSEN, Nils. Comparative Law and Comparative Knowledge. In: REIMANN, Mathias; ZIMMERMANN, Reinhard. **The Oxford Handbook of Comparative Law**. Oxford: Oxford University Press, 2006.

JEFFERSON, David. Development, Farmers' Right and the Ley Monsanto: the Struggle over the Ratification of UPOV 91 in Chile. **IDEA – The Intellectual Property Law Review**, v. 55, n. 1, p. 31-78, 2014.

JENKS, Wilfred. The Conflict of Law-Making Treaties. **British Book of International Law**, v. 30, p. 401-453, 1953.

KAMERI-MBOTE, Patricia; OTIENO-ODEK, James. Genetic Use Restriction Technologies and Sustainable Development in Eastern and Southern Africa. In: MÉLENDEZ-ORTIZ, Ricardo; ROFFE, Pedro (Ed.). **Intellectual Property and Sustainable Development**: Developing Agendas in a Changing World. Cheltenham: Edward Elgar, 2009.

KANG, Peter; STONE, Clarck. IP, Trade and U.S – Singapore Relations: Significant Intellectual Property Provisions of the 2003 U.S – Singapore Free Trade Agreement. **The Journal of World Intellectual Property**, v. 6, n. 5, p. 721-731, Sep. 2003.

KONGOLO, Tshimanga. Morocco's Patent System and its International Connection. **IDEA: The Journal of Law and Technology**, v. 42, n.1, p. 181-204, p. 2002.

KUANPOTH, Jakkrit. TRIPS-Plus Rules under Free Trade Agreements: An Asian Perspective. In: HEATH, Christopher; SANDERS, Anselm (Ed.). **Intellectual Property and Free Trade Agreements**. Oxford: Hart, 2007.

KUNG, Angela; MACHADO, José. Comentários à Lei N. 10.603/02. Proteção às Informações Não Divulgadas. **Revista da Associação Brasileira de Propriedade Intelectual**, v. 64, p. 63-66, May./Jun. 2003.

LEITE, Márcio. **O Patenteamento de Invenções de Segundo Uso no Brasil**. 2011. 152 f. Dissertação (Mestrado em Direito) – Universidade de São Paulo, São Paulo, 2011.

LI, Yahong. Intellectual Property and Public Health: Two Sides of the Same Coin. **Asian Journal of WTO & International Health Law and Policy**, v. 6, n. 2, p. 389 - 428, Sep. 2011.

LIMA, Newton et al. **A Revisão da Lei de Patentes**: Inovação em Prol da Competitividade Nacional. Brasília: Edições Câmara, 2013.

LINDSTROM, Beatrice. Scaling Back TRIPS-Plus: Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific. **New York University Journal of International Law and Politics**, v. 42, n. 3, p. 917 – 980, Spring 2010.

LLANOS, María Victoria. Reflections on the Moroccan Patent System. **Queen Mary Journal of Intellectual Property**, London, 2015. Available at: <https://qmjip.wordpress.com/2015/07/17/reflections-on-the-moroccan-patent-system/>. Accessed on: 18 Nov. 2017.

LOUREIRO, Luiz Guilherme. **A Lei da Propriedade Industrial**: comentada. São Paulo: Lejus, 1999.

LOWENFELD, Andreas. **International Economic Law**. 2 ed. Oxford: Oxford University Press, 2011.

MALBON, Justin; LAWSON, Charles; DAVISON, Mark. **The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights**: a Commentary. Cheltenham: Edward Elgar, 2014.

MANNERS, Ian. Normative Power Europe: A Contradiction in Terms? **Journal of Common Market Studies**, v. 40, n. 2, p. 235-258, Jun. 2002.

MARCEU, Gabrielle; REIMAN, Cornelis. When and how is a regional trade agreement compatible with the WTO? **Legal Issues of Economic Integration**, v. 28, n. 3, p. 297-336, 2001.

MASKUS, Keith; OKEDIJI, Ruth. Legal and Economic Perspectives on International Technology Transfer in Environmentally Sound Technologies. In: CIMOLI, Mario; DOSI,

Giovanni; MASKUS, Keith; OKEDIJI, Ruth (Ed.). **Intellectual Property Rights**: Legal and Economic Challenges for Development. Oxford: Oxford University Press, 2014.

MASKUS, Keith. Implications of Regional and Multilateral Agreements for Intellectual Property. **The World Economy**, v. 20, n. 5, p. 681-694, Aug. 1997.

MAVROIDIS, Petros. **Trade in Goods**. Oxford: Oxford University Press, 2007.

MAX PLANCK INSTITUTE. **Declaration on Patent Protection**: Regulatory Sovereignty under TRIPS. Munich: Max Planck Institute for Innovation and Competition, 2014. Available at: <https://www.mpg.de/8133454/Patent-Declaration1.pdf>. Accessed on 2 Jun. 2017.

MAY, Christopher. The World Intellectual Property Organization and the Development Agenda. **Global Governance**, v. 13, n. 2, p. 161 – 170, Apr./Jun. 2007.

MEITINGER, Ingo. Implementation of Test Data Protection According to Article 39.3. TRIPS: The Search for a Fair Interpretation of the Term "Unfair Commercial Use." **The Journal of World Intellectual Property**, v. 8, n. 2, p. 123-139, Mar. 2005.

MELÉNDEZ-ORTIZ, Ricardo. Foreword. In: BARTON, John. **Intellectual Property and Access to Clean Energy Technologies in Developing Countries**. Geneva: ICTSD, 2007.

MERCADO COMUM DEL SUR – MERCOSUR. **Protocol on Harmonization of Rules on Intellectual Property in Mercosur, in the Matter of Trademarks, Indications of Origin, and Names of Origin**. Available at: <http://www.mercosur.int/innovaportal/v/2648/12/innova.front/tratados-protocolos-e-acordos>. Accessed on: 30 Nov. 2017.

MERCURIO, Bryan. TRIPS-Plus Provisions in FTAs: Recent Trend. In: BARTELS, Lorand; ORTINO, Federico (Ed.). **Regional Trade Agreements and the WTO System**. Oxford: Oxford University Press, 2006.

MESIDOR, Marie Dagmar. Intellectual Property Rights in Competition Law: Compulsory License Issues in Developing Countries. **Revista da Associação Brasileira de Propriedade Intelectual**, v. 128, 17-30, Jan./Fev. 2014.

MEY, Brenda. Unfettered Consumer Access to Affordable Therapies in the Post-TRIPS Era: a Dead-End Journey for Patients? Kenya and India Case Studies. **Journal of World Intellectual Property**, v. 13, n. 3, p. 403 – 473, Jan. 2010.

MICHAEL, Gabriel. International Coercion and the Diffusion of Regulatory Data Protection. **Journal of World Intellectual Property**, v. 19, n. 2, p. 2-127, Mar. 2016.

MINISTÉRIO DA AGRICULTURA, PECUÁRIA E ABASTECIMENTO – MAPA. **Registro de Produtos Veterinários de Natureza Farmacêutica**. Available at: <http://www.agricultura.gov.br/acesso-a-informacao/acoes-e-programas/cartas-de-servico/defesa-agropecuaria-produtos-de-uso-veterinario/registro-de-produtos-veterinarios-de-natureza-farmaceutica>. Accessed on: 27 Sep. 2017.

MINISTÉRIO DA ÍNDÚSTRIA, COMÉRCIO EXTERIOR E SERVIÇOS – MDIC. **Acordos dos quais o Brasil é Parte**. Available at: <http://www.mdic.gov.br/comercio-exterior/negociacoes-internacionais/796-negociacoes-internacionais-2>. Accessed on: 14 Dec. 2017.

MINISTÉRIO DAS RELAÇÕES EXTERIORES – MRE. **The Latin American Integration Association (ALADI-LAIA)**. Available at: <http://www.itamaraty.gov.br/en/politica-externa/integracao-regional/5975-aladi-en>. Accessed on: 30 Nov. 2017.

MITCHELL, Andrew; VOON, Tania. Patents and Public Health in the WTO, FTAs and Beyond: Tension and Conflict in International Law. **Journal of World Trade**, v. 43, n. 3, p. 571-601, Jun. 2015.

MONT'ALVERNE, Tarin. A Convenção sobre a Biodiversidade e o Acordo sobre os Aspectos dos Direitos de Propriedade Intelectual Relacionados ao Comércio: Possível Conciliação? XIX Encontro Nacional do CONPEDI, 2010, Fortaleza. **Proceedings…** Florianópolis: Fundação Boiteux, 2010. Available at: <http://150.162.138.7/documents/download/537;jsessionid=763186337307456227 34A0AFD559325D>. Accessed on: 13 Jun. 2017.

MOMIROV, Aleksandar; FOURIE, Andria. Vertical Comparative Law Methods: Tools for Conceptualising the International Rule of Law. **Erasmus Law Review**, v. 2, n. 3, p. 291-309, Nov. 2009.

MOON, Surie. Meaningful Technology Transfer to the LDCs: a Proposal for a Monitoring Mechanism for TRIPS Article 66.2. **ICTSD Policy Brief**, Geneva, n. 9, p 1 - 18, Apr. 2001.

MUSUNGU, Sisule. The TRIPS Agreement and Public Health. In: CORREA, Carlos; YUSUF, Abdulqawi (Ed.). **Intellectual Property and International Trade**: the TRIPS Agreement. New York: Wolters Kluwer, 2008.

MUSUNGU, Sisule; OH, Cecilia. **The Use of Flexibilities in TRIPS by Developing Countries**: can they promote access to medicines? Geneva: South Center, 2006.

OKEDIJI, Ruth. Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection. **University of Ottawa Law & Technology Journal**, v. 1, n. 1, p. 125 – 147, 2004.

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT. **OECD History**. Available at: <https://www.oecd.org/about/history/>. Accessed on: 2 Apr. 2017a.

_____. **Intellectual Property (IP) Statistics and Analysis**. Available at: <http://www.oecd.org/innovation/intellectual-property-statistics-and-analysis.htm>. Accessed on: 2 Apr. 2017b.

ÖRÜCÜ, A. Esin. Methodology of Comparative Law. In: SMITS, Jan (Ed.). Elgar Encyclopedia of Comparative Law. 2 ed. Cheltenham: Edward Elgar, 2012.

PAUWELYN, Joost. **Conflict of Norms in Public International Law**: How WTO Law Relates to other Rules of International Law. Cambridge: Cambridge University Press, 2003.

PAUWELYN, Joost; ALSCHNER, Wolfgang. The network of relations between PTAs and double PTAs. In: DÜR, Andreas; ELSIG, Manfred (Ed.). **Trade Cooperation**: the Purpose, Design and Effects of Preferential Trade Agreement. Cambridge: Cambridge University Press, 2015.

POLIDO, Fabrício; DOS ANJOS, Lucas. Acordos de Investimento e a Proteção de Direito de Propriedade Intelectual: Relação Natural, ou Casamento de Conveniência? Reflexões sobre experiências do Mercosul e do Nafta. **Revista de la Secretaría del Tribunal Permanente de Revisión**, v. 8, p. 258-282, Aug. 2016.

PRICE, David. The U.S – Bahrain Free Trade Agreement and Intellectual Property Protection. **The Journal of World Intellectual Property**, v. 7, n. 6, p. 829-850, Nov. 2004.

PRIFTI, Viola. Plant Variety Protection: Options under the TRIPS Agreement. In: CORREA, Carlos; YUSUF, Abdulqawi (Ed.). **Intellectual Property and International Trade**: the TRIPS Agreement. 3 ed. Alphen ann den Rijn: Wolters Kluwer, 2016.

PUGATCH, Meir. Intellectual Property, Data Exclusivity, Innovation and Market Access. In: ROFFE, Pedro; TANSEY, Geoff; VIVAS-EUGUI, David (Ed.). **Negotiating Health**: Intellectual Property and Access to Medicines. London: Earthscan, 2006.

RAMOS, André; GUTERRES, Thiago. **Lei de Propriedade Industrial Comentada**: Lei 9.279, de 14 de Maio de 1996. Salvador: JusPodivm, 2016.

RAUSTIALA, Kal. Density and Conflict in International Intellectual Property Law. **UC Davis Law Review**, v. 40, n. 3, p. 1021-1038, Mar. 2007.

RAYOL, Alice. Tendências de exame dos pedidos de Patente na Área da Biotecnologia. **Revista da Associação Brasileira de Propriedade Intelectual**, n. 63, p. 49-56, Mar./Apr. 2003.

REICH, Arie. The WTO as Law-Harmonizing Institution. **University of Pennsylvania Journal of International Economic Law**, v. 25, n. 1, p. 321-382, Spring 2004.

REICHMAN, Jerome; RAI; Arti; NEWELL, Richard; WIENER, Jonathan. Intellectual Property and Alternatives: Strategies for Green Innovation. In: CIMOLI, Mario; DOSI, Giovanni; MASKUS, Keith; OKEDIJI, Ruth (Ed.). **Intellectual Property Rights**: Legal and Economic Challenges for Development. Oxford: Oxford University Press, 2014.

REICHMAN, Jerome. Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options. **Journal of Law, Medicine and Ethics**, v. 37, n. 2, p. 247-263, Jun. 2009.

REIMANN, Mathias. Beyond National Systems: A Comparative Law for the International Age. **Tulane Law Review**, v. 75, n. 4, p. 1103-1120, Mar. 2001.

RODRIGUES, Daniele. As Flexibilidades do Acordo TRIPS na Nova Dinâmica Comercial Internacional. In: AMARAL JÚNIOR, Alberto; CELLI JÚNIOR, Umberto (Org.). **A OMC**: desafios e perspectivas. São Paulo: Aduaneiras, 2014.

ROFFE, Pedro; SANTA CRUZ, Maximiliano. **Intellectual Property Rights and Sustainable Development**: a Survey of Major Issues. Santiago: ECLAC, 2007.

ROFFE, Pedro. **Bilateral Agreements and a TRIPS-Plus World: the Chile-USA Free Trade Agreement**. Ottawa: Quaker International, 2004.

RORIZ, João Henrique; TASQUETTO, Lucas. Comércio e Regras sobre Propriedade Intelectual nos Acordos Preferenciais de Comércio. In: OLIVEIRA, Ivan; BADIN, Michelle (Org.). **Tendências Regulatórias nos Acordos Preferenciais de Comércio no Século XXI**: os Casos de Estados Unidos, União Europeia, China e Índia. Brasília: IPEA, 2013.

ROS, Viorel. Protection of Inventions in the Pharmaceutical Sector Through Supplementary Protection Certificate. **Lex et Scientia International Journal**, n. 22, v.1, p. 7-30, Jun. 2015.

ROSENBERG, Barbara. Propriedade Intelectual. In: THORSTENSEN, Vera; JANK, Marcos (Coord.). **O Brasil e os Grandes Temas do Comércio Internacional**. São Paulo: Aduaneiras, 2005.

RUSE-KHAN, Henning Grosse. **The Protection of Intellectual Property in International Law**. Oxford: Oxford University Press, 2016.

_____. The Role of TRIPS in a Fragmented IP World. **International Review of Intellectual Property and Competition Law**, v. 43, n. 8, p. 881-884, Dec. 2012.

SACCARO JÚNIOR, Nilo. O Uso dos Recursos Genéticos para o Desenvolvimento Sustentável Brasileiro. **Boletim Regional, Urbano e Ambiental**, v. 7, p. 35-43, Jan./Jun. 2013.

SANDERS, Anselm. The Development Agenda for Intellectual Property: Rational Humane Policy or Modern-Day Communism? In: HEATH, Christopher; SANDERS, Anselm (Ed.). **Intellectual Property and Free Trade Agreements**. Oxford: Hart, 2007.

SARNOFF, Joshua. The Patent System and Climate Change. **Virginia Journal of Law & Technology**, v. 16, n. 2, p. 301-360, Mar. 2011.

SCARCIGLIA, Roberto. Comparative Methodology and Pluralism in Legal Comparison in a Global Age. **Beijing Law Review**, v. 6, n. 1, p. 42-48, Mar. 2015.

SCHAFFER, Gregory; SELL, Susan. Transnational Legal Ordering and Access to Medicines. In: OKEDIJI, Ruth; BAGLEY, Margo (Ed.). **Patent Law in Global Perspective**. Oxford: Oxford University Press, 2014.

SCHÄLI, Mathias. Freihandelsabkommen Schweiz – China: Zeitenwende beim Schutz des geistigen Eigenturms? In: HERREN, Jürg; MÜNCH, Peter; HOCHREUTENER, Inge (Org.). **IP-Herausforderungen in China**: Hintergrund, Entwicklungen, Lösungsansätze. Bern: Growth Publisher, 2016.

SCHOTT, Jeffrey. Free Trade Agreements: Boon or Bane of the World Trading System. In: SCHOTT, Jeffrey (Ed.). **Free Trade Agreements:** US Strategies and Priorities. Washington: Institute for International Economics, 2004.

SEARLE, Nicola; BRASSELL, Martin. **Economic Approaches to Intellectual Property**. Oxford: Oxford University Press, 2016.

SEGGER, Marie-Claire. Advancing the Paris Agreement on Climate Change for Sustainable Development. **Cambridge Journal of International and Comparative Law**, v. 5, n. 2, p. 202-237, Jan. 2016.

SELL, Susan. TRIPS Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP. **Journal of Intellectual Property Law**, v. 18, n. 2, p. 447-478, Mar. 2011.

_____. TRIPS-Plus Free Trade Agreements and Access to Medicines. **Liverpool Law Review**, v. 28, n. 1, p. 41-75, Apr. 2007.

SEUBA, Xavier. Intellectual Property in Preferential Trade Agreements: What Treaties, What Content? **The Journal of World Intellectual Property**, v. 16, n. 5-6, p. 240-261, Dec. 2013.

_____. **Trade, Public Health, and the 2030 Agenda for Sustainable Development**. Geneva: ICTSD, 2017.

SHADLEN, Kenneth; GUENNIF, Samira; GUZMÁN, Alenka; LALITHA, N. Globalization, Intellectual Property Rights and Pharmaceuticals: meeting the challenges to addressing health gaps in the new international environment. In: SHADLEN, Kenneth; GUENNIF, Samira; GUZMÁN, Alenka; LALITHA, N. (Ed.). **Intellectual Property, Pharmaceuticals and Public Health**: Access to Drugs in Developing Countries. Cheltenham: Edward Elgar, 2011.

SHIPAN, Charles; VOLDEN, Craig. Policy Diffusion: Seven Lessons for Scholars and Practitioners. **Public Administration Review**, v. 72, n. 6, p. 788-796, Nov./Dec. 2012.

_____. The Mechanisms of Policy Diffusion. **American Journal of Political Science**, v. 52, n. 4, p. 840-857, Oct. 2008.

SICHEL, Ricardo. Licença Compulsória de Patentes. **Revista da Escola da Magistratura Regional Federal da 2ª Região**, v. 13, n.1, p. 151-164, May 2010.

SILVA, Ana Paula; VALLINI, Juliana. A Proteção à Informação Não Divulgada na Área de Saúde: Uma Abordagem Internacional. In: CARVALHO, Patrícia (Coord). **Propriedade Intelectual**. Estudos em Homenagem à Professora Maristela Basso. Curitiba: Juruá, 2005.

SILVEIRA, Newton. **Propriedade Intelectual**: propriedade industrial, direito do autor, software, cultivares, nome empresarial, abuso de patentes. 5 ed. Barueri: Manole, 2014.

SIMMA, Bruno; PULKOWSKI, Dirk. Of Planets and the Universe: Self-Contained Regimes in International Law. **The European Journal of International Law**, v. 17, n. 3, p. 483-529, Jun. 2006.

SIMMONS, Beth; DOBBIN, Frank; GARRETT, Geoffrey. Introduction: the International Diffusion of Liberalism. **International Organization**, v. 60, n. 4, p. 781-810, Oct. 2006.

SKILLINGTON, G.; SOLOVY, Eric. The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement. **Northwestern Journal of International Law and Business**, v. 24, n. 1, p. 1-52, Fall 2003.

SOLÍS, Mireya; KATADA, Saori. Explaining FTA Proliferation: A Policy Diffusion Framework. In: SÓLIS, Mireya; STALLINGS, Barbara; KATADA, Saori (Ed.). **Competitive Regionalism**: FTA Diffusion in the Pacific Rim. Hampshire: Palgrave MacMillian, 2009.

STRANG, David. Adding Social Structure to Diffusion Models: An Event History Framework. **Sociological Methods and Research**, v. 19, n. 3, p. 324-353, Feb. 1991.

SWISS FEDERAL INSTITUTE OF INTELLECTUAL PROPERTY – IGE/IPI. **Supplementary Protection Certificates**. Available at: <https://www.ige.ch/en/protecting-your-ip/patents/after-your-patent-has-been-granted/supplementary-protection-certificates.html>. Accessed on: 18 Oct. 2017.

TANG, Yi Shin; TEODORO, João Paulo. The Politics and Outcomes of Preferential Trade Strategies: Evidence from TRIPS-Plus Provisions in US-Latin American Relations. **Journal of World Trade**, v. 50, n. 6, p. 1061-1084, Dec. 2016.

TAUBMAN, Antony; WAGER, Hannu; WATAL, Jayashree. **A Handbook on the WTO TRIPS Agreement**. Cambridge: Cambridge University Press, 2012.

THORSTENSEN, Vera; FERRAZ, Lucas (Coord.). **A Multiplicação dos Acordos Preferenciais de Comércio e o Isolamento do Brasil**. São Paulo: Instituto de Estudos para o Desenvolvimento Industrial, 2013. Available at: <http://www.iedi.org.br/anexos_legado/51d18e9168afa9d0.pdf>. Accessed on: 15 Sep. 2017.

_____. **Brazil**: Exploring New Paths with the European Union. São Paulo: CCGI, 2015. Available at: <http://ccgi.fgv.br/sites/ccgi.fgv.br/files/file/Publicacoes/Brazil-EU-New%20paths%20-%20VF%20-%2015-11-2015.pdf>. Accessed on: 15 Dec. 2017.

THORSTENSEN, Vera; KOTZIAS, Fernanda. Integração Regulatória: uma proposta de Coerência, Convergência e Cooperação para a Modernização do Mercosul. **Boletim de Economia e Política Internacional**, Brasília, n. 20, p. 21-29, May/Aug. 2015.

THORSTENSEN, Vera; CASTELAN, Daniel; RAMOS, Daniel; MÜLLER, Carolina. Propriedade Intelectual. In: THORSTENSEN, Vera; OLIVEIRA, Ivan (Org.). **Os BRICS**

na OMC: políticas comerciais comparadas de Brasil, Rússia, Índia, China e África do Sul. Brasília: IPEA, 2012.

TWINING, William. Diffusion of Law: A Global Perspective. **Journal of Comparative Law**, v.1, n. 1, p. 237-260, 2006.

_____. **Globalisation and Legal Theory**. Evanston: Northwestern University Press, 2000.

UNITED NATIONS – UN. **2017 World Economic Situation Prospects**. New York: United Nations, 2017. Available at: <https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/2017wesp_full_en.pdf>. Accessed on 2 Nov. 2017.

_____. **Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines**: promoting innovation and access to health technologies. September, 2016. Available at: <http://www.unsgaccessmeds.org/final-report/>. Accessed on: 23 Apr. 2017.

UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION – UNESCO. **Universal Copyright Convention**. UNESCO. Available at: <http://www.unesco.org/new/en/culture/themes/creativity/creative-industries/copyright/universal-copyright-convention/>. Accessed on: 30 Jun. 2017.

UNITED NATIONS COMMISSION ON INTERNATIONAL TRADE LAW – UNICITRAL. **UNCITRAL Legislative Guide on Secured Transactions**: Supplement on Security Rights in Intellectual Property. New York: United Nations, 2011.

UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT – UNCTAD; INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT – ICTSD. **Resource Book on TRIPS and Development**: an authoritative and practical guide to the TRIPS Agreement. Cambridge: Cambridge University Press, 2005.

UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT – UNCTAD. **About the Intellectual Property Programme Division on Investment and Enterprise**. Available at: <http://unctad.org/en/Pages/DIAE/Intellectual%20Property/About-the-Programme.aspx>. Accessed on: 29 Jun. 2017a.

_____. **2017 World Investment Report**: Investment and the Digital Economy. Available at: <http://unctad.org/en/PublicationsLibrary/wir2017_en.pdf>. Accessed on: 10 Jun. 2017b.

UNITED NATIONS FRAMEWORK CONVENTION ON CLIMATE CHANGE – UNFCCC. **Report of the Conference of Parties on its Sixteenth Session, held in Cancun from 29 November to 10 December 2010**. Addendum: Part Two: Action taken by the Conference of the Parties at its Sixteenth Session. FCCC/CP/2010/Add.1. Available at: <http://unfccc.int/resource/docs/2010/cop16/eng/07a01.pdf>. Accessed on: 26 June 2017.

UNITED STATES FOOD AND DRUG ADMINISTRATION – FDA. **What are "biologics"?** Question and Answers. Available at:

<https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm>. Accessed on: 18 Sep. 2017.

UNITED STATES PATENT AND TRADEMARK OFFICE – USPTO. **General Information About 35 U.S.C 161 Plant Patents**. Available at: <https://www.uspto.gov/patents-getting-started/patent-basics/types-patent-applications/general-information-about-35-usc-161>. Accessed on: 22 Nov. 2017.

VALDÉS, Raymundo; McCANN, Maegan. Intellectual Property Provisions in Regional Trade Agreements: revision and update. **World Trade Organization Economic Research and Statistic Division**, Staff Working Paper ERSD-2014-14, p. 1-70, Sep. 2014. Available at: <https://www.wto.org/english/res_e/reser_e/ersd201414_e.pdf>. Accessed on: 14 Jan. 2017.

VALDÉS, Raymundo; TAVENGWA, Runyowa. Intellectual Property Provisions in Regional Trade Agreements. **World Trade Organization Economic Research and Statistic Division**, Staff Working Paper ERSD-2012-21, p. 1-64, Oct. 2012. Available at: <https://www.wto.org/english/res_e/reser_e/ersd201221_e.pdf>. Accessed on: 29 May 2017.

VAN DEN BOSSCHE, Peter; ZDOUC, Werner. **The Law and Policy of the World Trade Organization**. 3 ed. Cambridge University Press: Cambridge, 2013.

VAN LANGENHOVE, Luk. **Building Regions**: The Regionalization of the World Order. Surrey: Ashgate Publishing Company, 2013.

VÉLEZ, Eduardo. Brazil's Practical Experience with Access and Benefit Sharing and the Protection of Traditional Knowledge. In: WERTH, Alexander; REYES-KNOCHE, Susanne (Ed.). **Triggering the Synergies Between Intellectual Property Rights and Biodiversity**. Eschborn: GTZ, 2010.

VIVA-EYGUI, David; OLIVA, María Julia. **Biodiversity Related Intellectual Property Provisions in Free Trade Agreements**. Geneva: ICTSD, 2010.

WATAL, Jayashree. The TRIPS Agreement and Developing Countries: Strong, Weak or Balanced Protection? **Journal of World Intellectual Property**, v. 1, n. 2, p. 281-307, Mar. 1998.

WORLD CUSTOMS ORGANIZATION – WCO. **WCO in Brief**. Available at: <http://www.wcoomd.org/en/about-us/what-is-the-wco.aspx>. Accessed on: 2 Apr. 2017a.

_____. **Enforcement and Compliance – Responsibilities**: the WCO and the Protection of Intellectual Property Rights (IPR). Available at: <http://www3.wcoomd.org/valelearningoncustomsvaluation_epipr.htm>. Accessed on: 13 Apr. 2017b.

WORLD HEALTH ORGANIZATION – WHO. **Public Health, Innovation, Intellectual Property and Trade**. Available at: <http://www.who.int/phi/about/en/>. Accessed on: 29 Jun. 2017.

WORLD HEALTH ORGANIZATION, WORLD INTELLECTUAL PROPERTY ORGANIZATION, WORLD TRADE ORGANIZATION. **Promoting Access to Medical Technologies and Innovation**: Intersections Between Public Health, Intellectual Property and Trade. Geneva: WTO, 2012.

WORLD INTELLECTUAL PROPERTY ORGANIZATION – WIPO. **WIPO Intellectual Property Handbook**. 2 ed. Geneva: WIPO, 2004.

_____. **2016 World Intellectual Property Indicators**. Geneva: WIPO, 2016. Available at: <http://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2016.pdf>. Accessed on: 18 Oct. 2017.

_____. **WIPO Development Agenda**. Geneva: WIPO, 2009. Available at: <http://www.wipo.int/edocs/pubdocs/en/general/1015/wipo_pub_l1015.pdf>. Accessed on: 3 Apr. 2017.

_____. **Database on Flexibilities in the Intellectual Property System**. Available at: <http://www.wipo.int/ip-development/en/agenda/flexibilities/search.jsp>. Accessed on: 2 Jun. 2017.

_____. **WIPO Handbook on Industrial Property Information and Documentation**: Terms and Abbreviations. Geneva: WIPO, 2013. Available at: <http://www.wipo.int/export/sites/www/standards/en/pdf/08-01-01.pdf>. Accessed on: 18 Oct. 2017.

WORLD TRADE ORGANIZATION – WTO. **2017 Annual Report**. Geneva: WTO, 2017. Available at: <https://www.wto.org/english/res_e/booksp_e/anrep_e/anrep17_e.pdf>. Accessed on: 30 Nov. 2017a.

_____. **Regional Trade Agreements**. Available at: <https://www.wto.org/english/tratop_e/region_e/region_e.htm>. Accessed on: 15 Jun. 2017b.

_____. **The European Union and the WTO**. Available at: <https://www.wto.org/english/thewto_e/countries_e/european_communities_e.htm>. Accessed on: 2 Apr. 2017c.

_____. **TRIPS and Pharmaceutical Patents**: Developing countries' Transition Periods. Available at: <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm04_e.htm>. Accessed on: 11 Aug. 2017d.

_____. **Who are the Developing Countries in the WTO?** Available at: <https://www.wto.org/english/tratop_e/devel_e/d1who_e.htm>. Accessed on: 19 Sep. 2017e.

_____. **2017 Brazil Trade Policy Review**. Available at: <https://www.wto.org/english/tratop_e/tpr_e/s358_e.pdf>. Accessed on: 13 Oct. 2017f.

_____. **DS199: Brazil – Measures Affecting Patent Protection**. Available at: <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm>. Accessed on: 9 Oct. 2017g.

_____. **2016 Morocco Trade Policy Review**. Geneva: WTO, 2016.

_____. **WTO Dispute Settlement One-Page Case Summaries**: 1995 – 2014. Geneva: WTO, 2015.

_____. **2013 World Trade Report**: factors shaping the future of world trade. Geneva: WTO, 2013a.

_____. **2013 European Union Trade Policy Review**. Geneva: WTO, 2013b.

_____. **Doha Ministerial Declaration**. November 14, 2001. Available at: <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm>. Accessed: 25 May 2017.

_____. Council for Trade-Related Aspects of Intellectual Property Rights. **Review of article 27.3 (b): communication from Brazil**. IP/C/W/228 (24 Nov. 2000). Available at: <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=41900,39525,3384,3141,49720,719,3378,3117,15700,559&CurrentCatalogueIdIndex=8&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=True&HasSpanishRecord=True>. Accessed on: 12 Jun. 2017.

XIONG, Ping. Patents in TRIPS-Plus Provisions and the Approaches to Interpretation of Free Trade Agreements and TRIPS: Do They Affect Public Health? **Journal of World Trade**, 46, n.1, p. 155-186, Nov. 2012.

YAMANE, Hiroko. **Interpreting TRIPS**: Globalisation of Intellectual Property Rights and Access to Medicines. Oxford: Hart Publishing, 2011.

YU, Peter. The Non-Multilateral Approach to International Intellectual Property Norm Setting. In: GERVAIS, Daniel (Ed.). **International Intellectual Property**: a Handbook of Contemporary Research. Cheltenham: Elgar, 2015.

YU, Peter. The International Enclosure Movement. **Indiana Law Journal**, v. 82, N. 4, p. 827-907, Fall 2007.

YUSUF, Abdulqawi. TRIPS: Background, Principles and General Provisions. In: CORREA, Carlos; YUSUF, Abdulqawi. **Intellectual Property and International Trade**: the TRIPS Agreement (Ed.). 3 ed. Alphen aan den Rijn: Kluwer, 2016.

ANNEX 1
COUNTRY CLASSIFICAITOIN BY WESP

Developed Economies				
North America	European Union		Other Europe	Asia and Pacific
	EU-15	EU-13		
Canada	Austria	Bulgaria	Iceland	Australia
United States	Belgium	Croatia	Norway	Japan
	Denmark	Cyprus	Switzerland	New Zealand
	Finland	Czech Republic		
	France	Estonia		
	Germany	Hungary		
	Greece	Latvia		
	Ireland	Lithuania		
	Italy	Malta		
	Luxembourg	Poland		
	Netherlands	Romania		
	Portugal	Slovakia		
	Spain	Slovenia		
	Sweden			
	United Kingdom			

Source: WESP, 2017, p. 153.

Economies in Transition		
South-Eastern Europe	Commonwealth of Independent States and Georgia	
Albania	Armenia	Republic of Moldova
Bosnia and Herzegovina	Azerbaijan	Russian Federation
Montenegro	Belarus	Tajikistan
Serbia	Georgia	Turkmenistan
The Former Yugoslav Republic of Macedonia	Kyrgyzstan	Uzbekistan

Source: WESP, 2017, p. 153.

Developing Economies			
Africa		Asia	Latin America and Caribbean
North Africa	Southern Africa	East Asia	Caribbean
Algeria	Angola	Brunei Darussalam	Bahamas
Egypt	Botswana	Cambodia	Barbados
Libya	Lesotho	China	Cuba
Mauritania	Malawi	Fiji	Dominican Republic
Morocco	Mauritius	Hong Kong SAR	Guyana
Sudan	Mozambique	Indonesia	Haiti
Tunisia	Namibia	Kiribati	Jamaica
Central Africa	South Africa	Lao People's Democratic Republic	Trinidad and Tobago
Cameroon	Swaziland	Malaysia	Mexico and Central America
	Zambia	Mongolia	
Central African Republic	Zimbabwe	Myanmar	Belize
Chad	West Africa	Papua New Guinea	Costa Rica
Congo	Benin	Philippines	El Salvador
Equatorial Guinea	Burkina Faso	Republic of Korea	Guatemala
Gabon	Cabo Verde	Samoa	Honduras
São Tomé and Principe	Côte d'Ivoire	Singapore	Mexico
East Africa	Gambia	Solomon Islands	Nicaragua
Burundi	Ghana	Taiwan Province of China	Panama
Comoros	Guinea	Thailand	South America
Democratic Republic of Congo	Guinea-Bissau	Timor-Leste	Argentina
Djibouti	Liberia	Vanuatu	Bolivia
Eritrea	Mali	Viet Nam	Brazil
Ethiopia	Niger	South Asia	Chile
Kenya	Nigeria	Afghanistan	Colombia
Madagascar	Senegal	Bangladesh	Ecuador
Rwanda	Sierra Leone	Bhutan	Paraguay
Somalia	Togo	India	Peru
Uganda		Iran	Suriname
United Republic of Tanzania		Maldives	Uruguay
		Nepal	Venezuela
		Pakistan	
		Sri Lanka	
		Western Asia	
		Bahrain	
		Iraq	
		Israel	
		Jordan	
		Kuwait	
		Lebanon	
		Oman	
		Qatar	
		Saudi Arabia	
		Syrian Arabic Republic	
		Turkey	
		United Arab Emirates	
		Yemen	

Source: WESP, 2017, 154.